



FEDERAL REGISTER

Vol. 89

Wednesday,

No. 152

August 7, 2024

Pages 64353–64778

OFFICE OF THE FEDERAL REGISTER



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

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

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

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

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

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

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

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

How To Cite This Publication: Use the volume number and the page number. Example: 89 FR 12345.

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

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	202-512-1800
Assistance with public subscriptions	202-512-1806

General online information 202-512-1530; 1-888-293-6498

Single copies/back copies:

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

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	FRSubscriptions@nara.gov
Phone	202-741-6000

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



Contents

Federal Register

Vol. 89, No. 152

Wednesday, August 7, 2024

Agriculture Department

See Animal and Plant Health Inspection Service

See Food Safety and Inspection Service

See Forest Service

See Rural Business-Cooperative Service

See Rural Utilities Service

Animal and Plant Health Inspection Service

NOTICES

Evaluation of the Classical Swine Fever Disease Status of Costa Rica, 64401–64402

Imports:

Fresh Cape Gooseberry Fruit from Peru, Pest Risk Analysis, 64402

Army Department

NOTICES

Hearings, Meetings, Proceedings, etc.:

Army Education Advisory Committee, 64434–64435

Bureau of Consumer Financial Protection

RULES

Quality Control Standards for Automated Valuation Models, 64538–64580

Centers for Medicare & Medicaid Services

RULES

Medicare Program:

FY 2025 Inpatient Psychiatric Facilities Prospective Payment System; Rate Update, 64582–64675

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 64462–64467

Coast Guard

RULES

Drawbridge Operations:

Okeechobee Waterway, Stuart, FL, 64367–64369

Safety Zone:

Boat Race; Lake Michigan, Sheboygan, WI, 64369–64371

Green River, Calhoun, KY, 64371–64373

NOTICES

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 64472–64476

Commerce Department

See Foreign-Trade Zones Board

See International Trade Administration

See National Oceanic and Atmospheric Administration

NOTICES

Open Government Plan, 64405–64406

Comptroller of the Currency

RULES

Quality Control Standards for Automated Valuation Models, 64538–64580

Defense Department

See Army Department

NOTICES

Request for Information:

2026 Department of Defense State Policy Priorities Impacting Service Members and Their Families, 64435–64436

Education Department

PROPOSED RULES

Proposed Waiver and Extension of Project Period:

Postsecondary Programs for Students with Intellectual Disabilities—National Technical Assistance and Dissemination Center Program, 64399–64400

Employee Benefits Security Administration

NOTICES

Hearings, Meetings, Proceedings, etc.:

Advisory Council on Employee Welfare and Pension Benefit Plans, 64482–64483

Energy Department

See Federal Energy Regulatory Commission

Environmental Protection Agency

RULES

Air Quality State Implementation Plans; Approvals and Promulgations:

Kansas; Regional Haze, 64373–64383

NOTICES

Cancellation Order:

Chlorpyrifos; Certain Pesticide Registrations and Amendments to Terminate Uses, 64458–64460

Emergency Order:

Suspending the Registrations of All Pesticide Products Containing Dimethyl Tetrachloroterephthalate, 64445–64458

Proposed Settlement Agreement, Stipulation, Order, and Judgment, etc.:

Covenant Not to Sue by Prospective Purchaser, 64458

Federal Communications Commission

NOTICES

Hearings, Meetings, Proceedings, etc., 64460–64461

Federal Deposit Insurance Corporation

RULES

Fair Hiring in Banking Act, 64353–64367

Quality Control Standards for Automated Valuation Models, 64538–64580

Federal Energy Regulatory Commission

NOTICES

Application:

Black Bayou Gas Storage, LLC, 64443–64445

Fiske Hydro, Inc., 64436–64437

Combined Filings, 64437–64438, 64441–64443

Environmental Assessments; Availability, etc.:

Eagle Crest Energy Co., 64441

Initial Market-Based Rate Filings Including Requests for

Blanket Section 204 Authorizations:

Mordor ES1 LLC, 64440–64441

Mordor ES2 LLC, 64440

Request under Blanket Authorization:

Florida Gas Transmission Co., LLC, 64438–64440

Federal Housing Finance Agency**RULES**

Quality Control Standards for Automated Valuation Models, 64538–64580

Federal Motor Carrier Safety Administration**NOTICES**

Exemption Application:

Qualification of Drivers; Epilepsy and Seizure Disorders, 64532–64534

Federal Reserve System**RULES**

Quality Control Standards for Automated Valuation Models, 64538–64580

NOTICES

Change in Bank Control:

Acquisitions of Shares of a Bank or Bank Holding Company, 64461–64462

Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 64461

Fish and Wildlife Service**NOTICES**

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

Approval Procedures for Nontoxic Shot and Shot Coatings, 64476–64477

Food and Drug Administration**NOTICES**

Hearings, Meetings, Proceedings, etc.:

Enhancing Diversity in Therapeutics Development for Pediatric Patients; Public Workshop, 64467

Food Safety and Inspection Service**PROPOSED RULES**

Salmonella Framework for Raw Poultry Products, 64678–64748

Foreign-Trade Zones Board**NOTICES**

Authorization of Production Activity:

Twin Disc, Inc., Foreign-Trade Zone 297, Lufkin, TX, 64406

Forest Service**NOTICES**

Proposed New Recreation Fee Site, 64402–64403

General Services Administration**NOTICES**

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

Nondiscrimination in Federal Financial Assistance for Real Property Recipients, 64462

Geological Survey**NOTICES**

Hearings, Meetings, Proceedings, etc.:

National Geospatial Advisory Committee, 64477–64478

Health and Human Services Department

See Centers for Medicare & Medicaid Services

See Food and Drug Administration

See Health Resources and Services Administration

See National Institutes of Health

Health Resources and Services Administration**NOTICES**

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

340B Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process, 64468–64469

Homeland Security Department

See Coast Guard

Interior Department

See Fish and Wildlife Service

See Geological Survey

See Land Management Bureau

See National Park Service

Internal Revenue Service**PROPOSED RULES**

Dual Consolidated Losses and the Treatment of Certain Disregarded Payments, 64750–64778

International Trade Administration**NOTICES**

Antidumping or Countervailing Duty Investigations, Orders, or Reviews:

Aluminum Wire and Cable from the People's Republic of China, 64406–64411

Raw Honey from the Socialist Republic of Vietnam, 64411–64412

Sales at Less Than Fair Value; Determinations, Investigations, etc.:

Mattresses from Italy; Correction, 64406

Justice Department**NOTICES**

Proposed Consent Decree:

Clean Air Act, 64482

Labor Department

See Employee Benefits Security Administration

Land Management Bureau**RULES**

Temporary Closure and Restriction Orders, 64383–64397

NOTICES

Alaska Native Claims Selection, 64479–64480

Hearings, Meetings, Proceedings, etc.:

Southern New Mexico Resource Advisory Council, New Mexico, 64478–64479

Wyoming Resource Advisory Council, 64480–64481

Oil and Gas Lease:

NMNM105679576, New Mexico, Proposed Reinstatement, 64481

Public Land Order:

No. 7946; Extension of Public Land Order No. 7608 for Chief Joseph Dam Additional Units Project, Washington, 64478

National Archives and Records Administration**NOTICES**

Records Schedules, 64483–64484

National Credit Union Administration**RULES**

Quality Control Standards for Automated Valuation Models, 64538–64580

National Institutes of Health**NOTICES**

Hearings, Meetings, Proceedings, etc.:

National Center for Advancing Translational Sciences, 64470

National Institute of Diabetes and Digestive and Kidney Diseases, 64469–64471

National Institute of General Medical Sciences, 64469

National Institute on Aging, 64469–64471

Office of the Director, National Institutes of Health, 64471–64472

National Oceanic and Atmospheric Administration**RULES**

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

Commercial Closure for Blueline Tilefish in the South Atlantic, 64397–64398

NOTICES

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

Reporting of Sea Turtle Incidental Take in Virginia

Chesapeake Bay Pound Net Operations, 64433–64434

Endangered and Threatened Species:

Initiation of a 5-Year Review for the Mediterranean Monk Seal, 64413

Hearings, Meetings, Proceedings, etc.:

International Whaling Commission, 64412–64413

Requests for Nominations:

Advisory Committee and Species Working Group Technical Advisor Appointments to the U.S. Section to the International Commission for the Conservation of Atlantic Tunas, 64432–64433

Taking or Importing of Marine Mammals:

Marine Site Characterization Surveys off New York and New Jersey in the New York Bight, 64414–64420

Weyerhaeuser Company for their Log Export Dock Project on the Columbia River near Longview, WA, 64420–64432

National Park Service**NOTICES**

National Register of Historic Places:

Pending Nominations and Related Actions, 64481–64482

National Science Foundation**NOTICES**

Permits; Applications, Issuances, etc.:

Antarctic Conservation Act, 64484–64485

Nuclear Regulatory Commission**RULES**

Miscellaneous Corrections; Correction, 64353

NOTICES

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

Facility Security Clearance and Safeguarding of National Security Information and Restricted Data, 64485–64486

Licenses; Exemptions, Applications, Amendments etc.:

Palisades Nuclear Plant, Holtec Decommissioning International, LLC, and Holtec Palisades, LLC, 64486–64493

Licenses; Exemptions, Applications, Amendments, etc.:

Palisades Nuclear Plant and the Palisades Independent Spent Fuel Storage Installation, Holtec Decommissioning International, LLC, Holtec Palisades, LLC, and Palisades Energy, LLC, 64493–64496

Nuclear Waste Technical Review Board**NOTICES**

Hearings, Meetings, Proceedings, etc., 64496–64497

Postal Regulatory Commission**NOTICES**

New Postal Products, 64497

Rural Business-Cooperative Service**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 64403–64404

Rural Utilities Service**NOTICES**

Agency Information Collection Activities; Proposals, Submissions, and Approvals, 64404–64405

Securities and Exchange Commission**NOTICES**

Application:

Fidus Investment Corp. et al., 64505

KOR Reporting, Inc., 64526–64532

Order:

Approving and Declaring Effective an Amendment to the Plan for the Allocation of Regulatory Responsibilities Among NYSE American LLC, etc., 64497–64504

Program for Allocation of Regulatory Responsibilities;

Cboe BZX Exchange, Inc., Cboe BYX Exchange, Inc.,

BOX Exchange LLC, et al., 64517–64523

Self-Regulatory Organizations; Proposed Rule Changes:

Municipal Securities Rulemaking Board, 64505–64507

NYSE Arca, Inc., 64508–64511

NYSE National, Inc., 64523–64526

The Depository Trust Co., 64511–64516

Transportation Department

See Federal Motor Carrier Safety Administration

NOTICES

Performance Review Board Members, 64534–64536

Treasury Department

See Comptroller of the Currency

See Internal Revenue Service

Separate Parts In This Issue**Part II**

Bureau of Consumer Financial Protection, 64538–64580

Federal Deposit Insurance Corporation, 64538–64580

Federal Housing Finance Agency, 64538–64580

Federal Reserve System, 64538–64580

National Credit Union Administration, 64538–64580

Treasury Department, Comptroller of the Currency, 64538–64580

Part III

Health and Human Services Department, Centers for

Medicare & Medicaid Services, 64582–64675

Part IV

Agriculture Department, Food Safety and Inspection Service, 64678–64748

Part V

Treasury Department, Internal Revenue Service, 64750–64778

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.

9 CFR**Proposed Rules:**

381 64678

10 CFR

50 64353

52 64353

54 64353

12 CFR

34 64538

225 64538

303 64353

308 64353

323 64538

722 64538

741 64538

1026 64538

1222 64538

26 CFR**Proposed Rules:**

1 64750

301 64750

33 CFR

117 64367

165 (2 documents) 64369,

64371

34 CFR**Proposed Rules:**

Ch. III 64399

40 CFR

52 64373

42 CFR

412 64582

43 CFR

8360 64383

50 CFR

622 64397

Rules and Regulations

Federal Register
Vol. 89, No. 152
Wednesday, August 7, 2024

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

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

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50, 52, and 54

[NRC-2024-0091]

RIN 3150-AL15

Miscellaneous Corrections; Correction

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule; correction.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is correcting a final rule that was published in the Federal Register on July 16, 2024, regarding the amendment of NRC’s regulations to make miscellaneous corrections to include clarifying language and correcting grammatical and typographical errors, punctuation, references, and terms. This action is necessary to correct an inadvertent error in the final rule.

DATES: The correction takes effect on August 15, 2024.

ADDRESSES: Please refer to Docket ID NRC-2024-0091 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

• Federal Rulemaking Website: Go to https://www.regulations.gov and search for Docket ID NRC-2024-0091. Address questions about NRC dockets to Helen Chang; telephone: 301-415-3228; email: Helen.Chang@nrc.gov. For technical questions, contact the individual listed in the FOR FURTHER INFORMATION

CONTACT section of this document.

• NRC’s Agencywide Documents Access and Management System (ADAMS): You may obtain publicly available documents online in the ADAMS Public Documents collection at https://www.nrc.gov/reading-rm/adams.html. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact

the NRC’s Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to pdr.resource@nrc.gov.

• NRC’s PDR: The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Tricia Lizama, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-4110; email: TriciaDolores.Lizama@nrc.gov.

SUPPLEMENTARY INFORMATION: 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-2024-0091. 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-2024-0091); (2) click the “Subscribe” link; and (3) enter an email address and click on the “Subscribe” link.

Corrections

In FR Doc. 2024-15234, appearing on page 57717 in the Federal Register of Tuesday, July 16, 2024, the NRC makes the following corrections:

Preamble

■ 1. On page 57718, in the first column, in the eighth paragraph, the sentence “This final rule amends § 52.110(e) to remove the incorrect reference to § 50.2 and the introductory text of § 52.110(f) to remove the incorrect reference to § 52.1, since neither reference contains a definition for “decommissioning activities.” is corrected to read “This final rule amends the introductory text of § 52.110(f) to remove the incorrect reference to § 52.1, since the reference does not contain a definition for “decommissioning activities.”

Regulatory Text

■ 2. On page 57721, in the first column, amendatory instruction 20 for § 52.110 is corrected to read “In § 52.110, revise

and republish paragraphs (f) and (h)(1) to read as follows:”

§ 52.110 [Corrected]

* * * * *

(f) Licensees shall not perform any decommissioning activities, that—
(1) Foreclose release of the site for possible unrestricted use;
(2) Result in significant environmental impacts not previously reviewed; or
(3) Result in there no longer being reasonable assurance that adequate funds will be available for decommissioning.

* * * * *

(h)(1) Decommissioning trust funds may be used by licensees if—
(i) The withdrawals are for expenses for legitimate decommissioning activities consistent with the definition of decommissioning in § 52.1;
(ii) The expenditure would not reduce the value of the decommissioning trust below an amount necessary to place and maintain the reactor in a safe storage condition if unforeseen conditions or expenses arise; and
(iii) The withdrawals would not inhibit the ability of the licensee to complete funding of any shortfalls in the decommissioning trust needed to ensure the availability of funds to ultimately release the site and terminate the license.

* * * * *

Dated: August 1, 2024.
For the Nuclear Regulatory Commission.

Krupskaya T. Castellon,
Acting Chief, Regulatory Analysis and Rulemaking Support Branch, Division of Rulemaking, Environmental, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2024-17325 Filed 8-6-24; 8:45 am]

BILLING CODE 7590-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Parts 303 and 308

RIN 3064-AF92

Fair Hiring in Banking Act

AGENCY: Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Federal Deposit Insurance Corporation (FDIC) is revising

its regulations to conform with the Fair Hiring in Banking Act (FHBA)—which was enacted on and immediately effective as of December 23, 2022. Among other provisions, the FHBA excluded or exempted categories of otherwise-covered offenses from the scope of statutory prohibitions on participation in banking. These categories pertain to certain older offenses, offenses committed by individuals 21 or younger, and relatively minor offenses. The FHBA also clarified several definitions in section 19 and provided application-processing procedures. The FDIC considers most of the revisions to its regulations to be required by the FHBA. Most other revisions reflect the FDIC's interpretation of statutory prohibitions in light of the FHBA.

DATES: rule will be effective on October 1, 2024.

FOR FURTHER INFORMATION CONTACT:

Timothy Schuett, Senior Review Examiner, 763–614–9473, tschuett@fdic.gov; Brian Zeller, Senior Review Examiner, 571–345–8170, bzeller@fdic.gov, Division of Risk Management Supervision; or Graham Rehrig, Counsel, 703–314–3401, grehrig@fdic.gov, Legal Division.

SUPPLEMENTARY INFORMATION:

I. Policy Objective

The policy objective of the rule is to revise the FDIC's regulations concerning section 19 of the Federal Deposit Insurance Act (section 19)¹ to conform with the FHBA.² These regulations provide, among other things, the application process for insured depository institutions (IDIs) and individuals who seek relief from section 19 as well as information about section 19 and the FDIC's interpretation of the statute.

II. Background and Public Comments

Section 19 prohibits, without the prior written consent of the FDIC (the FDIC refers to applications for such consent as “consent applications”),³ the participation in an IDI by any person who has been convicted of a crime involving dishonesty or breach of trust or money laundering or who has agreed

to enter into a pretrial diversion or similar program in connection with the prosecution for such an offense (collectively, covered offenses). Further, this law forbids an IDI from permitting such a person to engage in any such conduct or to continue any relationship prohibited by section 19. Section 19 also imposes a separate 10-year minimum for the automatic prohibition of a person convicted of certain crimes enumerated in title 18 of the United States Code (U.S.C.), although an exception may be granted upon a motion by the FDIC and approval by the sentencing court.

From 1998 until 2020, the FDIC had a Statement of Policy that was issued related to section 19, occasionally revised, and published in the **Federal Register**.⁴ The purpose of the Statement of Policy, as amended through the years, was “to provide the public with guidance relating to section 19 and the FDIC's application thereof.”⁵ In 2020, following notice and comment, the FDIC revised and codified the Statement of Policy into the FDIC's Filing Procedures under 12 CFR part 303, subpart L, and Rules of Practice and Procedure under 12 CFR part 308, subpart M.⁶

On December 23, 2022, the President signed into law the FHBA, which significantly revised section 19 and was effective immediately. The FHBA created several categories of exceptions or exemptions to the prohibition on participating in banking, including the following:

- *Certain older offenses:* (1) if it has been 7 years or more since the offense occurred; (2) if the individual was incarcerated with respect to the offense and it has been 5 years or more since the individual was released from incarceration; or (3) for individuals who committed an offense when they were 21 years of age or younger, if it has been more than 30 months since the sentencing occurred.⁷

- *Offenses for which an order of expungement, sealing, or dismissal has been issued* in regard to the conviction in connection with such offense and it is intended by the language in the order itself, or in the legislative provisions under which the order was issued, that the conviction shall be destroyed or sealed from the individual's State, Tribal, or Federal record even if exceptions allow the record to be

considered for certain character and fitness evaluation purposes.

- *De minimis offenses:* a category of relatively minor offenses that are either specified by the FHBA or by the FDIC through regulations. In the FHBA, a subcategory of *de minimis* offenses is called “designated lesser offenses,” which offenses include the use of fake identification, shoplifting, trespass, fare evasion, driving with an expired license or tag (and such other low-risk offenses as the FDIC may designate), if 1 year or more has passed since the applicable conviction or program entry.

- *Misdemeanor criminal offenses involving dishonesty*, if the offense was committed more than one year before the date on which an individual files a consent application, excluding any period of incarceration.

- *A criminal offense involving dishonesty that “involv[es] the possession of controlled substances.”*

The FHBA clarifies several terms in section 19, including “criminal offense involving dishonesty” and “pretrial diversion or similar program.” It also provides conditions regarding *de minimis* offenses, to the extent the FDIC provides *de minimis* exemptions by rule.

The FHBA codifies procedures for consent applications filed with the FDIC. It requires the FDIC to make all forms and instructions related to consent applications available to the public, including on the FDIC's website. It requires the FDIC to primarily rely on the criminal history record of the Federal Bureau of Investigation when evaluating consent applications and to provide such records to the applicant to review for accuracy. Further, it requires the FDIC to assess evidence of an individual's rehabilitation including: the applicant's age at the time of the conviction or program entry; the time that has elapsed since conviction or program entry; and the relationship of an individual's offense to the responsibilities of the applicable position. Other information, including an individual's employment history, letters of recommendation, certificates documenting participation in substance abuse programs, successful participation in job preparation and educational programs, other relevant mitigating evidence, and any additional information the FDIC determines necessary for safety and soundness shall also be considered.

On November 14, 2023, the FDIC published a notice of proposed rulemaking (proposal) to conform the FDIC's section 19 regulations with the

¹ 12 U.S.C. 1829.

² The FHBA appears at section 5705 of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023, Public Law 117–263, 136 Stat. 2395, 3411.

³ Under the FHBA, a “consent application” “means an application filed with [the FDIC] by an individual (or by an insured depository institution or depository institution holding company on behalf of an individual) seeking the written consent of the [FDIC] under [12 U.S.C. 1829(a)(1)].” 12 U.S.C. 1829(g)(1).

⁴ See 63 FR 66177 (Dec. 1, 1998); 72 FR 73823 (Dec. 28, 2007) with correction issued at 73 FR 5270 (Jan. 29, 2008); 76 FR 28031 (May 13, 2011); 77 FR 74847 (Dec. 18, 2012); 83 FR 38143 (Aug. 3, 2018).

⁵ See 84 FR 68353 (Dec. 16, 2019).

⁶ See 85 FR 51312 (Aug. 20, 2020).

⁷ These exceptions do not apply to the offenses described under 12 U.S.C. 1829(a)(2).

FHBA.⁸ The FDIC issued the proposal following consultation and coordination with the National Credit Union Administration (NCUA), the Board of Governors of the Federal Reserve System (FRB), and the Office of the Comptroller of the Currency (OCC) “to promote consistent implementation [of the FHBA] where appropriate.”⁹ The FDIC proposed to revise its rules and procedures in order to conform them to the FHBA and to clarify certain provisions of that statute. For example, the FDIC proposed to revise 12 CFR part 303, subpart L, to reflect the FHBA’s exclusion of certain older offenses from the scope of section 19. The FDIC requested comments on all aspects of its approach to section 19 and, specifically, the following topics of interpretation:

- the date on which a criminal offense “occurred” or was “committed;”
- the date on which “sentencing occurred;”
- whether section 19 encompasses foreign convictions and pretrial diversions;
- the standard for expungements, sealings, and dismissals;
- “offenses involving controlled substances;” and
- *de minimis* offenses.

The comment period closed on January 16, 2024. The FDIC received five comments from six different commenters, consisting of two individuals and four advocacy groups (two advocacy groups provided a joint comment). All of the comments generally supported the proposal. The comment received from one advocacy group did not offer specific changes to the proposal but urged the FDIC and other financial regulators to strengthen their enforcement practices. The other commenters suggested a variety of changes. The comments and the FDIC’s responses are discussed below in sections III and V of this document.

III. Description of the Final Rule

The primary purpose of the final rule is to align the FDIC’s section 19 regulations with the FHBA. The amendments address, among other topics, the types of offenses covered by section 19, the effect of the completion of sentencing or pretrial-diversion program requirements in the context of section 19, and the FDIC’s procedures for reviewing applications filed under section 19. Significant revisions to the

FDIC’s current regulations¹⁰ include the following:

A. Revised Provisions of 12 CFR Part 303, Subpart L

1. Section 303.220 What is section 19 of the Federal Deposit Insurance Act?

Paragraph (b) clarifies that each IDI must make a “reasonable, documented inquiry” to verify an applicant’s history to ensure that a person who has a covered offense on the person’s record is not hired or permitted to participate in its affairs without the written consent of the FDIC. In the FDIC’s 2020 Final Rule concerning revisions to its section 19 regulations, the FDIC stated, “The procedures that constitute a reasonable inquiry will vary from bank to bank, and the FDIC believes that this determination is best left to the business judgments of these institutions.”¹¹ The FDIC reaffirms this position (with the added requirement since 2020 that the inquiry be documented), in response to one commenter’s suggestion.

One commenter recommended that the FDIC clarify that a “reasonable, documented inquiry” would include verifying that the date of any conviction or program entry occurred at least one year or seven years prior, as applicable. (This commenter did not take into consideration the offenses enumerated in 12 U.S.C. 1829(a)(2) that are not affected by the FHBA’s time-based exclusions.) As discussed in greater detail later in this preamble, the FDIC interprets the terms “offense occurred” and “offense committed” in the FHBA to mean the last date of the underlying misconduct rather than the date of conviction or program entry. But since the date of conviction or program entry necessarily follows the last date on which the underlying misconduct occurred, there may be circumstances in which the date of conviction or program entry may provide sufficient information to an IDI that an offense is excluded from the scope of section 19. For example, if a State felony conviction occurred 10 years ago, it would be clear from the criminal record that the conviction is not subject to section 19’s prohibitions, and the use of the conviction date could be used by the IDI to establish a reasonable, documented inquiry. On the other hand, if an IDI cannot ascertain whether an offense is subject to section 19 based on the date of conviction or program entry, it may be necessary for the IDI to perform additional research to determine the last

date of the underlying misconduct. The FDIC is not, however, prescribing the exact procedures that IDIs should follow in conducting a reasonable, documented inquiry.

2. Section 303.221 Who is covered by section 19?

Paragraph (d) more closely aligns its restrictions with the analogous FRB regulations under 12 CFR 225.41 and 238.31 and the FDIC’s regulations under 12 CFR part 303, subpart E, concerning Change in Bank Control applications. A person will be deemed to exercise “control” if that person: (1) has the ability to direct the management or policies of an IDI; (2) has the power to vote 25 percent or more of the voting shares of an IDI; or (3) has the power to vote 10 percent of the voting shares of an IDI if: (a) no other person owns, controls, or has the power to vote more shares; or (b) the institution has registered securities under section 12 of the Securities Exchange Act of 1934.¹² Under the same standards, a person will be deemed to “own” an IDI if that person owns: (1) 25 percent or more of the institution’s voting stock; or (2) 10 percent of the voting shares if: (a) no other person owns more; or (b) the institution has registered securities under section 12 of the Securities Exchange Act of 1934. Paragraph (d) retains language concerning individuals acting in concert with others so as to have such ownership or control. The FDIC has clarified in paragraph (a), however, that the term “acting in concert” has the meaning given to that term in 12 CFR part 303, subpart E (including the rebuttable presumption of “acting in concert” stated in that subpart).

3. Section 303.222 Which offenses qualify as “Covered Offenses” under section 19?

Paragraph (a) reflects the statutory definition of “criminal offense involving dishonesty.”¹³ The FHBA excludes from the scope of such offenses “an offense involving the possession of controlled substances.”¹⁴ The FDIC interprets this phrase concerning controlled substances to exclude, at a minimum, criminal offenses involving the simple possession of controlled substances and possession with intent to distribute a controlled substance. This exclusion may also apply to other drug-related offenses depending on the statutory elements of the offenses or from court determinations that the statutory provisions of the offenses do

⁸ See 88 FR 77906 (Nov. 14, 2023).

⁹ See 12 U.S.C. 1829(f)(9) (“In carrying out this section, the [FDIC] shall consult and coordinate with the National Credit Union Administration as needed to promote consistent implementation where appropriate”).

¹⁰ The rule would also make a number of technical or clarifying edits to the section 19 regulations that are not discussed in this section.

¹¹ 85 FR at 51317.

¹² 15 U.S.C. 781.

¹³ See 12 U.S.C. 1829(g)(2).

¹⁴ 12 U.S.C. 1829(g)(2)(C)(ii).

not involve dishonesty, breach of trust, or money laundering. Potential applicants may contact their appropriate FDIC Regional Office if they have questions about whether their offenses are covered under section 19. This revised regulatory language marks a shift from the FDIC's current section 19 regulations, which require an application for all convictions and pretrial diversions concerning the illegal manufacture, sale, distribution of, or trafficking in controlled substances.

One commenter specifically supported the FDIC's proposal concerning controlled substances. Another commenter said that the FDIC's proposed language was overly broad and contrary to congressional intent and that the proposed exclusion should be limited to the offense of simple possession of controlled substances. This commenter added that banks would face reputational risks if they hired individuals who had been convicted of the crime of possession with the intent to distribute controlled substances. This commenter also recommended that the FDIC retain its regulatory text concerning the illegal manufacture, sale, distribution of, or trafficking in controlled substances.

The FDIC believes that the proposed language is consistent with the text and purposes of the FHBA and would align the FDIC's interpretation of section 19 as to offenses involving controlled substances more closely with other Federal banking regulators. The FHBA explicitly excludes from the category of "criminal offense involving dishonesty" "an offense *involving* the possession of controlled substances," not just the offense of "possession of controlled substances."¹⁵ The modifier "involving," in the FDIC's view, expands that exclusion beyond simple-possession offenses. The revised regulatory language, however, will recognize that a drug-related offense *could* potentially involve dishonesty, breach of trust, or money laundering. Moreover, while section 19 provides statutory barriers to the employment of certain individuals due to their criminal history, IDIs otherwise retain the discretion, under that statute, as to which applicants they want to hire. The FDIC also notes that this revision to its section 19 regulations will *not* affect the FDIC's ability to consider drug-related offenses, as they pertain to the suitability of an individual, under other statutory provisions, including the

Change in Bank Control Act and section 32 of the FDI Act.

The FHBA also states that the term "criminal offense involving dishonesty" does not include "a misdemeanor criminal offense committed more than one year before the date on which an individual files a consent application, excluding any period of incarceration."¹⁶ The FDIC interprets the term "offense committed" to mean the "last date of the underlying misconduct," based on the plain text of the statute. In instances with multiple offenses, "offense committed" means the last date of any of the underlying offenses.

Revised paragraph (c) includes new language reflecting the statute's exception of certain older offenses from the scope of section 19.¹⁷ Among other exceptions, the FHBA states that section 19's restrictions will not apply to an offense if "it has been 7 years or more since the offense occurred."¹⁸ The FDIC considers the phrases "offense committed"—noted above—and "offense occurred" to be substantially similar. Accordingly, the FDIC interprets the term "offense occurred" to mean the "last date of the underlying misconduct." In instances with multiple offenses, "offense occurred" means the last date of any of the underlying offenses.

Two commenters disagreed with the FDIC's proposal and stated that "offense occurred" or "offense committed" should mean the date of the plea, conviction, or program entry. In the FDIC's view, however, the plain meaning of the terms "committed" and "occurred" mean when the underlying misconduct happened. This interpretation is buttressed by Congress's use of the date of conviction or program entry elsewhere in the statute; that is, the statute distinguishes between when misconduct was "committed" or "occurred" and the date of a "conviction" or "program entry."¹⁹

Two commenters expressed concerns that IDIs would have difficulty with ascertaining the underlying date(s) of misconduct for job applicants, as part of background inquiries. The commenters noted that background-check reports that are commercially or otherwise

available tend to list the date of arrest, conviction, or release from incarceration but not necessarily the date of the underlying misconduct. The FDIC believes that, for many applicants, an IDI will be able to determine whether an offense is covered by section 19 using the background-check reports noted by the commenters. And as stated earlier in this preamble, an IDI may conduct a reasonable, documented inquiry by using the date of conviction or program entry if it is clear from that information that an applicant's offense is not subject to section 19 due to the amount of time that has elapsed. On the other hand, if an IDI cannot ascertain whether an offense is subject to section 19 based on the date of conviction or program entry, it may be necessary for the IDI to perform additional research to determine the last date of the underlying misconduct.

Revised paragraph (c) contains another FHBA exception: section 19's restrictions would not apply to an offense if "the individual was incarcerated with respect to the offense and it has been 5 years or more since the individual was released from incarceration."²⁰ While the language of the statute is clear, the FDIC notes that there could be situations in which an individual who was incarcerated with respect to an offense would be permitted to work at an IDI before a similarly situated individual who was not incarcerated in connection with an offense. This difference is due to the FHBA's use of a shorter time period for individuals who were incarcerated for an offense than for individuals who did not serve jail time. Revised paragraph (c) also tracks the FHBA's language concerning offenses committed by individuals 21 years of age or younger. The FHBA states that, for individuals who committed an offense when the individual was 21 years of age or younger, section 19 "shall not apply to the offense if it has been more than 30 months since the sentencing occurred."²¹ The FDIC interprets "sentencing occurred" to mean the date on which a court imposed the sentence (as indicated by the date on the court's sentencing order), not the date on which all conditions of sentencing were completed. Moreover, revised paragraph (c) notes that its exclusions—which are derived from the FHBA—do not apply to the enumerated offenses described under 12 U.S.C. 1829(a)(2).²²

One commenter agreed with the FDIC that the term "sentencing occurred"

¹⁵ See 12 U.S.C. 1829(g)(2)(C)(ii) (emphasis added).

¹⁶ 12 U.S.C. 1829(g)(2)(C)(i).

¹⁷ See 12 U.S.C. 1829(c)(1).

¹⁸ 12 U.S.C. 1829(c)(1)(A)(i).

¹⁹ See, e.g., 12 U.S.C. 1829(c)(3)(D) ("Subsection (a) shall not apply to certain lesser offenses (including the use of a fake ID, shoplifting, trespass, fare evasion, driving with an expired license or tag, and such other low-risk offenses as the Corporation may designate) if 1 year or more has passed since the applicable conviction or program entry" (emphasis added).)

²⁰ 12 U.S.C. 1829(c)(1)(A)(ii).

²¹ 12 U.S.C. 1829(c)(1)(B).

²² See 12 U.S.C. 1829(c)(1)(C).

should mean the date when sentence was imposed by the court. Another commenter—to the NCUA's parallel notice of proposed rulemaking under the FHBA²³—suggested that the term “sentencing occurred” should mean the date that appears on the sentencing order, instead of the date the court's clerk entered the order on the docket. The FDIC agrees with this suggestion, as indicated above.

Revised paragraph (d) adds language to codify the FDIC's long-held position that individuals who are convicted of or enter into a pretrial diversion program for a criminal offense involving dishonesty, breach of trust, or money laundering in foreign jurisdictions are subject to section 19, unless the offense is otherwise excluded by 12 CFR part 303, subpart L.

One commenter stated that foreign convictions and pretrial diversions should be excluded from the scope of section 19. This commenter cited the difficulty of investigating criminal matters in foreign jurisdictions in which an applicant may have worked or resided, noted that banks might not have operations in such jurisdictions, and expressed concern that banks could expose themselves to liability in foreign jurisdictions through conducting background checks. Moreover, this commenter said that certain applicants for bank employment may already have completed a background check for the visa process; therefore, there would be a risk of duplication with a bank's investigation.

The FDIC has retained its proposed language as to foreign offenses due to the importance of ensuring that individuals with covered offenses do not participate in the affairs of IDIs without the FDIC's consent. Employers may be unaware of an applicant's foreign offenses without conducting their own inquiry, and many countries have their own application processes to conduct criminal background checks. The FDIC reiterates several non-exhaustive ways in which banks could comply with this requirement. For IDI operations outside the United States, the IDI could conduct a reasonable, documented inquiry to verify an applicant's history, in accordance with 12 CFR 303.220, by inquiring about potential covered offenses that may have occurred in that foreign country (or countries) in which the IDI conducts operations, as well as in the United States. As another example of such an inquiry, if an IDI plans to hire someone in the United States who is from a foreign country, the IDI could inquire

about potential covered offenses that may have occurred in the United States and in that foreign country. And if a foreign jurisdiction forbade background investigations by an IDI, the IDI could note this restriction as part of its reasonable, documented inquiry.

4. Section 303.223 What constitutes a conviction under section 19?

Paragraph (c) has been revised to reflect statutory language related to the treatment of orders of expungement, sealing, or dismissal of criminal records.²⁴ The FHBA provides a two-pronged test to determine whether a covered offense should be considered expunged, dismissed, or sealed and therefore excluded from the scope of section 19. First, there must be an “order of expungement, sealing, or dismissal that has been issued in regard to the conviction in connection with such offense”; second, it must be “intended by the language in the order itself, or in the legislative provisions under which the order was issued, that the conviction shall be destroyed or sealed from the individual's State, Tribal, or Federal record, even if exceptions allow the record to be considered for certain character and fitness evaluation purposes.”²⁵ The statute does not address expungements, sealings, or dismissals by operation of law, and the FDIC has sought to harmonize its current regulations concerning expunged and sealed records with the statutory language to provide a more comprehensive framework as to such records. The FDIC has also added language to the second (intent) prong of the expungement framework to encompass the language in the expungement order itself, the legislative provisions under which the order was issued, *and other legislative provisions*. This revision also seeks to harmonize the FDIC's current regulations concerning expungements with the FHBA's provisions. The FDIC believes that all of the additional language is consistent with the purposes of the statute.

Revised paragraph (d) clarifies that it encompasses the terms “youthful offender” and “juvenile delinquent” *and similar terms*, since a court does not have to specifically use these terms in an adjudication in order for paragraph (d)'s provisions to apply.

5. Section 303.224 What constitutes a pretrial diversion or similar program (program entry) under section 19?

This section has been revised to reflect the statutory definition of “pretrial diversion or similar program.”²⁶

6. Section 303.225 What are the types of applications that can be filed?

This section has been revised to reflect the updated statutory filing procedures. The statute removes the FDIC's former policy that an institution sponsor a consent application or that an individual seek a waiver of the institution filing requirement. Moreover, the statute enables a depository institution holding company to file an application on behalf of an individual (previously, only IDIs could file such sponsored applications).²⁷ In order to avoid duplication of applications filed with the FRB and the FDIC, revised paragraph (a) states that the FDIC will accept applications from: an individual; an IDI applying on behalf of an individual; a depository institution holding company applying on behalf of an individual with respect to a depository institution subsidiary of the holding company; and a depository institution holding company applying on behalf of an individual who will work at the holding company but also participate in the affairs of the IDI or who would be in a position to influence or control the management or affairs of the IDI, in accordance with 12 CFR 303.221(a).

Revised paragraph (b), consistent with the FHBA, states that an individual or an institution may file applications at separate times. Under either approach, the application(s) must be filed with the appropriate FDIC Regional Office.²⁸

7. Section 303.226 When may an application be filed?

This revised section notes that, before an application may be filed, “all of the sentencing requirements associated with a conviction, or conditions imposed by the program entry, including but not limited to, imprisonment, fines, condition of rehabilitation, and probation requirements, must be completed, and the case must be considered final by the procedures of the applicable jurisdiction.” The FDIC includes this revised language to accord with several of the FHBA's exclusions from section 19 that are not tied to the completion of sentencing requirements.

²³ See 88 FR 76702 (Nov. 7, 2023).

²⁴ See 12 U.S.C. 1829(c)(2).

²⁵ 12 U.S.C. 1829(c)(2).

²⁶ See 12 U.S.C. 1829(g)(3).

²⁷ See 12 U.S.C. 1829(f)(1).

²⁸ See 12 U.S.C. 1829(f)(1).

Furthermore, the FHBA requires the FDIC to “make all forms and instructions related to consent applications available to the public, including on the website of the Corporation.”²⁹ These forms and instructions “shall provide a sample cover letter and a comprehensive list of items that may accompany the application, including clear guidance on evidence that may support a finding of rehabilitation.”³⁰ While the FDIC has not explicitly mentioned these requirements in its regulations, the agency will comply with them. One commenter agreed with the FDIC’s proposal concerning this provision of forms and instructions.

8. Section 303.227 De minimis Exemption

The FDIC has made a number of changes to this section based on the statutory revisions and helpful comments received. Two commenters asked for additional clarity on what constitutes a *de minimis* offense. Another commenter requested that the FDIC revise this section to exempt *de minimis* offenses from the scope of section 19’s prohibition, to align with the FHBA. In agreement, the FDIC has revised this section to treat *de minimis* offenses—a category that includes the sub-category “designated lesser offenses”—as offenses that are excluded from the prohibitions of 12 U.S.C. 1829(a) (assuming certain conditions are met) and for which offenses no application is required. This is a substantive departure from the FDIC’s longstanding treatment of *de minimis* offenses, in which potential applicants with such offenses on their records did not need to file an application with the FDIC because the FDIC deemed their (potential) application automatically approved. In other words, the FDIC considered such offenses covered under section 19 while the FHBA exempts those offenses entirely from section 19.

The FHBA removed the use of fake identification from the scope of section 19, and revised paragraphs (a)(1) and (b)(4) reflect this exclusion.³¹ Revised paragraph (a)(2) reflects the FHBA’s confinement criteria as to the FDIC’s determination of *de minimis* offenses.³² Revised paragraph (a)(5) requires that, in order for an offense or offenses to qualify under the general *de minimis* framework, each offense must not have been committed against an IDI or insured credit union. This language

aligns with the current FDIC regulations.

Revised paragraph (b)(1) (Age of person at time of Covered Offense) clarifies that, for a reduced waiting period to apply before an individual may qualify for the *de minimis* exemption, the underlying convictions or program entries must meet the other *de minimis* criteria in paragraph (a) of § 303.227. This clarification reflects the FDIC’s existing interpretation of this paragraph.

The FDIC has revised the *de minimis* requirement related to the aggregate total face value of all “bad” or insufficient funds checks in paragraph (b)(2)(i) from \$1,000 to \$2,000 to conform with the statute.³³ Revised paragraph (b)(4) excludes from the scope of covered offenses “designated lesser offenses” (for example, using fake identification), as specified in 12 U.S.C. 1829(c)(3)(D), if one year or more has passed since the applicable conviction or program entry. One commenter requested that the FDIC should explain which offenses are considered “designated lesser offenses” that do not require FDIC consent. The FDIC believes that the revised regulations adequately define such offenses.

The FDIC has deleted former § 303.227(c) concerning fidelity bond coverage and disclosure of *de minimis* offenses to IDIs. This now-deleted paragraph had required that any person who meets the criteria under this section shall be covered by a fidelity bond to the same extent as others in similar positions, and must disclose the presence of the conviction(s) or program entry(ies) to all IDIs in the affairs of which that person intends to participate. Since the FHBA has excluded *de minimis* offenses from the scope of section 19, however, the FDIC believes that these requirements should no longer attach to individuals who have committed such offenses. This change is in response to one commenter’s request that the FDIC clarify its position concerning *de minimis* offenses and is related to another commenter’s suggestion that the FDIC treat *de minimis* offenses the same way as “designated lesser offenses” by excluding both types of offenses from the scope of section 19.

9. Section 303.228 How To File an Application

This revised section eliminates the institution filing requirement and waiver process and indicates that an “institution”—an IDI or a depository institution holding company—may file

an application on behalf of an individual, rather than just an IDI. The individual may also file an application. These revisions are due to the updated statutory language.³⁴ This revised section also clarifies that the appropriate FDIC Regional Office for an institution-sponsored application is the office covering the state where the institution’s home office is located and that the appropriate FDIC Regional Office for an application filed by an individual is the office covering the state where the person resides.

10. Section 303.229 How an Application Is Evaluated

Revised paragraph (a) reflects new statutory requirements related to the FDIC’s review process, including the requirement that the FDIC primarily rely on the criminal history record provided by the Federal Bureau of Investigation in the FDIC’s review and provide such record to the applicant to review for accuracy.³⁵ The FDIC interprets the term “criminal history record” to mean “identity history summary checks,” which are commonly known as “rap sheets.” Under revised paragraph (a)—and in accordance with the FHBA—the FDIC, in reviewing a consent application, will provide a copy of the rap sheet to the individual who is the subject of the application to review for accuracy.³⁶

One commenter requested that the FDIC establish a deadline to evaluate the application once received and a deadline of five days to return the copy of the criminal history record once received from the Federal Bureau of Investigation. The FDIC adopts this recommendation in part. Under revised paragraph (a)(2), the FDIC will make reasonable efforts to communicate with the subject of the application within 15 calendar days of receipt of this record from the Federal Bureau of Investigation to inform the individual that the FDIC will be providing them with a copy of the report and to verify the individual’s contact information. The FDIC will also make reasonable efforts to send the report to the individual within 5 business days of successful verification of the individual’s contact information. If the individual believes that there are any inaccuracies in the report, the FDIC will direct the individual to an appropriate contact at the Federal Bureau of Investigation where the individual can seek corrections to the report.

²⁹ 12 U.S.C. 1829(f)(5)(A).

³⁰ 12 U.S.C. 1829(f)(5)(B).

³¹ See 12 U.S.C. 1829(c)(3)(D).

³² See 12 U.S.C. 1829(c)(3)(B).

³³ See 12 U.S.C. 1829(c)(3)(C).

³⁴ See 12 U.S.C. 1829(f)(1).

³⁵ See 12 U.S.C. 1829(f)(6)(A)(i).

³⁶ See 12 U.S.C. 1829(f)(6)(A)(ii).

Revised paragraph (b) states that the FDIC will not require an individual to provide certified copies of criminal history records unless the FDIC determines that there is a clear and compelling justification to require additional information to verify the accuracy of the criminal history record provided by the Federal Bureau of Investigation (that is, the rap sheet).³⁷

Revised paragraph (d) clarifies how the FDIC will evaluate evidence of rehabilitation and other evidence, as required by the FHBA.³⁸

Revised paragraph (g) eliminates references to the former application-waiver requirement.

Finally, revised paragraph (h) incorporates statutory language explaining when a new institution-sponsored application would be necessary due to changes in the scope of an applicant's employment.³⁹

11. Section 303.230 What will the FDIC do if the application is denied?

Revised paragraph (b) clarifies that, for institution-sponsored applications, either the institution or the subject individual (or both, as a consolidated request) may file a written request for a hearing (or a request for written submission in lieu of a hearing) under 12 CFR part 308, subpart M.

12. Section 303.231 Waiting Time for a Subsequent Application if an Application Is Denied

This revised section, among other provisions, requires a one-year waiting period to file a consent application, following the issuance of a decision denying such an application. This general requirement is substantially unchanged from existing regulations, but the FDIC has made several technical amendments to align this section with the FHBA. Revised paragraph (a) acknowledges that the passage of time may remove an offense from the scope of section 19. And the final rule creates a new paragraph (b)—which notes that an institution-sponsored application is not subject to the one-year waiting period if the application (1) follows the denial of an individual application, or (2) follows the denial of an institution-sponsored application and the subsequent application is sponsored by a different institution or is for a different position.

³⁷ 12 U.S.C. 1829(f)(6)(B).

³⁸ 12 U.S.C. 1829(f)(7). While the statute uses the terms "rehabilitation" and "mitigating" as separate categories of evidence, the terms appear to be substantially similar, in the context of section 19 applications, and the use of both terms in these regulations may create confusion. Therefore, the rule uses the term "rehabilitation" not "mitigating."

³⁹ See 12 U.S.C. 1829(f)(8).

B. Revised Provisions of 12 CFR Part 308, Subpart M

The rule makes several technical amendments to subpart M. The rule revises the subpart's title to reflect that, following a denial of an application under 12 CFR part 303, subpart L, an applicant may request either a hearing or written submissions in lieu of a hearing. The rule also amends §§ 308.156, 308.157, and 308.158 to do the following: (1) encompass applications that are sponsored by depository institution holding companies; (2) explain that, if an application has been denied under 12 CFR part 303, subpart L, an applicant may request either a hearing or written submissions in lieu of a hearing; (3) clarify several sentences concerning hearing procedures; and (4) use more consistent terminology.

IV. Expected Effects

As previously discussed, the rule aligns the FDIC's regulations with the FHBA's provisions, makes additional changes to further clarify the FDIC's regulations related to section 19, more closely aligns the FDIC's section 19 regulations with those of other Federal financial regulators, and makes a number of non-substantive, technical edits. As of the quarter ending March 31, 2024, there were 4,577 FDIC-insured depository institutions, all of which are covered by the rule and therefore could be affected.⁴⁰ Additionally, the rule applies to persons covered by the provisions of section 19, including those who are or wish to become employees, officers, directors, or controlling shareholders of an IDI or who otherwise are or wish to become an institution-affiliated party (IAP) of an IDI.

To estimate the number of institutions and individuals affected by the rule, the FDIC counted the number of section 19 applications it has received between 2021 and 2023. Over this period, the FDIC received 16 bank-sponsored section 19 applications, an average of 5 per year. Additionally, the FDIC received 115 individual section 19 applications during the same period, an average of approximately 38 per year.⁴¹ Therefore, the FDIC estimates that the rule could affect at least 5 FDIC-insured depository institutions and 38 individuals per year. Assuming that each application involves a different institution, approximately 1 percent of insured institutions, or 43, could be affected per year on average.⁴²

⁴⁰ FDIC Call Report data, March 31, 2024.

⁴¹ FDIC Application Tracking System.

⁴² $(43/4,577) * 100 = 0.9$ percent.

As previously described, the rule aligns the FDIC's regulations with the FHBA's provisions. In particular, the FHBA created several categories of exceptions or exemptions to the prohibition on participating in banking. The rule incorporates these categories of exemptions and exceptions. The FDIC believes that the additional categories for exceptions or exemptions to the prohibition on participating in banking established by the FHBA could benefit certain individuals and IDIs by reducing the number of applications they would otherwise be required to file under section 19. Additionally, the categories of exceptions or exemptions to the prohibition on participating in banking established by the FHBA could benefit IDIs by marginally expanding the supply of labor available. However, these changes were created by the FHBA and were effective immediately upon passage, and the rule aligns the FDIC's regulations with these elements of the FHBA; therefore, the associated changes in the rule will have no direct effect on individuals or IDIs.

The rule amends the FDIC's existing section 19 application-procedure regulations to incorporate the FHBA's provisions. The FDIC's current section 19 regulations contain references to existing application procedures that are similar in substance to those established by FHBA. However, the FHBA, among other requirements, compels the FDIC to primarily rely on the criminal history record of the Federal Bureau of Investigation when reviewing consent applications. It is the current practice of the FDIC to consider all relevant information when evaluating a section 19 application. However, the establishment of a common source of criminal history, together with only requiring certified copies of criminal history records if there exists clear and compelling justification for doing so, could benefit certain individuals and IDIs by marginally reducing the volume of information they need to supply to the FDIC. The FDIC believes that, while these changes to the application procedures will directly affect certain individuals and institutions that file section 19 applications, they may not have a substantial effect on potential applicants. These changes, moreover, were created by the FHBA and were effective immediately upon passage, and the rule aligns the FDIC's regulations with these elements of the FHBA; therefore, the associated changes in the rule will have no direct effect on individuals or IDIs.

Finally, in seeking to align its section 19 regulations with the provisions of the FHBA, the FDIC used its discretion to

marginally increase the scope of certain terms so as to better reflect the purposes of the FHBA and adopt certain deadlines to facilitate processing. In particular, the FDIC has provided broader language as to the scope of expunged, sealed, or dismissed offenses. This aspect of the rule could potentially benefit persons covered by the provisions of section 19, including individuals who are or wish to become employees, officers, directors, or controlling shareholders of an IDI, or who otherwise are or wish to become an IAP of an IDI. Further, the FDIC has established certain deadlines to further clarify the evaluation process for future applicants and facilitate processing. However, given that most of the amendments are focused on aligning the FDIC's regulations with the FHBA, the marginal effect of these aspects of the rule are likely to be small.

V. Other Alternatives Considered

As discussed above, almost all of the significant changes to the FDIC's section 19 regulations stem from the FHBA's revisions to section 19. The FDIC had limited discretion in adopting alternatives to those statutory revisions. The FDIC considered other proposals that were submitted by the commenters but believes that the final amendments represent the most appropriate option for covered entities and individuals. This section discusses those other proposals.

A. More Aggressive Enforcement

One commenter said that federal financial regulators should increase the number of enforcement actions against and the severity of the punishments for executives of large banks who harm consumers and threaten the country's financial stability. This comment, in the FDIC's view, is outside the scope of this rulemaking.

B. Data Collection, and Consider Effects on Criminal Justice System

One commenter suggested that the FDIC should collect information on instances of criminal recidivism among bank employees, in light of the FHBA's exclusion of previously covered offenses from the scope of section 19. The FDIC declines to adopt this proposal because it would be administratively impracticable for the FDIC to obtain this information from the thousands of IDIs subject to section 19, and this proposal would impose significant compliance burdens on those institutions.

One commenter suggested that the FDIC consider how the rule might affect the federal criminal justice system and public safety. This commenter noted

that some individuals may be released from prison early or receive shorter sentences due to the First Step Act of 2018.⁴³ In response, the FDIC notes that it is finalizing this rulemaking in accordance with the policy choices of Congress and the President.

C. Proposals Received by the NCUA

On November 7, 2023, the NCUA issued a notice of proposed rulemaking to implement the FHBA as to the NCUA's regulations,⁴⁴ and the NCUA received several comments addressing the following topics. (Earlier in this Preamble, the FDIC addressed a suggestion from an NCUA commenter that concerned the date on which a court imposed a sentence.) The FDIC considered these other proposals—as part of its statutory obligation to consult and coordinate with the NCUA to promote consistent implementation of the FHBA⁴⁵—and has decided not to incorporate them into the final rule. These commenters made the following recommendations, among others.

Several commenters suggested that the *de minimis* exclusion should not be available for offenses committed against any depository institution or credit union—not just insured depository institutions and insured credit unions. The FDIC's position is that the primary purpose of section 19 is to protect IDIs and, by extension, the Deposit Insurance Fund. Accordingly, the FDIC's *de minimis* framework focuses on offenses that have been committed against such institutions (and insured credit unions) rather than against non-federally insured institutions. For this reason, the FDIC declines to implement this suggestion.

One commenter recommended excluding pardoned offenses from the scope of section 19 and suggested that pardoned offenses should be treated the same as expunged offenses. The FDIC disagrees with this recommendation and notes its longstanding position that covered offenses that have been pardoned—and which are not otherwise excluded from the scope of section 19—will still require an application. A pardon typically cancels the punishment for a criminal offense, not the underlying finding of guilt. In contrast, an expungement or sealing is significantly more likely to result—by applicable statute of court order—in the removal of the finding of guilt or otherwise result in a legal determination that the offense should not be used against an individual for employment

purposes. Accordingly, in the FDIC's view, a person with such an expunged or sealed offense tends to present less of a risk to the banking system than a person whose same offense has been pardoned.

One commenter suggested that the FDIC should increase the maximum potential penalty threshold from \$2,500 to \$5,000 under the general *de minimis* framework, in keeping with a certain federal criminal statute. The FDIC declines to expand the *de minimis* framework as proposed because the FDIC considers the current threshold appropriate. The \$2,500 amount is comparable to the \$2,000 *de minimis* threshold for insufficient-fund offenses under the FHBA.⁴⁶

VI. Regulatory Analysis

A. The Paperwork Reduction Act

In accordance with the requirements of the Paperwork Reduction Act (PRA),⁴⁷ the FDIC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number.

The FDIC received one comment that appears to relate to the PRA. The commenter suggested that the FDIC should collect information on instances of criminal recidivism among bank employees, in light of the FHBA's exclusion of previously covered offenses from the scope of section 19. The FDIC declines to adopt this proposal because it would be administratively impracticable for the FDIC to obtain this information from the thousands of IDIs subject to section 19, and this proposal would impose significant compliance burdens on those institutions. In other words, the compliance burden associated with collecting this information would outweigh the benefits and practical utility of collecting this information.

The FDIC will revise its section 19 application form to conform with the changes to section 19 under the FHBA. These changes amend the FDIC's existing information collection associated with this rule, entitled “Application Pursuant to Section 19 of the Federal Deposit Insurance Act” (3064–0018). For this reason, the information collection requirements contained in this final rule will be submitted by the FDIC to OMB for review and approval under section 3507(d) of the PRA (44 U.S.C. 3507(d)) and § 1320.11 of the OMB's

⁴³ Public Law 115–391, 132 Stat. 5194.

⁴⁴ See 88 FR 76702.

⁴⁵ See 12 U.S.C. 1829(f)(9).

⁴⁶ See 12 U.S.C. 1829(c)(3)(C).

⁴⁷ 44 U.S.C. 3501 *et seq.*

implementing regulations (5 CFR part 1320).

Based on available data, the number of respondents and the estimated annual burden associated with the information collection will decrease.

Information Collection

Title: “Application Pursuant to Section 19 of the Federal Deposit Insurance Act”.

OMB Number: 3064–0018.

Affected Public: Insured depository institutions and individuals.

SUMMARY OF ESTIMATED ANNUAL BURDENS [OMB No. 3064–0018]

IC description	Type of burden (obligation to respond)	Frequency of response	Number of respondents	Number of responses/respondent	Hours per response	Annual burden (hours)
Application Pursuant to Section 19 of the Federal Deposit Insurance Act.	Reporting (Required to obtain or retain benefits).	On occasion	43	1	16	688
Total Annual Burden Hours						688

Source: FDIC.

B. The Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency, in connection with a final rule, to prepare and make available for public comment a final regulatory flexibility analysis that describes the impact of the final rule on small entities.⁴⁸ However, a final regulatory flexibility analysis is not required if the agency certifies that the final rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. The Small Business Administration (SBA) has defined “small entities” to include banking organizations with total assets of less than or equal to \$850 million.⁴⁹ Generally, the FDIC considers a significant economic impact to be a quantified effect in excess of 5 percent of total annual salaries and benefits or 2.5 percent of total noninterest expenses. The FDIC believes that effects in excess of one or more of these thresholds typically represent significant economic impacts for FDIC-supervised institutions.

As discussed further below, the FDIC certifies that the final rule will not have a significant economic impact on a substantial number of FDIC-supervised small entities.

As of the quarter ending March 31, 2024, the FDIC insured 4,577 depository institutions, of which 3,259 are defined

as small banking organizations for the purposes of the RFA.⁵⁰ In the period from 2021 through 2023, the FDIC received 5 bank-sponsored section 19 applications from small, FDIC-insured institutions, an average of 2 per year. Additionally, the FDIC received 115 section 19 applications from individuals during the same period, an average of about 38 per year.⁵¹ To determine the maximum number of small, FDIC-insured institutions that could be affected by the final rule, this analysis assumes that each applicant is seeking employment at a different bank and that each bank is a small, FDIC-insured institution. Based on these assumptions, 40 (1.2 percent of) small, FDIC-insured institutions, on average, annually, could be affected by the final rule.⁵² Section 19 applications from individuals are compelled by the applicant’s intent to seek employment at FDIC-insured institutions, many of which are not small. Therefore, the FDIC believes that the number of small, FDIC-insured institutions affected by the final rule is likely to be less than 40.

As discussed in the **SUPPLEMENTARY INFORMATION** section, the final rule would align the FDIC’s regulations with the FHBA’s provisions, make additional changes to further clarify the FDIC’s regulations related to section 19, more closely align the FDIC’s section 19 regulations with those of other Federal financial regulators, and make a number of non-substantive, technical edits. Most of the amendments were precipitated by the FHBA—which was effective immediately upon passage—and the final rule aligns the FDIC’s regulations with these elements of the FHBA; therefore, most of the associated changes in the final rule will have no

direct effect on individuals or IDIs. Further, since the FDIC estimates that a maximum of 40 small, FDIC-insured institutions could be affected by the final rule, on average, annually, any direct effects realized as a result of the final rule are likely to be small and affect a relatively small number of entities.

In light of the foregoing, the FDIC certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

C. Plain Language

Section 722 of the Gramm-Leach Bliley Act⁵³ requires the Federal banking agencies to use plain language in all proposed and final rulemakings published in the **Federal Register** after January 1, 2000. FDIC staff believes the final rule is presented in a simple and straightforward manner. The FDIC invited comments regarding the use of plain language in the proposed rule but did not receive any comments on this topic.

D. Riegle Community Development and Regulatory Improvement Act of 1994

Under section 302(a) of the Riegle Community Development and Regulatory Improvement Act (RCDRIA),⁵⁴ in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on IDIs, each Federal banking agency must consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the

⁴⁸ 5 U.S.C. 601 *et seq.*

⁴⁹ The SBA defines a small banking organization as having \$850 million or less in assets, where an organization’s “assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.” See 13 CFR 121.201 (as amended by 87 FR 69118, effective December 19, 2022). In its determination, the “SBA counts the receipts, employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates.” See 13 CFR 121.103. Following these regulations, the FDIC uses an IDI’s affiliated and acquired assets, averaged over the preceding four quarters, to determine whether the insured depository institution is “small” for the purposes of the RFA.

⁵⁰ FDIC Call Report, March 31, 2024.

⁵¹ FDIC Application Tracking System.

⁵² $(40/3,259) * 100 = 1.23$ percent.

⁵³ Public Law 106–102, sec. 722, 113 Stat. 1338, 1471 (1999), *codified at* 12 U.S.C. 4809.

⁵⁴ 12 U.S.C. 4802(a).

benefits of such regulations. In addition, section 302(b) of RCDRIA requires new regulations and amendments to regulations that impose additional reporting, disclosures, or other new requirements on IDIs generally to take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form.⁵⁵ The FDIC has determined that the final rule would impose additional reporting, disclosure, or other new requirements on IDIs, and is making this final rule effective in accordance with the requirements of the RCDRIA.

E. Congressional Review Act

For purposes of the Congressional Review Act (5 U.S.C. 801 *et seq.*), the OMB makes a determination as to whether a final rule constitutes a “major rule.” If a rule is deemed a “major rule” by the OMB, the Congressional Review Act generally provides that the rule may not take effect until at least 60 days following its publication.⁵⁶ The Congressional Review Act defines a “major rule” as any rule that the Administrator of the Office of Information and Regulatory Affairs of the OMB finds has resulted in or is likely to result in—(1) an annual effect on the economy of \$100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets.⁵⁷ The OMB has determined that the final rule is not a major rule for purposes of the Congressional Review Act and the FDIC will submit the final rule and other appropriate reports to Congress and the Government Accountability Office for review.

List of Subjects

12 CFR Part 303

Administrative practice and procedure, Bank deposit insurance, Banks, Banking, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 308

Administrative practice and procedure, Bank deposit insurance, Banks, Banking, Claims, Crime, Equal

access to justice, Fraud, Investigations, Lawyers, Penalties, Savings associations.

Authority and Issuance

For the reasons stated in the preamble and under the authority of 12 U.S.C. 1819 (Seventh and Tenth), the FDIC amends 12 CFR parts 303 and 308 as follows:

PART 303—FILING PROCEDURES

■ 1. The authority citation for part 303 is revised to read as follows:

Authority: 12 U.S.C. 378, 1464, 1813, 1815, 1817, 1818, 1819(a) (Seventh and Tenth), 1820, 1823, 1828, 1829, 1831a, 1831e, 1831o, 1831p-1, 1831w, 1835a, 1843(l), 3104, 3105, 3108, 3207, 5414, 5415, and 15 U.S.C. 1601–1607.

■ 2. Revise subpart L, consisting of §§ 303.220 through 303.231, to read as follows:

Subpart L—Section 19 of the Federal Deposit Insurance Act (Consent To Service of Persons Convicted of, or Who Have Program Entries for, Certain Criminal Offenses)

Sec.

- 303.220 What is section 19 of the Federal Deposit Insurance Act?
- 303.221 Who is covered by section 19?
- 303.222 Which offenses qualify as “Covered Offenses” under section 19?
- 303.223 What constitutes a conviction under section 19?
- 303.224 What constitutes a pretrial diversion or similar program under section 19?
- 303.225 What are the types of applications that can be filed?
- 303.226 When may an application be filed?
- 303.227 De minimis exemption.
- 303.228 How to file an application.
- 303.229 How an application is evaluated.
- 303.230 What will the FDIC do if the application is denied?
- 303.231 Waiting time for a subsequent application if an application is denied.

§ 303.220 What is section 19 of the Federal Deposit Insurance Act?

(a) This subpart covers applications under section 19 of the Federal Deposit Insurance Act (FDI Act), 12 U.S.C. 1829. The FDIC refers to such applications as “consent applications.” Under section 19, any person who has been convicted of any criminal offense involving dishonesty, breach of trust, or money laundering, or has agreed to enter into a pretrial diversion or similar program (program entry) in connection with a prosecution for such offense (collectively, Covered Offenses), may not become, or continue as, an institution-affiliated party (IAP) of an insured depository institution (IDI); own or control, directly or indirectly, any

IDI; or otherwise participate, directly or indirectly, in the conduct of the affairs of any IDI without the prior written consent of the FDIC.

(b) In addition, the law prohibits an IDI from permitting such a person to engage in any conduct or to continue any relationship prohibited by section 19. IDIs must therefore make a reasonable, documented inquiry to verify an applicant’s history to ensure that a person who has a Covered Offense under section 19 is not hired or permitted to participate in its affairs without the written consent of the FDIC issued under this subpart. FDIC-supervised IDIs may extend a conditional offer of employment contingent on the completion of a background check satisfactory to the institution to determine if the applicant is prohibited under section 19, but the applicant may not work for, be employed by, or otherwise participate in the affairs of the IDI until the IDI has determined that the applicant is not prohibited under section 19 (including persons who have had a consent application approved).

(c) If there is a conviction or program entry covered by the prohibitions of section 19, an application under this subpart must be filed seeking the FDIC’s consent in order to become, or to continue as, an IAP; to own or control, directly or indirectly, an IDI; or to otherwise participate, directly or indirectly, in the affairs of the IDI. The application must be filed, and consented to, prior to serving in any of the foregoing capacities unless such application is not required under the subsequent provisions of this subpart. The purpose of an application is to provide the applicant an opportunity to demonstrate that, notwithstanding the prohibition, a person is fit to participate in the conduct of the affairs of an IDI without posing a risk to its safety and soundness or impairing public confidence in that institution. The burden is upon the applicant to establish that the application warrants approval.

§ 303.221 Who is covered by section 19?

(a) Persons covered by section 19 include IAPs, as defined by 12 U.S.C. 1813(u), and others who are participants in the conduct of the affairs of an IDI. Therefore, all directors, officers, and employees of an IDI who fall within the scope of section 19, including *de facto* employees, as determined by the FDIC based upon generally applicable standards of employment law, will also be subject to section 19. Whether other persons are covered by section 19 depends upon their degree of influence

⁵⁵ *Id.* at 4802(b).

⁵⁶ See 5 U.S.C. 801.

⁵⁷ See 5 U.S.C. 804(2).

or control over the management or affairs of an IDI. For example, section 19 would apply to directors and officers of affiliates, subsidiaries, or joint ventures of an IDI if they participate in the affairs of the IDI or are in a position to influence or control the management or affairs of the IDI. Typically, an independent contractor does not have a relationship with the IDI other than the activity for which the institution has contracted. However, an independent contractor who also influences or controls the management or affairs of the IDI would be covered by section 19.

(b) The term *person*, for purposes of section 19, means an individual and does not include a corporation, firm, or other business entity.

(c) Individuals who file an application with the FDIC under the provisions of section 19 who also seek to participate in the affairs of a bank holding company or savings and loan holding company may have to comply with any filing requirements of the Board of the Governors of the Federal Reserve System under 12 U.S.C. 1829(d) and (e). Conversely, an individual who works at a bank holding company or savings and loan holding company who would like to participate in the affairs of an IDI or be in a position to influence or control the management or affairs of an IDI must file an application with the FDIC under this subpart.

(d) Section 19 specifically prohibits a person subject to its provisions from owning or controlling, directly or indirectly, an IDI. The terms *control*, *ownership*, and *acting in concert* under section 19 have the meaning given to those terms in subpart E of this part (including the rebuttable presumptions stated in subpart E of this part).

(1) A person will be deemed to exercise “control” if that person—

(i) Has the ability to direct the management or policies of an IDI;

(ii) Has the power to vote 25 percent or more of the voting shares of an IDI; or

(iii) Has the power to vote 10 percent of the voting shares of an IDI if—

(A) No other person owns, controls, or has the power to vote more shares; or

(B) The institution has registered securities under section 12 of the Securities Exchange Act of 1934 (15 U.S.C. 78l).

(2) Under this paragraph (d), a person will be deemed to “own” an IDI if that person owns—

(i) 25 percent or more of the institution’s voting stock; or

(ii) 10 percent of the voting shares if—

(A) No other person owns more; or

(B) The institution has registered securities under section 12 of the

Securities Exchange Act of 1934 (15 U.S.C. 78l).

(3) The standards in this paragraph (d) would also apply to an individual acting in concert with others so as to have such ownership or control. Absent the FDIC’s consent, persons subject to the prohibitions of section 19 must divest their control or ownership of shares above the foregoing limits.

§ 303.222 Which offenses qualify as “Covered Offenses” under section 19?

(a) *Categories of Covered Offenses.* The conviction or program entry must be for a criminal offense involving dishonesty, breach of trust, or money laundering.

(1) The term *criminal offense involving dishonesty*—

(i) Means an offense under which an individual, directly or indirectly—

(A) Cheats or defrauds; or

(B) Wrongfully takes property belonging to another in violation of a criminal statute;

(ii) Includes an offense that Federal, State, or local law defines as dishonest, or for which dishonesty is an element of the offense; and

(iii) Does not include—

(A) A misdemeanor criminal offense committed more than one year before the date on which an individual files a consent application, excluding any period of incarceration; or

(B) An offense involving the possession of controlled substances. At a minimum, this exclusion applies to criminal offenses involving the simple possession of a controlled substance and possession with intent to distribute a controlled substance. This exclusion may also apply to other drug-related offenses depending on the statutory elements of the offenses or from court determinations that the statutory provisions of the offenses do not involve dishonesty, breach of trust, or money laundering, as noted in paragraph (b) of this section. Potential applicants may contact their appropriate FDIC Regional Office if they have questions about whether their offenses are covered under section 19.

(iv) The term *offense committed* in paragraph (a)(1)(iii)(A) of this section means the last date of the underlying misconduct. In instances with multiple offenses, *offense committed* means the last date of any of the underlying offenses.

(2) The term *breach of trust* means a wrongful act, use, misappropriation, or omission with respect to any property or fund that has been committed to a person in a fiduciary or official capacity, or the misuse of one’s official or fiduciary position to engage in a

wrongful act, use, misappropriation, or omission.

(b) *Elements of the offense.* Whether a crime involves dishonesty, breach of trust, or money laundering will be determined from the statutory elements of the offense itself or from court determinations that the statutory provisions of the offense involve dishonesty, breach of trust, or money laundering.

(c) *Certain older offenses excluded—*
(1) *Exclusions for certain older offenses.* Section 19 does not apply to an offense if—

(i) It has been 7 years or more since the offense occurred; or

(ii) The individual was incarcerated with respect to the offense and it has been 5 years or more since the individual was released from incarceration.

(iii) The term *offense occurred* means the last date of the underlying misconduct. In instances with multiple Covered Offenses, *offense occurred* means the last date of any of the underlying offenses.

(2) *Offenses committed by individuals 21 years of age or younger.* For individuals who committed an offense when they were 21 years of age or younger, section 19 does not apply to the offense if it has been more than 30 months since the sentencing occurred. The term *sentencing occurred* means the date on which a court imposed the sentence (as indicated by the date on the court’s sentencing order), not the date on which all conditions of sentencing were completed.

(3) *Limitation.* This paragraph (c) does not apply to an offense described under 12 U.S.C. 1829(a)(2).

(d) *Foreign convictions.* Individuals who are convicted of or enter into a pretrial diversion program for a criminal offense involving dishonesty, breach of trust, or money laundering in any foreign jurisdiction are subject to section 19, unless the offense is otherwise excluded by this subpart.

§ 303.223 What constitutes a conviction under section 19?

(a) *Convictions requiring an application.* There must be a conviction of record. Section 19 does not cover arrests or pending cases not brought to trial, unless the person has a program entry as set out in § 303.224. Section 19 does not cover acquittals or any conviction that has been reversed on appeal, unless the reversal was for the purpose of re-sentencing. A conviction with regard to which an appeal is pending requires an application. A conviction for which a pardon has been granted requires an application.

(b) *Convictions not requiring an application.* When an individual is charged with a Covered Offense and, in the absence of a program entry as set out in § 303.224, is subsequently convicted of an offense that is not a Covered Offense, the conviction is not subject to section 19.

(c) *Expungement, dismissal, and sealing.* A conviction is not considered a conviction of record and does not require an application if—

(1) There is an order of expungement, sealing, or dismissal that has been issued in regard to the conviction in connection with such offense, or if a conviction has been otherwise expunged, sealed, or dismissed by operation of law; and

(2) It is intended by the language in the order itself, or in the legislative provisions under which the order was issued, or in other legislative provisions, that the conviction shall be destroyed or sealed from the individual's State, Tribal, or Federal record, even if exceptions allow the conviction to be considered for certain character and fitness evaluation purposes.

(d) *Youthful offenders.* An adjudication by a court against a person as a "youthful offender" (or similar term) under any youth-offender law applicable to minors as defined by State law, or any judgment as a "juvenile delinquent" (or similar term) by any court having jurisdiction over minors as defined by State law, does not require an application. Such an adjudication does not constitute a matter covered under section 19 and is not a conviction or program entry for determining the applicability of § 303.227.

§ 303.224 What constitutes a pretrial diversion or similar program under section 19?

(a) The term *pretrial diversion or similar program* (program entry) means a program characterized by a suspension or eventual dismissal or reversal of charges or criminal prosecution upon agreement by the accused to restitution, drug or alcohol rehabilitation, anger management, or community service. Whether the outcome of a case constitutes a program entry is determined by relevant Federal, State, or local law, and, if not so designated under applicable law, then the determination of whether a disposition is a program entry will be made by the FDIC on a case-by-case basis. Program entries prior to November 29, 1990, are not covered by section 19.

(b) When a Covered Offense either is reduced by a program entry to an offense that would otherwise not be covered by section 19 or is dismissed

upon successful completion of a program entry, the offense remains a Covered Offense for purposes of section 19. The Covered Offense will require an application unless it is *de minimis* as provided by § 303.227.

(c) Expungements, dismissals, or sealings of program entries will be treated the same as those for convictions.

§ 303.225 What are the types of applications that can be filed?

(a) The FDIC will accept applications from—

(1) An individual;

(2) An IDI applying on behalf of an individual;

(3) A depository institution holding company applying on behalf of an individual with respect to an IDI subsidiary of the holding company; and

(4) A depository institution holding company applying on behalf of an individual who will work at the holding company but also participate in the affairs of the IDI or who would be in a position to influence or control the management or affairs of the IDI, in accordance with § 303.221(a).

(b) An individual or an institution may file applications at separate times. Under either approach, the application(s) must be filed with the appropriate FDIC Regional Office, as required by this subpart.

§ 303.226 When may an application be filed?

Except for situations in which no application is required under section 19 and this subpart, an application must be filed when there is a conviction by a court of competent jurisdiction for a Covered Offense by any adult or minor treated as an adult or when such person has a program entry regarding that offense. Before an application may be filed, all of the sentencing requirements associated with a conviction, or conditions imposed by the program entry, including but not limited to, imprisonment, fines, conditions of rehabilitation, and probation requirements, must be completed, and the case must be considered final by the procedures of the applicable jurisdiction. The FDIC's application forms as well as additional information concerning section 19 can be accessed from the FDIC's Regional Offices or on the FDIC's website.

§ 303.227 De minimis Exemption.

(a) *In general.* The prohibitions of 12 U.S.C. 1829(a) will not apply, and an application will therefore not be required, where all of the following *de minimis* criteria are met. (Paragraph

(b)(4) of this section contains separate exemption criteria from paragraphs (a) through (b)(3) of this section, and an offense that qualifies for exemption under paragraph (b)(4) of this section is excluded from consideration in the criteria of paragraphs (a) through (b)(3) of this section.)

(1) The individual has been convicted of, or has program entries for, no more than two Covered Offenses, including those subject to paragraphs (b)(1) through (3) of this section; and for each Covered Offense, all of the sentencing requirements associated with the conviction, or conditions imposed by the program entry, have been completed (the sentence- or program-completion requirement does not apply under paragraph (b)(2) of this section).

(2) For each Covered Offense, the individual could have been sentenced to a term of confinement in a correctional facility of three years or less and/or a fine of \$2,500 or less, and the individual actually served three days or less of jail time for each Covered Offense.

(3) Jail time under paragraph (a)(2) of this section is calculated based on the time an individual spent incarcerated as a punishment or a sanction—not as pretrial detention—and does not include probation or parole where an individual was restricted to a particular jurisdiction or was required to report occasionally to an individual or a specific location. Jail time includes confinement to a psychiatric treatment center in lieu of a jail, prison, or house of correction on mental-competency grounds. The definition is not intended to include either of the following: persons who are restricted to a substance-abuse treatment program facility for part or all of the day; or persons who are ordered to attend outpatient psychiatric treatment.

(4) If there are two convictions or program entries for a Covered Offense, each conviction or program entry was entered at least three years prior to the date an application would otherwise be required, except as provided in paragraph (b)(1) of this section.

(5) Each Covered Offense must not have been committed against an IDI or insured credit union.

(b) *Other types of offenses for which the de minimis exemption applies and no application is required—*(1) *Age of person at time of Covered Offense.* If there are two convictions or program entries for a Covered Offense, and the actions that resulted in both convictions or program entries all occurred when the individual was 21 years of age or younger, then the *de minimis* criteria in paragraph (a)(4) of this section will be met if the convictions or program

entries were entered at least 18 months prior to the date an application would otherwise be required. For this reduction in waiting time to apply, the convictions or program entries must meet the other *de minimis* criteria in paragraph (a) of this section.

(2) *Convictions or program entries for insufficient funds checks.* The prohibitions of 12 U.S.C. 1829(a) will not apply, and an application will therefore not be required, as to convictions or program entries of record based on the writing of “bad” or insufficient funds check(s) if the following conditions apply:

(i) The aggregate total face value of all “bad” or insufficient funds check(s) cited across all the conviction(s) or program entry(ies) for “bad” or insufficient funds checks is \$2,000 or less;

(ii) No IDI or insured credit union was a payee on any of the “bad” or insufficient funds checks that were the basis of the conviction(s) or program entry(ies); and

(iii) The individual has no more than one other *de minimis* offense under this section.

(3) *Convictions or program entries for small-dollar, simple theft.* The prohibitions of 12 U.S.C. 1829(a) will not apply, and an application will therefore not be required, as to convictions or program entries based on the simple theft of goods, services, or currency (or other monetary instrument) if the following conditions apply:

(i) The value of the currency, goods, or services taken was \$1,000 or less;

(ii) The theft was not committed against an IDI or insured credit union;

(iii) The individual has no more than one other offense that is considered exempt under this section; and

(iv) If there are two offenses—each of which, by itself, is considered exempt under this section—each conviction or program entry was entered at least three years prior to the date an application would otherwise be required, or at least 18 months prior to the date an application would otherwise be required if the actions that resulted in the conviction or program entry all occurred when the individual was 21 years of age or younger.

(v) Simple theft excludes burglary, forgery, robbery, identity theft, and fraud.

(4) *Convictions or program entries for using fake identification, shoplifting, trespassing, fare evasion, or driving with an expired license or tag.* The prohibitions of 12 U.S.C. 1829(a) will not apply, and an application will therefore not be required, as to the following offenses, if one year or more

has passed since the applicable conviction or program entry: using fake identification; shoplifting; trespassing; fare evasion; and driving with an expired license or tag.

(c) *Non-qualifying convictions or program entries.* No conviction or program entry for a violation of the title 18 sections set out in 12 U.S.C. 1829(a)(2) can qualify under any of the *de minimis* exemptions set out in this section.

§ 303.228 How to file an application.

Forms and instructions should be obtained from the FDIC’s Regional Offices or on the FDIC’s website (www.fdic.gov), and the application(s) must be filed with the appropriate FDIC Regional Office. An application may be filed by an individual or by an IDI or depository institution holding company on behalf of an individual, or by both. The appropriate Regional Office for an institution-sponsored application is the office covering the state where the institution’s home office is located. The appropriate Regional Office for an application filed by an individual is the office covering the state where the person resides. States covered by each FDIC Regional Office can be located on the FDIC’s website.

§ 303.229 How an application is evaluated.

(a) *Criminal-history records.* In reviewing an application, the FDIC will—

(1) Primarily rely on the criminal history record provided by the Federal Bureau of Investigation (rap sheet); and

(2) Provide such record to the subject of the application to review for accuracy. The FDIC will make reasonable efforts to communicate with the subject of the application within 15 calendar days of receipt of this record from the Federal Bureau of Investigation to inform the individual that the FDIC will be providing them with a copy of the report and to verify the individual’s contact information. The FDIC will make reasonable efforts to send the report to the individual within 5 business days of successful verification of the individual’s contact information. If the individual believes that there are any inaccuracies in the report, the FDIC will direct the individual to an appropriate contact at the Federal Bureau of Investigation where the individual can seek corrections to the report.

(b) *Certified copies.* The FDIC will not require an applicant to provide certified copies of criminal history records unless the FDIC determines that there is a clear and compelling justification to require additional information to verify the

accuracy of the criminal history record provided by the Federal Bureau of Investigation.

(c) *Ultimate determinations.* The ultimate determinations in assessing an application are whether the person has demonstrated their fitness to participate in the conduct of the affairs of an IDI, and whether the affiliation, ownership, control, or participation by the person in the conduct of the affairs of the institution may constitute a threat to the safety and soundness of the institution or the interests of its depositors or threaten to impair public confidence in the institution.

(d) *Individualized assessment.* When evaluating applications, the FDIC will conduct an individualized assessment that will consider:

(1) Whether the conviction or program entry is subject to section 19, and the specific nature and circumstances of the offense;

(2) Whether the participation directly or indirectly by the person in any manner in the conduct of the affairs of the IDI constitutes a threat to the safety and soundness of the institution or the interests of its depositors or threatens to impair public confidence in the institution;

(3) Evidence of rehabilitation, including the person’s age at the time of the conviction or program entry, the time that has elapsed since the conviction or program entry, and the relationship of the individual’s offense to the responsibilities of the applicable position;

(4) The individual’s employment history, letters of recommendation, certificates documenting participation in substance-abuse programs, successful participation in job preparation and educational programs, and other relevant evidence;

(5) The ability of management of the IDI to supervise and control the person’s activities;

(6) The level of ownership or control the person will have of an IDI;

(7) The applicability of the IDI’s fidelity bond coverage to the person; and

(8) Any additional factors in the specific case that appear relevant to the application or the individual including, but not limited to, the opinion or position of the primary Federal or State regulator.

(e) *No re-consideration of guilt.* The question of whether a person, who was convicted of a crime or who agreed to a program entry, was guilty of that crime will not be at issue in a proceeding under this subpart or under 12 CFR part 308, subpart M.

(f) *Factors considered for enumerated offenses.* The foregoing factors will also be applied by the FDIC to determine whether the interests of justice are served in seeking an exception in the appropriate court when an application is made to terminate the ten-year ban prior to its expiration date under 12 U.S.C. 1829(a)(2) for certain Federal offenses.

(g) *Mandatory conditions of approval.* All approvals and orders will be subject to the condition that the person be covered by a fidelity bond to the same extent as others in similar positions. If the FDIC has approved an application filed by an individual and has issued a consent order, the individual must disclose the presence of the conviction(s) or program entry(ies) to all IDIs in the affairs of which they wish to participate.

(h) *Institution-sponsored applications: work at same employer.* When deemed appropriate by the FDIC, institution-sponsored applications are to allow the individual to work for the same employer (without restrictions on the location) and across positions, except that the prior consent of the FDIC (which may require a new application) will be required for any proposed significant changes in the individual's security-related duties or responsibilities, such as promotion to an officer or other positions that the employer determines will require higher security screening credentials.

(i) *Work at a different employer after certain approvals.* In situations in which an approval has been granted for a person to participate in the affairs of a particular IDI and the person subsequently seeks to participate at another IDI, another application must be submitted and approved by the FDIC prior to the person participating in the affairs of the other IDI.

§ 303.230 What will the FDIC do if the application is denied?

(a) The FDIC will inform the applicant in writing that the application has been denied and summarize or cite the relevant considerations specified in § 303.229.

(b) The denial will also notify the applicant that a written request for a hearing (or a request for written submissions in lieu of a hearing) under 12 CFR part 308, subpart M, may be filed with the FDIC Executive Secretary within 60 days after the denial. For institution-sponsored applications, either the institution or the subject individual (or both, as a consolidated request) may file such a written request. A request must include the relief desired, the grounds supporting the

request for relief, and any supporting evidence.

§ 303.231 Waiting time for a subsequent application if an application is denied.

(a) An application under section 19 must be made in writing and may not be made less than one year following the issuance of a decision denying an application under section 19. If the original denial is subject to a request for a hearing or written submissions in lieu of a hearing, then the subsequent application may be filed at any time more than one year after the decision of the FDIC Board of Directors, or its designee, denying the application. Unless with the passage of time the individual is no longer subject to section 19, the prohibition against participating in the affairs of an IDI under section 19 will continue until the individual has been granted consent in writing to participate in the affairs of an IDI by the Board of Directors or its designee.

(b) An institution-sponsored application is not subject to the one-year waiting period if the application—

(1) Follows the denial of an individual application; or

(2) Follows the denial of an institution-sponsored application and the subsequent application is sponsored by a different institution or is for a different position.

PART 308—RULES OF PRACTICE AND PROCEDURE

■ 3. The authority citation for part 308 continues to read as follows:

Authority: 5 U.S.C. 504, 554–557; 12 U.S.C. 93(b), 164, 505, 1464, 1467(d), 1467a, 1468, 1815(e), 1817, 1818, 1819, 1820, 1828, 1829, 1829(b), 1831i, 1831m(g)(4), 1831o, 1831p–1, 1832(c), 1884(b), 1972, 3102, 3108(a), 3349, 3909, 4717, 5412(b)(2)(C), 5414(b)(3); 15 U.S.C. 78(h) and (i), 78o(c)(4), 78o–4(c), 78o–5, 78q–1, 78s, 78u, 78u–2, 78u–3, 78w, 6801(b), 6805(b)(1); 28 U.S.C. 2461 note; 31 U.S.C. 330, 5321; 42 U.S.C. 4012a; Pub. L. 104–134, sec. 31001(s), 110 Stat. 1321; Pub. L. 109–351, 120 Stat. 1966; Pub. L. 111–203, 124 Stat. 1376; Pub. L. 114–74, sec. 701, 129 Stat. 584.

■ 4. Revise the heading of subpart M to read as follows:

Subpart M—Procedures Applicable to the Request for and Conduct of a Hearing (or the Request for Written Submissions in Lieu of a Hearing) After Denial of an Application Under Section 19 of the Federal Deposit Insurance Act

■ 5. Revise § 308.156 to read as follows:

§ 308.156 Scope.

The rules and procedures set forth in this subpart will apply to an application filed under section 19 of the FDI Act, 12 U.S.C. 1829 (section 19), and 12 CFR part 303, subpart L, by an insured depository institution (IDI), depository institution holding company, or an individual (any of which could be termed an applicant). Section 19 states that if an individual has been convicted of any criminal offense involving dishonesty, a breach of trust, or money laundering, or who has agreed to enter into a pretrial diversion or similar program in connection with the prosecution of such offense, the individual must seek the prior written consent of the FDIC to: become or continue as an institution-affiliated party (IAP) with respect to an IDI; own or control directly or indirectly an IDI; or participate directly or indirectly in any manner in the conduct of the affairs of an IDI. This subpart will apply only after such application has been denied under 12 CFR part 303, subpart L.

■ 6. Revise § 308.157 to read as follows:

§ 308.157 Denial of applications.

If an application is denied under 12 CFR part 303, subpart L, then the applicant may request a hearing (or request a written submission in lieu of a hearing) under this subpart M. The applicant will have 60 days after the date of the denial to file a written request with the Administrative Officer. In the request, the applicant must state the relief desired, the grounds supporting the request for relief, and provide any supporting evidence that the applicant believes is responsive to the grounds for the denial.

■ 7. Amend § 308.158 by revising paragraphs (b) and (d) through (f) to read as follows:

§ 308.158 Hearings and written submissions in lieu of a hearing.

* * * * *

(b) *Burden of proof.* The burden of going forward with a *prima facie* case will be upon the FDIC. The ultimate burden of proof will be upon the applicant seeking the FDIC's consent for an individual to become or continue as an IAP with respect to an IDI, or control directly or indirectly an IDI, or otherwise participate directly or indirectly in any manner in the conduct of the affairs of an IDI.

* * * * *

(d) *Written submissions in lieu of hearing.* The applicant may in writing waive a hearing and elect to have the matter determined on the basis of written submissions.

(e) *Failure to request or appear at hearing.* Failure to request a hearing will constitute a waiver of the opportunity for a hearing. Failure to appear at a hearing in person or through an authorized representative will constitute a waiver of a hearing. If a hearing is waived, and if there has not been a written submission in lieu of a hearing, the individual will remain prohibited under section 19.

(f) *Decision by Board of Directors or its designee.* Within 60 days following the Administrative Officer's certification of the record to the Board of Directors or its designee, the Board of Directors or its designee will notify the applicant whether the individual will remain prohibited under section 19. The notification will state the basis for any decision of the Board of Directors or its designee that is adverse to the applicant.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on July 30, 2024.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2024-17327 Filed 8-6-24; 8:45 am]

BILLING CODE 6714-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2022-0222]

RIN 1625-AA09

Drawbridge Operation Regulation; Okeechobee Waterway, Stuart, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary interim rule with request for comments.

SUMMARY: The Coast Guard is temporarily modifying the operating schedule that governs the Florida East Coast (FEC) Railroad Bridge, across the Okeechobee Waterway (OWW), mile 7.41, at Stuart, FL. This action is necessary to allow for continuity of drawbridge operations while the Coast Guard reviews comments and documents associated with the temporary test deviation. Allowing the drawbridge to return to its regular operating schedule would not meet the reasonable needs of navigation given the increase in railway traffic.

DATES: This temporary interim rule is effective from August 9, 2024, through 11:59 p.m. on December 31, 2024.

Comments and related material must reach the Coast Guard on or before September 23, 2024.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>. Type the docket number USCG-2022-0222 in the "SEARCH" box and click "SEARCH". In the Document Type column, select "Supporting & Related Material."

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary interim rule, call, or email Ms. Jennifer Zercher, Bridge Management Specialist, Seventh Coast Guard District; telephone 571-607-5951, email Jennifer.N.Zercher@uscg.mil.

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
OMB Office of Management and Budget
NPRM Notice of Proposed Rulemaking (Advance, Supplemental)
§ Section
U.S.C. United States Code
FL Florida
NPRM Notice of Proposed Rulemaking
TIR Temporary Interim Rule
FECR Florida East Coast Railway
FEC Florida East Coast
OWW Okeechobee Waterway

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary interim 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), 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. Allowing the drawbridge to return to its regular operating schedule would not meet the reasonable needs of navigation given the increase in railway traffic. The regular operating schedule does not provide predictable and reliable drawbridge openings.

On February 6, 2024, the Coast Guard published a notice of temporary deviation from regulations; request for comments, in the **Federal Register** (89 FR 8074) which allowed the bridge owner, Florida East Coast Railway (FECR), to deviate from the current operating schedule in 33 CFR 117.317(c). This action was necessary to test an alternate drawbridge operating schedule due to an increase in railway traffic. The test deviation will run past

the end date of August 9, 2024, of the General Deviation due to the delay in receipt and Coast Guard analysis of the marine traffic study. The Coast Guard commissioned an independent third party to conduct a marine traffic study to analyze the type, size, time of day and number of vessels that transit through the FEC Railroad Bridge while in the open and closed to navigation positions. The Coast Guard received the draft report on July 11, 2024. The bridge cannot be brought back to the regular operating schedule as it does not meet the reasonable needs of navigation given the increase in railway traffic. Therefore, there is insufficient time to provide a reasonable comment period and then consider those comments before issuing the modification.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective in less than 30 days after publication in the **Federal Register**. For reasons presented above, delaying the effective date of this rule would be impracticable and contrary to the public interest due to the fact that the bridge's regular operating schedule does not meet the reasonable needs of navigation and does not provide predictable and reliable drawbridge openings.

We are soliciting comments on this rulemaking. If the Coast Guard determines that changes to the temporary interim rule are necessary, we will publish a temporary final rule or other appropriate document.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 499. The FEC Railroad Bridge across the OWW, mile 7.41, at Stuart, FL, is a single-leaf bascule bridge with a six-foot vertical clearance at mean high water in the closed position. The normal operating schedule for the bridge is found in 33 CFR 117.317(c).

The regular drawbridge regulation, 33 CFR 117.313(c), states that the draw is normally in the fully open position . . . when a train approaches the bridge . . . the draw lowers and locks . . . and remains down for a period of eight minutes or while the approach track circuit is occupied. The Coast Guard has determined that allowing the drawbridge to return to its regular operating schedule would not meet the reasonable needs of navigation given the increase in railway traffic. The regular operating schedule does not provide predictable and reliable drawbridge openings. The Coast Guard needs sufficient time to review the marine traffic study and other documentation,

while providing continuity in the operation of the drawbridge.

IV. Discussion of the Temporary Interim Rule

The Coast Guard is issuing this rule, which permits a temporary deviation from the operating schedule that governs FEC Railroad Bridge across the OWW, mile 7.41, at Stuart, FL. This rule allows the bridge to provide continuity with predictable and reliable drawbridge openings through 11:59 p.m. on December 31, 2024.

When determining if this temporary deviation will meet the reasonable needs of competing modes of transportation, sufficient time to review and mitigate public comments and the marine traffic study is necessary. The marine traffic study was delayed and the Coast Guard did not receive the draft document until July 11, 2024. A proper review of the marine traffic study and mitigation of comments is anticipated to be completed by December 31, 2024.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the fact that little, or no commercial or recreational vessel traffic will be impacted by this rule. Furthermore, the drawbridge, as of date of the publication of this rule, cannot resume its regular operating schedule as it does not meet the reasonable needs of navigation given the increase in railway traffic. The regular operating schedule does not provide predictable and reliable drawbridge openings.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Government

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

Also, this rule does not have tribal implications under Executive Order

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01, Rev.1, associated implementing instructions, and Environmental Planning Policy COMDTINST 5090.1 (series) which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA)(42 U.S.C. 4321–4370f). The Coast Guard has determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule promulgates the operating regulations or procedures for drawbridges and is categorically excluded from further review, under paragraph L49, of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

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

VI. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

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–2022–0222 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.

To view documents mentioned in this rule 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. We review all comments received, but we will only post comments that address the topic of the rule. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive. Additionally, if you click on the “Dockets” tab and then the proposed rule, you should see a “Subscribe” option for email alerts. Selecting this option will enable notifications when comments are posted, or if/when a final rule is published.

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).

List of Subjects in 33 CFR Part 117

Bridges.

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

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

Authority: 33 U.S.C. 499; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 00170.1. Revision No. 01.3

■ 2. Section 117.261 is amended by staying paragraph (c) and adding paragraph (k).

§ 117.317 Okeechobee Waterway.

* * * * *

(k) Florida East Coast Railroad (FEC) Bridge, mile 7.41, at Stuart. The draw shall operate as follows:

(1) The drawbridge will be maintained in the fully open-to-navigation position, except during

periods when it is closed for the passage of train traffic, to conduct inspections, and to perform maintenance and repairs authorized by the Coast Guard.

(2) The drawbridge will not be closed for more than 50 consecutive minutes in any given hour during daytime operations (6 a.m. to 8 p.m.) and for more than 7 total hours during daytime operations (6 a.m. to 8 p.m.).

(3) Notwithstanding paragraph (k)(1), the drawbridge will open and remain open to navigation for a fixed 10-minute period at the top of each hour from 6 a.m. to 8 p.m.

(4) From 8:01 p.m. until 5:59 a.m. daily, the drawbridge will remain in the fully open-to-navigation position, except during periods when it is closed for the passage of train traffic, to conduct inspections, and to perform maintenance and repairs authorized by the Coast Guard. The drawbridge will not be closed more than 60 consecutive minutes.

(5) If a train is in the track circuit at the start of a fixed opening period, the opening may be delayed up to, but not more than, five minutes. Once the train has cleared the circuit, the bridge must open immediately for navigation to begin the fixed opening period.

(6) The drawbridge will be tended from 6 a.m. to 8 p.m., daily. The bridge tender will monitor VHF–FM channels 9 and 16 and will provide estimated times of drawbridge openings and closures, or any operational information requested. Operational information will be provided 24 hours a day by telephone at (772) 403–1005.

(7) The drawbridge owner will maintain a mobile application. The drawbridge owner will publish drawbridge opening times, and the drawbridge owner will provide timely updates to schedules, including but not limited to, impacts due to emergency circumstances, inspections, maintenance, and repairs authorized by the Coast Guard.

(8) Signs will be posted and visible to marine traffic, displaying VHF radio contact information, application information, and the telephone number for the bridge tender.

(9) A copy of the drawbridge logbook for the previous week will be provided to the Seventh Coast Guard District Bridge Manager by 4 p.m. each Monday.

* * * * *

Dated: July 31, 2024.

Douglas M. Schofield,

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

[FR Doc. 2024–17452 Filed 8–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0701]

RIN 1625–AA00

Safety Zone; Boat Race; Lake Michigan, Sheboygan, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of Lake Michigan in Sheboygan, WI. This rule is necessary to protect personnel, vessels, and the marine environment from potential hazards associated during a high-speed boat race. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Lake Michigan.

DATES: This rule is effective from August 9 through August 11, 2024, but it will only be enforced from 8:00 a.m. to 6:00 p.m. each day.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0701 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 Chief Petty Officer Aaron Sunstrom, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414–747–7148, email Aaron.R.Sunstrom@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 sponsors of the Sheboygan Midwest Challenge advised the Coast Guard on July 30, 2024, that they planned to hold their high-speed boat race beginning on August 9, 2024. There is insufficient time to propose a rule, consider comments, and publish a final rule in time to respond to the potential safety risk associated with the high-speed boat race before August 9; therefore, the Coast Guard is issuing this

temporary rule under the authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that it is impracticable and contrary to the public interest to delay promulgation of the rule to take comments and that good cause therefore exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule addresses.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule is impracticable because the safety zone regulation must be effective on August 09, 2024.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Lake Michigan (COTP) has determined that potential hazards associated with the Sheboygan Midwest Challenge would be a safety concern for anyone within the safety zone that is not participating in the event. The purpose of this rule is to ensure safety of vessels and the navigable waters in the safety zone before, during, and after the scheduled event.

IV. Discussion of the Rule

This rule establishes a safety zone which will be enforced each day, from 8:00 a.m. to 6:00 p.m., starting on August 9, 2024, and continuing through August 11, 2024. The safety zone will cover certain waters of Lake Michigan with a rectangle shaped racecourse offshore of Sheboygan, WI. The area will be bounded by the points beginning at 43°44′54.32″ N, 87°42′5.77″ W; then east to 43°44′54.10″ N, 87°41′3.21″ W; then south to 43°42′26.73″ N, 87°40′54.66″ W; then west to 43°42′27.10″ N, 87°42′10.11″ W; then returning to the point of origin. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the high-speed boat race. No vessels 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 on characteristics of the safety zone. The safety zone created by this rule will be relatively small, is designed to minimize its impact on navigable waters, and is not anticipated to exceed 10 hours in duration each day the rule is in place. Furthermore, under certain conditions vessels may still transit through the safety zone when permitted by the Captain of the Port of designated representative.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, does not apply to rules not subject to notice and comment. As the Coast Guard has, for good cause, waived notice and comment requirement that would otherwise apply to this rulemaking, the Regulatory Flexibility Act’s provisions do not apply here.

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 10 hours in duration each day that will prohibit entry into certain waters of Lake Michigan with a rectangle shaped racecourse offshore of Sheboygan, WI. The area will be bounded by the points beginning at 43°44′54.32″ N, 87°42′5.77″ W; then east to 43°44′54.10″ N, 87°41′3.21″ W; then south to 43°42′26.73″ N, 87°40′54.66″ W; then west to 43°42′27.10″ N, 87°42′10.11″ W; then returning to the

point of origin. It is categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

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.T09–0701 to read as follows:

§ 165.T09–0701 Boat Race; Lake Michigan, Sheboygan, WI.

(a) *Location.* All waters of Lake Michigan with a rectangle shaped racecourse offshore of Sheboygan, WI. The area will be bounded by the points beginning at 43°44′54.32″ N, 87°42′5.77″ W; then east to 43°44′54.10″ N, 87°41′3.21″ W; then south to 43°42′26.73″ N, 87°40′54.66″ W; then west to 43°42′27.10″ N, 87°42′10.11″ W; then returning to the point of origin.

(b) *Enforcement period.* The safety zone described in paragraph (a) of this section will be enforced from 8:00 a.m. to 6:00 p.m., each day from August 9, 2024, through August 11, 2024.

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

(2) This safety zone is 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 zone 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 zone must comply with all directions given to them by the COTP or an on-scene representative.

Dated: August 1, 2024.

Gregory J. Knoll,

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

[FR Doc. 2024–17369 Filed 8–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2024–0708]

RIN 1625–AA00

Safety Zone; Green River, Calhoun, KY

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

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters of the Green River from Mile Marker 61 to 62 in Calhoun, KY. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by a power line replacement due to unstable powerline poles. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port, Sector Ohio Valley.

DATES: This rule is effective without actual notice from 6 a.m. on August 7, 2024, through 8 p.m. on August 9, 2024. For the purposes of enforcement, actual notice will be used from 6 a.m. on August 5, 2024, through 8 p.m. on August 7, 2024. This safety zone will be enforced each day it is effective from 6 a.m. until 8 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to <https://www.regulations.gov>, type USCG–2024–0708 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 Marine Safety Technician Second Class Bryan Crane, Sector Ohio Valley, U.S. Coast Guard; telephone 502–779–5334, email Bryan.M.Crane@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 under authority in 5 U.S.C. 553(b)(B). This statutory provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” The Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the power line poles failed the internal integrity test and prompt action is needed to respond to the potential safety hazards associated with the overhead power lines. It is impracticable to publish an NPRM because we must establish this safety zone by August 5, 2024, to preserve safety of vessels transiting this area during the repairs. We note that a similar regulation was published establishing a safety zone from July 16, 2024, through July 19, 2024 (89 FR 57359). However, inclement weather prevented the repairs from being completed. Therefore, we are establishing this safety zone so that repair work can be conducted from August 5, 2024, through August 9, 2024.

Also, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because prompt action is needed to respond to the potential safety hazards associated with the unstable powerline poles and overhead power lines, and the repair work that will be conducted starting August 5, 2024.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Ohio Valley (COTP) has determined that potential hazards associated with the power line replacement starting August 5, 2024,

will be a safety concern for anyone within one (1) mile of the location of the powerline replacement location. This repair work on powerlines and powerline poles is inherently dangerous. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone while the powerlines or powerline poles are being replaced.

IV. Discussion of the Rule

This rule establishes a safety zone during daylight hours on August 5, 2024, through August 9, 2024. The safety zone will cover all navigable waters within one (1) Nautical Mile of vessels and machinery being used by personnel to repair the powerline poles between Mile Markers 61 and 62 on the Green River, in Calhoun, KY. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters while the powerline poles are being repaired. No vessel or person will 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 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 during the times that powerline work is not being conducted. Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF-FM marine channel 16 about the zone, and the rule would allow vessels to seek permission to enter the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule 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 four days that will prohibit entry within 1 nautical mile of the location of the power line crossing, Green River between Mile Markers 61 and 62, specifically 61.5. It is categorically excluded from further review under paragraph L60c of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

- 2. Add § 165.T08–0708 to read as follows:

§ 165.T08–0708 Safety Zone; Green River, Calhoun, KY.

(a) *Location.* The following area is a safety zone: All navigable waters of the Green River from Mile Marker 61 to 62.

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

(2) To seek permission to enter, contact the COTP or the COTP's representative by VHF CH. 16. Those in the safety zone must comply with all lawful orders or directions given to them by the COTP or the COTP's designated representative.

(c) *Enforcement period.* This section will be subject to enforcement each day from 6 a.m. to 8 p.m. on August 5, 2024, through August 9, 2024.

Dated: August 1, 2024.

M.D. Winland,

Commander, U.S. Coast Guard, Acting Captain of the Port Sector Ohio Valley.

[FR Doc. 2024–17574 Filed 8–5–24; 11:15 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY**40 CFR Part 52**

[EPA–R07–OAR–2023–0582; FRL–11576–02–R7]

Air Plan Approval; Kansas; Regional Haze

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to

disapprove a revision to Kansas's State Implementation Plan (SIP) submitted on July 28, 2021, intended to satisfy applicable requirements under the Clean Air Act (CAA) and EPA's Regional Haze Rule (RHR) for the program's second planning period. As required by the CAA, the RHR calls for State and Federal agencies to work together to improve visibility, including by reducing or eliminating regional haze, in 156 national parks and wilderness areas. The rule requires the States, in coordination with the EPA, the National Park Service (NPS), U.S. Fish and Wildlife Service (FWS), the U.S. Forest Service (FS), and other interested parties, to develop and implement air quality protection plans in which States revise their long-term strategies (LTS) for making reasonable progress towards the national goal of preventing any future, and remedying any existing, anthropogenic impairment of visibility in these mandatory Class I Federal Areas. Disapproval does not trigger imposition of mandatory sanctions. The effective date of this action does trigger an obligation for the EPA to issue a Federal Implementation Plan (FIP) within two years.

DATES: This final action is effective on September 6, 2024.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2023–0582. All documents in the docket are listed on the <https://www.regulations.gov> website. Although listed in the index, some information may not be publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through <https://www.regulations.gov> or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information.

FOR FURTHER INFORMATION CONTACT: Jed D. Wolkins Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7588; email address: wolkins.jed@epa.gov.

SUPPLEMENTARY INFORMATION:

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

Table of Contents

- I. What is being addressed in this document?
II. Background
III. The EPA's Response to Comments

- A. Conservation Groups Comments and Responses
B. KDHE Comments and Responses
C. Kansas Utilities' Comments and Responses
IV. What action is the EPA taking?
V. Statutory and Executive Order Reviews

I. What is being addressed in this document?

The EPA is disapproving Kansas's regional haze plan for the second planning period. As required by section 169A of the CAA, the Federal RHR calls for State and Federal agencies to work together to improve visibility in 156 national parks and wilderness areas. The rule requires the States, in coordination with the EPA, the NPS, FWS, the FS, and other interested parties, to develop and implement air quality protection plans to reduce the pollution that causes visibility impairment in mandatory Class I Federal areas. Visibility impairing pollutants include fine and coarse particulate matter (PM) (*e.g.*, sulfates, nitrates, organic carbon, elemental carbon, and soil dust) and their precursors (*e.g.*, sulfur dioxide (SO₂), oxides of nitrogen (NO_x), and, in some cases, volatile organic compounds (VOC) and ammonia (NH₃)). As discussed in further detail in our Notice of Proposed Rulemaking (NPRM) and in this document, the EPA finds that Kansas submitted a regional haze SIP revision that does not meet the regional haze requirements for the second planning period. The State's submission and the NPRM can be found in the docket for this action.

II. Background

On July 28, 2021, Kansas submitted a revision to its SIP to address regional haze for the second implementation period. Kansas made this submission in order to satisfy the requirements of the CAA's regional haze program pursuant to CAA sections 169A and 169B and 40 Code of Federal Regulations (CFR) 51.308. The State's submission met the public notice requirements in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on its SIP revision from May 27, 2021, to June 28, 2021, and received comments from five parties, including the EPA. Kansas made some changes to its SIP revision based on some of the public comments. However, Kansas disagreed with most of the comments pointing out flaws in its SIP revision, and the State made no changes based on those comments.

On January 2, 2024 (89 FR 178), the EPA published the NPRM proposing a

disapproval of Kansas's July 28, 2021 SIP submission for not satisfying the regional haze requirements for the second planning period contained in the CAA and 40 CFR 51.308. The EPA is now determining that the Kansas SIP revision for the second RHR planning period does not meet the applicable statutory and regulatory requirements in CAA section 169A and 40 CFR 51.308 and is thus disapproving Kansas's submission.

III. The EPA's Response to Comments

The purpose of the proposed rulemaking was to take public comment on the EPA's intent to disapprove Kansas's July 28, 2021 SIP submission because it does not satisfy regional haze requirements for the second planning period. In the NPRM, the EPA proposed to disapprove the submission for, *inter alia*, failing to consider the four statutorily required factors in CAA section 169A for developing the State's long-term strategy (LTS).¹ The public comment period on the EPA's proposed rule opened January 2, 2024, the date of its publication in the **Federal Register**, and closed on February 1, 2024. During this period, the EPA received three comment letters: (1) collective comments from the National Parks Conservation Association, Sierra Club, and the Coalition to Protect America's National Parks (collectively referred to as "the Conservation Groups" throughout this document); (2) comments from the Kansas Department of Health and Environment (KDHE); and (3) collective comments from the Kansas City Board of Public Utilities—Unified Government of Wyandotte County/Kansas City, Kansas (BPU), Evergy, Inc (Evergy), and Sunflower Electric Power Corporation (Sunflower) (collectively referred to as "the Kansas Utilities" throughout this document). All the public comments are available in the docket for this final action via Docket ID Number EPA–R07–OAR–2023–0582 on the <https://www.regulations.gov> website.

In the rest of this section, the EPA has summarized and provided responses to the adverse comments received on the NPRM. No response is necessary for the comments received in support of the NPRM or the comments that were not directly related to the NPRM. After carefully considering the comments received, the EPA is finalizing its disapproval of the Kansas SIP submission for the RHR second planning period.

A. Conservation Groups Comments and Responses

Conservation Groups Comment 1: The Conservation Groups stated that executive orders, action plans, and commitments direct the Agency to consider environmental justice in Agency actions. The comment noted that the same pollutants that affect scenic views at national parks and wilderness areas also cause significant public health impacts.

The Conservation Groups commented that the EPA ignores the environmental justice impacts of our action on Kansas's SIP revision. The commenters acknowledged that requiring Kansas to correct the deficiencies in the SIP revision may result in the State identifying new emission control measures to reduce pollution that negatively impacts low-income communities and communities of color. The commenters then provided information from the EPA's EJScreen tool to state that there are overburdened communities exposed to pollution near some large stationary sources, including Kansas City-BPU's Nearman Creek Power Station, the Jeffrey Energy Center, and the Lawrence Energy Center. The Conservation Groups stated that the EPA must analyze the potential disparate impacts or environmental justice benefits of its action on Kansas's SIP revision.

Response to Conservation Groups Comment 1: The EPA disagrees with this comment but acknowledges the EJScreen information provided by the commenters. The CAA does not explicitly address considerations of environmental justice and neither do the regulatory requirements of the second planning period in 40 CFR 51.308(f), (g)(1) through (5), and (i). As explained in "EPA Legal Tools to Advance Environmental Justice,"² the CAA provides States with the discretion to consider environmental justice in developing rules and measures related to regional haze. While a State may consider environmental justice under the reasonable progress factors, neither the statute nor the regulations require States to conduct an environmental justice analysis as a condition of the EPA approving a SIP revision. Furthermore, the CAA and the RHR neither prohibit nor require such an evaluation of environmental justice with regard to a regional haze SIP revision. The EPA is not identifying

environmental justice as a basis for its decision to disapprove Kansas's SIP revision.

The Conservation Group commenters provided additional information from multiple EJ Screen analyses. Without agreeing with the particular relevance or accuracy of this information, the EPA acknowledges the EJ Screen information provided as part of the comment, which identifies certain demographic and environmental information regarding communities near the Kansas City-BPU's Nearman Creek Power Station, the Jeffrey Energy Center, and the Lawrence Energy Center. As discussed in the NPRM and in this document, the EPA has evaluated Kansas's SIP submission against the statutory and regulatory regional haze requirements and determined that it has not satisfied those minimum requirements.

B. KDHE Comments and Responses

KDHE Comment 1: KDHE commented that Kansas adopted the LTS the State previously set out in its regional haze SIP revision for the first implementation period (2011 SIP), including enforceable emission limitations, compliance standards, and other measures that are necessary to make reasonable progress toward reducing visibility impairment at nearby Class I areas. The commenter suggested Kansas provided substantial data in support of this decision.

KDHE stated that per 40 CFR 51.308(f)(2), the 2021 SIP's LTS evaluated whether any emission reductions measures were "necessary to make reasonable progress" and determined no additional measures were necessary. KDHE stated that the CenSARA Area of Influence (AOI) results show that for the 20% most impaired days in base year 2016, no Kansas facility had an individual impact greater than 0.84% (nitrate and sulfate impacts combined) at any of the Class I areas studied. KDHE maintained that 0.84% is not a significant level of visibility impact. KDHE asserted that neither the EPA nor federal land manager (FLM) staff criticized the use of combined nitrates and sulfates, and Kansas was only notified of the EPA's preference to separate nitrates and sulfates in comments during the public comment period.

Response to KDHE Comment 1: The EPA disagrees with the commenter's statements that KDHE conducted an analysis that considered the four statutory factors or that meets regulatory requirements of 40 CFR 51.308(f) to determine what emission reduction measures are necessary to make reasonable progress in the second planning period. The EPA also disagrees

¹ For more information on the RHR requirements, specifically the LTS requirements, see our NPRM in the docket for this action.

² See EPA Legal Tools to Advance Environmental Justice, p. 35–36 <https://www.epa.gov/system/files/documents/2022-05/EJ%20Legal%20Tools%20May%202022%20FINAL.pdf>. The EPA Office of General Counsel (May 2022).

with the commenter's statement that KDHE's reliance on the CenSARA AOI results was appropriate, as this reliance resulted in KDHE producing an analysis that failed to consider the statutory and regulatory requirements. Finally, the EPA acknowledges the commenter's statement that the EPA did not provide feedback criticizing the use of combined nitrates and sulfates' impact on source selection criteria prior to Kansas's formal public comment period, but we do not agree that it has any bearing on the EPA's disapproval of the SIP revision.

As explained in the NPRM, the State must evaluate and determine the emission reduction measures that are necessary to make reasonable progress by considering the four statutory factors.³ As part of its reasonable progress determinations for the second planning period, the State must describe the criteria used to determine which sources or group of sources were evaluated (*i.e.*, subjected to four-factor analysis) for the second implementation period and how the four factors were taken into consideration in selecting the emission reduction measures for inclusion in the LTS. 40 CFR 51.308(f)(2)(i). Since Kansas did not select sources, or groups of sources, for a four-factor analysis, it did not meet this requirement in developing a LTS for the second planning period.

The 1999 RHR established an iterative planning process that requires States that impact visibility at Class I areas to periodically submit SIP revisions to address such impairment. 64 FR 35714 (1999); CAA section 169A(b)(2). While the 1999 RHR outlined the regional haze requirements for the first planning period, the EPA revised the RHR in 2017 to establish the regional haze requirements for the second planning period. 82 FR 3078 (2017). For example, the LTS requirements for the first planning period are laid out in 40 CFR 51.308(d)(3), and the LTS requirements for the second planning period are laid out in 40 CFR 51.308(f)(2). This therefore necessitates separate analyses in line with the regulatory language dictating the requirements for the development of each planning period's LTS.⁴ In its SIP revision, Kansas

included information on the emissions impacts of numerous sources on the Hercules Glades Wilderness Area, the Salt Creek Wilderness Area, the Upper Buffalo Wilderness Area, the Wheeler Peak Wilderness Area, the White Mountain Wilderness Area, and the Wichita Mountains National Wildlife Reserve, but did not select any sources for evaluation, did not conduct a four-factor analysis, and did not analyze possible efficiency improvements for sources' existing measures during this planning period. Thus, Kansas did not follow the regulatory requirements as outlined in 40 CFR 51.308(f). As stated in the NPRM, Kansas failed to consider the four statutory factors for any sources, thereby not providing the required analysis to support a conclusion that no additional measures are necessary for reasonable progress in its LTS for the second planning period.

Kansas also argues that the SO₂ reductions achieved by Kansas sources during the first planning period make Kansas's contribution to impairment of Class I areas insignificant in comparison to other States. The EPA acknowledges that Kansas made significant reductions in SO₂ emissions in the first planning period and that surrounding States may have a larger total of SO₂ emissions, but neither the RHR nor the CAA allow a State to not evaluate sources or consider the four factors in reliance on its previous planning period reductions or due to higher emissions in other States.⁵

KDHE's reliance on the CenSARA AOI results to determine reasonable progress is misplaced. CAA section 169A(g)(1) outlines that "in determining reasonable progress, there shall be taken into consideration the costs of compliance, the time necessary for compliance, and the energy and non-air quality environmental impacts of compliance, and the remaining useful life of any existing source subject to such requirements." Moreover, the RHR outlines that in order to evaluate and determine the emission reduction measures that are necessary to make reasonable progress, States must consider "the costs of compliance, the time necessary for compliance, the energy and non-air quality environmental impacts of compliance, and the remaining useful life of any potentially affected anthropogenic

15 year) strategy for making reasonable progress toward meeting the national goal of preventing future, and remedying existing, visibility impairment in Class I areas.

⁵ 64 FR 35721 (1999) "EPA has concluded . . . that all States contain sources whose emissions are reasonably anticipated to contribute to regional haze in a Class I area and, therefore, must submit regional haze SIPs."

source of visibility impairment." 40 CFR 51.308(f)(2)(i). The individual impact of a State's sources on the Class I area and the significance of visibility impact should not undermine the role of the four-factor analysis when determining reasonable progress in accordance with the regulations.⁶ Therefore, the EPA cannot approve Kansas's SIP submission because it did not meet the statutory and regulatory requirements.

While the EPA cannot speak for the FLMS as to why they did not address the use of combined nitrates and sulfates, the EPA choose to not address this issue in its initial comments to Kansas on the proposed SIP revision during early engagement (*i.e.*, prior to Kansas's formal SIP submittal). Rather the EPA choose to discuss the most glaring issue that would prevent approval, which was the failure to select sources for four-factor analysis or provide a reasoned explanation for why sources were not selected. When Kansas declined to amend its SIP revision following the EPA's comments, we were compelled to address the choice to combine nitrates and sulfates, specifically when Kansas claimed it did not need to select sources based upon other States' contributions to regional haze and the emission reductions achieved during the first planning period.⁷ While we could have made this comment in early engagement, we did make it during KDHE's public comment period prior to the SIP revision being submitted to the EPA.

Kansas did not meet the statutory and regulatory requirements for the second planning period SIP revision, and therefore, the EPA cannot approve Kansas's SIP submission.

KDHE Comment 2: KDHE commented that it utilized a threshold methodology for selection of sources that reasonably considers the actual visibility impact and expectations for reasonable progress consistent with the CAA. KDHE stated that the EPA has failed to provide any quantifiable threshold for visibility impacts on Class I areas. KDHE

⁶ "Under the RHR, each State has an obligation to submit a long-term strategy that addresses the regional haze visibility impairment resulting from emissions from within that State. 40 CFR 51.308(f)(2). This obligation is not discharged simply because another State's contributions to visibility impairment may be greater." Clarifications Regarding Regional Haze State Implementation Plans for the Second Implementation Period, p. 3 <https://www.epa.gov/system/files/documents/2021-07/clarifications-regarding-regional-haze-state-implementation-plans-for-the-second-implementation-period.pdf>. The EPA Office of Air Quality Planning and Standards, Research Triangle Park (July 8, 2021) ("2021 Clarifications Memo").

⁷ Applying a combined sulfate and nitrate impact may exclude sources whose only or main impact may be from a sulfate or nitrate.

³ The amount of progress that is "reasonable progress" is based on applying the four statutory factors in CAA section 169A(g)(1) in an evaluation of potential control options for sources of visibility impairing pollutants, which is referred to as a "four-factor" analysis. The outcome of that analysis is the emission reduction measures that a particular source or group of sources needs to implement in order to make reasonable progress towards the national visibility goal. See 40 CFR 51.308(f)(2)(i).

⁴ CAA section 169A(b)(2)(B) requires States to include in their SIP submissions a long-term (10–

proposed that < 1.0% visibility impact is not significant impairment of visibility and does not warrant four-factor evaluation. KDHE contended that a significance threshold of 1.0% is not unreasonable and is very conservative, considering the large universe of Title V sources being analyzed using the AOI modeling method.

KDHE stated the language of CAA section 169A(b) requires a SIP to “contain such emission limits, schedules of compliance and other measures as may be necessary to make reasonable progress toward meeting the national goal” and asserted that the trigger warranting evaluation of the four statutory factors is, by statute, whether it is first “necessary” to meet the national goal. KDHE asserted that Kansas sources’ de minimis impact to visibility and trending reduction of visibility impairment makes conducting four-factor analyses unnecessary to ensure reasonable progress. KDHE stated that the EPA’s insistence that every State carry out four-factor analysis despite having insignificant sources with respect to visibility impact is not justified. KDHE concluded that the threshold the EPA currently uses exceeds the statutory requirement, is inconsistent with legislative intent, and is arbitrary.

Response to KDHE Comment 2: The EPA disagrees with this comment. In order to meet the statutory and regulatory requirements, as stated in the EPA’s 2021 Clarifications Memo and discussed in the NPRM, States have discretion to choose any source selection threshold or methodology that is reasonable; however, whatever choices States make should be reasonably explained and produce a reasonable set of sources, or groups of sources, on which to apply the four statutory factors when evaluating potential control measures for inclusion in the LTS. 2021 Clarifications Memo at 3. Reasonableness will depend on the specific circumstances. Kansas’s chosen threshold of 1.0% is unreasonable for a number of reasons.

First, Kansas’s chosen source selection methodology analyzed visibility impacts from Kansas and compared those to visibility impacts to other States that impact the same Class I areas. In so doing, Kansas concluded that its in-state contribution to visibility impairment at the affected Class I area is insignificant and therefore, it was unnecessary to undertake an evaluation of control measures by applying the four statutory factors. This was improper. Under the RHR, each State has an obligation to submit a LTS that addresses the regional haze visibility

impairment resulting from emissions from within that State, and that obligation “is not discharged simply because another State’s contributions to visibility impairment may be greater.” *Id.* There is no exclusion in the CAA or RHR to support the contention that if a State can show emissions are “insignificant” or “de minimis”, then it does not have to comply with 40 CFR 51.308(f). Therefore, just because emissions from Kansas may not impact Class I areas as much as emissions from other States, Kansas still nonetheless has an obligation to evaluate a reasonable set of sources for additional controls, which it did not do.

KDHE provided information including graphs and tables showing the improving visibility impairment at Class I areas impacted by Kansas emissions, year over year of decreasing emissions, and Kansas’s low impact compared to other nearby States. While we agree that these are true, as stated throughout this document, these facts do not relieve Kansas from the requirement to have a LTS by considering the four statutory factors.

Secondly, Kansas’s chosen threshold of 1.0% is unreasonable because it excluded all of the State’s largest visibility impairing sources from selection. Generally, a threshold that captures only a small portion of a State’s contribution to visibility impairment in Class I areas is more likely to be unreasonable. *Id.* A State that relies on a visibility (or proxy for visibility impact) threshold to select sources for four-factor analysis should set the threshold at a level that captures a meaningful portion of the State’s total in-state contribution to visibility impairment to Class I areas.⁸ Not only did Kansas not evaluate its largest sources for visibility impairment, it also opted not to evaluate groups of its smaller sources, which, especially as it relates to Kansas, was unreasonable.

CAA section 169A(b)(2)(B), requires each State having emissions that may affect visibility in a Class I area to include in its SIP emission limits, schedules of compliance, and other measures as may be necessary to make reasonable progress toward meeting the national goal. CAA section 169A(b)(2)(B). The national goal, as laid out in section 169A(a)(1) of the CAA is to prevent future, and to remedy

existing manmade impairment of visibility in Class I areas.

In the 1999 RHR, the EPA stated that the “prevention component of the national goal requires that States have the framework in place to address future growth in emissions. . . . For this reason, the EPA does not believe that it is appropriate to establish criteria for excluding States or geographic areas from consideration as potential contributors to regional haze.” 64 FR 35721 (1999). Then, in the 2017 RHR, the EPA “reiterat[ed] that the CAA requires States to consider the four statutory factors . . . in each implementation period to determine the rate of progress towards natural visibility conditions that is reasonable for each Class I area.” 82 FR 3080 (2017).

The 2017 RHR also recognized that, due to the nature of regional haze (visibility impairment that is caused by the emissions of air pollutants from numerous anthropogenic sources located over a wide geographic area), numerous and sometimes (relatively) smaller in-state sources may need to be selected and evaluated for control measures as part of the reasonable progress analysis. As stated in response to comments on the 2017 RHR, “[a] state should not fail to address its many relatively low-impact sources merely because it only has such sources and another state has even more low-impact sources and/or some high impact sources.”⁹ However, despite acknowledging that emissions from Kansas impacted numerous Class I areas, Kansas did not select any sources, large or small, to evaluate for emission reduction measures.

Once a State has selected sources, or groups of sources, for evaluation, it then must consider the four statutory factors to evaluate the emission reduction measures that are necessary to make reasonable progress. CAA section 169A(g)(1); 40 CFR 51.308(f)(2). Control measures that are necessary to make reasonable progress toward the national goal of natural visibility conditions must be included in the State’s LTS in the SIP. CAA section 169A(b)(2)(B); 40 CFR 51.308(f)(2). Kansas did not select any sources to evaluate and did not apply the four statutory factors in order to determine what is necessary for reasonable progress, thus resulting in an unjustified LTS for the second planning period. The EPA therefore finds

⁸ Guidance on Regional Haze State Implementation Plans for the Second Implementation Period. p. 19 <https://www.epa.gov/visibility/guidance-regional-haze-state-implementation-plans-second-implementation-period>. The EPA Office of Air Quality Planning and Standards, Research Triangle Park (August 20, 2019) (“2019 Guidance”).

⁹ Responses to Comments on Protection of Visibility: Amendments to Requirements for States Plans; Proposed Rule (81 FR 26942, May 4, 2016) at 87–88, available at <https://www.regulations.gov/document/EPA-HQ-OAR-2015-0531-0635>; See 2021 Clarifications Memo p. 4.

Kansas's selected threshold to be unreasonable and not in accordance with the CAA or the RHR. We therefore find the chosen source selection threshold and the resulting lack of analysis of controls and application of the four statutory factors to be unreasonable.

In addition, Kansas's interpretation of the phrase "as may be necessary to make reasonable progress toward meeting the national goal" is incorrect. Kansas's statutory construction comment is inconsistent with the EPA's interpretation and explanation laid out in the 2017 RHR preamble. To achieve the national goal, it is "necessary" for all States to reduce or eliminate visibility-impairing emissions, which includes contributions from sources in Kansas. While the EPA has created an iterative planning process to achieve Congress' ambitious goal, that process will take many years. Thus, in the second planning period, it nonetheless remains "necessary" for States to consider the four statutory factors and evaluate potential control measures to ensure that they are making reasonable progress toward that goal.

Kansas's conclusion that a four-factor analysis should only be conducted if visibility impacts are significant (*i.e.*, not *de minimis*) is incorrect. The EPA acknowledges that for many States, including Kansas, there has been a reduction of visibility impairment since the first planning period. While the impact from the highest-emitting sources may be less than the first planning period, sources from Kansas, large or small, still emit visibility impairing pollutants and Kansas thus must comply with the RHR. While Kansas is correct that the EPA has not mandated a specific threshold, the EPA has provided States with guidance and flexibility on how to define a threshold in order to select a reasonable set of sources for analysis of control measures, as set out above.

The EPA also disagrees with KDHE's contention that it is not necessary for every State to take into consideration the four statutory factors when determining the control measures that are a part of their LTS for the second planning period. CAA section 169A(b)(2) requires each State whose emissions may reasonably contribute to visibility impairment to include in its regional haze SIP the measures that are necessary to make reasonable progress toward meeting the national goal of preventing future, and eliminating existing, visibility impairment in Class I areas. Within these SIPs, CAA section 169A(b)(2)(B) also requires long-term (10–15 year) strategies for making

reasonable progress. CAA 169A(g)(1) outlines that in determining reasonable progress, the four factors must be considered, which is also outlined in the RHR. As outlined in the 1999 RHR, the EPA concluded that "all States contain sources whose emissions are reasonably anticipated to contribute to regional haze in a Class I area and, therefore, must submit regional haze SIPs." 64 FR 35721 (1999). This determination did not change with the 2017 RHR.¹⁰ Because the time period for Kansas to take issue with the second planning period regulations has passed, it is thus outside of the scope of this action.

Therefore, in the second planning period, just as with the first planning period, all States are required to submit SIPs to address regional haze and those SIPs must include a LTS for making reasonable progress, which considers the four statutory factors.¹¹

In applying the requirements of the regional haze program, the EPA's disapproval is consistent with, and within, the bounds of the CAA and its legislative intent.

KDHE Comment 3: KDHE asserted that Kansas's 2021 SIP declined to select sources for four-factor analyses only after Kansas determined that the effect of existing measures employed during the first implementation period made conducting such analyses unnecessary to ensure reasonable progress with the national goal. To that point, KDHE further stated that it provided additional analyses of certain sources in its reply to the EPA comments. KDHE directed the EPA to review the 2021 SIP submission again and notice that each factor required by regulation to be discussed for an LTS was identified and commented on in the submission. The commenter suggested the SIP submission followed the 2019 Guidance by robustly discussing and considering the four statutory factors and concluding that further action was unnecessary to make reasonable progress.

Response to KDHE Comment 3: The EPA disagrees that Kansas's SIP submission included a robust demonstration, based on the four statutory factors, that no additional controls are necessary in the second

planning period. As stated in the RHR, the NPRM, and throughout this document, application of the four factors is required by the CAA for a second planning period SIP's LTS. Neither the CAA nor the RHR establish a visibility impact threshold in order for a State to conduct the analysis. As noted in the 2019 Regional Haze Guidance, it is reasonable for States to consider visibility alongside the four statutory factors when determining the emission reduction measures that are necessary to make reasonable progress. 2019 Guidance at 28. However, considering visibility as an additional factor must be done "in a reasonable way that does not undermine or nullify the role of the four statutory factors in determining what controls are necessary to make reasonable progress."¹²

As discussed above in Responses to KDHE Comments 1 and 2, the support proffered for Kansas' decision to decline to select sources included Kansas's mistaken belief that the surrounding States should match the level of control at Kansas sources before Kansas evaluates sources for further controls and that, in Kansas's interpretation of CAA section 169A(b)(1), the impacts from individual Kansas sources are so insignificant so as to not require controls. As stated above, the EPA does not find these assertions to be aligned with the statute or RHR, and thus we find that Kansas has not reasonably explained its decision to not select sources for analysis.

If KDHE wanted to rely upon its first planning period analysis and approach, the 2019 Guidance and 2021 Clarifications Memo explain that the State must support its conclusion with a sound analysis that no new significant information is available that changes the first planning period approach. 2019 Guidance at 36; 2021 Clarifications Memo at 5. Kansas's submission did not include an analysis of its first planning period source selection and four factor considerations. Instead, Kansas points to the SO₂ reductions achieved during the first planning period compared to other States. The EPA finds that this is not a reasonable analysis of Kansas's first planning period approach. The EPA acknowledged in its 2021 Clarifications Memo that many of the largest individual visibility impairing sources have either been controlled or retired and that visibility improvement has occurred in most Class I areas. 2021 Clarifications Memo at 14. Nonetheless,

¹⁰ In the 2017 RHR, the EPA "reiterat[ed] that the CAA requires States to consider the four statutory factors . . . in each implementation period to determine the rate of progress towards natural visibility conditions that is reasonable for each Class I area." 82 FR 3080.

¹¹ See 64 FR 35721–35722 for additional explanation as to the EPA's determination that emissions from all States reasonably contribute to visibility impairment and thus are subject to the regional haze regulations.

¹² 2021 Clarifications Memo at 13 (quoting Response to Comments on Protection of Visibility: Amendments to Requirements for State Plans; Proposed Rule at 186).

the EPA emphasized that additional progress is needed to achieve the national goal set by Congress,¹³ such as evaluating control measures for relatively smaller sources. 2021 Clarifications Memo at 14.

KDHE cites to the 2019 Guidance and the 2021 Clarifications Memo for how a State can reasonably explain its decision to not select sources. However, without conducting the proper analyses required by the rule, KDHE cannot determine that additional controls or optimization of current controls to reduce emissions and improve visibility would not be cost-effective or necessary for reasonable progress.

On June 28, 2021, the EPA submitted comments on the Kansas regional haze plan revision during the public comment period. After the State's public comment period closed, in the SIP's Responsiveness Summary, Kansas addressed the EPA's comment by providing "narrative analyses for the two most impactful facilities based on nitrates-only and sulfates-only AOI results" in order to satisfy the requirement of 40 CFR 51.308(f)(2)(i). The narrative analyses discussed NO_x controls at Evergy—La Cygne and SO₂ controls at Sunflower Electric—Holcomb.

The EPA notes that Kansas did generally undertake an evaluation of emission reduction measures necessary to make reasonable progress for Evergy—La Cygne and Sunflower Electric—Holcomb. However, the EPA disagrees with Kansas's assertion in the Responsive Summary and its comment on the NPRM that the narrative analyses satisfy the requirement to consider the four statutory factors for two reasons, one substantive and the other procedural.

Substantively, Kansas's four-factor analysis for Evergy—La Cygne and Sunflower Electric—Holcomb is not sufficient. The EPA notes that the 2019 Guidance provides the opportunity for a State to forgo a full four-factor analysis for a particular source if it is already "effectively controlled," as long as the State explains why it is reasonable to assume that a four-factor analysis would likely result in the conclusion that no further controls are reasonable. 2019 Guidance at 22. Further, the EPA's 2021 Clarifications Memo guides that if a source can achieve, or is achieving, a lower emission rate using its existing measures than the rate assumed for the "effective control," a State should further analyze the lower emission rate(s) as a potential control option. 2021 Clarifications Memo at 5. In its

analysis, Kansas discusses the current control equipment, control efficiencies and current enforceable emission limitations for Evergy—La Cygne NO_x and Sunflower Electric—Holcomb SO₂. Kansas states that the recent actual emissions are below the current enforceable emission limits and did not analyze the actual emission rates as potential control options for the sources. While Kansas's analysis is informative, it is insufficient because the information provided was very cursory and did not evaluate a full range of control options.

Procedurally, the four-factor analysis of NO_x controls at Evergy—La Cygne and SO₂ controls at Sunflower Electric—Holcomb was not part of Kansas's regional haze plan revision that went out for public comment from May 27, 2021, to June 22, 2021. 40 CFR 51.102(a) requires States to provide the opportunity to submit written comments on SIP submittals. 40 CFR 51.102(a). 40 CFR 51.104(c) states "EPA will approve revisions only after applicable hearing requirements of § 51.102 have been satisfied." 40 CFR 51.104(c). The public did not have an opportunity to submit written comments on the narrative four-factor analysis provided by Kansas in the Responsive Summary, thus resulting in a procedural defect.

A State that has emissions that may affect visibility in a Class I area must develop a LTS that includes the enforceable emission limitations, compliance schedules, and other measures that are necessary to make reasonable progress in such Class I areas. 40 CFR 51.308(f)(2). The State must evaluate and determine the emission reduction measures that are necessary to make reasonable progress by considering the four factors of CAA section 169A(g)(1). The outcome of that analysis is used to determine the emission reduction measures that a particular source or group of sources needs to implement in order to make reasonable progress towards the national visibility goal. The State must include in its implementation plan a description of the criteria it used to determine which sources or groups of sources it evaluated and how the four factors were taken into consideration in selecting the measures for inclusion in its LTS. In addition, emission reduction measures that are necessary to make reasonable progress may be either new, additional control measures for a source, or they may be the existing emission reduction measures that a source is already implementing, and those measures must be included in the SIP. 2019 Guidance at 45; 2021 Clarifications Memo at 8–10.

As stated in the NPRM, Kansas's submission identifies one hundred and twenty-eight (128) sources in Kansas that impact Class I areas. If Kansas had followed the RHR and properly analyzed a set of these sources, it could potentially have identified additional cost-effective control measures to achieve SO₂ or NO_x emission reductions that would help make progress toward visibility goals in affected Class I areas. Instead, Kansas selected no sources for which to take into consideration the four factors. Consequently, Kansas did not, nor could not, describe the criteria it used to determine which sources or groups of sources it evaluated and how the four factors were applied in selecting the measures included in the LTS for the second planning period.

KDHE Comment 4: KDHE commented that it demonstrated that substantive revision of the existing implementation plan is unnecessary to achieve established goals. KDHE stated that per 40 CFR 51.308(f)(5), revisions of a SIP also serve as "a progress report" and that at the same time the State is "required to submit *any* progress report," the State is directed to determine the adequacy of the existing implementation plan. KDHE contended that the regulation clearly and unambiguously establishes that a State may determine that no substantive revision to the existing SIP is necessary, and that the 2021 SIP submission reasonably determined that such is the case. KDHE requested the EPA approve the SIP revision.

Response to KDHE Comment 4: The EPA disagrees with KDHE's interpretation of 40 CFR 51.308(f)(5). 40 CFR 51.308(a) "establishes requirements for implementation plans, plan revisions, and periodic progress reviews to address regional haze." 40 CFR 51.308(f) sets forth the requirements for the periodic State implementation plan revisions, which are to be submitted by July 31, 2021, July 31, 2028, and every 10 years thereafter. 40 CFR 51.308(f). These SIP revisions are referred to as the second planning period, third planning period, etc. 40 CFR 51.308(g) details the requirements for periodic reports describing progress towards reasonable progress goals, which are to be submitted by January 31, 2025, July 31, 2033, and every 10 years thereafter. 40 CFR 51.308(g).

The determination of adequacy for the existing implementation plan found under 40 CFR 51.308(h) is not applicable to the second planning period SIP revisions under 40 CFR 51.308(f)(2), as KDHE mistakenly asserts. Rather, the requirements for

¹³ See CAA section 169A(a)(1).

States to submit a declaration of adequacy under 40 CFR 51.308(h) is triggered when a State is required to submit a progress report pursuant to the deadline requirements of 40 CFR 51.308(g). Under 40 CFR 51.308(g), States are required to submit a progress report containing a declaration of adequacy under 40 CFR 51.308(h) to the EPA by January 31, 2025, July 31, 2033, and every 10 years thereafter. The “progress report” submitted under Kansas’ second planning period SIP revision under 40 CFR 51.308(f)(2) was due to the EPA on July 21, 2021, and does not serve as a progress report as required under 40 CFR 51.308(g). The language under 40 CFR 51.308(h) is clear in that the determination of adequacy is only applicable “at the same time the State is required to submit any progress report to the EPA in accordance with [40 CFR 51.308](g).”

The EPA reiterates that KDHE did not submit a progress report in accordance with 40 CFR 51.308(g) when it submitted its second planning period SIP revision due July 21, 2021. Rather, the progress report provided in the second planning period SIP revision was to fulfill its 40 CFR 51.308(f)(5) requirements. The regulatory language under 40 CFR 51.308(f)(5) directs States *only* to consider the general progress report requirements under 40 CFR 51.308(g)(1) through 40 CFR 51.308(g)(5), and not the additional progress report requirements (such as 40 CFR 51.308(g)(6) or 40 CFR 51.308(g)(8)) that are contained under the entirety of 40 CFR 51.308(g). Furthermore, the established deadlines and timeframes under 40 CFR 51.308(g) ensure that a plan revision under 40 CFR 51.308(f) and a progress report under 40 CFR 51.308(g) will never overlap.

Thus, for the reasons described in this response, KDHE is mistaken that it can use a declaration of adequacy under 40 CFR 51.308(h) in order to avoid considering the four statutory factors to fulfill its LTS requirements for the second planning period under 40 CFR 51.308(f)(2). KDHE has *not* submitted a progress report under 40 CFR 51.308(g) to fulfill its requirements for the next regulatory due date for progress reports.¹⁴ Rather, KDHE has submitted a progress report to meet its SIP revision obligations under 40 CFR 51.308(f)(2), which contains an obligation to meet the requirements of 40 CFR 51.308(f)(5). There is no regulatory option for KDHE to make a declaration of the existing plan when submitting a revision to meet

the requirements of 40 CFR 51.308(f)(2). Thus, Kansas cannot utilize 40 CFR 51.308(h)(1) to assert that Kansas does not need to revise its regional haze plan for the second planning period under 40 CFR 51.308(f)(2).

KDHE Comment 5: KDHE commented that Kansas used a reasonable threshold for source selection consistent with the CAA. KDHE asserted that the EPA arbitrarily concludes that any impairment of visibility greater than zero requires completely utilizing the four-factor analysis, and this conclusion unnecessarily saddles States with the overly burdensome endeavor of engaging in four factor analysis for sources whose impact to visibility is insignificant. KDHE argued that the EPA disregards the cost and futility associated with revision of the SIP and “proposes to disapprove the 2021 SIP for no other reason beyond requiring Kansas to complete arbitrary formalities established by regulations that are inconsistent with the [CAA] and exceed the authority granted to EPA.”

Response to KDHE Comment 5: The EPA disagrees with KDHE’s statement that Kansas used a threshold for source selection consistent with the requirements of the CAA and that the EPA’s conclusions are arbitrary. As discussed in the Responses to KDHE’s Comment 1 and 2, Kansas’s chosen threshold which resulted in no sources being selected for a four-factor analysis is not reasonable because it excluded all of the State’s largest visibility impairing sources and every State is required to include the LTS in the SIP revision.

The EPA disagrees that it is arbitrary for the Agency to require second planning period regional haze SIP submissions to develop a LTS that will make reasonable progress towards the national goal specified in CAA section 169A(a)(1), through consideration of the four factors specifically outlined in the CAA section 169A(g)(1). Kansas decided to not select any sources and, as stated in the NPRM, the EPA does not find its decision to be reasonable. Kansas’s own submission lists one hundred twenty-eight (128) sources in Kansas with some, albeit low, visibility impacts on at least one Class I area. When SO₂ and NO_x emissions were considered together by Kansas, impacts from individual Kansas sources ranged from 0.01% to 0.84% of the total estimated visibility impact. As stated in the NPRM, Kansas did not provide any statutory or regulatory based explanation as to why it was reasonable not to select and analyze potential control options for any of these sources. Therefore, as submitted, the SIP revision did not include the statutorily and regulatorily required

consideration of the four statutory factors and a LTS for the second planning period.

The 2017 RHR Revision directed all States that impact Class I areas to evaluate major and minor emission sources and consider the four factors in the second planning period SIP revision. It is already established that Kansas emissions impact Class I areas. As mentioned previously, the EPA acknowledges that there has been visibility improvement and source retirements since the first planning period. However, the fact remains that there is no exclusion in the CAA or RHR to support the contention that if a State can show emissions are “insignificant” or “de minimis”, then it does not have to comply with 40 CFR 51.308(f). The EPA has long established that achieving the Congressional goal of natural visibility will take reductions from multiple sources, across all States, over multiple planning periods.

The EPA also disagrees that source selection and a four-factor analysis is a costly and futile formality of the RHR. The 2019 Guidance and 2021 Clarifications Memo provide States with latitude by which to formulate the LTS, so long as the result is reasonably supported. 2019 Guidance at 9; 2021 Clarifications Memo at 3. As stated in the NPRM, Kansas has not conducted a reasonably supported analysis to in developing its LTS for the second planning period. Had Kansas selected sources to analyze for a four-factor analysis or properly explained its decision not to, it is possible that there would be no new cost-effective controls. If that were the case, then Kansas’s existing controls would be necessary for reasonable progress and would need to be in the State’s LTS. However, Kansas did not demonstrate that with a proper analysis. 2021 Clarifications Memo at 10.

Additionally, as discussed in Response to KDHE Comment 3, the EPA also does not find KDHE’s narrative analyses for Every—La Cygne for NO_x and Sunflower Energy for SO₂ in its Responsive Summary to properly analyze that these sources are effectively controlled. Therefore, the EPA proposed to disapprove the SIP revision and declines KDHE’s request to approve it.

C. Kansas Utilities’ Comments and Responses

Kansas Utilities’ Comment 1: BPU stated that they submitted comments to KDHE on June 28, 2021, during the State’s public review and comment period. BPU’s comments to the State included modeling results performed by Trinity Consultants, which BPU

¹⁴ The next regulatory deadline for the regional haze second planning period progress reports under 40 CFR 51.308(g) is January 31, 2025.

contended confirm KDHE's conclusion that Kansas's existing plan required no further revision to show reasonable progress toward achieving its LTS for reducing regional haze in affected Class I areas. BPU stated that Kansas has seen significant declines in visibility-impairing emissions due to substantial efforts taken by BPU and other Kansas utilities. BPU also provided a copy of BPU's comments as submitted to KDHE during its comment period on the proposed plan revision for the second planning period, dated June 28, 2021 and reiterated to the EPA the modeling results performed by Trinity consultants for BPU's Nearman Creek Power Station. These comments include a narrative discussion of costs and remaining useful life of the Nearman Creek Power Station regarding SO₂ emissions. BPU stated the dry scrubbers installed in 2017 achieve very high levels of SO₂ control. BPU states these levels are very near what a wet scrubber could do. BPU discussed how the dry scrubbers get better control of acids and are used for Mercury control to meet the Mercury and Air Toxics Standard. BPU concluded that additional controls, specifically new wet controls would be unreasonable.

Response to Kansas Utilities'

Comment 1: Generally, the EPA does not disagree with BPU's comment; however, the information provided by BPU in its public comment on the NPRM is a summary of Trinity Consultants' modeling results and a narrative discussion of costs and remaining useful life for Nearman Creek Power Station. The actual modeling was not provided to the EPA, the FLMs, or the public, and KDHE did not revise the SIP revision so it could properly rely on the information. We disagree with BPU's argument that the SIP submission is approvable.

As previously stated, in order to demonstrate that no additional controls were necessary for reasonable progress at sources in Kansas, KDHE was required by the CAA and the RHR to evaluate sources or groups of sources and determine the emission reduction measures that are necessary to make reasonable progress by considering the four statutory factors. Specifically, the Kansas SIP revision for the second planning period did not provide a substantive analysis related to the effectiveness of controls, nor did Kansas clarify that it determined that the existing controls were necessary for reasonable progress and thus a part of its LTS for the second planning period.¹⁵ It is significant that Kansas jumped to the conclusion that no

controls were required for the second planning period without conducting a proper cost effectiveness analysis for those existing measures.

Further, the comment presented summaries from Trinity's modeling analysis and provided a copy of BPU's comment letter submitted to KDHE during the State's public review and comment period. Neither Kansas nor BPU provided the modeling files or documentation of Trinity's modeling analysis during the EPA's comment period. The 2019 Guidance provides a mechanism for a State to decline to select a source "if the source owner has recently made a significant expenditure that resulted in significant reductions of visibility impairing pollutants at an emissions unit, it may be reasonable for the State to assume that additional controls on the unit are unlikely to be reasonable for the upcoming implementation period." 2019 Guidance at 22–23. The Guidance directs the State to "explain why the decision is consistent with the requirement to make reasonable progress, *i.e.*, why it is reasonable to assume for the purposes of efficiency and prioritization that a full four-factor analysis would likely result in the conclusion that no further controls are necessary." *Id.* at 23. BPU and Kansas did no such analysis to justify the decision to not select sources, and thus cannot be considered by the EPA.

As to BPU's discussion of costs and remaining useful life of Nearman Creek Power Station and its controls regarding SO₂ emissions, we acknowledge that a full cost analysis may confirm BPU's assertion. In other words, at sources like Nearman Creek Power Station, with highly effective air pollution controls, it may be cost prohibitive to replace or improve the efficiency of the controls. In recognition of these potential scenarios, the EPA included the option for States to not select effectively controlled sources in order to focus on other sources which may impact Class I areas in the 2019 Guidance. *Id.* at 22. The EPA guidance, though, is based upon the recognition that the highly effective control emission rates must be made Federally enforceable within the SIP. No emission control measures were submitted to the EPA for incorporation into the Kansas SIP.

The EPA understands that if KDHE was to select Nearman Creek Power Station and conduct a four-factor analysis, with full documentation and cost numbers, the result for SO₂ may be that the existing controls are all that is needed for reasonable progress and thus should be a part of its LTS for the second planning period. However,

without the proper analysis in Kansas's formal SIP revision, and without inclusion of any existing control measures for incorporation into the SIP, we cannot consider BPU's comment alone as Kansas's application of the four factors for SO₂ controls, or as an explanation as to why the Nearman Creek Power Station should not be selected for four-factor analysis for SO₂ controls. We are also not opining on what a four-factor analysis would show in regard to NO_x emissions and controls, only that if Kansas selects Nearman Creek Power Station, we expect NO_x to also be considered.

Furthermore, BPU's comment was not provided to the FLMs during the consultation process or included in the State's plan revision for public notice and comment. Therefore, the analysis does not satisfy the substantive or procedural requirements of the statute or regulations.¹⁶ The EPA acknowledges that the information from BPU is informative, but from a technical perspective, the EPA cannot consider this as Kansas satisfying the requirement to evaluate major or minor emissions sources and consider the four statutory factors because KDHE did not modify its SIP revision to the EPA as a result of BPU's June 28, 2021, comment to include an analysis of the controls at Nearman Station.

Kansas Utilities' Comment 2: Evergy commented that the EPA's proposed disapproval is discouraging because Kansas sources have reduced contributions of NO_x and SO₂ to Class I areas. Such large emission reductions have been achieved through investments making the energy grid smarter, cleaner, more dynamic, more flexible, and more secure while providing affordable and reliable service to customers. Evergy stated that emissions of NO_x and SO₂ from Kansas electric generating units are down 85 and 97 percent, respectively, over the period from 2005 to 2022, and Evergy provided the specific reductions attributable to its emission sources during the first planning period. Evergy asserted that the "above and beyond" first planning period reductions made by Evergy would be utilized in the second planning period. Evergy commented that no neighboring State or FLM requested additional reductions from any Kansas emission sources, including Evergy sources, during the second planning period consultation process. Evergy further argued that instead of recognizing this, the EPA insists on continually burdening Kansas emissions sources by requiring analyses

¹⁵ See Response to KDHE Comment 3.

¹⁶ See Response to KDHE Comment 3.

that will result in no meaningful reduction in visibility impairing pollutants.

Response to Kansas Utilities'

Comment 2: As previously discussed in response to KDHE's comments, the EPA disagrees that previous emissions reductions achieved in prior planning periods relieves Kansas from its obligations to submit a second planning period SIP revision that meets the requirements of the CAA and RHR.¹⁷ The EPA is guided by, and implements, the regional haze program as established in the CAA and the regulations, which do not provide a measurement by which States are excluded from the RHR requirements. CAA section 169A(a)(1); 40 CFR 51.308(f). Therefore, Kansas, like every other State, (and the District of Columbia and the U.S. Virgin Islands) regardless of what transpired in the first planning period, is required to submit a second planning period SIP that meets the requirements of the CAA, as established in the RHR.

If KDHE wanted to rely upon the emission reductions achieved by Evergy and other Kansas sources during the first planning period, then Kansas must document the technical basis on which it is relying to determine that those emissions reductions measures are necessary to make reasonable progress for the second planning period. 40 CFR 51.308(f)(2)(iii). Kansas's submission did not provide the requisite documentation, including a reasoned analysis of why it declined to select any sources; did not make a connection between the source selection step for the second planning period and the emissions controls implemented; and did not provide an analysis of its first planning period source selection and four factor considerations. Instead, Kansas simply points to the SO₂ reductions achieved during the first planning period compared to other States. The EPA finds that this is not a reasonable analysis when determining what measures are necessary for reasonable progress for the second planning period.

Additionally, the statute and rule require evaluation of emissions sources and consideration of the four statutory factors to be part of the State's SIP revision for the second planning period for regional haze regardless of the outcome of the required state-to-state consultation. During the consultation, a State may agree to certain measures necessary to make reasonable progress at a Class I area, and those measures must be included in the SIP revision. The state-to-state consultation also

allows States to share the emission reduction measures that have been identified to reduce emissions from their own sources. Therefore, the state-to-state consultation is just one facet, among many, in determining which emission reduction measures for selected sources, or groups of sources, should be included in a State's LTS.

Kansas's SIP submission included documentation of its consultations with Colorado and New Mexico, and neither State appeared to disagree with or comment on Kansas's LTS approach. However, the EPA disagrees with the assertion that, based on consultation, it was reasonable for Kansas to determine it did not have to select sources, apply the four statutory factors, or describe how the statutory factors were evaluated when selecting measures for inclusion in the LTS.

As far as the EPA "burdening Kansas emissions sources with even more analyses and financial obligations", the EPA is obligated to implement the mandate created by Congress to prevent future, and remedy existing visibility impairment by requiring States to submit SIP revisions that include a LTS to make reasonable progress. CAA section 169A(a)(1), (b)(2)(B). For the second planning period, the EPA conducted a rulemaking with public comment on how the States should be required to address the Congressional mandate. Notably, during that comment period, the EPA received no comments from Kansas or Kansas emission sources to this effect, nor any lawsuits from said parties. If Kansas or Kansas emissions sources have ideas on how to meet the Congressional mandate without further burden on States or sources, we encourage said parties to be involved in the public discourse with the EPA as it relates to the third planning period.

Kansas Utilities' Comment 3: Evergy and Sunflower commented that the EPA failed to consider Kansas's analyses of sources that KDHE included in its Responsiveness Summary. Evergy asserted that the analyses performed by KDHE demonstrate the current NO_x controls at the Evergy—La Cygne facility satisfy the requirements to consider additional controls. Sunflower commented that the narrative analyses demonstrate that the current SO₂ controls at the Sunflower—Holcomb unit result in a reasonable conclusion that further analysis of this unit is not reasonable.

The commenters stated the EPA should review the 2021 SIP again and notice that each factor required to be discussed was identified and commented on in the 2021 SIP submission. Evergy and Sunflower

argued the EPA's statement that the 2021 SIP lacks a LTS is patently false.

Response to Kansas Utilities'

Comment 3: As similarly addressed in response to KDHE's Comment 3, the EPA disagrees with Evergy and Sunflowers that KDHE's narrative analyses satisfy the regulatory requirements.¹⁸ The narrative analyses are insufficient because the analyses did not include an explanation of why it is reasonable to assume that the four-factor analysis would likely result in the conclusion that no further controls are reasonable for these two sources. Furthermore, Kansas did not analyze lower emission rate(s) as a potential control option for these sources. The narrative analyses states that the recent actual emissions for La Cygne and Holcomb are below the current enforceable emission limits, and therefore, Kansas failed to evaluate a full range of control options as required.

Additionally, the Responsiveness Summary fails to satisfy the procedural requirements for public notice and comment in 40 CFR part 51 because it was not part of Kansas's regional haze plan revision that went out for state-level public comment from May 27, 2021, to June 28, 2021. 40 CFR 51.102(a) requires States to provide the opportunity to submit written comments on SIP submittals. 40 CFR 51.102(a). 40 CFR 51.104(c) states "EPA will approve revisions only after applicable hearing requirements of § 51.102 have been satisfied." 40 CFR 51.104(c). The public did not have an opportunity to submit written comments on the analyses provided by Kansas in the Responsive Summary.

Due to the substantive and procedural defects surrounding the Responsiveness Summary, the EPA has determined that the narrative analyses do not meet the RHR requirements, and therefore, the EPA proposes disapproval of Kansas's SIP revision.¹⁹

Kansas Utilities' Comment 4: The Kansas Utilities stated the EPA is authorized to require by regulation that a SIP "contain such emission limits, schedules of compliance and other measures as may be necessary to make reasonable progress toward meeting the national goal . . ." The commenters argued that the trigger warranting evaluation of those factors is, by statute, whether it is first "necessary" to meet the national goal, and an evaluation is unnecessary in instances where the visibility impact is <1.00%. The Kansas Utilities asserted that Kansas demonstrated that "substantive"

¹⁷ See Response to KDHE Comment 1.

¹⁸ See Response to KDHE Comment 3.

¹⁹ See Response to KDHE comment 3.

revision of the existing SIP is unnecessary because the regulation clearly and unambiguously establishes that a State may determine that no substantive revision to the existing SIP is necessary. The Kansas Utilities concluded that Kansas reasonably determined that no substantive revision of the SIP is necessary based on all of the information provided in the 2021 SIP.

Response to Kansas Utilities'

Comment 4: As similarly addressed in Responses to KDHE Comments 2 and 4, the EPA disagrees with this comment. The Kansas Utilities makes the same arguments and provide similar data as KDHE regarding when evaluation of the four statutory factors is "necessary" under the CAA and RHR. As such, the EPA's Response to KDHE Comment 2 is applicable to this comment. To the extent that the Kansas Utilities assert KDHE's argument that, per 40 CFR 51.308(f)(5), Kansas has demonstrated a substantive revision of the existing plan is unnecessary, the EPA's Response to KDHE Comment 4 is applicable and conveys why this regulatory interpretation is incorrect.

Kansas Utilities' Comment 5: The commenters stated that the existing Kansas regional haze emission limits will continue to show reasonable progress towards achieving visibility gains in the affected Class I areas through the second planning period.

Response to Kansas Utilities'

Comment 5: As stated throughout this document, while the EPA recognizes the gains made at most of the Class I areas affected by Kansas sources, Kansas is nonetheless still required to comply with the regulatory requirements of analyzing sources, or groups of sources, via application of the four statutory factors, to determine if there are new or additional cost effective controls that would result in reasonable progress towards natural visibility.

If Kansas wanted to rely on an argument that their existing effective controls are necessary for reasonable progress in the second planning period, the EPA has provided guidance on how to analyze and provide the proper documentation to back up such a finding. However, Kansas did not properly analyze whether the Kansas sources' existing measures are necessary for reasonable progress and thus a part of their LTS for the second planning period. The 2021 Clarifications Memo states "the existence of an enforceable emission limit or other enforceable requirement reflecting a source's existing measures may also be evidence that the source will continue implementing those measures. . . .

States should provide information on any enforceable emission limits associated with sources' existing measures." 2021 Clarifications Memo at 9. The SIP should further identify the applicable permits and the relevant limits and provide a copy of the underlying permit with the SIP submission, if it is not publicly available. *Id.* at 9–10. Without this information, which is an integral part of the LTS, the SIP is deficient, and the EPA cannot approve the submission.

Kansas Utilities' Comment 6: The commenters stated that as Kansas was concluding the regional haze SIP revision process for the first planning period, it was recognized by all those involved that Everygy was going above and beyond the emission reductions required for the first regional haze planning period. Everygy asserted that there was recognition that these additional emission reductions or "reasonable progress emission reductions" would be utilized in the future to aid Kansas in complying with the second regional haze planning period.

Response to Kansas Utilities'

Comment 6: The EPA recognizes that Kansas made significant emissions reductions during the first planning period. However, beginning in 2015 and concluding in 2017, the EPA revised the RHR. As previously stated throughout this document, the revised rule clearly requires all States to have a LTS where the States evaluate and determine the emission reduction measures that are necessary for reasonable progress by considering the four statutory factors, and the emission reduction measures that are necessary for reasonable progress need to be Federally enforceable. The revised rule did not codify any exemption or use of early reductions for emission sources, or its predecessors or successors. Since Kansas did not select sources to evaluate for further controls, the EPA cannot evaluate any claims regarding certain sources, or groups of sources.

IV. What action is the EPA taking?

The EPA is taking final action to disapprove Kansas's SIP revision related to the regional haze requirements for the second planning period. Disapproval does not trigger imposition of mandatory sanctions. The effective date of this action does trigger an obligation for the EPA to issue a FIP within two years.

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission

that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this action merely 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 an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of the National Technology Transfer and Advancement Act (NTTA) because this action does not involve technical standards; and
- This action does not have Tribal implications as specified in Executive Order 13175. This action does not apply on any Indian reservation land, any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction, or non-reservation areas of Indian country. Thus, Executive Order 13175 does not apply to this action.
- Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, February 16, 1994) and Executive Order 14096 (Revitalizing Our Nation's Commitment to Environmental Justice for All, 88 FR 25251, April 21, 2023) directs Federal agencies to identify and address "disproportionately high and adverse human health or environmental effects" of their actions on minority

populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.” The EPA further defines the term fair treatment to mean that “no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.”

KDHE did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Due to the nature of the action being taken here, this action is expected to have a neutral 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. While the Conservation Groups did adversely comment that the EPA should consider EJ, they did not provide any different steps or outcomes the EPA should take or arrive at. See our response to comments document in the docket for this action.

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

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 7, 2024. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

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.

Dated: July 30, 2024.

Meghan A. McCollister,

Regional Administrator, Region 7.

[FR Doc. 2024–17182 Filed 8–6–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 8360

[BLM_HQ_FRN_MO4500179077]

RIN 1004–AE89

Temporary Closure and Restriction Orders

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rule.

SUMMARY: The Bureau of Land Management (BLM) is revising its regulations to modernize and streamline how the agency notifies the public of temporary closure and restriction orders; clarify that such orders may be issued to avoid conflicts among public land users and ensure the privacy of Tribal activities for traditional or cultural use; require that all orders specify the date and time that a temporary closure or restriction becomes effective and terminates; and harmonize the penalties for violating temporary closure and restriction orders consistent with current statutory authority.

DATES: This final rule is effective on September 6, 2024.

FOR FURTHER INFORMATION CONTACT:

Kevin Oliver, Division Chief, BLM Headquarters Division of Recreation and Visitor Services at (801) 450–3134 or via email at koliver@blm.gov. For questions relating to regulatory process issues, email Brittney D. Rodrigues at: brodrigues@blm.gov. Individuals in the United States who are deaf, blind, 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. For a summary of the final rule, please see the final rule summary document in docket No. BLM–2023–0007 on <https://www.regulations.gov>.

SUPPLEMENTARY INFORMATION:

I. Background

II. Response to Comments on the Proposed Rule

III. Discussion of the Final Rule

IV. Procedural Matters

I. Background

The Federal Land Policy and Management Act (FLPMA) (43 U.S.C. 1701–1787) establishes the BLM’s multiple use and sustained yield mandate. In managing the public lands in accordance with FLPMA, the BLM occasionally issues temporary closure and restriction orders under 43 CFR 8364.1 to protect persons, property, public lands, and resources. The need to temporarily close or restrict the use of public land arises in various situations, including in response to an emergency or unplanned event such as a flood, fire, hazardous material incident, discovery of unexploded ordnance, public health emergency, or change in public land use that creates a public safety hazard. For example, the BLM has issued temporary closure or restriction orders to protect the public from unsafe conditions in a community rock pit in Doña Ana County, New Mexico (88 FR 42984 (July 5, 2023)); close 9 acres of public land near Rowley, Utah, that were inundated with a hydrochloric acid spill (79 FR 26265 (May 7, 2014)); close approximately 31,000 acres of public land in California to protect the public from exposure to airborne asbestos (73 FR 24087 (May 1, 2008)); and close a recreation site near Challis, Idaho, to protect the public from dangerous flooding and ice jams (87 FR 25523 (April 29, 2022)).

The BLM also occasionally issues temporary closures or restrictions to protect resources or avoid conflicts among visitor use activities. In such situations, the BLM may restrict an area to certain types of travel to facilitate resource restoration or close an area to public access to facilitate special recreation events, such as the Burning Man Project (88 FR 39863 (June 20, 2023)); the King of the Hammers off-road race (87 FR 69300 (November 11, 2022)); the Reno Air Races (84 FR 31337 (July 1, 2019)); the Mint 400 off-road race in Las Vegas (88 FR 7994 (February 7, 2023)); and the Desert Classic racecourse (87 FR 20457 (April 7, 2022)).

As resource uses and demands for access to public lands have increased,

the need for the BLM to issue temporary closure and restriction orders under 43 CFR 8364.1 to protect persons, property, and public lands has also increased. However, some aspects of 43 CFR 8364.1—such as the requirement to publish temporary closure and restriction orders in the **Federal Register** and the absence of a provision authorizing the BLM to issue such orders with immediate full force and effect—can hinder the BLM’s ability to respond effectively to exigencies that arise on public lands.

Streamlining and modernizing how the BLM notifies the public about temporary closure and restriction orders, as well as providing managers with the ability to issue such orders with immediate effect, will enhance the BLM’s ability to perform its mission to responsibly manage public lands and protect public safety. Revising § 8364.1 will also make the BLM’s temporary closure and restriction authorities more consistent with those of the U. S. Forest Service (USFS), U.S. Fish and Wildlife Service (FWS), and the National Park Service (NPS) (agencies with which BLM-administered public lands often share a common boundary) and will allow the BLM to be a more effective cooperator with other Federal and local agencies when responding to multijurisdictional demands, including emergency incidents or unforeseen events.

Section 310 of FLPMA, which authorizes the Secretary to promulgate regulations to carry out the purposes of that Act and other laws with respect to public lands, authorizes this revision of the BLM’s regulatory authority for temporarily closing and restricting the use of public lands. Other statutes, such as the Archaeological Resources Protection Act (16 U.S.C. 470aa–470mm), also authorize the Secretary to promulgate regulations relating to closures and use restrictions in certain contexts.

II. Response to Comments on the Proposed Rule

The BLM published a proposed rule on November 21, 2023 (88 FR 81022), soliciting public comments for 60 days. The BLM received 79 submissions from members of the public, including individuals, State and local governments, regional law enforcement groups, livestock grazing organizations, recreation groups, and wilderness organizations. The BLM considered each comment in developing the final rule. Some comments fully or partially supported the proposed rule. Other comments were critical of the proposed rule and expressed concern regarding,

among other issues, its scope, how the BLM would notify the public about temporary closure and restriction orders, how such orders would comply with the National Environmental Policy Act (NEPA), the BLM’s ability to exempt certain persons from temporary closure and restriction orders, the lack of a mandatory public participation requirement, and the length of time that temporary closure and restriction orders could remain in place. Additional comments expressed a desire for the BLM’s temporary closure and restriction authority to align more closely with the temporary closure and restriction authorities of other Federal agencies.

Comments that are similar in nature have been categorized by subject and, in some instances, have been combined with related comments.

A. Scope of the Proposed Rule

Comment: Several commenters expressed concern about the language in the proposed rule providing that the BLM could issue temporary closure and restriction orders to “provide for implementation of management responsibilities.” Some commenters described this language as too vague, while others expressed concern that it impermissibly expanded the situations in which the agency could issue temporary closure and restriction orders.

Response: The BLM originally proposed to include the clause regarding the implementation of management responsibilities in § 8364.1 to make the BLM’s temporary closure and restriction authority align more closely with the NPS’s analogous regulation, which permits temporary closures and public use limits “based upon a determination that such action is necessary for. . . implementation of management responsibilities” (36 CFR 1.5(a)). The BLM also intended to clarify that the agency may currently close or restrict the use of public lands temporarily to facilitate construction, demolition, resource monitoring, invasive species control projects, and other typical management responsibilities in which the BLM regularly engages. However, while this clause would be consistent with the BLM’s authority to manage public lands under FLPMA, the BLM understands how it could be misinterpreted to broaden the scope of the agency’s temporary closure and restriction authority. Accordingly, the BLM has excluded the clause “provide for implementation of management responsibilities” from the text of the final rule. Excluding this clause from the text of the final rule should not

impair or otherwise affect the BLM’s ability to perform typical management responsibilities, as activities such as construction, demolition, resource monitoring, and invasive species control projects are already typically accompanied by a temporary closure or restriction order under the existing regulations where necessary to protect persons, property, public lands, or resources. As a result, the BLM expects to continue to be able to issue temporary closure and restriction orders to facilitate such activities under the final rule.

Comment: Several commenters expressed concern that the proposed rule would allow the BLM to implement large-scale conservation leasing without adequate public input. According to the commenters, this concern was driven, in part, by ambiguity concerning the language in the proposed rule providing for the issuance of temporary closure and restriction orders for the implementation of management responsibilities.

Response: This final rule does not establish a leasing program or authorize the BLM to permanently close public lands to recreational or other uses. Rather, it will allow the BLM to protect persons, property, public lands, or resources, avoid conflicts among public land users, and ensure the privacy of Tribal activities for traditional or cultural use in a more efficient and expeditious manner. The BLM has excluded the language concerning implementation of management responsibilities to help clarify the scope and intent of the final rule.

Comment: Several commenters stated that the BLM should not address temporary closure and restriction orders relating to emergencies and permitted events through a single regulatory provision. According to these commenters, closures and restriction orders intended to address emergency situations and permitted events differ significantly in their nature, and attempting to address them through a single regulation exacerbates those discrepancies.

Response: The BLM does not believe that separate regulatory provisions are necessary. The agency has long relied on a single regulatory provision to issue temporary closure and restriction orders for both emergencies and permitted events, and the revisions to 43 CFR 8364.1 effectuated through this rulemaking do not warrant a different approach. While the elimination of a **Federal Register** notice requirement will enhance the BLM’s ability to respond to emergency situations and other unforeseen events, the publication

of a **Federal Register** notice is not the most effective way for the public to learn of a temporary closure or restriction order, even in non-emergency situations. Under the final rule, the bureau retains discretion to publish a notice in the **Federal Register** or use other means, such as social media and other online communication systems, to inform the public of a temporary closure or restriction order. The BLM therefore does not believe that temporary closure and restriction orders related to emergencies and permitted events must be addressed in separate regulatory provisions.

Comment: Several commenters agreed that procedures should be available to the BLM to expedite temporary closure and restriction orders that address emergencies. But many of these same commenters contended that those same processes should not apply to non-emergency situations, such as temporary closures intended to facilitate planned events or avoid user conflicts, because the BLM is typically aware of these situations well before they occur. These commenters believe that adequate time exists to publish temporary closure and restriction orders associated with non-emergencies in the **Federal Register**.

Response: Although non-emergency situations typically do not pose the same time constraints as emergencies, the BLM does not believe that temporary closure and restriction orders associated with non-emergencies must be published in the **Federal Register**. Some situations may not clearly constitute an emergency but may nevertheless warrant a quick response. In such situations, BLM managers should not delay taking action to protect persons, property, public land, or resources because they are concerned that a particular situation does not necessarily qualify as an “emergency” and, therefore, the agency’s response must follow a slower process. Instead, managers should have the discretion, but not the requirement, to publish certain temporary closure and restrictions in the **Federal Register** when appropriate, such as when the closure or restriction affects an area with limited local media outlets and the BLM believes that publication in the **Federal Register** is necessary to communicate area and use limitations to the public adequately. Moreover, eliminating the **Federal Register** notice requirement aligns 43 CFR 8364.1 more closely with the closure and restriction authorities of the USFS, FWS, and NPS, none of which require **Federal Register** publication for many non-emergency closures and restrictions.

Comment: Several commenters argued that the proposed rule should permit temporary closure and restriction orders only for emergencies. Some commenters suggested that allowing the BLM to issue temporary closure and restriction orders based on non-emergency conditions could be overly open-ended and would not be based on adequate public input.

Response: Since the original promulgation of 43 CFR 8364.1, the BLM has had authority to temporarily close or restrict the use of public lands to respond to emergencies and non-emergencies alike. The final rule retains this authority, which is an essential tool in managing the public lands for present and future generations.

Comment: Several commenters expressed concern that the proposed rule would allow the BLM to issue temporary closure and restriction orders based on climate emergencies or other impacts of climate change. Commenters suggested that such closures could be overly open-ended or could occur without appropriate NEPA review.

Response: Climate-related emergencies could necessitate a temporary closure or restriction order to protect persons, property, public lands, or resources. If temporary closure and restriction orders are necessary to address climate-related emergencies, the BLM would issue them in accordance with the same procedures used to issue other § 8364.1 orders. For example, the BLM would need to comply with NEPA and other applicable laws and specify in the order the date (and time) on which the closure or restriction would terminate.

Comment: Some commenters asserted that it is unnecessary to eliminate the **Federal Register** publication requirement to modernize and streamline how the BLM communicates temporary closure and restriction orders to the public. These commenters assert that it is legally feasible to notify the public about temporary closures and restrictions using both the **Federal Register** and other forms of communication.

Response: Retaining the requirement to publish notice of all temporary closure and restriction orders in the **Federal Register**, though legally feasible, would fail to achieve one of the other primary aims of this rulemaking: enhancing the BLM’s ability to address emergencies and unforeseen events in a timely manner. Nevertheless, under the final rule, the BLM retains the discretion to publish temporary closure and restriction orders in the **Federal Register** where appropriate, such as when time allows or when the agency

believes that other communication methods may not provide adequate notice to the public.

Comment: Several commenters suggested that the proposed rule expand opportunities for public participation by requiring the BLM to seek public input prior to issuing a temporary closure or restriction order.

Response: The BLM does not believe that it is necessary to seek public input prior to issuing a temporary closure or restriction order for several reasons. First, the agency has never been required to obtain public input before issuing a closure or restriction order under 43 CFR 8364.1, and the BLM does not think it is necessary to impose such a requirement now. As stated above, the BLM is revising the final rule, in part, to enhance its ability to respond to emergencies and other unforeseen events in a timely manner. Requiring public input prior to issuing a temporary closure or restriction order could undermine that purpose. The BLM took a similar position when promulgating 43 CFR 8341.2, a provision which allows for emergency closures to off-road vehicle use. In response to commenters who expressed concern about the absence of a provision for public participation in that regulation, the BLM explained that the rule is intended to provide the BLM with a “tool to take timely emergency action,” and “[a]dding a provision for public discussion would defeat th[at] purpose.” (44 FR 34834 (June 15, 1979)) Similar logic applies here.

Second, the BLM is also revising 43 CFR 8364.1 to make it more consistent with closure authorities of the USFS, FWS, and NPS, none of which are generally required to seek public input before issuing closure or restriction orders. Third, even though public participation is not required prior to the BLM issuing a closure or restriction order, the BLM provides for public participation in the form of being able to appeal such orders to the Department of the Interior’s Board of Land Appeals (IBLA) in accordance with the regulations contained in 43 CFR part 4. As a result, members of the public retain an ability to voice opposition to a closure or restriction order that they believe was issued improperly. Finally, the fact that this final rule does not require the BLM to seek public input does not mean that there will never be opportunities for public participation before the BLM issues temporary closure and restriction orders. Orders issued under this section must comply with NEPA, and that process will often provide opportunities for public participation. Moreover, depending on

the nature of the closure or restriction at issue, other statutory and regulatory provisions may require public participation prior to issuance of an order.

Comment: Several commenters expressed concerns with the proposed rule providing authority to issue temporary closure and restriction orders to avoid conflicts among public land users. These commenters were concerned that the BLM could use this authority to give preference to certain public land users over others.

Response: FLPMA obligates the BLM to manage the public lands for a broad array of uses. This statutory requirement can occasionally lead to conflicts among users. In response, the BLM must evaluate and choose an appropriate balance of uses, a task which frequently involves making tradeoffs between competing uses. Since it was originally promulgated, 43 CFR 8364.1 has provided for the BLM to issue temporary closure and restriction orders, where necessary, to manage the appropriate balance of resources through its authority to protect persons, public lands, and resources. At times, the BLM has utilized this authority to issue temporary closure and restriction orders to avoid user conflicts, such as when the agency has closed areas of the public lands to general access to facilitate a permitted off-road race. The final rule reinforces this existing authority by clarifying that the BLM's ability to issue temporary closure and restriction orders to protect persons extends to avoiding user conflicts.

Comment: One commenter sought clarification about whether the proposed rule applies to all BLM-managed lands, including national monuments and other special designations.

Response: The final rule applies to all BLM-managed lands. Temporary closure and restriction orders issued under 43 CFR 8364.1 can apply to national monuments and other public lands managed by the BLM under special designations. Moreover, the final rule is compatible with other legal and regulatory authorities that allow the BLM to close or restrict the use of public lands in specific contexts. For example, the final rule does not constrain the BLM's discretion to implement the closure provision at 43 CFR 8351.2, which authorizes the BLM to close or restrict the use of certain lands and waters within the boundary of a component of the National Wild and Scenic Rivers System, or the provision at 43 CFR 9212.2, which authorizes the BLM to issue fire prevention orders to

prevent wildfire or facilitate its suppression.

B. Coordination, Communication, and NEPA

Comment: Several commenters requested that the BLM clarify how this proposed rule interacts with requirements of the John. D. Dingell, Jr. Conservation, Management, and Recreation Act (Dingell Act). For example, one commenter requested that the final rule include language regarding the Dingell Act's requirements to coordinate with state agencies, to consider the impact of closures on hunting, fishing, and recreational shooting, and to close the smallest area for the least amount of time. Another commenter asked that the final rule specify that the public have an opportunity to comment in accordance with section 4103 of the Dingell Act if the agency is proposing to close public lands to hunting, fishing, or recreational shooting.

Response: The final rule does not change how the BLM complies with the Dingell Act. If a proposed closure to hunting, fishing, or recreational shooting falls within the purview of the Dingell Act, the BLM will publish a notice in the **Federal Register**, consult with state wildlife agencies, provide an opportunity for public comment, and satisfy the other procedural and substantive requirements of section 4103. It is therefore unnecessary to incorporate aspects of the Dingell Act into the text of the final rule.

Comment: One commenter suggested that the BLM explain in further detail where it would post notice of temporary closure and restriction orders and recommended that the BLM use all forms of communication available to inform the public.

Response: The BLM has not incorporated this suggestion into the final rule. The final rule, which requires that notice of temporary closure and restriction orders be posted in BLM offices with jurisdiction over the relevant public lands, at or near places where the order applies, in local media outlets, and on at least one BLM-controlled, publicly available online communication system, provides the BLM with discretion to ensure that the level of notice provided to the public is commensurate with the scale and location of the closure or restriction order at issue. In some instances, it may be necessary to post notice on numerous BLM web pages, including the national, state, district, and field office web pages. In other situations, more limited online notification may suffice. The final rule provides the flexibility

necessary to ensure that the level of notice is uniquely tailored to the closure or restriction order being issued.

Comment: One commenter asked the BLM to clarify what "BLM-controlled, publicly available online communication system" means.

Response: This phrase refers to a BLM-controlled system that is available to the public and facilitates the sharing of information or communication over a computer network or other digital means. Currently, many social media platforms and the BLM website would qualify as BLM-controlled, publicly available communication systems. However, because technology will change over time, the final rule purposely utilizes flexible language to allow it to adapt to new technologies.

Comment: One commenter contended that there are generational differences in how the public obtains information. This commenter suggested that certain generations could be adversely impacted by the proposed rule's reliance on online communication systems in place of the **Federal Register**.

Response: The final rule does not rely on the BLM's utilization of online communication systems to communicate all temporary closures and restrictions to the public. The BLM retains discretion to publish orders in the **Federal Register** or use other mechanisms to inform the public of temporary closure or restriction orders, where appropriate. Additionally, the final rule requires the BLM to post notices of temporary closure and restriction orders in the BLM offices with jurisdiction over the relevant public lands, at or near places where the order applies, and in local media outlets.

Comment: Several commenters requested that temporary closures and restrictions continue to be published in the **Federal Register** to facilitate communication in rural communities and retain public input and appeal opportunities.

Response: The final rule does not prohibit the BLM from publishing a notice in the **Federal Register** if the agency determines that doing so is appropriate. Thus, where the BLM determines that other forms of notice may prove insufficient, it may still elect to publish a notice in the **Federal Register**. The final rule, however, does not require the BLM to publish such a notice in all instances, even for temporary closures and restrictions in rural areas, in part because what constitutes "rural" can be relative, and demographics are not necessarily determinative of whether other notification methods are adequate. The

final rule does not alter the regulations with regard to public input or appeals.

Comment: Some commenters requested that, in addition to posting notice of temporary closure and restriction orders through an online communication system and notifying local media outlets, the final rule require the BLM to directly notify grazing permittees and other people affected by a temporary closure or restriction order through certified mail or some other means. These commenters feel that online communications systems and local media outlets are not sufficient effective means of communication in certain rural areas.

Response: The BLM has not incorporated this suggestion into the final rule. In most situations, online communication systems and local media outlets will be an effective means of communicating temporary closures and restrictions, even in rural areas. In those situations where online communication systems and local media outlets may not be effective means of communication, the final rule provides the BLM with sufficient flexibility to communicate the closures through other means of communication, such as directly notifying a permittee or other person affected by a temporary closure or restriction order. Generally, and as emergency conditions may dictate, the BLM will communicate with an affected permittee prior to implementing a closure. Furthermore, temporary closures implemented under the final rule will not necessarily impede a permittee's ability to manage livestock within a closure area, as § 8364.1(a)(4) permits the authorized officer to identify persons or groups who are exempt from the closure or restrictions.

Comment: Some commenters expressed concern that the proposed rule may cause changes to resource management plans (RMPs) without public input. The commenters emphasized that temporary closures should comply with applicable RMPs.

Response: The final rule does not substitute for land use planning, a separate process governed by BLM regulations at 43 CFR part 1600. Temporary closure and restriction orders under 43 CFR 8364.1 do not amend or revise land use plans and are issued independent of the planning process (*Utah Shared Access Alliance v. Carpenter*, 463 F.3d 1125, 1135–36 (10th Cir. 2006) (citing *Humboldt County v. United States*, 684 F.2d 1276 (9th Cir. 1982))). Implementation of the final rule will not change the content of RMPs. Under the final rule, all

temporary closures and restrictions must conform to approved RMPs.

Comment: Some commenters expressed the view that the proposed rule should require consultation or coordination with various stakeholders, including, but not limited to, local sheriffs, emergency services providers, State wildlife agencies, Tribes, and others.

Response: Consultation and coordination with stakeholders is an important aspect of managing public lands, and, where possible, the BLM always encourages coordination with local sheriffs, State law enforcement, government officials, State wildlife agencies, rights-of-way holders, permittees, and other interested stakeholders before temporarily closing or restricting the use of public lands. But consultation and coordination with external groups is not always feasible before implementing a closure or restriction order. For example, the BLM may not have time to engage in the suggested type of coordination when addressing an emergency. Additionally, which stakeholders are appropriate for the BLM to coordinate with will depend on the circumstances of the specific closure or restriction at issue. The BLM, therefore, has not incorporated a requirement to consult or coordinate with specific stakeholders prior to implementing a temporary closure or restriction order. Instead, the BLM has adopted a more individualized approach and intends to coordinate with appropriate stakeholders, the identity of which will depend on the circumstances giving rise to the need for the temporary closure or restriction order.

Comment: One commenter implied that under section 202(c)(9) of FLPMA, the BLM must incorporate a requirement to coordinate with State and local governments prior to implementing a temporary closure or restriction order.

Response: Consultation and coordination with State and local governments is an important aspect of managing public lands, and the BLM encourages land managers to do so in advance of issuing temporary closure and restriction orders where appropriate. However, section 202(c)(9) of FLPMA requires the BLM to coordinate with State and local governments only when engaging in land use planning in accordance with 43 CFR part 1600. As noted above, temporary closure and restriction orders under 43 CFR 8364.1 do not amend or revise land use plans and are issued independent of the planning process. Accordingly, section 202(c)(9) does not

require coordination with State and local governments prior to implementing a temporary closure or restriction order. Although not required, the BLM will continue to engage in such coordination where appropriate.

Comment: One commenter stated that the proposed rule, which does not require coordination with stakeholders before the issuance of a temporary closure or restriction order, conflicts with the community engagement strategy laid out in the BLM's Blueprint for 21st Century Outdoor Recreation.

Response: The final rule does not conflict with the Blueprint for 21st Century Outdoor Recreation (Blueprint), which presents the BLM's strategy for diversifying recreation investments and considering current and future recreation demands and program needs. While the Blueprint identifies increasing and improving collaboration with community service providers as a general goal, it does not suggest that collaboration with community stakeholders must occur before the BLM takes specific actions, such as issuing temporary closure or restriction orders. The BLM will continue to coordinate as appropriate with stakeholders through implementation of the Blueprint and other activities.

Comment: Two commenters requested that the BLM revise the proposed rule text to provide that the agency will issue a temporary closure or restriction order *only* after other management strategies and alternatives have been explored including, but not limited to, increased law enforcement, cooperative efforts with local governments, engineering, education, and outreach.

Response: While the BLM typically considers other management strategies before closing or restricting the use of public lands, it has not incorporated this suggestion into the final rule. There may not be sufficient time in all situations to coordinate fully or document those efforts before a closure or restriction must be implemented to protect people or resources.

Comment: Some commenters expressed concern that the proposed rule would not provide adequate opportunities for review or appeal of temporary closure or restriction orders.

Response: The final rule does not affect the appealability of temporary closure and restriction orders, nor does it affect the public's ability to immediately challenge a temporary closure or restriction order in Federal court. Such orders will continue to be administratively appealable in accordance with the regulations contained in 43 CFR part 4. Under the final rule, however, temporary closure

and restriction orders may become effective upon issuance, similar to several other types of decisions issued by the agency, such as rights-of-way, certain grazing and forestry decisions, and wild horse and burro removal decisions.

Comment: One commenter questioned the need to provide that temporary closure and restriction orders are issued with immediate full force and effect, asserting that such orders tend not to be appealed.

Response: Providing that temporary closure and restriction orders can have immediate full force and effect will not, nor is it intended to, limit the public's ability to appeal temporary closure and restriction orders. Providing that temporary closure and restriction orders may have immediate full force and effect is intended to enhance the BLM's ability to address emergencies and unforeseen events in a timely fashion. Previously, temporary closure and restriction orders were generally not effective until 30 days after their issuance, which hindered the agency's ability to protect public health, safety, property, and resources in a timely manner.

Comment: One commenter stated that existing regulations, including 43 CFR 4.21, 43 CFR 9212.2, and regulations allowing for alternative arrangements to comply with NEPA, provide adequate authority for the BLM to respond to emergency situations. This commenter therefore contended that the rule is not needed.

Response: The BLM disagrees that the regulations cited by the commenter provide the agency with adequate authority to respond effectively to all emergencies and other unforeseen events in a timely fashion. Under 43 CFR part 4, the IBLA may provide that a decision has immediate full force and effect when the public interest requires. But that regulation does not provide the BLM with similar authority, and in many situations, having to make a request of the IBLA would prevent the BLM from acting with sufficient speed. The provisions at 43 CFR 9212.2 are limited to fire prevention and suppression purposes, and the BLM must be able to close and restrict the use of public lands quickly in a broader set of circumstances. Finally, the BLM agrees that regulations promulgated by the Council on Environmental Quality and the Department of the Interior concerning the procedural requirements of NEPA would allow the BLM to make alternative arrangements for NEPA compliance when responding to an emergency. Those regulations, however, do not affect whether a temporary

closure or restriction order needs to be published in the **Federal Register** or whether it will be effective immediately. As a result, reliance on those NEPA regulations alone is insufficient to allow the BLM to respond to emergency situations and other unforeseen events in a sufficiently timely manner.

Comment: One commenter asserted that the proposed rule should not be used as a substitute for NEPA compliance for permits or planning.

Response: The final rule does not affect how the BLM complies with NEPA. Temporary closure and restriction orders issued under 43 CFR 8364.1 must comply with applicable law. Moreover, the final rule is not a substitute for land use planning. While the BLM has authority to temporarily close or restrict the use of public lands for a variety of reasons, the agency will continue to establish overarching goals, objectives, and management direction through the land use planning process in accordance with 43 CFR part 1600.

Comment: Several commenters were concerned that removing the requirement for publishing temporary closure and restriction orders in the **Federal Register** would circumvent public participation and other requirements of NEPA.

Response: The final rule does not change how the BLM complies with NEPA when issuing temporary closure and restriction orders. Before issuing a temporary closure or restriction order, the BLM must ensure that it is supported by an adequate environmental analysis, relies on a relevant categorical exclusion, or, in the case of emergencies, relies on alternative arrangements for NEPA compliance. The final rule does not change these requirements.

Comment: One commenter suggested that the proposed rule should be analyzed through an environmental impact statement under NEPA.

Response: Preparation of an environmental impact statement is unnecessary, as the rule is categorically excluded from further NEPA analysis under 43 CFR 46.210(i). The final rule is administrative and procedural in nature and, therefore, satisfies the first prong of § 46.210(i). The final rule is not self-executing in that its promulgation does not authorize or effectuate any specific closures or restrictions. The final rule merely clarifies the situations in which the agency may issue temporary closure and restriction orders, streamlines the process that the BLM uses to issue such orders, and updates the penalty provision to align with current statutory authority. Moreover, the final rule does not modify

the public's ability to participate in the BLM's decision-making process. When considering whether to issue a temporary closure or restriction order, the BLM must still comply with NEPA and other laws providing for public participation.

The final rule also satisfies the second prong of § 46.210(i). The details of specific closures or restrictions that the BLM may impose in accordance with the final rule are uncertain. As a result, the environmental effects of such future closures or restrictions are currently too speculative and conjectural to lend themselves to meaningful analysis. The environmental effects of future closure or restriction orders issued under the final rule will later be subject to the NEPA process when the agency can account for the site specificity that will make such analysis meaningful. Finally, reliance on the categorical exclusion at 43 CFR 46.210(i) is appropriate because none of the extraordinary circumstances described in 43 CFR 26.215 apply to the final rule.

Comment: Some commenters argued that the Burning Man Project, which was cited in the proposed rule as an example of a reason for issuing a non-emergency temporary closure, is a poor example because Burning Man is associated with a special recreation permit that is subject to NEPA and its attendant public participation requirements, whereas other temporary closures are not.

Response: The final rule does not change or affect the BLM's obligation to comply with NEPA when issuing temporary closure and restriction orders, regardless of whether those orders are associated with emergencies or easily foreseen events. Some temporary closure orders are associated with large-scale public events authorized through a special recreation permit, such as the Burning Man Project and the Reno Air Races. These events can be complex in nature and may require the BLM to temporarily close or restrict the use of public lands to provide for public safety. In such situations, the BLM will typically evaluate the environmental impacts associated with any necessary temporary closures or restrictions in the NEPA document supporting authorization of the underlying special recreation permit. However, even in situations when a temporary closure or restriction order is unrelated to a special recreation permit or other authorization that must comply with NEPA, the temporary closure or restriction order constitutes a Federal action for which NEPA compliance is necessary. The circumstances surrounding specific

temporary closure and restriction orders will determine how the BLM complies with NEPA when issuing such orders.

C. Closure Parameters—Timeframe and Size

Comment: Several commenters expressed concern about the statement in the proposed rule that “a temporary closure or restriction order would generally remain in effect until the situation it is addressing has ended or abated, it expires by its own terms, or the BLM issues a superseding decision, which can include incorporating the terms of a closure or restriction order into a resource management plan in accordance with the regulations at 43 CFR part 1600.” Some commenters asserted that such an order would not be “temporary,” while others contended that the statement in the proposed rule is in tension with the requirement that a temporary closure or restriction order specify the time and date on which it begins and ends.

Response: Temporary closure and restriction orders are generally intended to address emergencies or unforeseen events or facilitate time-limited uses that require specific restrictions. In many situations, such as when the BLM temporarily closes or restricts the use of public lands to protect persons during an off-road vehicle race, the BLM will know the specific duration that a closure or restriction must be in effect. In other situations, the necessary duration of a closure or restriction order is unknown, such as when the BLM closes an area to protect resources after an area has been burned in a fire. In both cases, the closure or restriction order issued by the BLM is temporary, in that the agency issues it outside of the land use planning process that the BLM uses to establish long-term management strategies. Additionally, in both cases, under the final rule, the BLM would specify in the temporary closure or restriction order the times and dates on which it takes effect and terminates. However, when the necessary duration of the order is unknown, the BLM may have to issue subsequent temporary closure or restriction orders that restrict public access or use until the situation posing a concern has abated, or to rescind an existing temporary closure or restriction order and issue a new order with a revised date or other changes to better reflect the purpose and intent of the order. By comparison, non-temporary closures and restrictions are those that the BLM issues through the land use planning process. Such closures and restrictions are part of the agency’s long-term strategy for managing areas of

public lands and are typically in place for longer durations. As a result, the agency issues such closures in accordance with 43 CFR part 1600, which provides multiple opportunities for public participation.

Comment: Several commenters requested that the BLM define the term “temporary” for purposes of this rule, while others suggested that the temporary closure and restriction orders issued under 43 CFR 8364.1 be limited to a specific duration, such as 6 months or 45 days.

Response: The BLM does not believe that it is necessary to define the term “temporary” for the purposes of the rule, nor does the BLM believe that temporary closure and restriction orders issued under 43 CFR 8364.1 should be limited to a specific duration. As noted above, the BLM issues temporary closure and restriction orders to address a wide variety of circumstances. While some of those circumstances involve specific durations that are known in advance (e.g., race closures), others do not (e.g., wildfire recovery). Attempting to define the term “temporary” or limit the duration of orders issued under 43 CFR 8364.1 would hinder the BLM’s ability to perform its multiple-use mission and protect persons, property, public lands, and resources.

Comment: One commenter requested that closures longer than 90 days be published in the **Federal Register**.

Response: Requiring that all temporary closure and restriction orders that last longer than 90 days be published in the **Federal Register** would neither enhance the BLM’s ability to respond to emergencies in a timely fashion nor communicate closures and restrictions to the public in the most efficient manner. Temporary closures and restrictions that last longer than 90 days may need to be put into effect immediately, which could be hampered by a **Federal Register** publication requirement. Moreover, more direct forms of communication may prove more effective at notifying the public of such closures and restrictions.

Comment: Many commenters stated that temporary closure end dates should be defined and expressed concern that the proposed rule would permit closures to last until land use plans are updated.

Response: The final rule requires the BLM to specify the date and time that a temporary closure or restriction order will terminate. However, if the situation that a temporary closure or restriction order addresses continues beyond the order’s end date, the BLM may issue a new order to extend the closure or restriction.

Comment: Two commenters recommended that closures be limited to the smallest size possible.

Response: The final rule requires that each closure be accompanied by a rationale for the closure or restriction, which can include a rationale for the geographic parameters of the closure. In general, the BLM strives to close or restrict the use of the smallest area of public lands possible.

D. Exemptions

Comment: One commenter expressed concern that the proposed rule would permit the BLM to restrict third parties from monitoring events such as offroad races.

Response: Under the final rule, each temporary closure or restriction order will specify the uses that are restricted, as well as any exemptions from the order. In the example given, the BLM would have discretion to exempt third-party race monitors from a restricted area. Notably, this rule does not change the requirement for the BLM to specify who is exempt from a temporary closure or restriction order.

Comment: Two commenters requested that the proposed rule provide that temporary closure and restriction orders not apply to valid existing rights or travel routes under litigation.

Response: Actions the BLM takes pursuant to FLPMA, including issuing temporary closure and restriction orders under 43 CFR 8364.1, are subject to valid existing rights. Additionally, under the final rule, the BLM will determine which individuals are exempt from temporary closure and restriction orders on a case-by-case basis. Where necessary and appropriate, the BLM will provide that certain individuals or groups are exempt from the limitations posed by a temporary closure or restriction order.

Comment: Many commenters discussed the provision permitting closures and restrictions for the purpose of ensuring privacy for certain Tribal uses. In general, commenters asked the BLM to clarify the meaning of that provision and explain why the proposed rule specifically mentions Tribal uses. Some commenters suggested that the proposed rule should not refer to Tribal activities specifically, but instead should use general language applying to all public land users.

Response: While FLPMA directs the BLM to manage public lands for a wide variety of uses and users, not all parcels of public lands must be made available to all uses (or users) at any one time. In certain places, and at certain times, the BLM may decide to facilitate specific uses, such as certain Tribal uses, over

others. The provision in the final rule authorizing the BLM to issue temporary closure and restriction orders to ensure privacy for certain Tribal uses stems from the United States' unique trust responsibility to Tribal Nations in the stewardship of public lands. Both Congress and the Executive Branch have declared it to be the policy of the United States to accommodate Tribal access to the public lands in certain circumstances. For example, the American Indian Religious Freedom Act provides that "it shall be the policy of the United States to protect and preserve for American Indians their inherent right of freedom to believe, express, and exercise the traditional religions of the American Indian, Eskimo, Aleut, and Native Hawaiians, including but not limited to *access to sites*, use and possession of sacred objects, and the freedom to worship through ceremonials and traditional rites." (42 U.S.C. 1996, emphasis added) Similarly, Executive Order (E.O.) 13007 directs Federal agencies to accommodate access to and ceremonial use of Indian sacred sites on Federal lands by Indian religious practitioners. It also directs Federal agencies, where appropriate, to maintain the confidentiality of such sites. Additionally, Secretarial Order 3403 (Joint Secretarial Order on Fulfilling the Trust Responsibility to Indian Tribes in the Stewardship of Federal Lands and Waters) directs Bureaus and Offices to "manage Federal lands and waters in a manner that seeks to protect the treaty, religious, subsistence, and cultural interests of federally recognized Indian Tribes."

While the provisions of 43 CFR 8364.1 authorizing the BLM to issue temporary closure and restriction orders to protect persons and avoid user conflicts would seemingly also cover closure to ensure privacy for Tribal uses, the BLM thinks it is worth clarifying the agency's authority to temporarily close or restrict the use of public lands to ensure privacy for Tribal activities for traditional or cultural use consistent with the direction in the above-discussed authorities. Expressly providing that the BLM may temporarily close or restrict the use of public lands to ensure privacy for certain Tribal activities will also allow the BLM to implement aspects of the Best Practices Guide for Federal Agencies Regarding Tribal and Native Hawaiian Sacred Sites that was developed to operationalize the direction in E.O. 13007, as well as facilitate commitments the BLM may make to specific Tribes as part of co-stewardship agreements governing

certain portions of the public lands. Moreover, because many Tribal traditional and cultural uses take place in the vicinity of cultural resources whose nature and location the BLM is required to keep confidential, this provision will help the BLM comply with related statutory obligations.

Comment: A few commenters recommended that emergency services and law enforcement personnel be exempt from temporary closures and restrictions, and one commenter asked that the BLM clarify the process for exempting some groups such as local entities with jurisdictional authority (State wildlife agencies, for example) from temporary closure and restriction orders.

Response: The existing regulation requires the BLM to identify any persons or groups who are exempt from a temporary closure or restriction order. Generally, the BLM exempts Federal, State, and local officers and employees, as well as members of organized rescue or firefighting forces, in the performance of their official duties from a temporary closure or restriction order. The agency may specify that additional persons or groups are exempt on a case-by-case basis.

Comment: One commenter expressed concern that there were insufficient "checks and balances" and that the proposed rule could permit the BLM to improperly exempt "preferred individuals" from closure or restriction orders.

Response: Prior to this rulemaking, 43 CFR 8364.1 required the BLM to identify the persons who are exempt from a temporary closure or restriction order. The final rule does not change that requirement. While the BLM's multiple-use mission inherently requires the agency to balance competing uses and users of the public lands, the agency does not intend to implement the final rule in a manner that gives preference to select members of the public. Additionally, all temporary closure and restriction orders must comply with NEPA and other applicable statutes. They are also subject to administrative appeal in accordance with 43 CFR part 4. Accordingly, the public has ample opportunity to express concerns with a temporary closure or restriction order, including concerns with individuals or groups exempted from its limitations.

E. Consistency With Other Legal Requirements

Comment: Two commenters asserted that the proposed rule is not consistent with the NPS's closure authority at 36 CFR 1.5. These commenters pointed out

that, except in the case of emergencies, **Federal Register** publication is required where an NPS closure or restriction is of a nature, magnitude, or duration that will result in a significant alteration in the public use pattern of the park area, adversely affect the park's natural, aesthetic, scenic or cultural values, requires a long-term or significant modification in the resource management objectives of the unit, or is of a highly controversial nature.

The commenters suggested that the BLM adopt a similar framework for this rulemaking.

Response: The final rule is not identical to 36 CFR 1.5. This rulemaking will nevertheless result in the BLM's temporary closure and restriction authority aligning more closely with the NPS regulation. For example, neither rule requires **Federal Register** publication of temporary closure and restriction orders that address emergency situations. Additionally, the final rule pertains only to temporary closure and restriction orders and not to land use planning, which is governed by 43 CFR part 1600, including requirements to publish certain land use planning-related notices in the **Federal Register**. The final rule also aligns with the NPS public notification processes set out in 36 CFR 1.7, which directs the NPS to use one or more different communication methods, including electronic media, when invoking certain authorities to, for example, "restrict or control a public use or activity" or "designate all or a portion of a park area as open or closed." Finally, while not addressed by the commenters, the final rule is similar to the USFS's and FWS's closure and restriction authority at 36 CFR 261.50 and 50 CFR 25.31, respectively, which do not require **Federal Register** publication for any closure or restriction orders.

Comment: One commenter pointed out that the Alaska National Interest Lands Conservation Act (ANILCA), Alaska Native Claims Settlement Act (ANCSA), and other statutes impose Alaska-specific legal obligations on the BLM. The commenter requested that the BLM make clear that the final rule does not apply to Alaska and instead prepare an Alaska-specific regulation. Alternatively, the commenter asked the BLM to acknowledge in the final rule that Alaska-specific statutes, such as ANILCA, apply where temporary closure or restriction orders impact access for traditional activities on conservation system units, access for subsistence activities on public land, or temporary access in the National Petroleum Reserve-Alaska.

Response: The BLM believes it is unnecessary to exempt Alaska from operation of the final rule or prepare an Alaska-specific temporary closure and restriction regulation. The final rule does not change or impact the requirements of ANILCA, ANCSA, or other statutes. It also does not revise, amend, or obviate any regulatory requirements not included in 43 CFR 8364.1, such as those implementing section 1110(a) of ANILCA at 43 CFR 36.11. The BLM has long recognized that those Alaska-specific legal requirements can work in tandem with the temporary closure and restriction authority provided in 43 CFR 8364.1 (51 FR 31619 (September 4, 1986)). Accordingly, when implementing a temporary closure or restriction in Alaska, it may be necessary for the BLM to comply with both the final rule and certain Alaska-specific statutory and regulatory requirements. Ultimately, the legal requirements that apply to a temporary closure or restriction order impacting BLM-managed public lands in Alaska will depend on the facts and circumstances of the particular temporary closure or restriction.

Comment: Several commenters were concerned that the proposed rule may conflict with the BLM's multiple-use mandate.

Response: The final rule is consistent with FLPMA's mandate to manage public lands "under the principles of multiple use and sustained yield." 43 U.S.C. 1732(a). When enacting FLPMA and establishing the BLM's multiple-use mandate, Congress declared it the policy of the United States that public lands "be managed in a manner that will protect the quality of scientific, scenic, historical, ecological, environmental, air and atmospheric, water resource, and archeological values," and "where appropriate, will preserve and protect certain public lands in their natural condition." 43 U.S.C. 1701(a)(8). This policy is effectuated in the definition of "multiple use," which means, in part, "the use of some land for less than all of the resources" and "making the most judicious use of the land for some or all . . . resources." 43 U.S.C. 1702(c). Courts have affirmed that complying with FLPMA's multiple-use mandate requires the BLM to "make judgments about incompatible uses" and does not "preclude the agency from taking a cautious approach to assure preservation of natural and cultural resources." (*Nat'l Mining Ass'n v. Zinke*, 877 F.3d 845, 872 (9th Cir. 2017) (citing *New Mexico ex rel. Richardson v. Bureau of Land Mgmt.*, 565 F.3d 683, 710 (10th Cir. 2009)). Indeed, when performing the "enormously

complicated task of striking a balance among the many competing uses to which land can be put," (*Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 58 (2004)), the BLM may decide that "a particular parcel [of public land] need not be put to all feasible uses or to any particular use." (*Nat'l Mining Ass'n*, 877 F.3d at 872). Moreover, in exercising its multiple-use mandate, FLPMA requires the BLM to "take any action necessary to prevent unnecessary or undue degradation of the [public] lands," 43 U.S.C. 1732(b), and courts have explained that closing or restricting the use of public land under 43 CFR 8364.1 to prevent such degradation "is a lawful discharge of the BLM's duty" under FLPMA. (*Utah Shared Access Alliance v. Carpenter*, 463 F.3d 1125, 1136 (10th Cir. 2006)). Accordingly, the final rule, which will help the BLM address competing uses of the public lands and enhance the agency's ability to protect persons, public lands, and resources, particularly in response to emergencies and unforeseen events, is consistent with both the text of FLPMA and courts' understanding of the BLM's multiple-use mission.

Comment: One commenter suggested that the proposed rule discuss its implications on the Secretary's authority to hire and compensate personnel in certain emergency situations.

Response: The issue raised is outside the scope of this rulemaking effort and is addressed separately by other statutes and regulations.

F. Need for the Proposed Rule

Comment: Multiple commenters asserted that the BLM already has sufficient authorities to close or restrict the use of public lands in response to emergencies and unforeseen events and, therefore, this rulemaking is unnecessary.

Response: The BLM disagrees. Protecting persons, public lands, and resources in an adequate fashion often requires a quick response and, as discussed above, the requirement to publish orders in the **Federal Register** and the general inability of the BLM to issue such orders with immediate full force and effect frequently hinders the BLM's ability to temporarily close or restrict the public lands to address emergencies and other unforeseen events in a timely manner. The USFS, FWS, and NPS have the requisite authority to close or restrict the use of Federal lands under their jurisdiction with little to no delay. Under the prior regulations, the BLM lacked that authority. This final rule will address that shortcoming and help align the

BLM's procedures with those of other land management agencies.

Comment: One commenter requested that the BLM identify the costs of implementing the final rule.

Response: The BLM expects the final rule to decrease costs. Preparing **Federal Register** notices associated with temporary closure and restriction orders takes considerable time and effort, and publishing notices requires payment to the Office of the Federal Register. Instead, the agency will be able to focus its time, money, and effort on using more direct and expedient methods of communication to inform the public about how the agency is managing public lands.

III. Discussion of the Final Rule

A. Overview

The existing regulation at 43 CFR 8364.1 sets out the BLM's authority and procedures for issuing temporary closure and restriction orders. Among other things, the existing regulation requires the BLM to publish temporary closure and restriction orders in the **Federal Register** and does not authorize the agency to make those orders effective immediately. Those restrictions, as well as other aspects of the existing rule, frequently impede the BLM's response to emergencies and other unforeseen events. Delays caused by the existing regulation have, in some cases, hindered the BLM's ability to reduce risks to public health, safety, property, and resources during such situations.

The final rule revises 43 CFR 8364.1 to improve the BLM's ability to respond quickly to changing conditions on public lands and facilitate more modern and direct methods of communicating its actions to the public by eliminating the requirement to publish temporary closure and restriction orders issued under this rule in the **Federal Register**. In place of that notice requirement, the final rule directs the BLM to inform the public about temporary closure and restriction orders by notifying local media outlets and posting information about the closure or restriction on at least one BLM-controlled, publicly available online communication system. By no longer requiring the BLM to publish temporary closure and restriction orders in the **Federal Register**, the final rule better positions the agency to serve the public and manage the public lands. The final rule continues to require the BLM to post temporary closure and restriction orders at appropriate BLM offices and at or near the closed or restricted area.

The final rule authorizes the BLM to make temporary closure and restriction orders effective immediately, which will improve the BLM's capacity to respond quickly to emergencies and other unforeseen events affecting public lands. This change will help the BLM more effectively fulfill its multiple-use mission without preventing those who are adversely affected from appealing the issuance of an order to the IBLA.

The final rule clarifies the broad range of situations in which the BLM may issue temporary closure and restriction orders. Under both the prior regulation and this final rule, the BLM may issue temporary closure and restriction orders to protect persons, property, and public lands and resources. The final rule also reinforces that the BLM may issue temporary closure and restriction orders to avoid conflicts among public land users and to ensure the privacy of Tribal activities for traditional or cultural use.

The final rule requires all temporary closure and restriction orders issued under 43 CFR 8364.1 to state the date and time that a closure or restriction will become effective and the date and time it will terminate. The final rule also clarifies that the BLM may exempt groups, such as law enforcement, emergency response, and Tribes, from temporary closures and restrictions as appropriate. By comparison, the prior regulation only expressly required the BLM to identify persons who are exempt from temporary closure and restriction orders.

Finally, the final rule harmonizes the penalty provision in 43 CFR 8364.1 with current statutory authorities and makes several other changes that improve the final rule's organization and readability.

The final rule does not itself close or restrict the use of any specific public land, nor will it require the BLM to issue any new or additional temporary closures or restrictions of public lands. Instead, the final rule makes administrative changes intended to modernize and streamline the procedures governing how the BLM issues temporary closure and restriction orders and, thereby, provides the public with better clarity about the scope of these orders and when they are effective. Under the final rule, the BLM will continue to consider other management strategies alongside or instead of temporary closures and restrictions including, but not limited to, increased law enforcement, cooperative efforts with local governments, engineering, education, and outreach.

The final rule does not change any public participation requirements or opportunities. While the prior

regulation required the BLM to publish temporary closure and restriction orders in the **Federal Register**, 43 CFR 8364.1 has never required the agency to solicit public feedback before temporarily closing or restricting the use of public lands. Under the final rule, public participation opportunities concerning temporary closure and restriction orders will continue to be governed by other laws including, but not limited to, NEPA, the Dingell Act, and the regulations implementing ANILCA. The final rule does not change or limit those opportunities or modify those authorities. For example, even though the final rule eliminates the **Federal Register** publication requirement in 43 CFR 8364.1, the BLM may still need to publish a **Federal Register** notice and provide the public with an opportunity to comment in accordance with section 4103 of the Dingell Act (16 U.S.C. 7913) if proposing to close public lands to hunting, fishing, or recreational shooting. The final rule does not, however, impose a requirement for the BLM to seek public feedback when not already required to do so by other legal authorities.

Relatedly, the final rule does not diminish or eliminate the public's opportunity to challenge temporary closure or restriction orders, which will remain subject to appeal to the IBLA in accordance with 43 CFR part 4 or to judicial review in Federal court. The final rule, however, enhances the BLM's ability to protect persons, property, public lands, or resources in a timely fashion by making temporary closure and restriction orders effective immediately, pending a decision on appeal or judicial review or the issuance of an administrative or judicial stay.

Each section of the final rule is discussed in further detail below.

B. Detailed Discussion

Paragraph (a)

The final rule reorganizes paragraph (a) for readability, adds the word "temporarily" to clarify the nature of the closure and restriction orders that the BLM issues under 43 CFR 8364.1, and enumerates the situations in which the BLM may temporarily close or restrict the use of public lands; namely, to protect persons, property, public lands, or resources, to avoid conflict among public land users, and to ensure the privacy of Tribal activities for traditional or cultural use.

The addition of the word "temporarily" is intended to differentiate temporary closures and restrictions issued under 43 CFR 8364.1 from closures and restrictions that are

established through the land use planning process. Closures and restrictions issued through the land use planning process are intended to be part of the BLM's long-term management strategy for an area and remain in place until the BLM either revises or amends the applicable land use plan in accordance with 43 CFR part 1600. Temporary closure and restriction orders issued under the final rule, which are generally intended to address emergencies or unforeseen events or facilitate time-limited uses that require specific restrictions, serve a different and generally more limited purpose. For example, the BLM typically issues temporary closure and restriction orders under 43 CFR 8364.1 to facilitate time-limited uses that require specific restrictions to avoid user conflicts or ensure public safety, privacy, or resource protection; to address emergencies that require timely responses; or to respond to events and circumstances that the BLM did not foresee when it was previously engaged in the land use planning process. Under the final rule, such orders are considered "temporary" in that they are implemented outside the land use planning process that typically guides how the BLM makes more long-term decisions. While the final rule requires the BLM to specify the time and date the closure or restriction imposed by such orders begins and ends, it does not impose any specific limitation on the duration that a temporary closure or restriction order may remain in place, nor does it prevent the BLM from issuing a new order that extends the time a temporary closure or restriction order is in effect, if necessary. Because not all situations requiring temporary closure or restriction orders will end within a preconceived timeframe, it may be necessary to issue a revised closure or restriction order to ensure the underlying situation has abated or the BLM has had an opportunity to address the situation in a longer-term fashion through the land use planning process.

The final rule adds the phrase "including roads, trails, and waterways" for internal consistency with paragraph (b) and to clarify that public roads, trails, and waterways under the BLM's jurisdiction are components of public lands. This change is intended to be clarifying only and is not intended to expand the scope of the BLM's authority or alter its obligations under this regulation.

The final rule revises paragraph (a) to provide that the BLM may issue temporary closure and restriction orders to avoid user conflicts on public lands. Although this authority was implicitly

contained in the existing provision authorizing the agency to issue temporary closure and restriction orders to protect persons, the final rule clarifies that such authority extends to issuing temporary closure and restriction orders to avoid user conflicts. As part of its multiple-use mission, the BLM is required to balance competing uses of the public lands. That task inherently requires the BLM to make judgments about incompatible uses and, at times, permit certain uses while prohibiting other, potentially conflicting, uses. For example, to avoid user conflicts during a permitted off-road race, the BLM might need to prohibit non-race uses of the course. The final rule clarifies that the BLM has authority to issue temporary closure and restriction orders to avoid such conflicts, thereby allowing the BLM to manage temporary user conflicts effectively and efficiently.

The final rule revises paragraph (a) to provide that the BLM may issue temporary closure and restriction orders to ensure the privacy of Tribal activities for traditional or cultural use. Similar to the provision concerning the avoidance of user conflicts, the authority to temporarily close or restrict the use of public lands to ensure the privacy of Tribal activities for traditional or cultural use was implicitly contained in the existing provision authorizing the agency to issue temporary closure and restriction orders to protect persons. However, the BLM believes that authority should be made explicit given the Federal Government's unique trust responsibility to Tribal Nations in the stewardship of public lands and the direction in Secretarial Order 3403, which directs Department of the Interior bureaus and offices to "manage Federal lands and waters in a manner that seeks to protect the treaty, religious, subsistence, and cultural interests of federally recognized Indian Tribes." Many Tribal Nations continue to use BLM-managed lands for traditional and cultural purposes, and in some cases those uses can be disrupted by simultaneous use by other members of the public. The final rule will help the BLM facilitate Tribal activities for traditional or cultural use on public lands without such disruptions.

The proposed rule would have authorized the BLM to issue temporary closures and restrictions to "provide for implementation of management responsibilities." The intent behind that proposal was to more closely align the BLM's temporary closure and restriction authority with the NPS's analogous regulation, which permits temporary closures and public use limits "based upon a determination that such action is

necessary for . . . implementation of management responsibilities." 36 CFR 1.5(a). Moreover, the BLM intended inclusion of the phrase to more explicitly allow the BLM to temporarily close or restrict the use of public lands to facilitate construction, demolition, resource monitoring, invasive species control projects, and other typical management responsibilities in which the agency regularly engages. However, several commenters expressed concerns that the phrase "implementation of management responsibilities" was vague and essentially removed all limits on the BLM's ability to close or restrict the use of public lands. The BLM agrees that the phrase, while commensurate with the BLM's authority to manage public lands under FLPMA, is potentially open to misinterpretation. Accordingly, the BLM has not included "provide for implementation of management responsibilities" as a reason for issuing a temporary closure or restriction order in the final rule. The deletion of the phrase from the final rule does not affect the BLM's ability to perform typical management responsibilities. Activities such as construction, demolition, resource monitoring, and invasive species control projects are already typically accompanied by a temporary closure or restriction order where necessary to protect persons, property, public lands, or resources. As a result, the BLM would still be able to issue such closures and restrictions under the authority that is included in the final rule.

Paragraph (b)

Paragraph (b) of the final rule outlines the contents of temporary closure and restriction orders.

The final rule revises paragraph (b)(1) to clarify that public roads, trails, or waterways are aspects of the public lands and, therefore, are subject to temporary closures or restrictions where appropriate. The prior text could arguably be interpreted to suggest that roads, trails, and waterways under the BLM's jurisdiction are not public lands, which is incorrect.

The final rule revises paragraph (b)(3) to improve readability and clarify that each temporary closure and restriction order must state the date and time when it will become effective and the date and time when it will terminate. Including both of those dates and times will help clearly communicate to the public how long the BLM expects a temporary closure or restriction order to last. As noted above, however, temporary closure and restriction orders are occasionally issued to address situations

that do not end or abate on a certain date. As a result, the final rule should not be understood to limit the BLM's authority to renew, extend, or modify temporary closures or restrictions. Where necessary, the BLM may renew, extend, or modify a temporary closure or restriction order by issuing a new order that contains different parameters following the same procedures that the agency uses to issue an order in the first instance.

The final rule revises paragraph (b)(4) to clarify that the BLM can exempt groups or persons from a closure or restriction as circumstances warrant. For example, the BLM generally exempts Federal, State, and local officers and employees, as well as members of organized rescue or firefighting forces, from temporary closures and restrictions when necessary for them to perform their official duties. The BLM may also exempt Tribal members who may need to access an otherwise closed area for traditional or cultural uses. The final rule clarifies the BLM's authority to exempt such groups.

The final rule moves former paragraphs (b)(5) and (6) to paragraph (c) to consolidate the notification requirements in one paragraph. Further revisions to those paragraphs are discussed below.

The final rule rennumbers and revises former paragraph (b)(7) to improve readability and for consistency with other provisions of the regulation. That revision is not intended to affect the BLM's duties under this regulation.

Paragraph (c)

The final rule revises paragraph (c) by removing the requirement to publish temporary closure and restriction orders in the **Federal Register** and, instead, requires the BLM to alert the public by notifying local media outlets and posting information on at least one BLM-controlled publicly available online communication system. The final rule retains the requirements to post temporary closure and restriction orders at relevant BLM offices and at or near the closed or restricted area. This revision will allow the BLM to notify the public about temporary closure and restriction orders in a timelier fashion, which will enhance the agency's ability to effectively respond to emergencies and other unforeseen events. This change will provide the BLM with greater flexibility to ensure that the level of notice provided to the public is commensurate with the scale, location, and potential expediency of the closure or restriction.

Although the **Federal Register** may have been an effective way to notify the public of access and use limitations when 43 CFR 8364.1 was promulgated in 1983, that is less true today, when tools to communicate with stakeholders and the public have become more numerous and direct. Government agencies have been increasingly using online systems, and new online systems are already evolving that may soon supersede or supplant those used today as the most effective means for informing public land users about government actions. The final rule is intended to describe the communication systems in common use today, while at the same time using sufficiently flexible language to account for new systems and rapidly emerging best practices in communications and public affairs. By intentionally incorporating flexibility into the wording of the final rule, the BLM hopes to avoid the need to update the rule again as communication methods and platforms continue to evolve.

Under the final rule, the BLM may post notices on multiple BLM web pages, including national, state, district, and field office web pages. In other situations, more limited online notification may be appropriate. The final rule permits the BLM to use the best methods available to reach the public depending on the circumstances of the closure or restriction, which can vary widely. Members of the public will still have reliable ways to learn about temporary closures and restrictions, including through posts at the relevant BLM offices and closed or restricted areas, the BLM's online communication systems, such as web pages, and local media.

The final rule's notification procedures will apply to all orders issued under 43 CFR 8364.1, including those unrelated to emergencies. Many commenters expressed that the agency should retain the **Federal Register** publication requirement for non-emergency temporary closure and restriction orders because they do not need to be issued urgently and, therefore, are not hindered by the time it takes to publish a notice in the **Federal Register**. While the BLM agrees that non-emergency situations may not always pose the same time constraints as emergency situations, it does not believe that imposing different notification procedures is necessary or prudent. Some situations may not clearly constitute an emergency but may nevertheless warrant a quick response. For example, if a dignitary unexpectedly visits public lands, it may be necessary for security reasons to issue a temporary

closure or restriction order quickly. Similarly, maintenance needs at campgrounds and other facilities may arise that cannot be foreseen in advance but nevertheless warrant timely action by the BLM. In such situations, BLM managers should not delay taking action to protect persons, property, public land, or resources because they are concerned that the instant situation may not fall within a specific definition of "emergency" and, therefore, a related temporary closure or restriction order must be published in the **Federal Register**.

The final rule is designed to avoid such situations by not requiring **Federal Register** publication in any circumstance and instead providing managers the discretion to publish certain temporary closure and restrictions in the **Federal Register** as circumstances warrant, such as when the closure or restriction affects an area with limited local media outlets and the BLM believes that **Federal Register** publication is necessary to adequately communicate the order's attendant limitations to the public. Additionally, in some circumstances, other authorities aside from this rule may require the BLM to publish temporary closure and restriction orders in the **Federal Register**. For example, section 4103 of the Dingell Act may require the BLM to publish a **Federal Register** notice and provide the public with an opportunity to comment if proposing to close public lands to hunting, fishing, or recreational shooting. This final rule does not affect how the BLM complies with the Dingell Act or other authorities requiring **Federal Register** notices.

Paragraph (c) of the final rule also incorporates the posting requirements that were previously included in paragraph (b) of 43 CFR 8364.1. The internal reorganization is intended to consolidate the final rule's notification requirements in a single paragraph, which will make it easier for the public to understand how to learn about potential temporary closures and restrictions on public lands.

Elimination of the requirement to publish temporary closure and restriction orders in the **Federal Register** will more closely align the BLM's regulatory authority to that of other land management agencies. The USFS's closure authority at 36 CFR 261.50 does not require **Federal Register** publication. Instead, it requires closure and restriction orders to be placed in the offices of the responsible Forest Supervisor and District Ranger and displayed in such locations and manner as to reasonably bring the prohibitions to the attention of the public. The NPS

similarly does not need to publish closure and restriction orders in the **Federal Register** in a wide variety of situations, such as in emergencies or for closures or restrictions that will not result in a significant alteration in the public use pattern of a park area and will not adversely affect a park's natural, aesthetic, scenic, or cultural values. And 50 CFR 25.31 provides the FWS with discretion to determine the best way to notify the public where access and use has been temporarily curtailed. Eliminating the **Federal Register** publication requirement in 43 CFR 8364.1 will enhance the BLM's ability to coordinate with other Federal land management agencies (as well as Tribal, State, and local government agencies), especially in situations where the agencies manage adjacent or nearby lands.

Paragraph (d)

The final rule adds a new paragraph (d), which authorizes the BLM to make temporary closure or restriction orders effective immediately. Prior to the final rule becoming effective, temporary closure and restriction orders issued under 43 CFR 8364.1 would typically not take effect during the 30-day period in which the order is appealable to the IBLA. However, emergencies and changing circumstances on public lands often require a quicker response, and the delay in a closure or restriction order taking effect has, in some cases, compromised the BLM's ability to carry out its mission and protect the public. To adequately meet the public's expectation for the BLM to protect health, safety, property, and resources, the agency needs the ability to issue temporary closure or restriction orders that are effective immediately when necessary. Under paragraph (d), temporary closure and restriction orders issued under 43 CFR 8364.1 will be effective upon issuance or a date and time established in the order. This change will enhance the BLM's ability to respond to emergencies and other unforeseen conditions while preserving the public's ability to appeal an order to the IBLA in accordance with 43 CFR part 4.

Like the elimination of the **Federal Register** notice requirement discussed above, allowing the BLM to issue temporary closure and restriction orders with immediate full force and effect will make 43 CFR 8364.1 more consistent with the closure and restriction authorities of the USFS, FWS, and NPS, all of which can issue temporary closure and restriction orders with immediate full force and effect. Aligning its authority with that of other land

management agencies will allow the BLM to be an effective partner and take more concerted action with those agencies.

Paragraph (e)

Former paragraph (d) addressed the penalties for violating temporary closure and restriction orders. The final rule rennumbers that paragraph and updates it to be consistent with current legal authorities. The Sentencing Reform Act of 1984, 18 U.S.C. 3571, which passed the year after 43 CFR 8364.1 was promulgated, authorizes fines that supersede those set out in FLPMA at 43 U.S.C. 1743. Under the final rule, the penalty provision will refer directly to 18 U.S.C. 3571, which will make it less likely that the BLM will need to revise the rule if Congress updates 18 U.S.C. 3571 in the future. The final rule also revises the penalty provision to refer to 43 U.S.C. 1733, which sets out the BLM's enforcement authority under FLPMA. Notably, neither of these revisions effect a substantive change, as 43 CFR 8364.1 has always been subject to these overarching statutory authorities. The change in the final rule is only intended to make the regulation reflect these statutory realities.

IV. Procedural Matters

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

E.O. 12866, as amended by E.O. 14094, provides that the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) will review all significant rules. OIRA has determined that the rule does not meet the criteria for significance under section 3(f) of E.O. 12866, as amended by E.O. 14094.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory ends. The E.O. directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. 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. The BLM has developed this final rule in a manner consistent with these requirements.

The BLM reviewed the requirements of the final rule and determined that it will not adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or Tribal governments or communities. For more detailed information, see the Economic and Threshold analysis prepared for the final rule. This analysis has been posted in the docket for the final rule on the Federal eRulemaking Portal: <https://www.regulations.gov>. In the searchbox, enter "RIN 1004-AE89", click the "Search" button, open the Docket Folder, and look under Supporting Documents.

Federal Actions To Address Environmental Justice in Minority or Low-Income Populations (E.O. 12898)

E.O. 12898 requires that, to the extent practicable and permitted by law, each Federal agency must make achieving environmental justice part of its mission. E.O. 12898 provides that each Federal agency conduct its programs, policies, and activities that substantially affect human health or the environment in a manner that ensures that such programs, policies, and activities do not have the effect of excluding persons (including populations) from participation in, denying persons (including populations) the benefits of, or subjecting persons (including populations) to discrimination under such programs, policies, and activities because of their race, color, or national origin.

This final rule revises the process the BLM uses to issue temporary closure and restriction orders. The final rule is not self-executing, in that it does not, in and of itself, temporarily close or restrict the use of any public lands, and it is not expected to affect any particular population. Therefore, this final rule is not expected to negatively impact any community or cause any disproportionately high or adverse impacts to minority or low-income communities.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that Federal agencies prepare a regulatory flexibility analysis for rules subject to the notice-and-comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 500 *et seq.*), if the rule will have a significant economic impact, whether detrimental or beneficial, on a substantial number of small entities. See 5 U.S.C. 601–612. Congress enacted the RFA to ensure that government regulations do not unnecessarily or

disproportionately burden small entities. Small entities include small businesses, small governmental jurisdictions, and small not-for-profit enterprises. The final rule will not have a significant impact on a substantial number of small entities. This certification is based on information contained in the economic and threshold analysis prepared for this rule. Therefore, neither a final regulatory flexibility analysis nor a small entity compliance guide is required.

Congressional Review Act

Based upon the BLM's economic and threshold analysis, this final rule does not meet the criteria under 5 U.S.C. 804(2), the Congressional Review Act. This rule will not:

- (a) Have an annual effect on the economy of \$100 million or more;
- (b) Cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and
- (c) 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

Under the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1531 *et seq.*), agencies must prepare a written statement about benefits and costs prior to issuing a proposed or final rule that may result in aggregate expenditure by State, local, and Tribal governments, or by the private sector, of \$100 million or more in any one year.

This final rule is not subject to the requirements under the UMRA. The final rule does not contain a Federal mandate that may result in expenditures of \$100 million or more for State, local, and Tribal governments, in the aggregate, or to the private sector in any one year. The final rule will not significantly or uniquely affect small governments. A statement containing the information required by the UMRA is not required.

Takings (E.O. 12630)

This final rule will not affect a taking of private property or otherwise have taking implications under E.O. 12630. The final rule will only affect the management of public lands. Accordingly, a takings implication assessment is not required.

Federalism (E.O. 13132)

Under the criteria in section 1 of E.O. 13132, this final rule does not have

sufficient federalism implications to warrant the preparation of a federalism summary impact statement. The final rule will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. The BLM will coordinate with State and local governments, as appropriate, when deciding whether to temporarily close or restrict the use of public lands under this final rule. A federalism summary impact statement is not required.

Civil Justice Reform (E.O. 12988)

This final rule complies with the requirements of E.O. 12988. Specifically, this final rule:

- (a) Meets the criteria of section 3(a) requiring that all regulations be reviewed to eliminate errors and ambiguity and be written to minimize litigation; and
- (b) Meets the criteria of section 3(b)(2) requiring that all regulations be written in clear language and contain clear legal standards.

Consultation With Indian Tribes (E.O. 13175 and Departmental Policy)

The Department of the Interior strives to strengthen its government-to-government relationship with Indian Tribes through a commitment to consultation with Indian Tribes and recognition of their right to self-governance and Tribal sovereignty.

In accordance with E.O. 13175, the BLM has evaluated this final rule and determined that it will not have substantial direct effects on federally recognized Indian Tribes. Nevertheless, the BLM consulted on a government-to-government basis with Tribal governments that wished to discuss the rule.

On March 22, 2023, the BLM sent a letter to federally-recognized Indian Tribes and Alaska Native Corporations notifying them about the BLM's intent to pursue this proposed rulemaking. In that letter, the BLM invited the Tribes and Corporations to engage in government-to-government consultation. Two Tribes requested additional information and engaged in consultation about aspects of the proposed rulemaking: one Tribe was concerned about the proposed rule and how it might affect management of lands for which the Tribe manages all surface rights; another Tribe shared that the proposed rule could play an important role in protecting Tribal cultural resources and facilitating cultural practices. In both cases, the consultation concluded with no

objections, no requests to modify the proposed rule, and no requests for follow-up consultation.

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

This final rule does not contain information collection requirements, and a submission to the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required.

National Environmental Policy Act

The BLM has determined that the final rule is not a major Federal action significantly affecting the quality of the human environment. A detailed statement under NEPA is not required because the final rule is categorically excluded from further analysis or documentation in accordance with 43 CFR 46.210(i). That categorical exclusion covers policies, directives, regulations, and guidelines that are of an administrative, financial, legal, technical, or procedural nature or whose environmental effects are too broad, speculative, or conjectural to lend themselves to meaningful analysis and will later be subject to the NEPA process, either collectively or case-by-case. The BLM has documented the applicability of the categorical exclusion concurrently with development of the final rule.

The final rule is procedural and administrative in nature and, therefore, satisfies the first prong of § 46.210(i). The final rule will not result in access being prohibited or use being restricted on any specific public lands. The final rule also will not limit or reduce any current public participation opportunities. The final rule clarifies the situations in which the agency may issue temporary closure and restriction orders, streamlines the administrative process through which the BLM issues and publicizes temporary closure and restriction orders, and updates the penalty provision in § 8364.1 to align with current statutory authority. When the BLM considers using the final rule to issue a temporary closure or restriction order, the agency will need to comply with NEPA and other applicable laws, including those requiring public participation.

The final rule also satisfies the second prong of 43 CFR 46.210(i). As noted above, the final rule does not prohibit access or restrict use of any specific public lands, and the potential environmental effects of future orders issued under the final rule that do prohibit access or restrict the use of public land are too speculative and conjectural to lend themselves to meaningful analysis at this time.

However, the effects of such orders will be individually subject to NEPA prior to being authorized.

The BLM has determined that the final rule does not involve any of the extraordinary circumstances listed in 43 CFR 46.215 that require further analysis under NEPA.

Effects on the Energy Supply (E.O. 13211)

Federal agencies must prepare and submit to OMB a Statement of Energy Effects for any proposed significant energy action. A "significant energy action" is defined as any action by an agency that: (1) Is a significant regulatory action under E.O. 12866, or any successor order; (2) Is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) Is designated by the Administrator of OIRA as a significant energy action. The final rule is not a significant action within the meaning of E.O. 12866 or any successor order. The final rule does not affect energy supply or distribution. Accordingly, a statement of energy effects is not required.

Authors

The principal authors of this final rule are: David Jeppesen, Cory Roegner, Kevin Oliver, and Greg Wolfgang, Recreation and Visitor Services; Nicole Hanna, Tribal Relations; Russell Scofield and Sandra McGinnis, National Experienced Workforce Solutions; Brittney Rodrigues, Regulatory Affairs; Rebecca Moore and Jeff Childers, Decision Support, Planning and NEPA; Heather Feeney, Public Affairs; Stephanie Rice and Pat Johnston, Wildlife, Aquatics and Environmental Protection; Stacy Silvester and Carmen Drieling, Forest, Rangeland and Vegetation Resources; Ernesto Felix, Law Enforcement and Security; assisted by the Office of the Solicitor.

Signing Authority

This action by the Principal Deputy Assistant Secretary is taken pursuant to an existing delegation of authority.

Steven H. Feldgus,

Principal Deputy Assistant Secretary, Land and Minerals Management.

List of Subjects in 43 CFR Part 8360

Penalties, Public lands, Recreation and recreation areas.

For the reasons set out in the preamble, the Bureau of Land Management amends 43 CFR part 8360 as follows:

PART 8360—VISITOR SERVICES

■ 1. The authority citation for part 8360 continues to read as follows:

Authority: 16 U.S.C. 470aaa, *et seq.*; 670, *et seq.*; 877, *et seq.*; 1241, *et seq.*; and 1281c; and 43 U.S.C. 315a and 1701 *et seq.*

■ 2. Revise § 8364.1 to read as follows:

§ 8364.1 Temporary closure and restriction orders.

(a) The authorized officer may issue an order to temporarily close or restrict the use of designated public lands, including roads, trails, and waterways, to protect persons, property, public lands, or resources; avoid conflict among public land users; or ensure the privacy of Tribal activities for traditional or cultural use.

(b) Each order shall:

(1) Identify the public lands, including roads, trails, or waterways, that are closed to entry or restricted as to use;

(2) Specify the uses that are restricted;

(3) Specify the date and period of time that the closure or restriction order will become effective and the date and time that the order will terminate;

(4) Identify any persons or groups who are exempt from the closure or restriction; and

(5) Identify the reasons for the closure or restriction.

(c) When issuing closure or restriction orders pursuant to this section, the authorized officer shall provide public notice by:

(1) Posting the order in a Bureau of Land Management (BLM) Office having jurisdiction over the public lands, including roads, trails, or waterways, to which the order applies;

(2) Posting the order at places near or within the area to which the closure or restriction applies, in such manner and location as is reasonable to bring prohibitions to the attention of users;

(3) Notifying local media outlets; and

(4) Posting information on at least one BLM-controlled, publicly available online communication system.

(d) Notwithstanding any contrary provisions in part 4 of this title, the authorized officer will provide that orders issued pursuant to this section will be effective upon issuance or at a date and time established in the order.

If appealed, such orders shall remain in effect pending the decision on appeal unless a stay is granted.

(e) Any person who violates a temporary closure or restriction order may be tried before a United States magistrate and fined in accordance with 18 U.S.C. 3571, imprisoned no more than 12 months under 43 U.S.C. 1733(a) and § 8360.0–7, or both.

[FR Doc. 2024–17065 Filed 8–6–24; 8:45 am]

BILLING CODE 4331–30–P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Part 622**

[Docket No. 140501394–5279–02; RTID 0648–XE157]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Commercial Closure for Blueline Tilefish in the South Atlantic

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS implements an accountability measure for blueline tilefish in the exclusive economic zone (EEZ) of the South Atlantic. NMFS estimates that commercial landings of blueline tilefish will soon reach the commercial annual catch limit (ACL) for the 2024 fishing year. Accordingly, NMFS closes the commercial sector for the harvest of blueline tilefish in the South Atlantic EEZ to protect the blueline tilefish resource from overfishing.

DATES: This temporary rule is effective from August 8, 2024, through December 31, 2024.

FOR FURTHER INFORMATION CONTACT: Mary Vara, NMFS Southeast Regional Office, telephone: 727–824–5305, email: mary.vara@noaa.gov.

SUPPLEMENTARY INFORMATION: The snapper-grouper fishery of the South Atlantic includes blueline tilefish and is managed under the Fishery

Management Plan for the Snapper-Grouper Fishery of the South Atlantic Region (FMP). The South Atlantic Fishery Management Council and NMFS prepared the FMP, and the FMP is implemented by NMFS under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) by regulations at 50 CFR part 622. All weights in this temporary rule are given in round weight.

Regulations at 50 CFR 622.193(z)(1)(i) specify the commercial ACL and accountability measure for blueline tilefish in the South Atlantic. The commercial ACL is 117,148 pounds (lb) or 53,137 kilograms (kg). NMFS is required to close the commercial harvest of blueline tilefish when NMFS projects its landings will reach or have reached the commercial ACL. NMFS estimates that for the 2024 fishing year, commercial landings of blueline tilefish will reach the commercial ACL by August 8, 2024. Accordingly, the commercial sector for South Atlantic blueline tilefish is closed from August 8, 2024, through December 31, 2024.

During the commercial closure, all sale or purchase of blueline tilefish is prohibited. Because the harvest of blueline tilefish by the recreational sector is also closed for the rest of 2024 (89 FR 19290, March 18, 2024), during this commercial closure all harvest and possession of blueline tilefish in or from the South Atlantic EEZ is also prohibited through the end of 2024. The bag and possession limits of zero blueline tilefish during the remainder of 2024 apply in state or Federal waters of the South Atlantic on a vessel for which NMFS has issued a valid commercial or charter vessel/headboat permit for South Atlantic snapper-grouper [50 CFR 622.193(z)(1)(i)].

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR 622.193(z)(1)(i), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment are unnecessary and contrary to the public interest. Such procedures are unnecessary because the regulations associated with the closure of the blueline tilefish commercial sector at 50 CFR 622.193(z)(1)(i) have already been subject to notice and public comment, and all that remains is to notify the

public of the closure. Prior notice and opportunity for public comment are contrary to the public interest because there is a need to immediately implement this action to protect blueline tilefish, because the capacity of the fishing fleet allows for rapid harvest of the commercial ACL. Prior notice and opportunity for public comment would require time and would potentially result in a harvest well in excess of the established commercial ACL.

For the reasons already stated, there is also good cause to waive the 30-day delay in the effectiveness of this action under 5 U.S.C. 553(d)(3).

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

Dated: August 2, 2024.

Lindsay Fullenkamp,

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

[FR Doc. 2024–17439 Filed 8–2–24; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register

Vol. 89, No. 152

Wednesday, August 7, 2024

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

DEPARTMENT OF EDUCATION

[Docket ID ED–2024–OPE–0098]

34 CFR Chapter III

Proposed Waiver and Extension of the Project Period for the Postsecondary Programs for Students With Intellectual Disabilities—National Technical Assistance and Dissemination Center (PPSID–NTAD) Program

AGENCY: Office of Postsecondary Education (OPE), Department of Education.

ACTION: Proposed waiver and extension of the project period.

SUMMARY: The Secretary proposes to waive the requirements in the Education Department General Administrative Regulations that generally prohibit project period extensions involving the obligation of additional Federal funds. The proposed waiver and extension would enable one project under ALN number 84.407C to receive funding for an additional period, not to exceed September 30, 2025.

DATES: We must receive your comments on or before September 6, 2024.

ADDRESSES: Submit your comments through the Federal eRulemaking Portal or via postal mail or commercial delivery. We will not accept comments submitted by fax or by email or those submitted after the comment period. To ensure that we do not receive duplicate copies, please submit your comments only once. In addition, please include the Docket ID at the top of your comments.

- *Federal eRulemaking Portal:* Go to www.regulations.gov to submit your comments electronically. Information on using *Regulations.gov*, including instructions for accessing agency documents, submitting comments, and viewing the docket, is available on the site under “FAQs.”

- *Postal Mail or Commercial Delivery:* The Department strongly encourages commenters to submit their comments

electronically. However, if you mail or deliver your comments, address them to: Postsecondary Programs For Students With Intellectual Disabilities—National Technical Assistance and Dissemination Center Program, ALN number 84.407C, Attention: Shedita Alston, U.S. Department of Education, 400 Maryland Avenue SW, Room 5C–131, Washington, DC 20202.

Privacy Note: The Department’s policy is to make all comments received from members of the public available for public viewing in their entirety on the Federal eRulemaking Portal at www.regulations.gov. Therefore, commenters should be careful to include in their comments only information that they wish to make publicly available.

FOR FURTHER INFORMATION CONTACT: Shedita Alston, U.S. Department of Education, 400 Maryland Avenue SW, Room 5C–131, Washington, DC 20202. Telephone: (202) 453–7090. Email: Shedita.Alston@ed.gov.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Invitation to Comment: We invite you to submit comments regarding this proposed waiver and extension.

We invite you to assist us in complying with the specific requirements of Executive Orders 12866, 13563, and 14094 and their overall requirement of reducing regulatory burden that might result from this proposed waiver and extension. Please let us know of any further ways we could reduce potential costs or increase potential benefits while preserving the effective and efficient administration of the program.

During and after the comment period, you may inspect all public comments about this proposed waiver and extension by accessing *Regulations.gov*. To inspect the public comments in person, please contact the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Assistance to Individuals with Disabilities in Reviewing the Rulemaking Record: On request, we will provide an appropriate accommodation or auxiliary aid to an individual with a disability who needs assistance to review the comments or other

documents in the public rulemaking record for this proposed waiver and extension. If you want to schedule an appointment for this type of aid, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Background

On August 5, 2021, the Department of Education (Department) published in the **Federal Register** (86 FR 42801) a notice inviting applications for projects for fiscal year (FY) 2021 under the PPSID–NTAD program, authorized under the Departments of Labor, Health and Human Services, and Education and Related Agencies Appropriations Act, 2021, H.R. 7614, 116th Congress (2020), and the explanatory statement accompanying H.R. 7614. The PPSID–NTAD program provides for the establishment of a technical assistance center to translate and disseminate research and best practices for all institutions of higher education (IHEs), including those not participating in the Transition and Postsecondary Programs for Students with Intellectual Disabilities (TPSID) program, for improving inclusive postsecondary education for students with intellectual disabilities (SWIDs). This center is designed to ensure that knowledge and products gained through research reaches more IHEs and students and improves postsecondary educational opportunities for SWIDs.

In August 2021, the Department made one 36-month award under the PPSID–NTAD program as follows:

Institution	State
University of Massachusetts at Boston.	MA

The current project period for this grantee ends on September 30, 2024.

Waiver and Extension

We are proposing to extend the project period for the PPSID–NTAD FY 2021 grantee in order to align and coordinate the funding cycle of the PPSID–NTAD program with TPSID and the TPSID–Coordinating Center (TPSID–CC) program grant authorized under title VII, part D, subpart 2 of the Higher Education Act of 1965, as amended (HEA) (20 U.S.C. 1140f *et seq.*), and title VII, part D, subpart 4 of the HEA (20 U.S.C. 1140q), respectively. Aligning the ends of the project periods across grants would allow the Department to better coordinate the TPSID program. While

the technical assistance center and the coordinating center have different audiences for the dissemination of their research, aligning the funding for the grantees who are doing this work will improve the efficiency and cost effectiveness of the technical assistance and dissemination efforts, and will help

ensure that both the TPSID grantees and other institutions that benefit from the research receive aligned supports from the centers.

For this reason, the Secretary proposes to waive the requirements in 34 CFR 75.261(a) and (c)(2), which allow the extension of a project period

only if the extension does not involve the obligation of additional Federal funds. The waiver would allow the Department to issue a one-time FY 2024 continuation award to the current PPSID–NTAD program grantee estimated as follows:

Institution	State	Award
University of Massachusetts at Boston	MA	\$1,543,686

Any activities carried out during the year of this continuation award must be consistent with the scope, goals, and objectives of the grantee’s application as approved in the FY 2021 competition. If we announce the proposed waiver and extension as final, we will base our decisions regarding a continuation award on the extent to which the grantee meets the requirements set forth in 34 CFR 75.253.

Regulatory Flexibility Act Certification

The Secretary certifies that the proposed waiver and extension of the project period would not have a significant economic impact on a substantial number of small entities. The only small entities that would be affected by the proposed waiver and extension of the project period is the current grantee and any other potential applicants.

The Secretary certifies that the proposed waiver and extension would not have a significant economic impact on these entities because the extension of an existing project period would impose minimal compliance costs to

extend the existing project, and the activities required to support the additional year of funding would not impose additional regulatory burdens or require unnecessary Federal supervision.

Paperwork Reduction Act of 1995

The proposed waiver and extension do not contain any information collection requirements.

Intergovernmental Review

This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79.

Accessible Format: On request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document in an accessible format. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is

the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov*. At this site you can view this document, as well as all other Department documents published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access Department documents published in the **Federal Register** by using the article search feature at *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1140f–1140i.

Nasser Paydar,
Assistant Secretary for Postsecondary Education.

[FR Doc. 2024–17560 Filed 8–6–24; 8:45 am]

BILLING CODE 4000–01–P

Notices

Federal Register

Vol. 89, No. 152

Wednesday, August 7, 2024

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2023–0048]

Notice of Availability of an Evaluation of the Classical Swine Fever Disease Status of Costa Rica

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that we are proposing to recognize Costa Rica as being free of classical swine fever. This proposed recognition is based on a risk evaluation we have prepared in connection with this action, which we are making available for review and comment.

DATES: We will consider all comments that we receive on or before September 6, 2024.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Enter APHIS–2023–0048 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2023–0048, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at regulations.gov or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Rebecca Gordon, Senior Staff Officer, Regionalization Evaluation Services, Veterinary Services, APHIS, USDA, 920 Main Campus Drive, Venture II, 3rd Floor, Raleigh, NC 27606; email: AskRegionalization@usda.gov; (919) 855–7741.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 94 (referred to below as the regulations) govern the importation of certain animals and animal products into the United States in order to prevent the introduction of various animal diseases, including classical swine fever (CSF), a dangerous and communicable disease of swine. In part 94, § 94.9 contains requirements governing the importation of pork or pork products from regions where CSF exists. Section 94.10 contains importation requirements for swine from regions where CSF is considered to exist.

In accordance with §§ 94.9(a)(1) and 94.10(a)(1), the Animal and Plant Health Inspection Service (APHIS) maintains a web-based list of regions that the Agency considers free of CSF. Sections 94.9(a)(2) and 94.10(a)(2) state that APHIS will add a region to this list after it conducts an evaluation of the region and finds that CSF is not present.

Finally, under § 94.32, the importation into the United States of swine, pork, and pork products from certain regions that are considered free of CSF in accordance with §§ 94.9 and 94.10 is still subject to mitigations for CSF, because the exporting region either supplements their pork supplies with fresh (chilled or frozen) pork imported from regions considered to be affected by CSF, or supplements their pork supplies with pork from CSF-affected regions that is not processed in accordance with the regulations, or shares a common land border with CSF-affected regions, or imports live swine from CSF-affected regions under conditions less restrictive than would be acceptable for importation into the United States. The section specifies that there is a web-based list of such regions.

In the regulations in 9 CFR part 92, § 92.2 contains requirements for requesting the recognition of the animal health status of a region (as well as for the approval of the export of a particular type of animal or animal product to the United States from a foreign region). If, after review and evaluation of the

information submitted in support of the request, APHIS believes the request can be safely granted, APHIS will make its evaluation available for public comment through a document published in the **Federal Register**. Following the close of the comment period, APHIS will review all comments received and will make a final determination regarding the request that will be detailed in another document published in the **Federal Register**.

In September 2020, the Government of the Republic of Costa Rica requested that APHIS evaluate the CSF disease status of the country. In response to Costa Rica's request, APHIS prepared an evaluation, titled "APHIS Evaluation of the Classical Swine Fever Status of the Republic of Costa Rica" (May 2023). Based on the evaluation, APHIS has determined that CSF is not known to exist in Costa Rica. APHIS has also determined that the surveillance, prevention, and control measures implemented by Costa Rica are sufficient to minimize the likelihood of introducing CSF into the United States via imports of species or products susceptible to this disease. However, because Costa Rica shares a common land border with regions in which CSF exists, we have also determined that requirements of § 94.32 should be operative, if Costa Rica is considered free of CSF. Our determination supports adding Costa Rica to the web-based list of regions that APHIS considers free of CSF.

Therefore, in accordance with the regulations in § 92.2, we are announcing the availability of our evaluation of the CSF status of Costa Rica for public review and comment. We are also announcing the availability of an environmental assessment (EA), which has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on Environmental Quality for implementing the procedural provision of NEPA (40 CFR parts 1500–1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372). The evaluation and EA may be viewed on the Regulations.gov website or in our reading room. (Instructions for accessing Regulations.gov and information on the location and hours of the reading room

are provided under the heading **ADDRESSES** at the beginning of this notice.) The documents are also available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Information submitted in support of Costa Rica's request is available by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

After reviewing any comments we receive, we will announce our decision regarding the disease status of Costa Rica with respect to CSF in a subsequent notice.

Authority: 7 U.S.C. 1633, 7701–7772, 7781–7786, and 8301–8317; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 1st day of August 2024.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2024–17428 Filed 8–6–24; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2023–0066]

Notice of Availability of a Pest Risk Analysis for the Importation of Fresh Cape Gooseberry Fruit From Peru Into the United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that we have prepared a pest risk analysis that evaluates the risks associated with the importation of fresh cape gooseberry fruit from Peru into the United States. Based on the analysis, we have determined that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh cape gooseberry fruit from Peru. We are making the pest risk analysis available to the public for review and comment.

DATES: We will consider all comments that we receive on or before October 7, 2024.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov. Enter APHIS–2023–0066 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.

- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2023–0066, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at www.regulations.gov in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Ms. Claudia Ferguson, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, Imports, Regulations, and Manuals PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1231; (301) 851–2352; email Claudia.Ferguson@usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in “Subpart L—Fruits and Vegetables” (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into or disseminated within the United States.

Section 319.56–4 contains a performance-based process for approving the importation of fruits and vegetables that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the five designated phytosanitary measures listed in paragraph (b) of that section.

APHIS received a request from the national plant protection organization (NPPO) of Peru to allow the importation of fresh cape gooseberry fruit (*Physalis peruviana* L.) from Peru into the United States. As part of our evaluation of Peru's request, we have prepared a pest risk assessment to identify the pests of quarantine significance that could follow the pathway of the importation of fresh cape gooseberry fruit into the United States from Peru. Based on the pest risk assessment, a risk management document (RMD) was prepared to identify phytosanitary measures that could be applied to the fresh cape gooseberry fruit to mitigate the pest risk.

Therefore, in accordance with § 319.56–4(c), we are announcing the availability of our pest risk assessment

and RMD for public review and comment. Those documents, as well as a description of the economic considerations associated with the importation of fresh cape gooseberry fruit from Peru, may be viewed on the Regulations.gov website or in our reading room (see **ADDRESSES** above for a link to Regulations.gov and information on the location and hours of the reading room). You may request paper copies of the pest risk assessment and RMD by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the subject of the analysis you wish to review when requesting copies.

After reviewing any comments we receive, we will announce our decision regarding the import status of fresh cape gooseberry fruit from Peru in a subsequent notice. If the overall conclusions of our analysis and the Administrator's determination of risk remain unchanged following our consideration of the comments, then we will authorize the importation of fresh cape gooseberry fruit from Peru into the United States subject to the requirements specified in the RMD.

Authority: 7 U.S.C. 1633, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of July 2024.

Michael Watson,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2024–17432 Filed 8–6–24; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Proposed New Recreation Fee Sites

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: The Huron-Manistee National Forests are proposing to establish several new recreation fee sites. Proposed recreation fees collected at the proposed recreation fee sites would be used for operation, maintenance, and improvement of the sites. An analysis of nearby recreation fee sites with similar amenities shows the proposed recreation fees that would be charged at the proposed recreation fee sites are reasonable and typical of similar recreation fee sites in the area.

DATES: If approved, the proposed recreation fees would be implemented no earlier than six months following the publication of this notice in the **Federal Register**.

ADDRESSES: Huron-Manistee National Forests, Attention: Recreation Fees, 1755 South Mitchell Street, Cadillac, MI 49601.

FOR FURTHER INFORMATION CONTACT: Nick Edington, Recreation Program Manager, (218) 308-0580 or nicholas.edington@usda.gov.

SUPPLEMENTARY INFORMATION: The Federal Lands Recreation Enhancement Act (16 U.S.C. 6803(b)) requires the Forest Service to publish a six-month advance notice in the **Federal Register** of establishment of new recreation fee sites. In accordance with Forest Service Handbook 2309.13, Chapter 30, the Forest Service will publish the proposed recreation fee sites and proposed recreation fees in local newspapers and other local publications for public comment. Most of the proposed recreation fee revenues would be spent where they are collected to enhance the visitor experience at the proposed recreation fee sites.

An expanded amenity recreation fee of \$10 per night would be charged for Cathedral Pines Backcountry Campsite, McKinley Horse Trail Campground, Buttercup Backcountry Campsites, Bear Island Backcountry Campsites, River Dune Backcountry Campsite, Meadow Springs Backcountry Campsites, and Luzerne Horse Trail Campgrounds. An expanded amenity recreation fee of \$15 per night would be charged at Condon Lake Backcountry Campsites, Sulak Recreation Area, and Sawkaw Lake Campgrounds. An expanded amenity recreation fee of \$40 per double site per night would be charged for Mack Lake Off-highway Vehicle, Kneff Lake, Gabions, and Jewell Lake Campgrounds. An expanded amenity recreation fee of \$30 per double site per night would be charged for Horseshoe, Meadows Off-highway Vehicle, and Au Sable Look Campgrounds. An expanded amenity recreation fee of \$60 per night for groups of up to 220 people would be charged for McKinley Horse Trail Group Campground, \$60 per night for groups of up to 230 people would be charged for Luzerne Horse Trail Group Campground, and an expanded amenity recreation fee of \$60 per night for groups of up to 200 people would be charged for the River Road Trail Group Campground. In addition, an expanded amenity recreation fee of \$150 per night would be charged for rental of Sprinkler Lake Cabins.

A standard amenity recreation fee of \$5 per day per vehicle would be charged at Lower Branch Bridge Carry-In Access. Additionally, a standard amenity recreation fee of \$5 per day, \$15 per week, and \$30 per year per vehicle

would be charged at East Bull Gap Off-Road Vehicle Trailhead, and Bull Gap Hill Climb Off-Road Vehicle Trailhead developed recreation sites. The Huron-Manistee National Forests Annual Day Use Pass and the America the Beautiful—the National Parks and Federal Recreational Lands Pass would be honored at these standard amenity recreation fee sites.

Expenditures from recreation fee revenues collected at the proposed recreation fee sites would enhance recreation opportunities, improve customer service, and address maintenance needs. Once public involvement is complete, the proposed recreation fee sites and proposed recreation fees will be reviewed by a Recreation Resource Advisory Committee prior to a final decision and implementation. Reservations for campgrounds and cabins could be made online at www.recreation.gov or by calling 877-444-6777. Reservations would cost \$8.00 per reservation.

Dated: August 1, 2024.

Jacqueline Emanuel,

Associate Deputy Chief, National Forest System.

[FR Doc. 2024-17442 Filed 8-6-24; 8:45 am]

BILLING CODE 3411-15-P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

[Docket #: RBS-24-NONE-0013]

Notice of Revision of a Currently Approved Information Collection

AGENCY: Rural Business-Cooperative Service.

ACTION: Notice; request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Rural Business-Cooperative Service (RBCS) announces its intention to request a revision for a currently approved information collection package for the Annual Survey of Farmer Cooperatives, as authorized in the Cooperative Marketing Act of 1926.

DATES: Comments on this notice must be received by October 7, 2024 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically by the Federal eRulemaking Portal, [regulations.gov](https://www.regulations.gov).

Other Information: Additional information about Rural Development (RD) and its programs is available on the internet at rd.usda.gov.

FOR FURTHER INFORMATION CONTACT:

Adyam Negasi, RD Innovation Center—Regulations Management Division, U.S.

Department of Agriculture, 1400 Independence Ave. SW, Washington, DC 20250; Tel: 202-221-9298; Email: Adyam.Negasi@usda.gov.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget's (OMB) regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104-13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that the Agency is submitting to OMB for revision.

Comments are invited on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumption used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques on other forms and information technology.

Comments may be sent through the Federal eRulemaking Portal, [regulations.gov](https://www.regulations.gov). In the "Search for dockets and documents on agency actions" box enter the Docket No. RBS-24-NONE-0013 and click the "Search" button. From the search results: click on or locate the document title and select the "Comment" button. To submit a comment: Insert comments under the "Comment" title. Select if you are an individual, organization, or anonymous. Select the box "I'm not a robot," and then select "Submit Comment." Information on using [regulations.gov](https://www.regulations.gov), including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "FAQ" link.

All comments will be available for public inspection online at the Federal eRulemaking Portal (<https://www.regulations.gov>).

Title: Annual Survey of Farmer Cooperatives.

OMB Control Number: 0570-0007.

Type of Request: Revision of a currently approved information collection under 7 CFR part 1738.

Abstract: One of the objectives of RBCS is to promote the understanding, use, and development of the cooperative

form of business as a viable option for enhancing the income of agricultural producers and other rural residents. RBCS' direct role is providing knowledge to improve the effectiveness and performance of farmer cooperative businesses through technical assistance, research, information, and education. The Annual Survey of Farmer Cooperatives collects basic statistics on cooperative business volume, net income, members, financial status, employees, and other selected information to support RBCS' objective and role. Cooperative statistics are published in an annual report and other formats for use by the U.S. Department of Agriculture, cooperative management and members, educators and researchers, other Federal agencies, cooperative trade associations, general agribusiness, cooperative development practitioners, students, teachers, consultants, and many others.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 0.78 hours per response.

Respondents: Cooperatives.

Estimated Number of Respondents: 1,035.

Estimated Number of Responses per Respondent: 1.

Estimated Number of Responses: 1,035.

Estimated Total Annual Burden on Respondents: 806 hours.

Copies of this information collection can be obtained from Adyam Negasi, RD Innovation Center—Regulations Management Division, at 202–221–9298 or Adyam.negasi@usda.gov.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Kathryn E. Dirksen Londrigan,
Administrator, Rural Business-Cooperative Service, USDA Rural Development.

[FR Doc. 2024–17405 Filed 8–6–24; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF AGRICULTURE

Rural Utilities Service

[Docket No.: RUS–24–ELECTRIC–0024]

Notice of a Revision to a Currently Approved Information Collection

AGENCY: Rural Utilities Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Rural Utilities

Service's (RUS or the Agency), an agency with the United States Department of Agriculture, Rural Development, intention to request a revision to a currently approved information collection package for the RUS Electric Loan Application and Related Reporting Burdens. The Agency invites comments on this information collection for which the Agency intends to request approval from the Office of Management and Budget (OMB).

DATES: Comments on this notice must be received by October 7, 2024 to be assured of consideration.

FOR FURTHER INFORMATION CONTACT:

Pamela Bennett, Rural Development Innovation Center—Regulations Management Division, USDA, 1400 Independence Avenue SW, STOP 1522, South Building, Washington, DC 20250–1522. Telephone: (202) 720–9639. Email pamela.bennett@usda.gov.

SUPPLEMENTARY INFORMATION: The OMB regulation (5 CFR part 1320) implementing provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13) requires that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities (see 5 CFR 1320.8(d)). This notice identifies an information collection that the Agency is submitting to OMB for revision.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) The accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (c) Ways to enhance the quality, utility and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on 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 may be sent by the Federal eRulemaking Portal: Go to <https://www.regulations.gov> and, in the "Search" box, type in the Docket No. located at the beginning of this notice. A link to the Notice will appear. You may submit a comment here by selecting the "Comment" button or you can access the "Docket" tab, select the "Notice," and go to the "Browse & Comment on Documents" Tab. Here you may view comments that have been submitted as well as submit a comment.

To submit a comment, select the "Comment" button, complete the required information, and select the "Submit Comment" button at the bottom. Information on using [Regulations.gov](https://www.regulations.gov), including instructions for accessing documents, submitting comments, and viewing the docket after the close of the comment period, is available through the site's "FAQ" link at the bottom.

A Federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB Control Number. Data furnished by the applicants will be used to determine eligibility for program benefits. Furnishing the data is voluntary; however, failure to provide data could result in program benefits being withheld or denied.

Title: RUS Electric Loan Application and Related Reporting Burdens.

OMB Control Number: 0572–0032.

Type of Request: Revision of a currently approved information collection.

Abstract: RUS was established in 1994 by the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (Pub. L. 103–354, 108 Stat. 3178, 7 U.S.C. 6941 *et seq.*) as successor to the Rural Electrification Administration (REA) with respect to certain programs, including the electric loan and loan guarantee program authorized under the Rural Electrification Act of 1936 (7 U.S.C. 901 *et seq.*, as amended) (RE Act). The RE Act authorizes and empowers the Administrator of RUS to make and guarantee loans to furnish and improve electric service in rural areas. These loans are amortized over a period of up to 35 years and secured by the borrower's electric assets and/or revenue. In the interest of protecting loan security, monitoring compliance with debt covenants, and ensuring that RUS loan funds are used for purposes authorized by law, RUS requires that borrowers prepare and submit for RUS evaluation certain studies and reports. Some of these studies and reports are required only once for each loan application; others must be submitted periodically until the loan is completely repaid. These forms and documents serve as support for electric loan applications and summarizes the types and estimated costs of facilities and equipment for which RUS financing is being requested.

The RE Act also authorizes and empowers the Administrator of RUS to make or cause to be made, studies, investigations, and reports concerning the condition and progress of the electrification of the several States and Territories; and to publish and disseminate information with respect thereto. Information supplied by borrowers forms the basis of many of these reports.

RUS uses an online application intake system called RDAApply that allows applicants to create an online application for RUS loans and grants as well as upload attachments, sign certifications, and draw service areas, to name a few features. RDAApply streamlines the application process, as well as provides identity security, reduces paper consumption and is expected to reduce the burden associated with this information collection package over time.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 19.07 hours per response.

Respondents: Non-profit organizations, business or other for profit.

Estimated Number of Respondents: 608.

Estimated Total Annual Responses: 1,967.

Estimated Number of Responses per Respondent: 3.24.

Estimated Total Annual Burden on Respondents: 37,514 Hours.

Copies of this information collection can be obtained from Pamela Bennett, Rural Development Innovation Center—Regulations Management Division, USDA, 1400 Independence Avenue SW, South Building, Washington, DC 20250–1522. Email: pamela.bennett@usda.gov.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Christopher A. McLean,

Acting Administrator, Rural Utilities Service.

[FR Doc. 2024–17478 Filed 8–6–24; 8:45 am]

BILLING CODE 3410–15–P

DEPARTMENT OF COMMERCE

Office of the Secretary

[Docket Number 240729–0207]

RIN 0605–XZ001

Department of Commerce Open Government Plan

AGENCY: Office of the Secretary, Department of Commerce.

ACTION: Notice and request for comments (RFC).

SUMMARY: The U.S. Department of Commerce's Office of Privacy and Open Government requests public comment on improvements for the presentation of the Department's eighth Open Government Plan. We are committed to creating opportunities for meaningful civic engagement and public participation and welcome public input on how to improve upon the organization, scope, form, and format of the Department's seventh Open Government Plan document, how to enhance readability and reach a broader audience, and how best to convey in the document how the Department's eighth Open Government Plan incorporates themes from the fifth U.S. Open Government National Action Plan that was issued on December 28, 2022.

DATES: Comments on this notice must be submitted on or before September 6, 2024.

ADDRESSES: You may submit comments via the Federal eRulemaking Portal at <https://www.regulations.gov/>. Follow the instructions for submitting comments. All public comments received are subject to the Freedom of Information Act and will be posted in their entirety at <https://www.regulations.gov/>, including any personal and business confidential information provided. Do not include any information you would not like to be made publicly available.

Instructions: Response to this RFC is voluntary. Responses should include the name of the person(s) or organization(s) filing the response. Responses containing references, studies, research, and other empirical data that are not widely published should include copies of or electronic links to the referenced materials. Please do not submit copyrighted material. Responses containing profanity, vulgarity, threats, or other inappropriate language or content will not be considered. Any information obtained from this RFC is intended to be used by the Government on a non-attribution basis. The Department of Commerce will not respond to individual submissions.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information should be directed to open@doc.gov with "Open Government Plan RFC" in the subject line, or by mail to Office of Privacy and Open Government, U.S. Department of Commerce, Attn: Jennifer Goode, Ph.D., Deputy Director for Open Government and Departmental Privacy Act Officer, 1401 Constitution Ave. NW,

Mail Stop 61013, Washington, DC 20230, (202) 482–1190.

SUPPLEMENTARY INFORMATION: In accordance with OMB Memorandum M–09–12, President's Memorandum on Transparency and Open Government—Interagency Collaboration, OMB Memorandum M–10–06, Open Government Directive, and OMB Memorandum M–16–16, 2016 Agency Open Government Plans, the Department continues to develop, publish, and update its Open Government Plan every two years. The Plan describes how the Department continuously strives to improve transparency and integrate public participation and collaboration into its activities. In September 2022, the Department published the seventh version of its Open Government Plan, building on the Department's long history of innovative approaches to data dissemination and highlighting the adoption of new tools and technology to facilitate the principles of open government.

Now, as the Department develops the eighth version of its Open Government Plan, we welcome public input on how to improve upon the approach we took for the presentation of the seventh version of the Open Government Plan, including how to improve the organization, scope, form and format of the plan; enhance readability; and reach a broader audience. We also welcome public input on how best to convey how the Department will incorporate the following themes from the fifth U.S. Open Government National Action Plan, issued on December 28, 2022:

- improving access to government data, research, and information;
- increasing civic space within which to engage with the public;
- transforming government service delivery;
- countering corruption and ensuring government integrity and accountability to the public; and
- ensuring equal justice under the law.

Please note: The focus of this request for information is the presentation of the Department's Open Government Plan document. Comments or suggestions for improvements to the Department's programs or activities in furtherance of open government will not be considered in connection with this request for information.

To learn more about the Department's commitment to open government and to access the seventh or previous versions of the Department's Open Government Plan, visit www.commerce.gov/open. To learn more about the fifth U.S. Open

Government National Action Plan, visit: <https://open.usa.gov/national-action-plan/5/>.

Charles Cutshall,

Director, Office of Privacy and Open Government.

[FR Doc. 2024–17445 Filed 8–6–24; 8:45 am]

BILLING CODE 3510–17–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–14–2024]

Foreign-Trade Zone (FTZ) 297; Authorization of Production Activity; Twin Disc, Inc.; (Power Transmission Products); Lufkin, Texas

On April 4, 2024, Twin Disc, Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 297A, in Lufkin, Texas.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (89 FR 25562, April 11, 2024). On August 2, 2024, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: August 2, 2024.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2024–17475 Filed 8–6–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–475–845]

Mattresses From Italy: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: The U.S. Department of Commerce (Commerce) published a notice in the **Federal Register** of May 15, 2024, containing the final determination of the less-than-fair-value (LTFV) investigation on mattresses from Italy. This notice incorrectly listed the

name of an exporter/producer under investigation as Gruppo Buoninfante Industriale S.P.A, in the sections entitled “Final Affirmative Determination of Critical Circumstances” and “Final Determination.”

FOR FURTHER INFORMATION CONTACT:

Adam Simons, 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) 482–6172.

SUPPLEMENTARY INFORMATION:

Background

On May 15, 2024, Commerce published in the **Federal Register** its final determination in the LTFV investigation on mattresses from Italy.¹ In this notice, Commerce incorrectly listed the name of one of the producers/exporters under investigation as Gruppo Buoninfante Industriale S.P.A. in the sections entitled “Final Affirmative Determination of Critical Circumstances” and “Final Determination.”

Correction

In the **Federal Register** of May 15, 2024, in FR Doc 2024–10565, on page 42430, in the second column, in the section entitled “Final Affirmative Determination of Critical Circumstances,” correct the name Gruppo Buoninfante Industriale S.P.A. to be Gruppo Industriale Buoninfante S.P.A. In addition, also on page 42430, in the third column, in the section entitled “Final Determination” in the table, correct the name Gruppo Buoninfante Industriale S.P.A. to be Gruppo Industriale Buoninfante S.P.A.

Notification to Interested Parties

This notice is issued and published in accordance with sections 735(d) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.210(c).

Dated: July 30, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–17390 Filed 8–6–24; 8:45 am]

BILLING CODE 3510–DS–P

¹ See *Mattresses from Italy: Final Affirmative Determination of Sales at Less Than Fair Value and Final Affirmative Determination of Critical Circumstances*, 89 FR 42432 (May 15, 2024).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–095, C–570–096]

Aluminum Wire and Cable From the People's Republic of China: Preliminary Negative Scope Determinations With Respect to Cambodia, Korea, and Vietnam; Preliminary Affirmative Determinations of Circumvention With Respect to Korea and Vietnam; Preliminary Negative Determination of Circumvention With Respect to Cambodia

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that imports of aluminum wire and cable (AWC) completed in Cambodia, the Republic of Korea (Korea), and the Socialist Republic of Vietnam (Vietnam) (collectively, the third countries) using certain AWC inputs manufactured in the People's Republic of China (China) are not covered by scope of the antidumping duty (AD) and countervailing duty (CVD) orders on AWC from China. In addition, Commerce preliminarily determines that AWC completed in Korea and Vietnam using certain AWC inputs manufactured in China are circumventing the orders. Commerce also preliminarily determines that AWC completed in Cambodia using certain AWC inputs manufactured in China are not circumventing the orders. Commerce is also imposing a certification requirement with respect to applicable entries from Korea and Vietnam. Interested parties are invited to comment on these preliminary determinations.

DATES: Applicable August 7, 2024.

FOR FURTHER INFORMATION CONTACT:

Gene H. Calvert, 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) 482–3586.

SUPPLEMENTARY INFORMATION:

Background

On December 23, 2019, Commerce published the orders in the **Federal Register**.¹ On October 19, 2023, pursuant to 19 CFR 351.225(b),

¹ See *Aluminum Wire and Cable from the People's Republic of China: Antidumping and Countervailing Duty Orders*, 84 FR 70496 (December 23, 2019) (*Orders*).

Commerce self-initiated scope inquiries to determine whether imports of AWC completed in Cambodia, Korea, and Vietnam using inputs manufactured in China are covered by the Orders.² On this same day, pursuant to 19 CFR 351.226(b) and section 781(b) of the Tariff Act of 1930, as amended (the Act), Commerce also self-initiated country-wide circumvention inquiries to determine whether imports of AWC from Cambodia, Korea, and Vietnam, if outside of the scope of the Orders, are nonetheless circumventing the Orders. Commerce aligned both the scope and circumvention inquiries in accordance with 19 CFR 351.225(e)(3) and 19 CFR 351.226(e)(e).

In the *Initiation Notice*, Commerce determined that it is appropriate to first determine whether the merchandise is subject to the scope of the Orders through a scope inquiry before considering whether the merchandise is circumventing the Orders. Commerce also stated that, accordingly, it would initially conduct a scope inquiry of the merchandise at issue, and then once it has made a determination as the scope coverage status of the merchandise, would determine whether to proceed with a circumvention inquiry.³

Between February 12 and 23, 2024, Commerce selected respondents from each of the third countries as mandatory respondents in these scope and circumvention inquiries.⁴ On March 8, 2024, Commerce extended the deadline for these preliminary determinations until June 13, 2024.⁵ On June 5, 2024, and based on a request from Encore Wire Corporation (Encore) and Southwire Company LLC (Southwire) (collectively, the petitioners),⁶ Commerce further extended these preliminary determinations to July 12,

2024.⁷ On July 12, 2024, we further extended the deadline for the preliminary determinations to July 24, 2024.⁸ On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days. The deadline for these preliminary determinations is now July 31, 2024.⁹ For a complete description of the events that followed initiation of these scope and circumvention investigations, see the Preliminary Decision Memoranda.¹⁰ The Preliminary Decision Memoranda are public documents and are 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, complete versions of the Preliminary Decision Memoranda can be accessed directly at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Scope of the Orders

The products subject to the Orders are aluminum wire and cable. For a full description of the scope of the Orders, see the Preliminary Decision Memoranda.

Merchandise Subject to the Scope and Anti-Circumvention Inquiries

These inquiries cover AWC assembled or completed in either Cambodia, Korea, or Vietnam using Chinese-origin AWC inputs (e.g., stranded wire and cables or unfinished AWC) that is subsequently exported from the third countries to the United States (inquiry merchandise). These inquiries cover exports of AWC from the third countries that are assembled or completed using inputs of Chinese origin which undergo further processing in the third countries.

Scope Determinations

As detailed in the Preliminary Decision Memoranda, Commerce preliminarily determines that the AWC in question that is produced in the third countries using Chinese inputs does not meet the physical description of the scope of the Orders and, therefore, the AWC produced in the third countries does not fall under the scope of the Orders.¹¹ Commerce noted in the Preliminary Decision Memoranda that it recently made a similar finding regarding merchandise subject to the scope of the Orders.¹²

Commerce notes that these preliminary scope determinations are subject to verification of record information submitted by the company respondents in the third countries that are subject to these inquiries. At the completion of these inquiries, Commerce will serve a copy of these scope determinations to interested parties on the scope service list. In addition, Commerce will issue appropriate instructions to U.S. Customs and Border Protection (CBP).

Methodology Regarding Circumvention Inquiries

Commerce made these preliminary circumvention determinations in accordance with section 781(b) of the Act and 19 CFR 351.226. With respect to Korea and Vietnam, we relied on the facts available under section 776(a) of the Act, including facts available with adverse inferences under section 776(b) of the Act, where appropriate.¹³ For a full description of the methodology underlying these preliminary determinations, see the Preliminary Decision Memoranda. A list of topics discussed in the Preliminary Decision Memoranda is included as Appendix I to this notice.

Affirmative Preliminary Determinations of Circumvention: Korea and Vietnam

As detailed in the Preliminary Decision Memoranda, Commerce preliminarily determines that U.S. imports of inquiry merchandise from Korea and from Vietnam are

² See *Aluminum Wire and Cable from the People's Republic of China: Initiation of Scope and Circumvention Inquiries of the Antidumping Duty and Countervailing Duty Orders*, 88 FR 72041 (October 19, 2023) (*Initiation Notice*), and accompanying Initiation Memorandum.

³ See *Initiation Notice*.

⁴ See Memoranda, "Respondent Selection Regarding the Scope and Circumvention Inquiries with Respect to the Republic of Korea," dated February 12, 2024; "Respondent Selection Regarding the Scope and Circumvention Inquiries with Respect to the Socialist Republic of Vietnam," dated February 12, 2024; and "Respondent Selection Regarding the Scope and Circumvention Inquiries for the Kingdom of Cambodia," dated February 23, 2024.

⁵ See Memorandum, "Extension of Deadlines for the Preliminary Determinations in Circumvention Inquiries," dated March 8, 2024.

⁶ See Petitioners' Letter, "Petitioners' Request that Commerce Extend the Deadlines for its Scope Rulings and Preliminary Circumvention Determinations," dated May 14, 2024.

⁷ See Memorandum, "Extension of Deadlines for the Final Determination in Circumvention Inquiries," dated June 5, 2024.

⁸ See Memorandum, "Extension of Deadlines for the Preliminary Determinations in Circumvention Inquiries," dated July 12, 2024.

⁹ See Memorandum, "Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings," dated July 22, 2024.

¹⁰ See Memoranda, "Preliminary Decision Memorandum for the Scope Inquiry and Preliminary Decision Memorandum for the Circumvention Inquiry with Respect to Cambodia," (Cambodia Preliminary Decision Memorandum); "Preliminary Decision Memorandum for the Scope Inquiry and Preliminary Decision Memorandum for the Circumvention Inquiry with Respect to the Republic of Korea;" and "Preliminary Decision Memorandum for the Scope Inquiry and Preliminary Decision Memorandum for the Circumvention Inquiry with Respect to the Socialist Republic of Vietnam," all dated concurrently with, and hereby adopted by this notice (collectively, Preliminary Decision Memoranda).

¹¹ See the Preliminary Decision Memoranda at the sections, "Scope Inquiry."

¹² *Id.*, citing *Notice of Scope Rulings*, 89 FR 47896 (June 4, 2024), at the section "A-570-096 and C-570-096: Aluminum Wire and Cable from China," and accompanying Memorandum, "Aluminum Wire and Cable from the People's Republic of China: Scope Ruling for Imperium Cables, LLC," dated December 2, 2023, a public document and is on file electronically via ACCESS.

¹³ See the Preliminary Decision Memoranda with Respect to Korea and Vietnam at the section, "Use of Facts Otherwise Available and Application of Adverse Inferences."

circumventing the *Orders* on a country-wide basis.¹⁴ As a result, Commerce preliminarily determines that it is appropriate to include inquiry merchandise within the *Orders* and to instruct CBP to suspend entries of AWC from Korea or from Vietnam that were produced in either Korea or Vietnam and that are produced using inputs sourced from China. To administer these preliminary affirmative determinations of circumvention, exporters and importers of AWC completed in Korea or Vietnam using non-Chinese origin aluminum wire rod, aluminum wire strand, or aluminum wire will be permitted to attest that specific entries are not subject to the suspension of liquidation or the collection of cash deposits.

See the “Suspension of Liquidation” section below for details regarding the suspension of liquidation and cash deposit requirements. See the “Certification” and “Certification Requirements” sections below regarding the use of certifications.

Suspension of Liquidation

Based on the preliminary affirmative country-wide determinations of circumvention with respect to Korea and Vietnam, in accordance with 19 CFR 351.225(l)(2), Commerce will direct CBP to suspend liquidation and to require a cash deposit of estimated duties on unliquidated entries of inquiry merchandise that were entered, or withdrawn from warehouse, for consumption, on or after October 19, 2023, the date of publication of the initiation of these circumvention inquiries in the **Federal Register**.¹⁵

Where companies subject to these inquiries have their own company-specific rate under the *Orders*, the cash deposit rate will be the company-specific rate. Otherwise, Commerce will instruct CBP to require AD cash deposits equal to the China-wide rate of 52.79 percent and CVD cash deposits equal to 33.44 percent.¹⁶ The suspension of liquidation will remain in effect until further notice.

Negative Preliminary Determination of Circumvention: Cambodia

Also as detailed in the Cambodia Preliminary Decision Memorandum, Commerce preliminarily determines that U.S. imports of inquiry merchandise from Cambodia are not

circumventing the *Orders*.¹⁷ As a result, in accordance with section 781(b) of the Act, Commerce preliminarily determines that the inquiry merchandise exported from Cambodia should not be included within the scope of the *Orders*.

Certified Entries

Entries for which the importer has met the certification requirements described below and in Appendix II to this notice will not be subject to suspension of liquidation, or the cash deposit requirements described above. Failure to comply with the applicable requisite certification requirements may result in the merchandise being subject to antidumping and countervailing duties.

Certifications

To administer the preliminary country-wide affirmative circumvention determinations for Korea and for Vietnam, Commerce has established importer and exporter certifications as provided for in Appendix II to this notice. These certifications will permit importers and exporters to establish that specific entries of AWC from Korea and Vietnam are not subject to suspension of liquidation or the collection of cash deposits pursuant to these preliminary country-wide affirmative determinations of circumvention because the merchandise was processed in either Korea or in Vietnam and does not incorporate Chinese-sourced aluminum wire rod, aluminum wire strand, or aluminum wire. Importers and exporters that claim that an entry of AWC is not subject to suspension of liquidation or the collection of cash deposits because the merchandise was processed in either Korea or in Vietnam and does not incorporate Chinese-sourced aluminum wire rod, aluminum wire strand, or aluminum wire must certify that these products satisfy the requirements of these certification requirements as described in Appendix II of this notice.

Certification Requirements for Korea and Vietnam

Importers are required to complete and maintain the applicable importer certification, and maintain a copy of the applicable exporter certification, and retain all supporting documentation for both certifications. The importer certification must be completed, signed, and dated by the time the entry summary is filed for the relevant entry. The importer, or the importer's agent,

must submit both the importer's certification and the exporter's certification to CBP as part of the entry process by uploading them into the document imaging system (DIS) in ACE. Where the importer uses a broker to facilitate the entry process, the importer should obtain the entry summary number from the broker. Agents of the importer, such as brokers, however, are not permitted to certify on behalf of the importer.

Exporters are required to complete and maintain the applicable exporter certification and provide the importer with a copy of that certification and all supporting documentation (e.g., invoice, purchase order, production records, etc.). The exporter certification must be completed, signed, and dated by the time of shipment of the relevant entries. The exporter certification should be completed by the party selling the AWC that was manufactured in Korea or Vietnam to the United States.

Additionally, the claims made in the certifications and any supporting documentation are subject to verification by Commerce and/or CBP. Importers and exporters are required to maintain the certifications and supporting documentation until the later of: (1) the date that is five years after the latest entry date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

For all AWC from Korea or Vietnam that were entered, or withdrawn from warehouse, for consumption during the period October 19, 2023 (the date of initiation of these circumvention inquiries) through the date of publication of these preliminary affirmative determinations in the **Federal Register**, where the entry has not been liquidated (and entries for which liquidation has not become final), the relevant certification should be completed and signed as soon as practicable, but not later than 45 days after the date of publication of these preliminary determinations in the **Federal Register**. For such entries, importers, and exporters each have the option to complete a blanket certification covering multiple entries, individual certifications for each entry, or a combination thereof. The exporter must provide the importer with a copy of the exporter certification within 45 days of the date of publication of these preliminary determinations in the **Federal Register**.

For unliquidated entries (and entries for which liquidation has not become final) of AWC that were declared as non-AD/CVD type entries (e.g., type 01)

¹⁴ See the Preliminary Decision Memoranda with respect to Korea and Vietnam at the section, “Certification Process and Country-Wide Preliminary Affirmative Determination of Circumvention.”

¹⁵ See *Initiation Notice*.

¹⁶ See *Orders*.

¹⁷ See Cambodia Preliminary Decision Memorandum at the section, “Country-Wide Preliminary Negative Determination of Circumvention.”

and entered, or withdrawn from warehouse, for consumption in the United States during the period October 19, 2023 (the date of initiation of these circumvention inquiries) through the date of publication of the preliminary determinations in the **Federal Register**, for which none of the above certifications may be made, importers must file a Post Summary Correction with CBP, in accordance with CBP's regulations, regarding conversion of such entries from non-AD/CVD type entries to AD/CVD type entries (e.g., type 01 to type 03). Importers should report those AD/CVD type entries using the following third-country case numbers: Korea A-580-095-000/C-580-096-000; and Vietnam A-552-095-000/C-552-096-000. Other third-country case numbers may be established following the process described above. The importer should pay cash deposits on those entries consistent with the regulations governing post summary corrections that require payment of additional duties.

If it is determined that an importer and/or exporter has not met the certification and/or related documentation requirements for certain entries, Commerce intends to instruct CBP to suspend, pursuant to these preliminary country-wide affirmative determinations of circumvention and the *Orders*,¹⁸ all unliquidated entries for which these requirements were not met and require the importer to post applicable AD and CVD cash deposits equal to the rates noted above.

Interested parties may comment on these certification requirements, and on the certification language contained in the appendices to this notice in their case briefs.

Verification

As provided in 19 CFR 351.226(f)(3), Commerce intends to verify the information relied upon in making its final determinations.

Public Comment and Request for Hearing

Case briefs or other written comments should be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which any verification report is issued. Rebuttal briefs, limited to issues raised in case briefs, may be submitted no later than five days after the deadline for case briefs.¹⁹ Pursuant

to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in these circumvention inquiries must submit: (1) a statement of the issue; and (2) a table of authorities. Case and rebuttal briefs should be filed using ACCESS.

As provided in 19 CFR 351.309(c)(2) and (d)(2), in prior proceedings we have encouraged interested parties to provide an executive summary of their brief that should be limited to five pages total, including footnotes. In these scope and circumvention inquiries, we instead request that interested parties provide at the beginning of their briefs, a public executive summary for each issue raised in their briefs.²⁰ Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final determination in these scope and circumvention inquiries. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).²¹

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 in the **Federal Register**, filed electronically via ACCESS. Requests should contain: (1) the requesting party's name, address, and telephone number; (2) the number of individuals from the requesting party that will attend the hearing; and (3) a list of the issues that the party intends to discuss at the hearing. 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.

U.S. International Trade Commission Notification

Commerce, consistent with section 781(e) of the Act, will notify the U.S. International Trade Commission (ITC) of

these preliminary determinations to include the merchandise subject to these circumvention inquiries within the *Orders*. Pursuant to section 781(e) of the Act, the ITC may request consultations concerning Commerce's proposed inclusion of the inquiry merchandise. If, after consultations, the ITC believes that a significant injury issue is presented by the proposed inclusion, it will have 60 days from the date of notification by Commerce to provide written advice.

Notification to Interested Parties

Commerce is issuing and publishing these determinations in accordance with section 781(b) of the Act, 19 CFR 351.225(g), and 19 CFR 351.226(g)(1).

Dated: July 31, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

Topics Discussed in the Preliminary Decision Memoranda

Cambodia

- I. Summary
- II. Background
- III. Scope of the *Orders*
- IV. Merchandise Subject to These Circumvention and Scope Inquiries
- V. Scope Inquiry
- VI. Circumvention Inquiry
- VII. Country-Wide Preliminary Negative Determination of Circumvention
- VIII. Recommendation

Korea

- I. Summary
- II. Background
- III. Treatment of Voluntary Respondent
- IV. Untimely Submission
- V. Scope of the *Orders*
- VI. Merchandise Subject to These Circumvention and Scope Inquiries
- VII. Use of Facts Otherwise Available and Application of Adverse Inferences
- VIII. Scope Inquiry
- IX. Circumvention Inquiry
- X. Summary of Statutory Analysis
- XI. Certification Process and Country-Wide Preliminary Affirmative Determination of Circumvention
- XII. Recommendation

Vietnam

- I. Summary
- II. Background
- III. Scope of the *Orders*
- IV. Merchandise Subject to These Circumvention and Scope Inquiries
- V. Use of Facts Otherwise Available and Application of Adverse Inferences
- VI. Scope Inquiry
- VII. Circumvention Inquiry
- VIII. Certification Process and Country-Wide Preliminary Affirmative Determination of Circumvention

88 FR 67069 (September 29, 2023) (*APO and Service Final Rule*).

²⁰ We use the term "issue" here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

²¹ See *APO and Service Final Rule*.

¹⁸ See *Orders*.

¹⁹ See 19 CFR 351.309(d); see also *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings*,

IX. Recommendation

Appendix II

Importer Certification

I hereby certify that:

(A) My name is {IMPORTING COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF IMPORTING COMPANY}, located at {ADDRESS OF IMPORTING COMPANY}.

(B) I have direct personal knowledge of the facts regarding the importation into the Customs territory of the United States of the aluminum wire and cable (AWC) assembled or completed in {select Korea or Vietnam} that under entry summary number(s), identified below, and are covered by this certification. "Direct personal knowledge" refers to facts the certifying party is expected to have in its own records. For example, the importer should have direct personal knowledge of the importation of AWC, including the exporter's and/or foreign seller's identity and location.

(C) If the importer is acting on behalf of the first U.S. customer, include the following sentence as paragraph C of this certification:

The AWC covered by this certification was imported by {IMPORTING COMPANY} on behalf of {U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER}.

If the importer is not acting on behalf of the first U.S. customer, include the following sentence as paragraph C of this certification:

{NAME OF IMPORTING COMPANY} is not acting on behalf of the first U.S. customer.

(D) The AWC covered by this certification was shipped to {NAME OF PARTY IN THE UNITED STATES TO WHOM THE MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

(E) I have personal knowledge of the facts regarding the production of the imported products covered by this certification. "Personal knowledge" includes facts obtained from another party, (e.g., correspondence received by the importer (or exporter) from the producer regarding the source of the inputs (i.e., aluminum wire rod, aluminum wire strand, or aluminum wire) used to produce the imported AWC).

(F) This certification applies to the following entries (repeat this block as many times as necessary):

Entry Summary #:

Entry Summary Line Item #:

Foreign Seller:

Foreign Seller's Address:

Foreign Seller's Invoice #:

Foreign Seller's Invoice Line Item #:

Country of Origin of HRS:

Producer:

Producer's Address:

(G) The AWC covered by this certification does not contain aluminum wire rod, aluminum wire strand, or aluminum wire produced in the People's Republic of China.

(H) I understand that {IMPORTING COMPANY} is required to maintain a copy of this certification and sufficient documentation supporting this certification (i.e., documents maintained in the normal course of business, or documents obtained by

the certifying party, for example, certificates of origin, product data sheets, mill test reports, productions records, invoices, etc.) until the later of: (1) the date that is five years after the date of the latest entry covered by the certification; or (2) the date that is three years after the conclusion of any litigation in the United States courts regarding such entries.

(I) I understand that {IMPORTING COMPANY} is required to maintain a copy of the exporter's certification (attesting to the production and/or exportation of the imported merchandise identified above), and any supporting documentation provided to the importer by the exporter, until the later of: (1) the date that is five years after the date of the latest entry covered by the certification; or (2) the date that is three years after the conclusion of any litigation in United States courts regarding such entries.

(J) I understand that {IMPORTING COMPANY} is required to provide U.S. Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with the importer certification, and any supporting documentation, and a copy of the exporter's certification, and any supporting documentation provided to the importer by the exporter, upon request of either agency.

(K) I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

(L) I understand that failure to maintain the required certification and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all entries to which this certification applies are within the scope of the antidumping duty and countervailing duty orders on AWC from China. I understand that such finding will result in:

(i) suspension of liquidation of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the cash deposits determined by Commerce; and

(iii) the importer no longer being allowed to participate in the certification process.

(M) I understand that agents of the importer, such as brokers, are not permitted to make this Certification.

This certification was completed and signed on, or prior to, the date of the entry summary if the entry date is more than 14 days after the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**. If the entry date is on or before the 14th day after the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**, this certification was completed and signed by no later than 45 days after publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**.

(N) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}
{TITLE OF COMPANY OFFICIAL}
{DATE}

Exporter Certification

The party that made the sale to the United States should fill out the exporter certification.

I hereby certify that:

(A) My name is {COMPANY OFFICIAL'S NAME} and I am an official of {NAME OF FOREIGN COMPANY THAT MADE THE SALE TO THE UNITED STATES}; located at {ADDRESS OF FOREIGN COMPANY THAT MADE THE SALE TO THE UNITED STATES}.

(B) I have direct personal knowledge of the facts regarding the production and exportation of the aluminum wire and cable (AWC) for which sales are identified below. "Direct personal knowledge" refers to facts the certifying party is expected to have in its own records. For example, an exporter should have direct personal knowledge of the producer's identity and location.

(C) The AWC covered by this certification was shipped to {NAME OF PARTY IN THE UNITED STATES TO WHOM THE MERCHANDISE WAS FIRST SHIPPED}, located at {U.S. ADDRESS TO WHICH THE MERCHANDISE WAS SHIPPED}.

(D) The AWC covered by this certification does not contain aluminum wire rod, aluminum wire strand, or aluminum wire produced in the People's Republic of China.

(E) This certification applies to the following sales to {NAME OF U.S. CUSTOMER}, located at {ADDRESS OF U.S. CUSTOMER} (repeat this block as many times as necessary):

Foreign Seller's Invoice # to U.S. Customer:
Foreign Seller's Invoice to U.S. Customer

Line item #:

Producer Name:

Producer's Address:

Producer's Invoice # to Foreign Seller: (If the foreign seller and the producer are the same party, put NA here.)

Name of Producer of AWC:
Location (Country) of Producer of AWC:

(F) The AWC covered by this certification was shipped to {NAME OF U.S. PARTY TO WHOM MERCHANDISE WAS SHIPPED}, located at {U.S. ADDRESS TO WHICH MERCHANDISE WAS SHIPPED}.

(G) I understand that {NAME OF FOREIGN COMPANY THAT MADE THE SALE TO THE UNITED STATES} is required to maintain a copy of this certification and sufficient documentation supporting this certification (i.e., documents maintained in the normal course of business, or documents obtained by the certifying party, for example, product data sheets, mill test reports, productions records, invoices, etc.) until the later of: (1) the date that is five years after the latest date of the entries covered by the certification; or (2) the date that is three years after the conclusion of any litigation in the United States courts regarding such entries.

(H) I understand that {NAME OF FOREIGN COMPANY THAT MADE THE SALE TO THE UNITED STATES} is required to provide the U.S. importer with a copy of this certification and is required to provide U.S.

Customs and Border Protection (CBP) and/or the U.S. Department of Commerce (Commerce) with this certification, and any supporting documents, upon request of either agency.

(I) I understand that the claims made herein, and the substantiating documentation, are subject to verification by CBP and/or Commerce.

(J) I understand that failure to maintain the required certification and supporting documentation, or failure to substantiate the claims made herein, or not allowing CBP and/or Commerce to verify the claims made herein, may result in a *de facto* determination that all sales to which this certification applies are within the scope of the antidumping duty order and countervailing duty order on AWC from China. I understand that such a finding will result in:

(i) suspension of all unliquidated entries (and entries for which liquidation has not become final) for which these requirements were not met;

(ii) the importer being required to post the cash deposits determined by Commerce; and

(iii) the seller/exporter no longer being allowed to participate in the certification process.

(K) I understand that agents of the seller/exporter, such as freight forwarding companies or brokers, are not permitted to make this certification.

(L) This certification was completed and signed, and a copy of the certification was provided to the importer, on, or prior to, the date of shipment if the shipment date is more than 14 days after the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**. If the shipment date is on or before the 14th day after the date of publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**, this certification was completed and signed, and a copy of the certification was provided to the importer, by no later than 45 days after publication of the notice of Commerce's preliminary determination of circumvention in the **Federal Register**.

(M) I am aware that U.S. law (including, but not limited to, 18 U.S.C. 1001) imposes criminal sanctions on individuals who knowingly and willfully make material false statements to the U.S. government.

Signature

{NAME OF COMPANY OFFICIAL}

{TITLE OF COMPANY OFFICIAL}

{DATE}

[FR Doc. 2024-17473 Filed 8-6-24; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-552-833]

Raw Honey From the Socialist Republic of Vietnam: Final Results of Antidumping Duty Changed Circumstances Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds the Socialist Republic of Vietnam (Vietnam) remains a non-market economy (NME) country for purposes of U.S. antidumping duty (AD) law due to the sustained and pervasive government influence over its country's economic activities.

DATES: Applicable August 7, 2024.

FOR FURTHER INFORMATION CONTACT:

Chien-Min Yang, Office of Policy, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-5484.

SUPPLEMENTARY INFORMATION:

Background

Commerce determined that Vietnam was an NME country under the U.S. AD law in 2002. Since then, Commerce has consistently treated Vietnam as an NME in all AD investigations and administrative reviews involving imported products from Vietnam.

On September 8, 2023, the Government of Vietnam (GOV) submitted a letter to Commerce requesting a review of Vietnam's status as an NME country within the context of a changed circumstances review (CCR) of the AD order on raw honey from Vietnam.¹ In response, Commerce initiated a NME CCR and published the initiation in the **Federal Register** on October 30, 2023.² This review examines whether Vietnam remains an NME country for purposes of the AD law, in accordance with sections 751(b) and 771(18)(C)(ii) of the Tariff Act of 1930, as amended (the Act).

To ensure full public and interested party participation in this inquiry, Commerce invited public comment on Vietnam's economic status as an NME country. All comments and rebuttal

comments were received by December 21, 2023, and February 1, 2024, respectively. Invitations for comments, along with the comments and rebuttal comments themselves, have remained accessible using the Federal eRulemaking portal at <https://www.regulations.gov> under Docket Number ITA-2023-0010.

On March 8, 2024, Commerce received new factual information from several domestic industries claiming that the GOV submitted false statements and omitted material facts regarding Vietnam's alleged reforms in the context of the ongoing review of Vietnam's status as an NME country.³ Given that Commerce has the inherent authority to protect the integrity of its proceedings, it accepted the alleged information as part of the administrative record and allowed all other interested parties as well as the public to comment on these allegations until April 5, 2024.⁴

On May 8, 2024, Commerce also held a public hearing regarding the CCR of Vietnam's status as an NME country.⁵ This hearing allowed the interested parties and the general public who participated in the proceeding to express their views.

Analysis of Comments Received

Commerce's analysis of the issues raised by parties to this CCR regarding Vietnam's status as a non-market economy country is included in the NME Analysis Memorandum.⁶ The NME Analysis Memorandum is a public document 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 NME Analysis Memorandum can be accessed directly

³ See Domestic Interested Parties' Letter, "Raw Honey from the Socialist Republic of Vietnam-Comments on the Government of Vietnam's False Statements and Material Omissions," dated March 8, 2024. The domestic interested parties are: Catfish Farmers of America and individual U.S. catfish processors America's Catch, Inc., Alabama Catfish, LLC d/b/a Harvest Select Catfish, Inc., Consolidated Catfish Companies, LLC d/b/a Country Select Catfish, Delta Pride Catfish, Inc., Guidry's Catfish, Inc., Heartland Catfish Company, Magnolia Processing, Inc. d/b/a Pride of the Pond, and Simmons Farm raised Catfish, Inc.

⁴ See Memorandum, "Changed Circumstances Review of the Socialist Republic of Vietnam's Status as a Non-market Economy Country: Extension of Time to File Rebuttal Comments," dated March 29, 2024.

⁵ See Hearing Transcript, "Public Hearing," dated May 8, 2024.

⁶ See Memorandum, "Review of Vietnam's Status as a Non-market Economy Country," dated concurrently with this notice (NME Analysis Memorandum).

¹ See GOV's Letter, "Request for the U.S. Commerce to Initiate a Changed Circumstances Review," dated September 8, 2023.

² See *Raw Honey from the Socialist Republic of Vietnam: Initiation of Antidumping Duty Changed Circumstances Review*, 88 FR 74152 (October 30, 2023).

at <https://access.trade.gov/public/FRNoticesListLayout.aspx>.

Final Results of Changed Circumstances Review

This CCR was conducted pursuant to section 771(18)(A) of the Act, which defines the term “non-market economy country” as a foreign country determined by Commerce not to “operate on market principles of cost or pricing structures, so that sales of merchandise in such country do not reflect the fair value of the merchandise.” Section 771(18)(B) of the Act lists six factors Commerce must consider in any inquiry made under section 771(18)(A) of the Act, and under section 771(18)(C)(i) of the Act, a country’s NME status remains in effect until revoked.

Section 771(18)(B) of the Act requires that Commerce take into account: (1) the extent to which the currency of the foreign country is convertible into the currency of other countries; (2) the extent to which wage rates in the foreign country are determined by foreign bargaining between labor and management; (3) the extent to which joint ventures or other investments by firms of other foreign countries are permitted in the foreign country; (4) the extent of government ownership or control of the means of production; (5) the extent of government control over the allocation of resources and over the price and output decisions of enterprises; and (6) such other factors as the administering authority (*i.e.*, Commerce) considers appropriate.

Since Commerce’s Vietnam NME Determination (2002),⁷ the GOVN has undertaken notable market-oriented reforms to promote the development of a more market-based economic system. These reforms have helped make its national currency, the dong, more readily convertible, increased Vietnam’s openness to foreign investment, and gradually reduced government ownership over the means of production within the economy.

Despite these market-oriented reforms, the GOVN remains entrenched in many aspects of the Vietnamese economy. The State Bank of Vietnam is still not independent and continues to intervene in the foreign exchange market to influence the value of the dong. Labor unions remain dominated by the state-controlled Vietnam General Confederation of Labor, hindering genuine collective bargaining and

ultimately creating conditions for suppressed wages and labor costs. Although Vietnam has taken steps to make its overall foreign direct investment environment more attractive, market access barriers, regulatory transparency, and restrictions on corporate control and foreign ownership persist.

In addition to the above referenced points, Vietnam’s economy is still characterized by significant state ownership and control over the means of production, most notably over companies and land. The GOVN continues to play a significant role over the pricing and allocation of credit in Vietnam. State-owned enterprises (SOE) command a disproportionate amount of lending credit, among other structural advantages, despite the SOE’s relatively low efficiency levels compared to their private-sector counterparts. The GOVN also uses state-directed planning to communicate its objectives for the economy in terms of business outcomes and resource allocations, and pervasive government price controls continue to influence final prices of goods in Vietnam. Finally, the Communist Party of Vietnam’s influence over the judicial system and persistent challenges with corruption continue to undermine some of Vietnam’s reform initiatives.

In sum, while Vietnam has implemented notable market-oriented reforms, the extent of government involvement in the economy continues to distort market conditions, rendering Vietnamese prices and costs unusable for U.S. antidumping duty calculations. Therefore, based on the totality of the six factors analyzed, Commerce determines that Vietnam remains a non-market economy for purposes of U.S. AD law.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(b) and 771(18)(C)(ii) of the Act.

Dated: August 1, 2024.

Ryan Majerus,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–17418 Filed 8–6–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE167]

International Whaling Commission; 69th Meeting; Announcement of Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: This notice announces the date, time, and access information of the public meeting being held, in a virtual format, prior to the 69th meeting of the International Whaling Commission (IWC). The meeting is open to U.S. citizens only.

DATES: The public meeting will be held August 26, 2024, at 3 p.m. EDT.

ADDRESSES: The meeting will be held in a virtual/online format. Attendees must register in advance to attend the public meeting at the following link: <https://noaanmfs-meets.webex.com/web/link/register/r938f01ef8632b12ac92ef60c5ba811f2>.

FOR FURTHER INFORMATION CONTACT:

Madison Harris, Madison.Harris@noaa.gov or (301) 427–8371.

SUPPLEMENTARY INFORMATION: The Secretary of Commerce is responsible for implementing the domestic obligations of the United States under the International Convention for the Regulation of Whaling, 1946. The U.S. IWC Commissioner has responsibility for the preparation and negotiation of U.S. positions on international issues concerning whaling and for all matters involving the IWC. The U.S. IWC Commissioner is staffed by the Department of Commerce and assisted by the Department of State, the Marine Mammal Commission, and other U.S. Government agencies.

The IWC will hold its 69th meeting in Lima, Peru on September 23–27, 2024. Additional information about the IWC meeting, including a draft agenda for the meeting, is posted on the IWC Secretariat’s website at <https://iwc.int/events-and-workshops/iwc69-2024>.

NOAA will hold a public meeting on August 26, 2024, to discuss the tentative U.S. positions for the September 2024 IWC meeting. Any U.S. citizen with an identifiable interest in U.S. whale conservation and management policy may participate, but NOAA reserves the authority to inquire about the interests of any person who appears at the meeting and determine the

⁷ See Memorandum, “Antidumping Duty Investigation of Certain Frozen Fish Fillets from the Socialist Republic of Vietnam—Determination of Market Economy Status,” dated November 8, 2002 (Commerce Vietnam NME Determination (2002)).

appropriateness of that person's participation. In particular, persons who represent foreign interests may not attend. Persons deemed by NOAA to be ineligible to attend will be asked to leave the meeting. These measures are necessary to limit statements to those conveying U.S. interests.

The August 26 meeting will be held at 3 p.m. EDT in a virtual format. Meeting access and conferencing platform information will be sent to those who register. To participate, interested persons must register in advance via the following link: <https://noaanmfsmeets.webex.com/weblink/register/r938f01ef8632b12ac92ef60c5ba811f>.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Madison Harris, Madison.Harris@noaa.gov or (301) 427-8371, by August 12, 2024.

Dated: August 2, 2024.

Alexa Cole,

Director, Office of International Affairs, Trade, and Commerce, National Marine Fisheries Service.

[FR Doc. 2024-17427 Filed 8-6-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XE163]

Endangered and Threatened Species; Notice of Initiation of a 5-Year Review for the Mediterranean Monk Seal

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

ACTION: Notice of initiation; request for information.

SUMMARY: The National Marine Fisheries Service (NMFS) announces the initiation of a 5-year review for the Mediterranean monk seal (*Monachus monachus*). NMFS is required by the Endangered Species Act (ESA) to conduct 5-year reviews to ensure that the listing classifications of species are accurate. The 5-year review must be based on the best scientific and commercial data available at the time of the review. We request submission of any such information on the Mediterranean monk seal, particularly information on the status, threats, and recovery of the species that has become available since the previous review in 2017.

DATES: To allow us adequate time to conduct this review, we must receive your information no later than October 7, 2024.

ADDRESSES: You may submit information on this document, identified by NOAA-NMFS-2024-0092, by the following method:

- **Electronic Submission:** Submit electronic information via the Federal e-Rulemaking Portal. Go to <https://www.regulations.gov> and enter NOAA-NMFS-2024-0092 in the Search box. Click on the "Comment" icon, complete the required fields, and enter or attach your comments.

Instructions: Information sent by any other method, to any other address or individual, or received after the end of the specified period, may not be considered by NMFS. All information received is a part of the public record and will generally be posted for public viewing on <https://www.regulations.gov> without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive or protected information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous submissions (enter "N/A" in the required fields if you wish to remain anonymous).

FOR FURTHER INFORMATION CONTACT:

Kristen Koyama (301) 427-8456 or Kristen.Koyama@noaa.gov.

SUPPLEMENTARY INFORMATION: This notice announces our review of the Mediterranean monk seal (*Monachus monachus*) listed as endangered under the ESA. Section 4(c)(2)(A) of the ESA requires that we conduct a review of listed species at least once every 5 years. The species was previously reviewed in 2017. The regulations in 50 CFR 424.21 require that we publish a notice in the **Federal Register** announcing species currently under active review. On the basis of such reviews under section 4(c)(2)(B), we determine whether any species should be removed from the list (i.e., delisted) or reclassified from endangered to threatened or from threatened to endangered (16 U.S.C. 1533(c)(2)(B)). As described by the regulations in 50 CFR 424.11(e), the Secretary shall delist a species if the Secretary determines based on consideration of the factors and standards set forth in paragraph (c) of that section, that the best scientific and commercial data available substantiate that: (1) the species is extinct; (2) the species has recovered to the point at which it no longer meets the definition of an endangered species or a threatened species; (3) new information that has

become available since the original listing decision shows the listed entity does not meet the definition of an endangered species or a threatened species; or (4) new information that has become available since the original listing decision shows the listed entity does not meet the definition of a species. Any change in Federal classification would require a separate rulemaking process.

Background information on the Mediterranean monk seal is available on the NMFS website at: <https://www.fisheries.noaa.gov/species/mediterranean-monk-seal>.

Public Solicitation of New Information

To ensure that the review is complete and based on the best available scientific and commercial information, we are soliciting new information from the public, governmental agencies, Tribes, the scientific community, industry, environmental entities, and any other interested parties concerning the status of *Monachus monachus*. Categories of requested information include: (1) species biology including, but not limited to, population trends, distribution, abundance, demographics, and genetics; (2) habitat conditions including, but not limited to, amount, distribution, and important features for conservation; (3) status and trends of threats to the species and its habitats; (4) conservation measures that have been implemented that benefit the species, including monitoring data demonstrating effectiveness of such measures; and (5) other new information, data, or corrections including, but not limited to, taxonomic or nomenclatural changes and improved analytical methods for evaluating extinction risk.

If you wish to provide information for the review, you may submit your information and materials electronically (see **ADDRESSES** section). We request that all information be accompanied by supporting documentation such as maps, bibliographic references, or reprints of pertinent publications.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: August 1, 2024.

Angela Somma,

Chief, Endangered Species Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2024-17401 Filed 8-6-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

[RTID 0648-XE026]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Site Characterization Surveys Off New York and New Jersey in the New York Bight

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

ACTION: Notice; request for comments on proposed renewal incidental harassment authorization.

SUMMARY: NMFS received a request from Attentive Energy, LLC (Attentive Energy), a company registered in Delaware, for the renewal of their previously issued incidental harassment authorization (IHA) (hereafter, the “initial IHA”) to take marine mammals incidental to marine site characterization surveys in coastal waters off of New York and New Jersey in the New York Bight, specifically within the Bureau of Ocean Energy Management (BOEM) Commercial Lease of Submerged Lands for Renewable Energy Development on the Outer Continental Shelf (Lease) Area OCS-A 0538 and associated export cable route (ECR) area. Pursuant to the Marine Mammal Protection Act (MMPA), prior to issuing the initial IHA, NMFS requested comments on both the proposed IHA and the potential for renewing the initial authorization if certain requirements were satisfied. The renewal requirements have been satisfied, and NMFS is now providing an additional 15-day comment period to allow for any additional comments on the proposed renewal not previously provided during the initial 30-day comment period.

DATES: Comments and information must be received no later than August 22, 2024.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, and should be submitted via email to ITP.Potlock@noaa.gov.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. Attachments to comments will be accepted in Microsoft

Word, Excel or Adobe PDF file formats only. All comments received are a part of the public record and will generally be posted online at <https://www.fisheries.noaa.gov/permit/incidental-take-authorizations-under-marine-mammal-protection-act> without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

Electronic copies of the original application, renewal request, and supporting documents (including NMFS **Federal Register** notices of the original proposed and final authorizations, and the previous IHA), as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/action/incidental-take-authorization-attentive-energy-llc-marine-site-characterization-surveys-0>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Kelsey Potlock, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:**Background**

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are promulgated or, if the taking is limited to harassment, an incidental harassment authorization is issued.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stocks for taking for certain subsistence uses (referred to here as “mitigation

measures”). NMFS must also prescribe requirements pertaining to monitoring and reporting of such takings. The definition of key terms such as “take,” “harassment,” and “negligible impact” can be found in the MMPA and the NMFS’s implementing regulations (see 16 U.S.C. 1362; 50 CFR 216.103).

NMFS’ regulations implementing the MMPA at 50 CFR 216.107(e) indicate that IHAs may be renewed for additional periods of time not to exceed 1 year for each reauthorization. In the notice of proposed IHA for the initial IHA, NMFS described the circumstances under which we would consider issuing a renewal for this activity, and requested public comment on a potential renewal under those circumstances.

Specifically, on a case-by-case basis, NMFS may issue a one-time 1-year renewal of an IHA following notice to the public providing an additional 15 days for public comments when: (1) up to another year of identical, or nearly identical, activities as described in the Detailed Description of Specified Activities section of the initial IHA issuance notice is planned; or (2) the activities as described in the Description of the Specified Activities and Anticipated Impacts section of the initial IHA issuance notice would not be completed by the time the initial IHA expires and a renewal would allow for completion of the activities beyond that described in the **DATES** section of the notice of issuance of the initial IHA, provided all of the following conditions are met:

1. A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1 year from expiration of the initial IHA).

2. The request for renewal must include the following:

- An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (e.g., reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and

- A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

3. Upon review of the request for renewal, the status of the affected

species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

An additional public comment period of 15 days (for a total of 45 days), with direct notice by email, phone, or postal service to commenters on the initial IHA, is provided to allow for any additional comments on the proposed renewal. A description of the renewal process may be found on our website at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-harassment-authorization-renewals>. Any comments received on the potential renewal, along with relevant comments on the initial IHA, have been considered in the development of this proposed IHA renewal, and a summary of agency responses to applicable comments is included in this notice. NMFS will consider any additional public comments prior to making any final decision on the issuance of the requested renewal, and agency responses will be summarized in the final notice of our decision.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216-6A, NMFS must review our proposed action (*i.e.*, the renewal of an IHA) with respect to potential impacts on the human environment. This action is consistent with categories of activities identified in “Categorical Exclusion B4” (incidental take authorizations with no anticipated serious injury or mortality) of the “Companion Manual for NOAA Administrative Order 216-6A”, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not

identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS determined that the issuance of the initial IHA qualified for categorical exclusion from further NEPA review. NMFS has preliminarily determined that the application of this categorical exclusion remains appropriate for this renewal IHA. We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the request to renew the IHA.

History of Request

On June 20, 2023, NMFS issued an IHA to Attentive Energy to take marine mammals incidental to conducting marine site characterization surveys in coastal waters off of New York and New Jersey in the New York Bight region, specifically within the BOEM Lease Area OCS-A-0538 and associated ECR area (88 FR 41888, June 28, 2023), effective from June 20, 2023, through June 19, 2024. On May 24, 2024, NMFS received an application for the renewal of that initial IHA. As described in the application for renewal IHA, the activities for which incidental take is requested consist of activities that were analyzed for the initial 2023 authorization, but would not be completed prior to its expiration. As required, the applicant also provided a preliminary monitoring report which confirms that the applicant has implemented the required mitigation and monitoring, and which also shows that no impacts of a scale or nature not previously analyzed or authorized have occurred as a result of the activities conducted.

Description of the Specified Activities and Anticipated Impacts

Under the initial IHA, Attentive Energy planned to conduct marine site characterization surveys, including high-resolution geophysical (HRG) surveys, in coastal waters off of New Jersey and New York in the New York Bight, specifically within the BOEM

Lease Area OCS-A 0538 and associated ECR areas. Challenges and delays with procurement, mobilization, and downtime contributed to less survey being completed during the initial IHA period than anticipated.

The surveys were designed to obtain data sufficient to meet BOEM guidelines for providing geophysical, geotechnical, and geo-hazard information for site assessment plan surveys and/or construction and operations plan development. The objective of the surveys was to support the site characterization, siting, and engineering design of offshore wind project facilities including wind turbine generators, offshore substations, and submarine cables within the Lease Area. At least two survey vessels would operate as part of the planned surveys with a maximum of two nearshore (<20 meters (m); <65.6 feet (ft)) vessels and a maximum of two offshore (≥20 m (≥65.6 ft)) vessels operating concurrently.

Attentive Energy is proposing to continue to conduct these survey activities, as per the initial IHA application, up to approximately 6,936 kilometers (km; 4,309.8 miles (mi)) of trackline. This is a subset of the survey trackline included in the initial IHA; the initial survey plan included 21,745 km (13,511.72 mi) across the entire project area (maximum-case scenario), which was split up by approximately 14,025 km (8,714.7 mi) in the Lease Area and 7,720 km (4,797 mi) in the ECR area. We note here that the Project Area is minimally expanded (primarily to the south) in the current survey plan as compared with the survey plan associated with the initial IHA (see figure 1); however, per discussions with Attentive Energy, this expanded area will not result in the need to survey additional tracklines. NMFS has determined that this slight change to the survey area constitutes a minor change that does not affect the previous analyses, mitigation and monitoring requirements, or take estimates.

BILLING CODE 3510-22-P

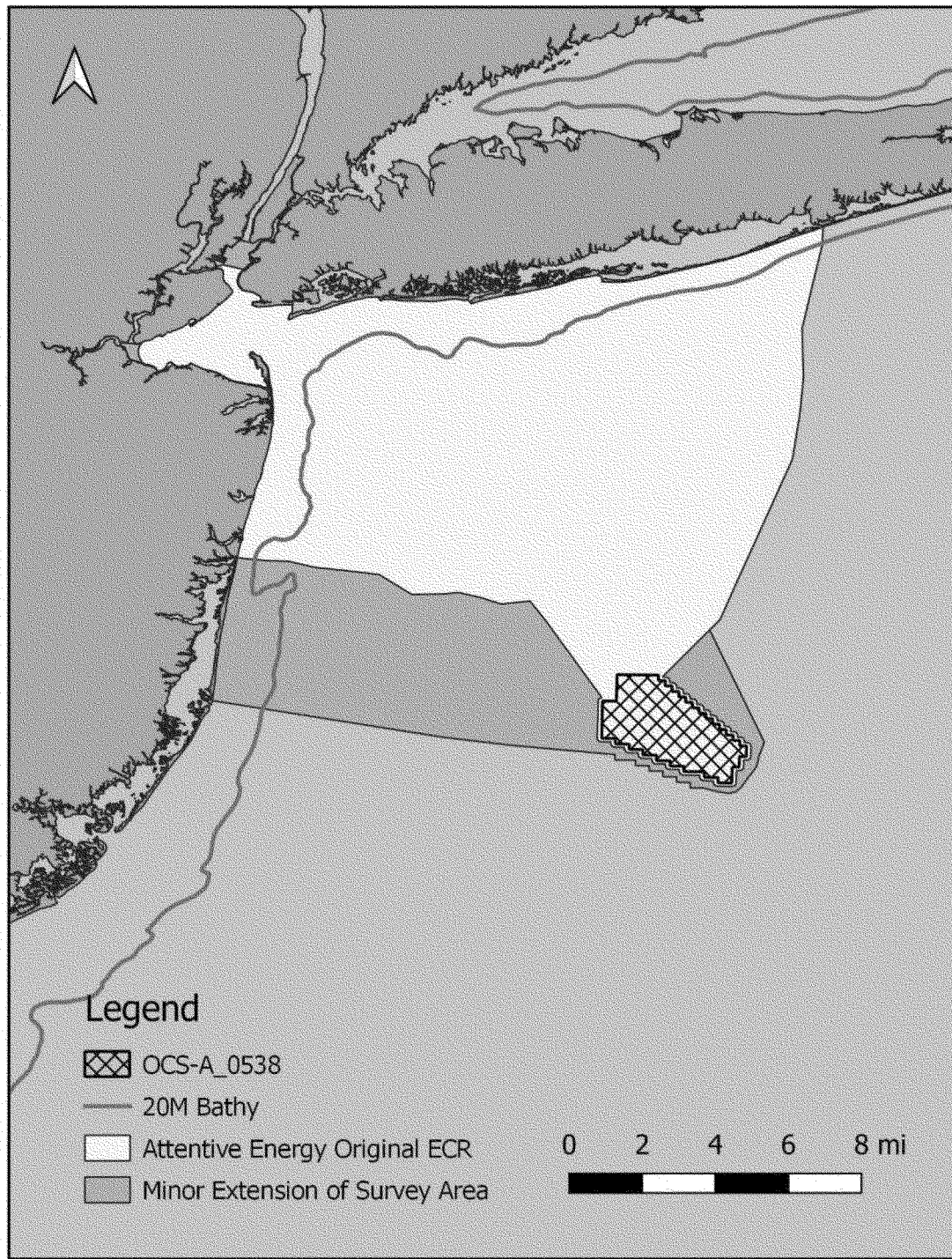


Figure 1 – Planned Survey Area

BILLING CODE 3510-22-C

The survey effort in the proposed project would be conducted over up to approximately 80 days across two vessels (in the same manner as the initial IHA). The survey effort proposed for this renewal IHA conservatively assumes that sparker acoustic sources, which have the largest estimated Level

B harassment area, would be used exclusively. In reality, other sources with smaller estimated harassment areas would be used during some proportion of survey effort.

The potential impacts of Attentive Energy's proposed activity on marine mammals would involve acoustic

stressors and are unchanged from the impacts described in the **Federal Register** notice for the proposed IHA (88 FR 41888, June 28, 2023). Acoustic stressors include effects of the marine site characterization surveys. Underwater disturbances from Attentive Energy's proposed activities has the

potential to result in Level B harassment of marine mammals in the specified geographic region.

This proposed renewal IHA is for the remainder of work that was not completed by the expiration of the initial IHA. This proposed renewal IHA would authorize incidental take, by Level B harassment only, of 15 species (16 stocks) of marine mammals for a subset of the initially planned marine site characterization survey activities to be completed in approximately 1 year, in a substantially similar area, and using the same survey methods and acoustic sources to those described in the initial IHA application. Therefore, the anticipated effects on marine mammals and the affected stocks also remain the same. All mitigation, monitoring, and reporting measures would remain exactly as described in the **Federal Register** notice of the issued initial IHA (88 FR 41888, June 28, 2023).

Detailed Description of the Activity

A detailed description of the marine site characterization survey activities for which incidental take is proposed here may be found in the **Federal Register** notice of the proposed IHA (88 FR 41888, June 28, 2023). The location and nature of these activities, including the types of equipment planned for use, are nearly identical to those described in the previous notice (as referenced in the request from Attentive Energy, available at: [https://www.fisheries.noaa.gov/action/incidental-take-authorization-](https://www.fisheries.noaa.gov/action/incidental-take-authorization-attentive-energy-llc-marine-site-characterization-surveys-0)

attentive-energy-llc-marine-site-characterization-surveys-0). The proposed renewal would be effective for a period not exceeding 1 year from the date of the expiration of the initial IHA.

The only change to this project would be the aforementioned slight expansion of the survey area to the south of the initial project area, which consists of additional potential ECRs (refer back to figure 1). However, as described above, Attentive Energy intends to maintain the same amount of remaining trackline, using the same number of vessels, and using the same acoustic sources as previously analyzed (*i.e.*, boomers and sparkers).

Description of Marine Mammals

A description of the marine mammals in the area of the activities for which authorization of take is proposed here, including information on abundance, status, distribution, and hearing, may be found in the **Federal Register** notice of the proposed IHA for the initial authorization (88 FR 24553, April 21, 2023). Since the publication of the final **Federal Register** notice (88 FR 41888, June 28, 2023), NMFS has reviewed the monitoring data from the initial IHA, the draft 2023 SARs, which included updates to certain stock abundances since the initial IHA was issued, information on relevant unusual mortality events (UME), and other scientific literature. The draft 2023 SAR updated the population estimate (N_{best}) of North Atlantic right whales from 338

to 340 and annual mortality and serious injury from 31.2 to 27.2. The updated population estimate in the draft 2023 SAR is based upon sighting history through December 2021 (89 FR 5495, January 29, 2024). Total annual average observed North Atlantic right whale mortality during the period 2017–2021 was 7.1 animals and annual average observed fishery mortality was 4.6 animals, however, estimates of 27.2 total mortality and 17.6 fishery mortality account for undetected mortality and serious injury (89 FR 5495, January 29, 2024). In October 2023, NMFS released a technical report identifying that the North Atlantic right whale population size based on sighting history through 2022 was 356 whales, with a 95 percent credible interval ranging from 346 to 363 (Linden, 2023).

The draft 2023 SARs include updates for additional marine mammal species and stocks (*i.e.*, North Atlantic right whale, fin whale, sei whale, minke whale, sperm whale, Atlantic spotted dolphin, Atlantic white-sided dolphin, bottlenose dolphin (Western North Atlantic—Offshore stock), common dolphin, long-finned pilot whales, Risso's dolphin, harbor porpoise, and gray seal), which are specifically included in table 1 below. For species for which there has been no change between the finalization of the final 2022 SARs to the release of the draft 2023 SARs, NMFS has noted that below.

TABLE 1—SPECIES AND STOCKS^a LIKELY IMPACTED BY THE PROPOSED SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ^b	Stock abundance (CV, N_{min} , most recent abundance survey) ^c	PBR	Annual M/SI ^d
Order Artiodactyla—Cetacea—Superfamily Mysticeti (baleen whales)						
<i>Family Balaenidae:</i> North Atlantic right whale ^e .	<i>Eubalaena glacialis</i>	Western Atlantic	E, D, Y	340 (0, 337, 2021)	0.7	127.2
<i>Family Balaenopteridae</i> (rorquals):						
Fin whale	<i>Balaenoptera physalus</i>	Western North Atlantic	E, D, Y	6,802 (0.24, 5,573, 2021)	11	2.05
Humpback whale	<i>Megaptera novaeangliae</i>	Gulf of Maine	-	No changes.		
Minke whale	<i>Balaenoptera acutorostrata</i>	Canadian Eastern Coastal	-	21,968 (0.31, 17,002, 2021).	170	9.4
Sei whale	<i>Balaenoptera borealis</i>	Nova Scotia	E, D, Y	6,292 (1.02, 3,098, 2021)	6.2	0.6
Superfamily Odontoceti (toothed whales, dolphins, and porpoises)						
<i>Family Physeteridae:</i> Sperm whale	<i>Physeter macrocephalus</i>	North Atlantic	E, D, Y	5,895 (0.29, 4,639, 2021)	9.28	0.2
<i>Family Delphinidae:</i>						
Atlantic spotted dol- phin.	<i>Stenella frontalis</i>	Western North Atlantic	-	31,506 (0.28, 25,042, 2021).	250	0
Atlantic white-sided dolphin.	<i>Lagenorhynchus acutus</i>	Western North Atlantic	-	93,233 (0.71, 54,443, 2021).	544	28
Bottlenose dolphin	<i>Tursiops truncatus</i>	Western North Atlantic—Off- shore ^f .	-	64,587 (0.24, 52,801, 2021).	507	28
Common dolphin	<i>Delphinus delphis</i>	Northern Migratory Coastal	-	No changes.		
		Western North Atlantic	-	93,100 (0.56, 59,897, 2021).	1,452	414

TABLE 1—SPECIES AND STOCKS ^a LIKELY IMPACTED BY THE PROPOSED SPECIFIED ACTIVITIES—Continued

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ^b	Stock abundance (CV, Nmin, most recent abundance survey) ^c	PBR	Annual M/SI ^d
Long-finned pilot whale ^g .	<i>Globicephala melas</i>	Western North Atlantic	- , - , N	39,215 (0.30, 30,627, 2021).	306	5.7
Risso's dolphin	<i>Grampus griseus</i>	Western North Atlantic	- , - , N	44,067 (0.19, 30,662, 2021).	307	18
Family Phocoenidae (porpoises)						
Harbor porpoise	<i>Phocoena phocoena</i>	Gulf of Maine/Bay of Fundy	- , - , N	85,765 (0.53, 56,420, 2021).	649	145
Order Carnivora—Superfamily Pinnipedia						
Family Phocidae (earless seals):						
Gray seal ^h	<i>Halichoerus grypus</i>	Western North Atlantic	- , - , N	27,911 (0.20, 23,624, 2021).	1,512	4,570
Harbor seal	<i>Phoca vitulina</i>	Western North Atlantic		No changes.		

^aInformation on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (<https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies>).

^bEndangered Species Act (ESA) status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

^cNMFS' marine mammal stock assessment reports can be found online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>. CV is the coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

^dThese values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, ship strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

^eThe current SAR includes an estimated population (Nbest = 340) based on sighting history through December 2021 (<https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports>). In October 2023, NMFS released a technical report identifying that the North Atlantic right whale population size based on sighting history through 2022 was 356 whales, with a 95 percent credible interval ranging from 346 to 363 (Linden, 2023).

^fEstimates may include sightings of the coastal form.

^gKey uncertainties exist in the population size estimate for this species, including uncertain separation between short-finned and long-finned pilot whales, small negative bias due to lack of abundance estimate in the region between US and the Newfoundland/Labrador survey area, and uncertainty due to unknown precision and accuracy of the availability bias correction factor that was applied.

^hNMFS' stock abundance estimate (and associated PBR value) applies to the U.S. population only. Total stock abundance (including animals in Canada) is approximately 394,311. The annual M/SI value given is for the total stock.

On August 1, 2022, NMFS announced proposed changes to the existing North Atlantic right whale vessel speed regulations to further reduce the likelihood of mortalities and serious injuries to endangered North Atlantic right whales from vessel collisions, which are a leading cause of the species' decline and a primary factor in an ongoing Unusual Mortality Event (87 FR 46921, August 1, 2022). Should a final vessel speed rule be issued and become effective during the effective period of this proposed renewal IHA (or any other MMPA incidental take authorization), the authorization holder would be required to comply with any and all applicable requirements contained within the final rule. Specifically, where measures in any final vessel speed rule are more protective or restrictive than those in this or any other MMPA authorization, authorization holders would be required to comply with the requirements of the rule. Alternatively, where measures in this or any other MMPA authorization are more restrictive or protective than those in any final vessel speed rule, the measures in the MMPA authorization would remain in place. These changes would become effective immediately

upon the effective date of any final vessel speed rule and would not require any further action on NMFS's part.

Based on the information presented above, NMFS has determined that neither this nor any other new information affects which species or stocks have the potential to be affected or any other pertinent information in the Description of the Marine Mammals in the Area of Specified Activities contained in the supporting documents for the initial proposed (88 FR 24553, April 21, 2023) and final (88 FR 41888, June 28, 2023) **Federal Register** notices.

Potential Effects on Marine Mammals and Their Habitat

A description of the potential effects of the specified activity on marine mammals and their habitat for the activities for which an authorization of incidental take is proposed here may be found in the **Federal Register** notice for the proposed IHA for the initial authorization (88 FR 24553, April 21, 2023). NMFS has reviewed the monitoring data from the initial IHA, recent draft SAR, information on relevant Unusual Mortality Events, and other scientific literature, and determined that there is no new

information that affects our initial analysis of impacts on marine mammals and their habitat.

Estimated Take

A detailed description of the methods and inputs used to estimate take for the specified activity are found in the **Federal Register** notices of the proposed (88 FR 24553, April 21, 2023) and final (88 FR 41888, June 28, 2023) IHA for the initial authorization. Specifically, the source levels, days of operation, and marine mammal density/occurrence data applicable to this authorization remain unchanged from the previously issued IHA. Similarly, the stocks taken, methods of take, and types of take remain unchanged from the previously issued IHA. The number of takes proposed for authorization in this renewal IHA are a subset of the initial authorized takes that better represent the amount of activity that Attentive Energy has left to complete. The percentage of trackline remaining, for most stocks, is approximately 32 percent. The most variation in effort exists for both the Migratory Coastal and Offshore stocks of bottlenose dolphins as the estimated trackline remaining is based on the estimated overlapping

trackline with the cutoffs for the 20-m (65.6-ft) isobath (*i.e.* >20-m (>65.6-ft) isobath for the Offshore stock, <20-m

(<65.6-ft) isobath for the Migratory Coastal stock). All of these estimated takes, which reflect the estimated

remaining tracklines and survey days, are indicated below in table 2.

TABLE 2—PROPOSED NUMBER OF TAKES BY LEVEL B HARASSMENT BY SPECIES AND STOCKS, AND PERCENT OF TAKE BY STOCK

Common name	Population abundance	Percentage of trackline remaining in relevant habitat	Takes proposed for authorization based on remaining trackline	Percentage of population proposed to be taken
North Atlantic right whale	340	32	4	1.18
Fin whale	6,802	32	12	0.18
Humpback whale	1,396	32	8	0.57
Minke whale	21,968	32	57	0.26
Sei whale	6,292	32	4	0.06
Sperm whale	5,895	32	1	0.02
Atlantic spotted dolphin	31,506	32	28	0.09
Atlantic white-sided dolphin	93,233	32	66	0.07
Bottlenose dolphin—Western North Atlantic Offshore	64,587	28	489	0.76
Bottlenose dolphin—Northern Migratory Coastal	6,639	93	362	5.45
Common dolphin	93,100	32	658	0.71
Long-finned pilot whale	39,215	32	7	0.02
Risso's dolphin	44,067	32	7	0.02
Harbor porpoise	85,765	32	350	0.41
Gray seal	27,911	32	511	1.83
Harbor seal	61,336	32	511	0.83

Here, NMFS have utilized the draft 2023 SARs, rather than the final 2022 SARs, as the draft 2023 SARs represent the best available science and the most recently available data.

Description of Proposed Mitigation, Monitoring and Reporting Measures

The proposed mitigation, monitoring, and reporting measures included as requirements in this authorization are identical to those included in the **Federal Register** notice announcing the issuance of the initial IHA (88 FR 41888, June 28, 2023), and the discussion of the least practicable adverse impact included in that document and the **Federal Register** notice of the proposed IHA remains accurate (88 FR 24553, April 21, 2023). The following measures are proposed for this renewal:

- **Ramp-up:** A ramp-up procedure would be used for geophysical survey equipment capable of adjusting energy levels (*i.e.*, any acoustic source with a non-binary switch) at the start or re-start of survey activities;

- **Protected Species Observers (PSOs):** A minimum of one NMFS-approved PSO must be on duty and conducting visual observations at all times during daylight hours (*i.e.*, from 30 minutes prior to sunrise through 30 minutes following sunset). Two PSOs would be on duty during nighttime operations.

- **Pre-Operation Clearance Protocols:** Prior to initiating HRG survey activities, Attentive Energy would be required to implement a 30-minute pre-operation

clearance period. If any marine mammals are detected within the Exclusion Zones prior to or during ramp-up, the HRG equipment would be shut down (as described below);

- **Shutdown Zones:** If an HRG source is active and a marine mammal is observed within or entering a relevant shutdown zone, an immediate shutdown of the HRG survey equipment would be required. We note that this shutdown requirement would be waived for certain genera of small delphinids (*i.e.*, *Delphinus*, *Lagenorhynchus*, *Stenella*, or *Tursiops*) and pinnipeds;

- **Vessel Strike Avoidance Measures:** 500 m (1,640 ft) separation distances for North Atlantic right whales and other large ESA-listed whales (*i.e.*, fin whale, sei whale, and sperm whale), 100 m (328 ft) for other non-ESA listed baleen whales (*i.e.*, minke whale and humpback whale), and 50 m (164 ft) for all other marine mammals); as well as restricted vessel speeds and operational maneuvers; and

- **Reporting:** Attentive Energy would submit a marine mammal report within 90 days following their completion of the surveys.

Comments and Responses

NMFS published a notice of a proposed IHA (88 FR 24553, April 21, 2023) and solicited public comments on both our proposal to issue the initial IHA for marine site characterization surveys and on the potential for a renewal IHA, should certain

requirements be met. All public comments were addressed in the notice announcing the issuance of the initial IHA (88 FR 41888, June 28, 2023) and none of the comments specifically pertained to the potential renewal of the 2023 IHA.

Preliminary Determinations

Attentive Energy's proposed activities consist of a subset of activities analyzed in the initial IHA. In analyzing the effects of the activities for the initial IHA, NMFS determined that Attentive Energy's activities would have a negligible impact on the affected species or stocks and that authorized take numbers of each species or stock were small relative to the relevant stocks (*e.g.*, less than one-third the abundance of all stocks). The mitigation measures and monitoring and reporting requirements as described above are identical to the initial IHA.

NMFS has preliminarily concluded that there is no new information suggesting that our analysis or findings should change from those reached for the initial IHA. This includes consideration of the draft 2023 SAR estimated abundance of the North Atlantic right whale stock and other stocks, as shown above in table 1. Specifically, NMFS is proposing to authorize 4 takes of North Atlantic right whales by Level B harassment only, and the impacts resulting from the project's activities are neither reasonably expected nor reasonably likely to

adversely affect the stock through effects on annual rates of recruitment or survival. Additionally, only about 1.2 percent of this stock's abundance is proposed for take by Level B harassment.

Based on the information and analysis contained here and in the referenced documents, NMFS has determined the following: (1) the required mitigation measures will affect the least practicable adverse impact on marine mammal species or stocks and their habitat; (2) the proposed takes for authorization would have a negligible impact on the affected marine mammal species or stocks; (3) the takes proposed for authorization represent small numbers of marine mammals relative to the affected stock abundances; (4) Attentive Energy's activities will not have an unmitigable adverse impact on taking for subsistence purposes as no relevant subsistence uses of marine mammals are implicated by this action; and (5) appropriate monitoring and reporting requirements are included. This includes consideration of the estimated abundance of 13 stock(s) decreasing or increasing slightly, specific to each stock.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally, in this case with the NMFS Greater Atlantic Regional Fisheries Office (GARFO), whenever we propose to authorize take for endangered or threatened species.

NMFS Office of Protected Resources has proposed to authorize the incidental take of four species of marine mammals which are listed under the ESA (the North Atlantic right, fin, sei, and sperm whale) and has determined that these activities fall within the scope of activities analyzed in GARFO's programmatic consultation regarding geophysical surveys along the U.S. Atlantic coast in the three Atlantic Renewable Energy Regions (completed June 29, 2021; revised September 2021). The proposed renewal IHA provides no new information about the effects of the action, nor does it change the extent of effects of the action, or present any other basis to require re-initiation of consultation with NMFS GARFO; therefore, the ESA consultation has been

satisfied for the initial IHA and remains valid for the Renewal IHA.

Proposed Renewal IHA and Request for Public Comment

As a result of these preliminary determinations, NMFS proposes to issue a renewal IHA to Attentive Energy for conducting marine site characterization surveys in coastal waters off of New York and New Jersey in the New York Bight, from the date of issuance through June 19, 2025, provided the previously described mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed and final initial IHA can be found at <https://www.fisheries.noaa.gov/action/incidental-take-authorization-attentive-energy-llc-marine-site-characterization-surveys-0>. We request comment on our analyses, the proposed renewal IHA, and any other aspect of this notice. Please include with your comments any supporting data or literature citations to help inform our final decision on the request for MMPA authorization.

Dated: August 2, 2024.

Kimberly Damon-Randall,
Director, Office of Protected Resources,
National Marine Fisheries Service.

[FR Doc. 2024–17454 Filed 8–6–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE088]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Weyerhaeuser Company for Their Log Export Dock Project on the Columbia River Near Longview, Washington

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: In accordance with the regulations implementing the Marine Mammal Protection Act (MMPA) as amended, notification is hereby given that NMFS has issued an incidental harassment authorization (IHA) to Weyerhaeuser Company (Weyerhaeuser) to incidentally harass marine mammals during construction activities associated with the Log Export Dock Project on the Columbia River near Longview, Washington.

DATES: This authorization is effective from September 1, 2025 through August 31, 2026.

ADDRESSES: Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>. In case of problems accessing these documents, please call the contact listed below.

FOR FURTHER INFORMATION CONTACT: Rachel Wachtendonk, Office of Protected Resources (OPR), NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as “mitigation”); and requirements pertaining to the monitoring and reporting of the takings. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

Summary of Request

On October 29, 2023, NMFS received a request from Weyerhaeuser for an IHA to take marine mammals incidental to pile driving and removal activities associated with the Log Export Dock

Project on the Columbia River near Longview, Washington. Following NMFS' review of the application, Weyerhaeuser submitted a revised version on March 14, 2024. The application was deemed adequate and complete on April 16, 2024.

Weyerhaeuser's request is for take of harbor seal (*Phoca vitulina*), California sea lion (*Zalophus californicus*), and Steller sea lion (*Eumatopius jubatus*) by Level B harassment and, for harbor seals, by Level A harassment. Neither Weyerhaeuser nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of the Specified Activity

Overview

Weyerhaeuser is planning the partial demolition and replacement of the existing Log Export dock on the Columbia River, near Longview, Washington. The project includes impact and vibratory pile installation and vibratory pile removal. Vibratory and impact pile driving are expected to start in September 2025 and take about 120 days of in-water work within the U.S. Army Corps of Engineers (USACE) and the U.S. Fish and Wildlife Service (USFWS)-designated in-water work window (September 1, 2025–January 3, 2026). All pile installation will occur during the work window, which would minimize potential exposure of Endangered Species Act (ESA) listed fish species from impact pile driving. An additional 30 days of vibratory pile removal may occur outside the window.

The demolition and replacement of the 612-foot (ft), or 186.5-meter (m) berth A of the Log Export Dock would include the removal of 983 16-inch (in), or 0.41-m, timber piles, 36 16-in (0.41-m) steel pipe piles, 10 12-in (0.30-m) steel H-piles, 7 12-in (0.30-m) steel pipe piles, and 20 14- or 16-in (0.36- or 0.41-m) steel fender piles. Existing piles would be primarily removed by the deadpull method, with piles being removed with the vibratory hammer if the deadpull is unsuccessful. Broken or damaged piles would be cut at the mudline. It is anticipated that 75 percent of the existing 983 timber piles will be removed by the deadpull method, with the remaining 246 being removed with the vibratory hammer. The new structure will be supported by the installation of 325 30-in (0.76-m) steel pipe piles. In addition, up to 26 24-in (0.61 m) temporary steel pipe piles may be installed and removed to support permanent pile installation. Temporary and permanent piles would be initially installed with a vibratory

hammer, with permanent piles being followed by an impact hammer to embed them to their final depth. To reduce underwater noise produced by impact pile driving, an unconfined bubble curtain will be used during impact pile installation.

In order to maintain project schedules, it is possible that multiple pieces of equipment would operate at the same time within the project area. Piles may be driven on the same day or, less commonly, at the same time, by two impact hammers, one impact hammer and one vibratory hammer, or two vibratory hammers. The method of installation, and whether concurrent pile driving scenarios will be implemented, will be determined by the construction crew once the project has begun. Therefore, the total take estimate reflects the worst-case scenario (both hammers installing 30-in steel pipe piles) for the proposed project. However, the most likely scenario is the vibratory removal of a 16-in timber pile at the same time as installing a 30-in steel pipe piles by vibratory or impact methods.

A detailed description of the planned construction project is provided in the **Federal Register** notice for the proposed IHA (89 FR 48579, June 7, 2024). Since that time, no changes have been made to the planned activities. Therefore, a detailed description is not provided here. Please refer to that **Federal Register** notice for the description of the specific activity.

Comments and Responses

A notice of NMFS' proposal to issue an IHA to Weyerhaeuser was published in the **Federal Register** on June 7, 2024 (89 FR 48579). That notice described, in detail, Weyerhaeuser's activity, the marine mammal species that may be affected by the activity, and the anticipated effects on marine mammals. In that notice, we requested public input on the request for authorization described therein, our analyses, the proposed authorization, and any other aspect of the notice of proposed IHA, and requested that interested persons submit relevant information, suggestions, and comments. During the 30-day public comment period, NMFS did not receive any substantive comments on the proposed IHA.

Changes From the Proposed IHA to Final IHA

In table 5 of the proposed IHA **Federal Register** notice (89 FR 48579, June 7, 2024) the source levels for the impact driving of the 30-in steel pipe piles did not include the 5 decibel (dB) reduction from the bubble curtain.

These values have been corrected in tables 4 and 5 of this notice. The 5 dB reduction resulted in smaller Level A and Level B isopleths, which have been corrected in table 7 of this notice. The estimated number of takes by Level B harassment remains the same for all species because the smaller Level B isopleth still spans the width of the river and the same number of marine mammals are expected to be transiting through the project area. The estimated number of takes by Level A harassment for harbor seals was reduced to 56 to account for the smaller Level A isopleth which no longer spans the full width of the river. These values have been corrected in table 8 of this notice. Finally the smaller isopleths from the 5 dB reduction also decreased the minimum shutdown zone and harassment monitoring zone for impact pile driving. The reduced shutdown and monitoring zones have been corrected in table 9 of this notice.

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of Weyerhaeuser's application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS' Stock Assessment Reports (SARs; <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and more general information about these species (e.g., physical and behavioral descriptions) may be found on NMFS' website (<https://www.fisheries.noaa.gov/find-species>).

Table 1 lists all species or stocks for which take is expected and authorized for this activity and summarizes information related to the population or stock, including regulatory status under the MMPA and ESA and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated or authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of

the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock

abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' U.S. 2022 SARs. All values

presented in table 1 are the most recent available at the time of publication (including from the draft 2023 SARs) and are available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>.

TABLE 1—MARINE MAMMAL SPECIES ¹ LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ²	Stock abundance (CV, N _{min} , most recent abundance survey) ³	PBR	Annual M/SI ⁴
Order Carnivora—Pinnipedia						
<i>Family Otariidae (eared seals and sea lions).</i>						
California Sea Lion ..	<i>Zalophus californianus</i>	U.S.	-, -, N	257,606 (N/A, 233,515, 2014).	14,011	>321
Steller Sea Lion	<i>Eumetopias jubatus</i>	Eastern	-, -, N	36,308 (N/A, 36,308, 2022) ⁵ .	2,178	93.2
<i>Family Phocidae (earless seals):</i>						
Harbor Seal	<i>Phoca vitulina</i>	OR/WA Coastal ..	-, -, N	UNK (UNK, UNK, 1999)	UND	10.6

¹ Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (<https://marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies>; Committee on Taxonomy, 2022).

² ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

³ NMFS marine mammal SARs online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports-region>. CV is coefficient of variation; N_{min} is the minimum estimate of stock abundance. In some cases, CV is not applicable.

⁴ These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, ship strike). Annual mortality and serious injury (M/SI) often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

⁵ Nest is best estimate of counts, which have not been corrected for animals at sea during abundance surveys. Estimates provided are for the U.S. only.

As indicated above, all three species (with three managed stocks) in table 2 temporally and spatially co-occur with the activity to the degree that take is reasonably likely to occur.

A detailed description of the species likely to be affected by Weyerhaeuser's project, including brief introductions to the species and relevant stocks as well as available information regarding population trends and threats, and information regarding local occurrence, were provided in the **Federal Register** notice for the proposed IHA (89 (FR 48579, June 7, 2024); since that time, we are not aware of any changes in the status of these species and stocks; therefore, detailed descriptions are not provided here. Please refer to that **Federal Register** notice for these

descriptions. Please also refer to NMFS' website (<https://www.fisheries.noaa.gov/find-species>) for generalized species accounts.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (e.g., Richardson *et al.*, 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine

mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, *etc.*). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65-decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in table 2.

TABLE 2—MARINE MAMMAL HEARING GROUPS
[NMFS, 2018]

Hearing group	Generalized hearing range in hertz (Hz) and kilohertz (kHz) *
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, <i>Kogia</i> spp., river dolphins, Cephalorhynchids, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.

TABLE 2—MARINE MAMMAL HEARING GROUPS—Continued
[NMFS, 2018]

Hearing group	Generalized hearing range in hertz (Hz) and kilohertz (kHz) *
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.*, all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on the ~65-dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.*, 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.*, 2006; Kastelein *et al.*, 2009; Reichmuth *et al.*, 2013). This division between phocid and otariid pinnipeds is now reflected in the updated hearing groups proposed in Southall *et al.* (2019).

For more detail concerning these groups and associated frequency ranges, see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

The effects of underwater noise from Weyerhaeuser's pile driving activities have the potential to result in behavioral harassment of marine mammals in the vicinity of the project area. The notice of the proposed IHA (FR 48579, June 7, 2024) included a discussion of the effects of anthropogenic noise on marine mammals and the potential effects of underwater noise from Weyerhaeuser's pile driving activities on marine mammals and their habitat. That information and analysis is incorporated by reference into this final IHA determination and is not repeated here; please refer to the notice of the proposed IHA (FR 48579, June 7, 2024).

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes authorized through the IHA, which will inform NMFS' consideration of "small numbers," the negligible impact determinations, and impacts on subsistence uses.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal

stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes will primarily be by Level B harassment, as use of the acoustic source (*i.e.*, pile driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for phocids because predicted auditory injury zones are larger than for otariids. Auditory injury is unlikely to occur for otariids. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or authorized for this activity. Here we describe how the information provided above is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and is authorized.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.*, previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the authorized take numbers.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals

would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur permanent threshold shift (PTS) of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.*, frequency, predictability, duty cycle, duration of the exposure, signal-to-noise ratio, distance to the source), the environment (*e.g.*, bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.*, Southall *et al.*, 2007, 2021; Ellison *et al.*, 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μ Pa)) for continuous (*e.g.*, vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μ Pa for non-explosive impulsive (*e.g.*, seismic airguns) or intermittent (*e.g.*, scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by temporary threshold shift (TTS) as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may

result in changes in behavior patterns that would not otherwise occur.

Weyerhaeuser's activity includes the use of continuous (vibratory pile driving) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1μPa are applicable.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0;

Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different types of sources (impulsive or non-impulsive). Weyerhaeuser's activity includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving) sources.

These thresholds are provided in the table below. The references, analysis, and methodology used in the development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance>.

TABLE 3—THRESHOLDS IDENTIFYING THE ONSET OF PTS

Hearing group	PTS onset acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	<i>Cell 1:</i> $L_{pk,flat}$: 219 dB $L_{E,LF,24h}$: 183 dB	<i>Cell 2:</i> $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	<i>Cell 3:</i> $L_{pk,flat}$: 230 dB $L_{E,MF,24h}$: 185 dB	<i>Cell 4:</i> $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	<i>Cell 5:</i> $L_{pk,flat}$: 202 dB $L_{E,HF,24h}$: 155 dB	<i>Cell 6:</i> $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	<i>Cell 7:</i> $L_{pk,flat}$: 218 dB $L_{E,PW,24h}$: 185 dB	<i>Cell 8:</i> $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	<i>Cell 9:</i> $L_{pk,flat}$: 232 dB $L_{E,OW,24h}$: 203 dB	<i>Cell 10:</i> $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μPa, and cumulative sound exposure level (L_E) has a reference value of 1 μPa²s. In this table, thresholds are abbreviated to reflect American National Standards Institute (ANSI) standards (ANSI, 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the proposed project. Pile driving generates underwater noise that can potentially result in disturbance to marine mammals in the project area. The maximum (underwater) area ensonified is determined by the topography of the Columbia River, including intersecting land masses that will reduce the overall area of potential impact. Additionally, vessel traffic, including the other half of the dock (berth B) remaining operational during construction, in the project area may contribute to elevated background noise levels, which may mask sounds produced by the project.

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth,

water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$$TL = B \times \log_{10} (R_1/R_2),$$

Where

TL = transmission loss in dB;

B = transmission loss coefficient; for practical spreading equals 15;

R_1 = the distance of the modeled SPL from the driven pile; and,

R_2 = the distance from the driven pile of the initial measurement.

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6-dB reduction in sound level for each doubling of distance from the source ($20 \times \log_{10}$ [range]). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the

water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source ($10 \times \log_{10}$ [range]). A practical spreading value of 15 is often used under conditions, such as the project site, where water increases with depth as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical spreading loss conditions. Practical spreading loss is assumed here.

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. In order to calculate the distances to the Level A harassment and the Level B harassment sound thresholds for the methods and piles being used in this project, NMFS used acoustic monitoring data from other locations to develop proxy source levels for the various pile types, sizes and methods (table 4). Generally, we choose source levels from similar pile types from locations (*e.g.*, geology, bathymetry) similar to the project.

TABLE 4—PROXY SOUND SOURCE LEVELS FOR PILE SIZES AND DRIVING METHODS

Pile type and size	Peak SPL (re 1 μ Pa)	RMS SPL (re 1 μ Pa)	SEL (re 1 μ Pa ² -s)	Source
Vibratory pile installation and removal				
16-in timber pile		162		Caltrans, 2020.
12-in steel pipe		158		Laughlin, 2012.
12-in steel H-pile		152		Laughlin, 2019.
16-in steel pipe ¹		161		Navy, 2015.
24-in temporary steel pipe		161		Navy, 2015.
30-in steel pipe		163		Anchor, QEA, 2021; Greenbush, 2019; Denes <i>et al.</i> , 2016, table 72.
Impact pile installation				
30-in steel pipe ²	210 (205)	190 (185)	177 (177)	Caltrans, 2020.

¹ For the purposes of this analysis, the underwater sound source level for removal of existing 16-in steel piles (*i.e.*, 161 dB RMS per Navy, 2015) has been used for the removal of approximately 36 16-in steel pipe piles and 20 fender piles (14- or 16-in steel pipe piles).

² Values in parentheses indicate the calculated proxy source value minus 5 dB of assumed attenuation from the unconfined bubble curtain.

For this project, two hammers, including any combination of vibratory and impact hammers, may operate simultaneously. As noted earlier, the estimated ensounded area reflects the worst-case scenario (both hammers installing 30-in steel pipe piles) for the project. However, the most likely scenario is the removal of a 16-in timber pile at the same time as installing a 30-in steel pipe pile. The calculated proxy source levels for the different potential concurrent pile driving scenarios are shown in table 5.

Two Impact Hammers

For simultaneous impact driving of two 30-in steel pipe piles (the most conservative scenario), the number of strikes per pile was doubled to estimate total sound exposure during simultaneous installation. While the likelihood of impact pile driving strikes completely overlapping in time is rare due to the intermittent nature and short duration of strikes, NMFS conservatively estimates that up to 20 percent of strikes may overlap completely in time. Therefore, to calculate Level B isopleths for simultaneous impact pile driving, dB addition (if the difference between the two sound source levels is between 0 and 1 dB, 3 dB are added to the higher sound source level) was used to calculate the combined sound source level of 188 dB RMS that was used in this analysis.

One Impact Hammer, One Vibratory Hammer

To calculate Level B isopleths for one impact and one vibratory hammer operating simultaneously, sources were treated as though they were non-overlapping and the isopleth associated with the individual source which results in the largest Level B harassment

isopleth was conservatively used for both sources to account for periods of overlapping activities.

Two Vibratory Hammers

To calculate Level B isopleths for two simultaneous vibratory hammers, the NMFS acoustic threshold calculator was used with modified inputs to account for accumulation, weighting, and source overlap in space and time. Using the rules of dB addition if the difference between the two sound source levels is between 0 and 1 dB, 3 dB are added to the higher sound source level), the combined sound source level for the simultaneous vibratory installation of two 30-in steel piles is 166 dB RMS.

The ensounded area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources, like pile driving, the optional User Spreadsheet tool predicts the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur PTS. Inputs used in

the optional User Spreadsheet tool, and the resulting estimated isopleths, are reported in table 6, below.

To calculate Level A isopleths for two impact hammers operating simultaneously, the NMFS User Spreadsheet calculator was used with modified inputs to account for the total estimated number of strikes for all piles. For simultaneous impact driving of two 30-in steel pipe piles (the most conservative scenario), the number of strikes per pile was doubled to estimate total sound exposure during simultaneous installation, and the number of piles per day was reduced to one. The source level for two simultaneous impact hammers was not adjusted because for identical sources the accumulation of energy depends only on the total number of strikes, whether or not they overlap fully in time. Therefore, the source level used for two simultaneous impact hammers was 172 dB single-strike sound exposure level (SEL_{ss}).

To calculate Level A isopleths of one impact hammer and one vibratory hammer operating simultaneously, sources were treated as though they were non-overlapping and the isopleth associated with the individual source which resulted in the largest Level A isopleth was conservatively used for both sources to account for periods of overlapping activities.

To calculate Level A isopleths of two vibratory hammers operating simultaneously, the NMFS acoustic threshold calculator was used with modified inputs to account for accumulation, weighting, and source overlap in space and time. Using the rules of dB addition (NMFS, 2024; if the difference between the two sound source levels is between 0 and 1 dB, 3 dB are added to the higher sound source

level), the combined sound source level for the simultaneous vibratory installation of two 30-in steel piles is 166 dB RMS.

TABLE 5—CALCULATED PROXY SOUND SOURCE LEVELS FOR POTENTIAL CONCURRENT PILE DRIVING SCENARIOS

Scenario	Pile type and proxy	Calculated proxy sound source level
Two impact hammers	Impact install of 30-in steel pipe pile (172 dB SEL, 185 dB RMS) AND impact install of 30-in steel pipe pile (172 dB SEL, 185 dB RMS).	172 dB SEL for Level A. 188 dB RMS for Level B
One impact hammer, one vibratory hammer.	Impact install of 30-in steel pipe pile (172 dB SEL, 185 dB RMS) AND vibratory install of 30-in steel pipe pile (163 dB RMS).	172 dB SEL for Level A. 163 dB RMS for Level B
Two vibratory hammers ...	Vibratory install of 30-in steel pipe pile (163 dB RMS) AND vibratory install of 30-in steel pipe pile (163 dB RMS).	166 dB RMS.

TABLE 6—NMFS USER SPREADSHEET INPUTS

Pile size and type	Spreadsheet tab used	Weighting factor adjustment (kHz)	Number of piles per day	Duration to drive a single pile (min)	Number of strikes per pile
Vibratory pile driving and removal					
16-in timber pile	A.1. Vibratory pile driving.	2.5	8	60	NA
12-in steel pipe	A.1. Vibratory pile driving.	2.5	8	60	NA
12-in steel H-pile	A.1. Vibratory pile driving.	2.5	8	60	NA
16-in steel pipe	A.1. Vibratory pile driving.	2.5	8	60	NA
24-in temporary steel pipe	A.1. Vibratory pile driving.	2.5	8	60	NA
30-in steel pipe	A.1. Vibratory pile driving.	2.5	8	60	NA
Impact pile driving					
30-in steel pipe	E.1. Impact pile driving	2	8	NA	1000
Concurrent pile driving ¹					
Impact install of 30-in steel pipe pile AND impact install of 30-in steel pipe pile.	E.1. Impact pile driving	2	1	NA	8000
Impact install of 30-in steel pipe pile AND vibratory install of 30-in steel pipe pile.	E.1. Impact pile driving	2	1	NA	8000
Vibratory install of 30-in steel pipe pile AND vibratory install of 30-in steel pipe pile.	A.1. Vibratory pile driving.	2.5	1	480	NA

¹ Number of strikes is no longer per pile, it is the total number of strikes per day. The number of piles per day has been reduced to one.

TABLE 7—CALCULATED LEVELS A AND B HARASSMENT ISOPLETHS

Pile size and type	Level A harassment zone (m/km ²)		Level B harassment zone (m/km ²)
	Phocid	Otariid	
Vibratory pile driving and removal			
16-in timber pile	20/0.000693	2/0.000012	6,310/8.25
12-in steel pipe	11/0.000226	1/0.000003	3,415/5.14
12-in steel H-pile	5/0.000055	1/0.000003	1,585/2.46
16-in steel pipe	17/0.000509	2/0.000012	5,412/7.47
24-in temporary steel pipe.			
30-in steel pipe	23/0.000906	2/0.000012	7,356 ^{a b} /8.96
Impact pile driving			
30-in steel pipe	395/0.25181	29/0.001393	464/0.35
Concurrent pile driving			
Impact install of 30-in steel pipe pile AND impact install of 30-in steel pipe pile	395/0.25181	29/0.001393	736/0.89
Impact install of 30-in steel pipe pile AND vibratory install of 30-in steel pipe pile ..			7,356 ^{a b} /8.96

TABLE 7—CALCULATED LEVELS A AND B HARASSMENT ISOPLETHS—Continued

Pile size and type	Level A harassment zone (m/km ²)		Level B harassment zone (m/km ²)
	Phocid	Otariid	
Vibratory install of 30-in steel pipe pile AND vibratory install of 30-in steel pipe pile	36/2,153	3/0.000023	11,660 ^b /10.52

^a The Level B harassment thresholds for the vibratory installation of a single 30-in steel pile are equivalent to the potential simultaneous installation of up to two 30-inch steel piles using one impact hammer and one vibratory hammer operating concurrently. As noted previously, Levels A and B harassment thresholds for simultaneous pile driving were analyzed based on interim guidance provided by NMFS (2024).

^b The Level B harassment thresholds reported above were calculated using the practical spreading loss model, although the extent of actual sound propagation will be limited to the areas identified in figure 6–3 of Weyerhaeuser's application due to the shape and configuration of the Columbia River in the vicinity.

Marine Mammal Occurrence and Take Estimation

In this section, we provide information about the occurrence of marine mammals that will inform the take calculations, and describe how the information provided is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and authorized. Daily occurrence data cones from USACE compiled weekly monitoring reports collected at the Bonneville Dam (river mile (RM) 146) from 2020 through 2021 (van der Leeuw and Tidwell, 2022). As pinnipeds would need to swim past the proposed project site to reach the dam, the number of animals observed at Bonneville Dam may be slightly lower than what would be observed at the project site. The take calculations for this project are:

Incidental take estimate = (number of days during work window × estimated number of animals per day) + (number of days outside work window × estimated number of animals per day).

California Sea Lion

The numbers of California sea lions observed at Bonneville Dam have been in decline in recent years and ranged from 149 in 2016 to a total of 24 in 2021 (van der Leeuw and Tidwell, 2022). During the spring period from January 1 to May 6, 2020, daily counts averaged 0.9 animals ± 3.3 standard deviation, with a high of seven individuals (Tidwell *et al.*, 2020). During spring 2021, California sea lions were present from late March through late May, but in relatively low numbers, with most days having five or fewer present (van der Leeuw and Tidwell, 2022). It is difficult to estimate the number of California sea lions that could potentially occur in the Level B harassment zone during the fall in-water

work window from these data, because the numbers at Bonneville Dam reflect a strong seasonal presence in spring. A conservative estimate of three California sea lions per day during the in-water work window and five California sea lions per day outside the in-water work window was used. Therefore, using the equation given above, the estimated number of takes by Level B harassment for California sea lions would be 510.

The largest Level A harassment zone for California sea lions extends 29 m from the sound source (table 7) during impact pile driving. All construction work would be shut down prior to a California sea lion entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the small Level A harassment isopleth and proposed shutdown requirements, no take by Level A harassment is anticipated or authorized for California sea lions.

Steller Sea Lion

Steller sea lions have been observed in varying numbers at Bonneville Dam throughout much of the year, with a peak in April and May (Tidwell *et al.*, 2020; van der Leeuw and Tidwell, 2022). Reports from a 2-year period observed daily counts of 12 to 20 Steller sea lions during the fall survey period (Tidwell *et al.*, 2020, Tidwell and van der Leeuw, 2021), and up to 27 Steller sea lions per day in the spring (van der Leeuw and Tidwell, 2022). A conservative estimate of 20 Steller sea lions per day during the in-water work window and 27 Steller sea lions per day outside the in-water work window was used. Therefore, using the equation given above, the estimated number of takes by Level B harassment for Steller sea lions would be 3,210.

The largest Level A harassment zone for Steller sea lions extends 29 m from the sound source (table 7) during impact pile driving. All construction work would be shut down prior to a Steller sea lion entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the small Level A harassment isopleth and proposed shutdown requirements, no take by Level A harassment is anticipated or authorized for Steller sea lions.

Harbor Seal

Harbor seals are rarely observed at Bonneville Dam, but have been recorded in low numbers over the past 10 years. A recent IHA issued for the Port of Kalama Manufacturing and Marine Export Facility (85 FR 76527), which is located near the proposed project site, used a conservative estimate based on anecdotal information of harbor seals residing near the mouths of the Cowlitz and Kalama Rivers and estimated that there could be up to 10 present on any given day of pile driving (NMFS, 2017; 81 FR 15064, March 21, 2016). Therefore, using the equation given above, the calculated estimate of take by Level B harassment for harbor seals would be 1,500.

The largest Level A harassment zone for harbor seals extends 395 m from the sound source (table 7) during impact pile driving. The Port of Kalama project estimated that one harbor seal per day could be present in the Level A harassment zone for each day of impact pile driving. Given that the largest Level A isopleth extends approximately half the width of the river (810 m), the calculated estimated take by Level A harassment for harbor seals would be 58 (1 seal on 48.5% of the 120 impact pile driving days).

TABLE 8—ESTIMATED TAKE BY LEVELS A AND B HARASSMENT

Common name	Stock	Stock abundance	Level A harassment	Level B harassment	Total authorized take	Authorized take as a percentage of stock
California sea lion	U.S. Stock	257,606	0	510	510	0.2
Steller sea lion	Eastern DPS	36,308	0	3,210	3,210	8.8
Harbor seal	OR/WA coastal stock	24,732	58	1,500	1,558	6.3

Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stock for taking for certain subsistence uses (latter not applicable for this action). NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the

likelihood that the measure will be effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and,

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

The mitigation measures described in the following paragraphs will apply to the Weyerhaeuser in-water construction activities.

Shutdown and Monitoring Zones

Weyerhaeuser must establish shutdown zones and Level B harassment monitoring zones for all pile driving activities. The purpose of a shutdown zone is generally to define an area within which shutdown of the activity would occur upon sighting of a marine animal (or in anticipation of an animal entering the defined area). Shutdown zones are based on the largest Level A harassment zone for each pile size/type and driving method, and behavioral monitoring zones are meant to encompass Level B harassment zones for each pile size/type and driving method, as shown in table 9. A minimum shutdown zone of 10 m will be required for all in-water construction activities to avoid physical interaction with marine mammals. Shutdown zones for each activity type are shown in table 9.

Prior to pile driving, Protected Species Observers (PSOs) will survey the shutdown zones and surrounding areas for at least 30 minutes before pile driving activities start. If marine mammals are found within the shutdown zone, pile driving will be delayed until the animal has moved out of the shutdown zone, either verified by an observer or by waiting until 15 minutes has elapsed without a sighting. If a marine mammal approaches or enters the shutdown zone during pile driving, the activity will be halted. Pile driving may resume after the animal has moved out of and is moving away from the shutdown zone or after at least 15 minutes has passed since the last observation of the animal.

All marine mammals will be monitored in the Level B harassment to the extent of visibility for the on-duty PSOs. If a marine mammal for which take is authorized enters the Level B harassment zone, in-water activities will continue and PSOs will document the animal's presence within the estimated harassment zone.

If a species for which authorization has not been granted, or for which the authorized takes are met, is observed approaching or within the Level B harassment zone, pile driving activities will be shut down immediately. Activities will not resume until the animal has been confirmed to have left the area or 15 minutes has elapsed with no sighting of the animal.

TABLE 9—SHUTDOWN AND LEVEL B MONITORING ZONES BY ACTIVITY

Method	Pile size and type	Minimum shutdown zone (m)		Harassment monitoring zone (m)
		Phocid	Otariid	
Vibratory	16-in timber pile removal	20	10	6,310
	12-in steel pipe pile removal	15	10	3,415
	12-in steel H-pile removal	10	10	1,585
	16-in steel pipe removal	20	10	5,412
	24-in steel pipe pile (temporary) installation and removal	20	10	5,412
	30-in steel pipe pile installation	25	10	7,356
Impact	30-in steel pipe pile installation	200	30	464
Concurrent pile driving	Two impact hammers	200	30	736
	One impact hammer and one vibratory hammer	200	30	7,356
	Two vibratory hammers	40	10	11,660

PSOs

The placement of PSOs during all pile driving and removal activities (described in detail in the Monitoring and Reporting section) will ensure that the ensonified area of the Columbia River is visible during pile installation.

Pre- and Post-Activity Monitoring

Monitoring must take place from 30 minutes prior to initiation of pile driving activities (*i.e.*, pre-clearance monitoring) through 30 minutes post-completion of pile driving. Prior to the start of daily in-water construction activity, or whenever a break in pile driving of 30 minutes or longer occurs, PSOs will observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone will be considered cleared when a marine mammal has not been observed within the zone for a 30-minute period. If a marine mammal is observed within the shutdown zones, pile driving activity will be delayed or halted. If work ceases for more than 30 minutes, the pre-activity monitoring of the shutdown zones will commence. A determination that the shutdown zone is clear must be made during a period of good visibility (*i.e.*, the entire shutdown zone and surrounding waters must be visible to the naked eye).

Bubble Curtain

A bubble curtain must be employed during all impact pile driving activities to interrupt the acoustic pressure and reduce impact on marine mammals. The bubble curtain must distribute air bubbles around 100 percent of the piling circumference for the full depth of the water column. The lowest bubble ring must be in contact with the mudline for the full circumference of the ring. The weights attached to the bottom ring must ensure 100 percent substrate contact. No parts of the ring or other objects may prevent full substrate contact. Air flow to the bubble rings must be balanced around the circumference of the pile. If simultaneous use of two impact hammers occurs, both piles must be mitigated with bubble curtains as described above.

Soft Start

Soft-start procedures are believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the impact hammer operating at full capacity. For impact driving, an initial set of three strikes will be made by the hammer at reduced energy, followed by a 30-second waiting period, then two subsequent three-strike sets before

initiating continuous driving. Soft start will be implemented at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer.

Based on our evaluation of the applicant's proposed measures, NMFS has determined that the proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.*, presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.*, source characterization, propagation, ambient noise); (2) affected species (*e.g.*, life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.*, age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;

- Effects on marine mammal habitat (*e.g.*, marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and,

- Mitigation and monitoring effectiveness.

Visual Monitoring

Marine mammal monitoring must be conducted in accordance with section 5 of the IHA. Marine mammal monitoring during pile driving and removal must be conducted by NMFS-approved PSOs in a manner consistent with the following:

- PSOs must be independent of the activity contractor (for example, employed by a subcontractor) and have no other assigned tasks during monitoring periods;

- At least one PSO must have prior experience performing the duties of a PSO during construction activity pursuant to a NMFS-issued incidental take authorization;

- Other PSOs may substitute education (degree in biological science or related field) or training for experience; and,

- Weyerhaeuser must submit PSO Curriculum Vitae for approval by NMFS prior to the onset of pile driving.

PSOs must have the following additional qualifications:

- Ability to conduct field observations and collect data according to assigned protocols;

- Experience or training in the field identification of marine mammals, including the identification of behaviors;

- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;

- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates, times, and reason for implementation of mitigation (or why mitigation was not implemented when required); and marine mammal behavior; and,

- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary. Weyerhaeuser will employ up to four PSOs. PSO locations will provide an unobstructed view of all water within the shutdown zone(s), and as much of the Level A harassment and Level B harassment zones as possible. PSOs will be stationed along the shore of the Columbia River.

Weyerhaeuser will ensure that construction supervisors and crews, the monitoring team, and relevant Weyerhaeuser staff are trained prior to the start of activities subject to the proposed IHA, so that responsibilities, communication procedures, monitoring protocols, and operational procedures are clearly understood. New personnel joining during the project will be trained prior to commencing work. Monitoring will occur for all pile driving activities during the pile installation work window (September 1, 2025 through January 31, 2026). For pile removal activities outside the work window, one PSO will be on site to monitor the ensonified area once every 7 calendar days, whether or not vibratory pile extraction occurs on that day. Monitoring will be conducted 30 minutes before, during, and 30 minutes after pile driving/removal activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving/removal activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

Data Collection

PSOs will use approved data forms to record the following information:

- Dates and times (beginning and end) of all marine mammal monitoring.
- PSO locations during marine mammal monitoring.
- Construction activities occurring during each daily observation period, including how many and what type of piles were driven or removed and by what method (*i.e.*, vibratory or impact).
- Weather parameters and water conditions.
- The number of marine mammals observed, by species, relative to the pile location and if pile driving or removal was occurring at time of sighting.
- Distance and bearings of each marine mammal observed to the pile being driven or removed.
- Description of marine mammal behavior patterns, including direction of travel.
- Age and sex class, if possible, of all marine mammals observed.
- Detailed information about implementation of any mitigation triggered (such as shutdowns and delays), a description of specific actions that ensued, and resulting behavior of the animal if any.

Reporting

A draft marine mammal monitoring report will be submitted to NMFS within 90 days after the completion of pile driving and removal activities. It would include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring.
- Construction activities occurring during each daily observation period, including the number and type of piles driven or removed and by what method (*i.e.*, vibratory driving) and the total equipment duration for cutting for each pile.
- PSO locations during marine mammal monitoring.
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance.
- Upon observation of a marine mammal, the following information: (1) name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; (2) time of sighting; (3) identification of the animal(s) (*e.g.*, genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; (4) distance and bearing of each marine mammal observed relative to the pile being driven for each sighting (if pile driving was occurring at time of sighting); (5) estimated number of animals (min/max/best estimate); (6) estimated number of animals by cohort (adults, juveniles, neonates, group composition, *etc.*); (7) animal's closest point of approach and estimated time spent within the harassment zone; and (8) description of any marine mammal behavioral observations (*e.g.*, observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.*, no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching).
- Number of marine mammals detected within the harassment zones, by species.
- Detailed information about any implementation of any mitigation triggered (*e.g.*, shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days, the draft final report would constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the event that personnel involved in the construction activities discover an injured or dead marine mammal, Weyerhaeuser shall report the incident to the OPR, NMFS and to the west coast regional stranding network as soon as feasible. If the death or injury was clearly caused by the specified activity, Weyerhaeuser must immediately cease the specified activities until NMFS is able to review the circumstances of the incident and determine what, if any, additional measures are appropriate to ensure compliance with the terms of the IHA. The IHA-holder must not resume their activities until notified by NMFS. The report must include the following information:

- Time, date, and location (latitude/longitude) of the first discovery (and updated location information if known and applicable);
- Species identification (if known) or description of the animal(s) involved;
- Condition of the animal(s) (including carcass condition if the animal is dead);
- Observed behaviors of the animal(s), if alive;
- If available, photographs or video footage of the animal(s); and,
- General circumstances under which the animal was discovered.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging

impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (e.g., as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the discussion of our analysis applies to California sea lions, Steller sea lions, and harbor seals, given that the anticipated effects of this activity on these different marine mammal stocks are expected to be similar. There is little information about the nature or severity of the impacts, or the size, status, or structure of any of these species or stocks that would lead to a different analysis for this activity.

Pile driving activities have the potential to disturb or displace marine mammals. Specifically, the project activities may result in take, in the form of Level A harassment and Level B harassment from underwater sounds generated from pile driving and removal. Potential takes could occur if individuals are present in the ensonified zone when these activities are underway.

The takes from Level B harassment would be due to potential behavioral disturbance, and TTS. Level A harassment takes would be due to PTS. No mortality or serious injury is anticipated given the nature of the activity, even in the absence of the required mitigation. The potential for harassment is minimized through the construction method and the implementation of the mitigation measures (see Mitigation section).

Take would occur within a limited, confined area (the Columbia River) of the stocks' ranges. Level A harassment and Level B harassment would be reduced to the level of least practicable adverse impact through use of mitigation measures described herein. Further, the amount of take authorized is extremely small when compared to stock abundance, and the project is not anticipated to impact any known important habitat areas for any marine mammal species.

Take by Level A harassment is authorized to account for the potential that an animal could enter and remain within the area between a Level A

harassment zone and the shutdown zone for a duration long enough to be taken by Level A harassment. Any take by Level A harassment is expected to arise from, at most, a small degree of PTS because animals would need to be exposed to higher levels and/or longer duration than are expected to occur here in order to incur any more than a small degree of PTS. Additionally, and as noted previously, some subset of the individuals that are behaviorally harassed could also simultaneously incur some small degree of TTS for a short duration of time. Because of the small degree anticipated, though, any PTS or TTS potentially incurred here would not be expected to adversely impact individual fitness, let alone annual rates of recruitment or survival.

Behavioral responses of marine mammals to pile driving at the project site, if any, are expected to be mild and temporary. Marine mammals within the Level B harassment zone may not show any visual cues they are disturbed by activities or could become alert, avoid the area, leave the area, or display other mild responses that are not observable such as changes in vocalization patterns. Given the limited number of piles to be installed or extracted per day and that pile driving and removal would occur across a maximum of 150 days within the 12-month authorization period, any harassment would be temporary.

Any impacts on marine mammal prey that would occur during Weyerhaeuser's activity would have, at most, short-term effects on foraging of individual marine mammals, and likely no effect on the populations of marine mammals as a whole. Indirect effects on marine mammal prey during the construction are expected to be minor, and these effects are unlikely to cause substantial effects on marine mammals at the individual level, with no expected effect on annual rates of recruitment or survival.

In addition, it is unlikely that minor noise effects in a small, localized area of habitat would have any effect on the stocks' annual rates of recruitment or survival. In combination, we believe that these factors, as well as the available body of evidence from other similar activities, demonstrate that the potential effects of the specified activities will have only minor, short-term effects on individuals. The specified activities are not expected to impact rates of recruitment or survival and will therefore not result in population-level impacts.

In summary and as described above, the following factors primarily support our determination that the impacts

resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- The intensity of anticipated takes by Level B harassment is relatively low for all stocks and would not be of a duration or intensity expected to result in impacts on reproduction or survival;
- No important habitat areas have been identified within the project area;
- For all species, the Columbia River is a very small and peripheral part of their range and anticipated habitat impacts are minor; and,
- Weyerhaeuser will implement mitigation measures, such as soft-starts for impact pile driving and shut-downs to minimize the numbers of marine mammals exposed to injurious levels of sound, and to ensure that take by Level A harassment, is at most, a small degree of PTS.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Table 8 demonstrates the number of animals that could be exposed to received noise levels that could cause Level B harassment for the work. Our analysis shows that less than 10 percent of each affected stock could be taken by harassment. The numbers of animals authorized to be taken for these stocks

would be considered small relative to the relevant stock's abundances, even if each estimated taking occurred to a new individual—an extremely unlikely scenario.

Based on the analysis contained herein of the activity (including the mitigation and monitoring measures) and the authorized take of marine mammals, NMFS finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

There are no relevant subsistence uses of the affected marine mammal stocks or species implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species.

No incidental take of ESA-listed species is authorized or expected to result from this activity. Therefore, NMFS has determined that formal consultation under section 7 of the ESA is not required for this action.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216–6A, NMFS must review our action (*i.e.*, the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216–6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly,

NMFS has determined that the issuance of this IHA qualifies to be categorically excluded from further NEPA review.

Authorization

NMFS has issued an IHA to Weyerhaeuser for the potential harassment of small numbers of three marine mammal species incidental to the Log Export Dock Project on the Columbia River near Longview, Washington that includes the previously explained mitigation, monitoring and reporting requirements.

Dated: August 2, 2024.

Kimberly Damon-Randall,
Director, Office of Protected Resources,
National Marine Fisheries Service.

[FR Doc. 2024–17470 Filed 8–6–24; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XE161]

Nominations for Advisory Committee and Species Working Group Technical Advisor Appointments to the U.S. Section to the International Commission for the Conservation of Atlantic Tunas

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

ACTION: Notice of request for nominations.

SUMMARY: NMFS is soliciting nominations (which may include self-nominations) to the Advisory Committee to the U.S. Section to the International Commission for the Conservation of Atlantic Tunas (ICCAT) as established by the Atlantic Tunas Convention Act (ATCA). NMFS is also soliciting nominations for Technical Advisors to the Advisory Committee's species working groups.

DATES: Nominations must be received by September 13, 2024.

ADDRESSES: Nominations, including a letter of interest and a resume or curriculum vitae, should be sent via email to Bryan Keller at bryan.keller@noaa.gov. Include in the subject line whether the nomination is for a position as an Advisory Committee member or as a Technical Advisor to one of the Committee's species working groups.

FOR FURTHER INFORMATION CONTACT: Bryan Keller, Office of International Affairs, Trade, and Commerce; email:

bryan.keller@noaa.gov; phone: 301–427–7725.

SUPPLEMENTARY INFORMATION:

The Convention and the Commission

ICCAT was established to provide an effective program of international cooperation in research and conservation in recognition of the unique problems related to the highly migratory nature of tunas and tuna-like species. The International Convention for the Conservation of Atlantic Tunas (Convention), which established ICCAT, entered into force in 1969. ICCAT usually holds an Annual Meeting in November of each year, and convenes meetings of its working groups and other subsidiary bodies between annual meetings as needed. Under ATCA (see 16 U.S.C. 971a), the United States is represented at ICCAT by not more than three U.S. Commissioners. Additional information about ICCAT is available at www.iccat.int.

Advisory Committee to the U.S. Section to ICCAT and its Species Working Groups

ATCA (see 16 U.S.C. 971 *et seq.*) establishes an advisory committee comprising: (1) Not less than 5 nor more than 20 individuals appointed by the U.S. Commissioners to ICCAT who shall select such individuals from the various groups concerned with the fisheries covered by the ICCAT Convention; and (2) the chairs (or their designees) of the New England, Mid-Atlantic, South Atlantic, Caribbean, and Gulf of Mexico Fishery Management Councils. Each member of the Advisory Committee shall serve for a term of 2 years and be eligible for reappointment. The Committee meets at least twice a year during which members receive information and provide advice on ICCAT-related matters. All members of the Advisory Committee are appointed in their individual professional capacity and undergo a background screening. Any individual appointed to the Committee who is unable to attend all or part of an Advisory Committee meeting may not appoint another person to attend such meetings as his or her proxy. Nominees should be able to fulfill the time and travel commitments required to participate in the Committee's annual spring and fall meetings, in addition to ad hoc meetings as necessary throughout the year. The annual spring and fall meetings are normally 2 days long and are usually held in Silver Spring, Maryland, or Miami, Florida.

Members of the Advisory Committee receive no compensation for their services. The Secretary of Commerce

and the Secretary of State may pay the necessary travel expenses of members of the Advisory Committee. The terms of all currently appointed Advisory Committee members expire on December 31, 2024. NMFS is soliciting nominees to serve as members of the Advisory Committee for a term of 2 years that will begin January 1, 2025, and expire December 31, 2026.

ATCA specifies that the U.S. Commissioners may establish species working groups for the purpose of providing advice and recommendations to the U.S. Commissioners and to the Advisory Committee on matters relating to the conservation and management of any highly migratory species covered by the ICCAT Convention (see 16 U.S.C. 971b-1). Any species working group shall consist of no more than seven members of the Advisory Committee and no more than four scientific or technical personnel, as considered necessary by the Commissioners. Currently, there are four species working groups advising the Committee and the U.S. Commissioners: a Bluefin Tuna and Albacore Working Group, a Swordfish/Sharks Working Group, a Billfish Working Group, and a Bigeye, Yellowfin, and Skipjack Tunas Working Group. Scientific or technical personnel (known as Technical Advisors) appointed to species working groups serve at the pleasure of the Commissioners; therefore, the Commissioners can choose to alter these appointments at any time. As with Committee Members, Technical Advisors may not be represented by a proxy during meetings of the Advisory Committee. Nominees should be able to fulfill the time and travel commitments required to participate in the annual spring meeting of the Advisory Committee, when the species working groups are convened, in addition to ad hoc meetings throughout the year, as appropriate.

Procedure for Submitting Nominations

Nominations to either the Advisory Committee or a species working group should include a letter of interest and a resume or curriculum vitae that describes the individual's knowledge and experience in a field related to the highly migratory species covered by the ICCAT Convention. Self-nominations are acceptable. Letters of recommendation are useful but not required. When making a nomination, please specify which appointment (Advisory Committee member or Technical Advisor to a species working group) is being sought. Nominees are also encouraged to indicate which of the four species working groups is

preferred, although placement on the requested group is not guaranteed.

NMFS encourages nominations for women and for individuals from underserved communities that meet the knowledge, experience, and other requirements of the positions described in this notice. See Executive Order (E.O.) 13985 (Advancing Racial Equity and Support for Underserved Communities Through the Federal Government) section 2 (defining "underserved communities" as populations sharing a particular characteristic, as well as geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life, 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.). E.O. 13985 is available at <https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government>.

Dated: August 2, 2024.

Alexa Cole,

*Director, Office of International Affairs,
Trade, and Commerce, National Marine
Fisheries Service.*

[FR Doc. 2024-17448 Filed 8-6-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Reporting of Sea Turtle Incidental Take in Virginia Chesapeake Bay Pound Net Operations

AGENCY: National Oceanic & Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of information collection, request for comment.

SUMMARY: The Department of Commerce, in accordance with the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to comment on proposed, and continuing information

collections, which helps us assess the impact of our information collection requirements and minimize the public's reporting burden. The purpose of this notice is to allow for 60 days of public comment preceding submission of the collection to OMB.

DATES: To ensure consideration, comments regarding this proposed information collection must be received on or before October 7, 2024.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at NOAA.PRA@noaa.gov. Please reference OMB Control Number 0648-0470 in the subject line of your comments. All comments received are part of the public record and will generally be posted on <https://www.regulations.gov> without change. Do not submit Confidential Business Information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Carrie Upite, Sea Turtle Recovery Coordinator, Greater Atlantic Regional Fisheries Office, National Marine Fisheries Service, 55 Great Republic Drive, Gloucester, MA 01930; (978) 282-8475; or carrie.upite@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for renewal of an approved information collection.

Since 2002, the National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS) has promulgated several rules restricting the use of large mesh and stringer pound net leaders in certain Virginia Chesapeake Bay waters during the late spring/early summer each year. On June 17, 2002, an interim final rule was published (67 FR 41196) restricting leader use, which also required year-round reporting of sea turtle takes. In 2004, NMFS issued a final rule further restricting pound net leader use in Virginia (69 FR 24997). The 2004 rule retained the reporting requirement from the 2002 rule. These regulations (modifications to 50 CFR parts 222 and 223) were implemented as a result of high sea turtle strandings each spring in Virginia and the documented take of sea turtles in pound net leaders. On March 31, 2018, a revised Biological Opinion on NMFS gear regulations in the Virginia pound net fishery was completed pursuant to section 7 of the Endangered Species Act of 1973, as amended (ESA). An Incidental Take Statement was included in this

Biological Opinion, exempting the incidental take of a certain number of loggerhead, Kemp's ridley, green and leatherback sea turtles in pound net operations.

A non-discretionary term and condition of the Incidental Take Statement involved the reporting to NMFS of live or dead sea turtles taken in pound net operations (reflected in 50 CFR 223.206). The collection of this information on the incidental take of sea turtles in the Virginia pound net fishery is necessary to ensure sea turtles are being conserved and protected, as mandated by the ESA. Documenting the accurate occurrence of sea turtle incidental take in pound net operations will help to determine if additional regulatory actions or management measures are necessary to protect sea turtles caught in pound net operations. This information will help NMFS better assess the Virginia pound net fishery and its impacts (or lack thereof) on sea turtle populations in the Virginia Chesapeake Bay. The collection of this information is also imperative to ensure that the Incidental Take Statement is not being exceeded, the anticipated take levels are appropriate, and the effects analysis in the Biological Opinion is accurate. Further, reporting the take of live, injured sea turtles caught in pound net gear will ensure these turtles are transferred immediately to a stranding and rehabilitation center for appropriate medical treatment.

II. Method of Collection

Reports may be made either by telephone or email.

III. Data

OMB Control Number: 0648-0470.

Form Number(s): None.

Type of Review: Regular submission (extension of a current information collection).

Affected Public: Individuals or households.

Estimated Number of Respondents: 37.

Estimated Time per Response: 10 minutes.

Estimated Total Annual Burden Hours: 167 hours.

Estimated Total Annual Cost to Public: \$231.

Respondent's Obligation: Mandatory.
Legal Authority: Endangered Species Act.

IV. Request for Comments

We are soliciting public comments to permit the Department/Bureau to: (a) Evaluate whether the proposed information collection is necessary for the proper functions of the Department,

including whether the information will have practical utility; (b) Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used; (c) Evaluate ways to enhance the quality, utility, and clarity of the information to be collected; and (d) Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Sheleen Dumas,

Department PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024-17425 Filed 8-6-24; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF DEFENSE

Department of the Army

Army Education Advisory Committee Meeting Notice

AGENCY: Department of the Army, DoD.

ACTION: Notice of open committee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the Army Education Advisory Committee (AEAC). This meeting is open to the public.

DATES: The Army Education Advisory Committee will meet from 8 a.m. to 5 p.m. on both August 21-22, 2024.

ADDRESSES: Army Education Advisory Committee, 950 Jefferson Avenue, Building 950, U.S. Training and Doctrine Command (TRADOC) Headquarters, Conference Room 2047, Ft. Eustis, VA 23604.

FOR FURTHER INFORMATION CONTACT: Dr. Justin M. Green, the Designated Federal Officer for the committee, in writing at ATTN: ATTG-TRI-G, TRADOC, 950

Jefferson Ave, Fort Eustis, VA 23604, by email at justin.m.green12.civ@army.mil, or by telephone at (757) 501-9935.

SUPPLEMENTARY INFORMATION: The committee meeting is being held under the provisions of the Federal Advisory Committee Act (FACA; 5 U.S.C. 10), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102-3.150.

Purpose of the Meeting: The purpose of the meeting is to review TRADOC Priorities, review the committee and subcommittee FY24 businesses, and to review the Fiscal Year 2024 AEAC Study which will focus on the modernization of the Special Operations School of Excellence (SOCoE).

Agenda: August 21-22: The committee is chartered to provide independent advice and recommendations to the Secretary of the Army on the educational, doctrinal, and research policies and activities of U.S. Army educational programs. The committee will complete all FACA annual requirements, finalize discussions related to the modernization of the Special Operations School of Excellence (SOCoE), and discuss and deliberate provisional findings and recommendations submitted by its subcommittees for FY 2024.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102-3.140 through 102-3.165, and subject to the availability of space, this meeting is open to the public. Seating is on a first to arrive basis. Attendees are requested to submit their name, affiliation, and daytime phone number seven business days prior to the meeting to Dr. Green, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section.

Because the meeting of the committee will be held in a Federal Government facility on a military base, security screening is required. A photo ID is required to enter base. Please note that security and gate guards have the right to inspect vehicles and persons seeking to enter and exit the installation. TRADOC Headquarters is fully handicap accessible. Wheelchair access is available in front at the main entrance of the building. For additional information about public access procedures, contact Dr. Green, the committee's Designated Federal Officer, at the email address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Comments or Statements: Pursuant to 41 CFR 102-3.105(j) and 102-3.140 and section 10(a)(3) of the

Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the committee in response to the stated agenda of the open meeting or in regard to the committee's mission in general. Written comments or statements should be submitted to Dr. Green, the committee Designated Federal Officer, 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 Designated Federal Official will review all submitted written comments or statements and provide them to members of the committee for their consideration. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Designated Federal Official at least seven business days prior to the meeting to be considered by the committee. Written comments or statements received after this date may not be provided to the committee until its next meeting.

Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow a member of the public to speak or otherwise address the Committee during the meeting. Members of the public will be permitted to make verbal comments during the Committee meeting only at the time and in the manner described below. If a member of the public is interested in making a verbal comment at the open meeting, that individual must submit a request, with a brief statement of the subject matter to be addressed by the comment, at least seven business days in advance to the committee's Designated Federal Official, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. The Designated Federal Official will log each request, in the order received, and in consultation with the committee Chair, determine whether the subject matter of each comment is relevant to the committee's mission and/or the topics to be addressed in this public meeting. A 15-minute period near the end of the meeting will be available for verbal public comments. Members of the public who have requested to make a verbal comment and whose comments have been deemed relevant under the process described above, will be allotted no more than three minutes during the period, and will be invited to speak in

the order in which their requests were received by Designated Federal Official.

James W. Satterwhite Jr.,

Army Federal Register Liaison Officer.

[FR Doc. 2024–17414 Filed 8–6–24; 8:45 am]

BILLING CODE 3711–02–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2024–OS–0027]

Request for Information for 2026 Department of Defense State Policy Priorities Impacting Service Members and Their Families; Response to Public Comments

AGENCY: Deputy Assistant Secretary of Defense for Military Community and Family Policy, Department of Defense (DoD).

ACTION: Request for information; response to public comments.

SUMMARY: On Tuesday, March 26, 2024, DoD published a request for information in the **Federal Register** that provided an opportunity for the public to submit issues that have an impact on Service members and their families where state governments are the primary agents for making positive change. Each year, DoD selects State Policy Priorities for states to consider that reduce barriers resulting from the transience and uncertainty of military life. The public submissions received will be considered by DoD in setting those priorities. For example, as a result of previous feedback provided by a non-profit educational research organization, DoD has educated states on the benefits of modifying their open enrollment policies to increase access to school options for military-connected children. This follow-up notice responds to the public comments received.

FOR FURTHER INFORMATION CONTACT: Ms. Geraldine Valentin-Smith, (703) 618–6907 (voice), geraldine.valentino-smith.civ@mail.mil (email), 4800 Mark Center Drive, Suite 14E08, Alexandria, Virginia 22350 (mailing address).

SUPPLEMENTARY INFORMATION: On Tuesday, March 26, 2024 (89 FR 20954), the DoD published a notice titled “Request for Information for 2026 DoD State Policy Priorities Impacting Service Members and Their Families.” Public comments were accepted for 30 days until April 25, 2024. Twenty public comments were received. The DoD responds to the comments as follows:

Seven comments were received which identified issues for potential inclusion as a State Policy Priority. We appreciate

your thoughtful engagement and recommendations. We respond to the comments as follows:

- *Bridging Support Systems During Permanent Change of Station (PCS) Transitions for Vulnerable Military Families.* We recognize military families face significant disruptions in essential state support services during PCS moves. Implementing an advance enrollment system for state-run support programs, such as Medicaid and the Supplemental Nutrition Assistance Program, similar to successful models in educational settings, may affect the continuity of care and support for military families during PCS transitions.

- *Enfranchising Military-Connected Voters.* We agree military voters face significant challenges in participating in elections. Various states have differing rules regarding absentee ballot deadlines and procedures for curing ballot discrepancies, with no standardized approach specifically accommodating the unique circumstances of military voters. We commend states which have enhanced the fairness and inclusivity of the electoral process, reinforcing the democratic values that military personnel defend.

- *Facilitating Guardianship Transfer for Military Families.* We understand that military families with guardianship responsibilities face significant legal and bureaucratic hurdles when moving between states due to permanent changes of station. The Uniform Adult Guardianship and Protective Proceedings Jurisdiction Act is an approach to enabling a more seamless transfer of guardianship for military families between all states.

- *Military Community Experience with Job Opportunity Scams.* We share concern that military spouses are particularly vulnerable to job opportunity scams, which pose a significant threat to their financial security and well-being. No current state law or initiative requires specific protections or targeted initiatives to address the unique vulnerability of military spouses to job scams. However, states have begun addressing claim sharks who target veterans by offering veteran and military benefit services in exchange for financial compensation and other predatory practices.

- *Military Family Agility and Children's Educational Success.* We concur that full implementation of the Interstate Compact on Educational Opportunity for Military Children (the Compact) enhances educational continuity and fairness for military children. The Compact has been crucial in addressing educational challenges

faced by military families when relocating. All states and the District of Columbia have adopted the Compact; however, discrepancies in implementation across states create unequal opportunities and support for these children.

- *Paid Military Family Leave.* We acknowledge the substantial role that employed military spouses play in maintaining the home front during activations and the reintegration period that follows. The current legislative landscape includes several states that have taken commendable steps toward supporting military families through paid family leave policies. These initiatives not only alleviate financial pressures but also contribute to the overall readiness and resilience of our forces.

- *Partial Credit During Mid-Term Transfers.* We continue to address academic disruptions faced by military children. Many sending schools do not award partial credit for coursework completed before a transfer, and receiving schools frequently do not accept such partial credits, forcing students to repeat entire courses upon a PCS move. States have begun implementing policies that require both sending and receiving schools to recognize and accept partial credits.

The Department will evaluate the seven issues independently for suitability, feasibility, desirability, acceptability, and sustainability.

One comment was received which related to an existing State Policy Priority:

- *Creating a State Holiday for Month of the Military Child.* Each year, the Department joins national, state, and local governments, schools, military serving organizations, companies, and private citizens in celebrating military children and the sacrifices they make during the month of April. There are more than 1.6 million military children who face many challenges and unique experiences as a result of their parents' service. This line of effort is part of the State Policy Priority for Purple Star School Programs.

Additionally, four comments were received which related to issues outside the criteria listed for consideration. The criteria include: States are primary responsible for resolving the problem; the solution should positively impact the quality of life of Service members and their families; should or positively contribute to readiness; should impact members of the military, recent veterans, and their family members; and for quality-of-life issues, the resolution should help eliminate a barrier caused

by the dynamics of military life. We respond to the comments as follows:

- *DoD-State Liaison Office Support to the Territories.* We appreciate the comment that military members and families benefit from the Department's engagement with state legislative and executive branches to support military family readiness and quality of life. Within the limits of available resources, increased engagement with the governments of the insular areas of the United States may include connecting with other states and territories to share best practices and address common challenges and building relationships with key state policymakers responsible for defense issues.

- *Establishment of a DoD-Specific Portable Medicaid Waiver for Military Children.* Military children with special needs face substantial disruptions in continuity of care due to frequent relocations mandated by their parents' military service. While creation of a portable Medicaid waiver for military children is not within the purview of state government to resolve, other state policies do account for the mobility of military families with special needs. States have enacted improvements to existing Medicaid waivers for the provision of Home and Community-Based Services, allowing military families to retain their positions on waiting lists for this program despite a military-directed move out of the state. Additionally, states have begun modifying state education statutes to build upon existing Federal requirements to minimize delays and reduce barriers for highly-mobile students with special education needs.

- *Inclusion of Military Spouse Attorneys in Licensing Portability Under the Servicemember Civil Relief Act.* While the solution proposed is not within the purview of states to consider, the Department continues to engage with state bar examiners to facilitate military spouse admission, including the issuing of a license within 30 days with minimal documentation requirements.

- *Improvements to the MyCAA Program.* We appreciate feedback submitted regarding the MyCAA program indicating the desire for additional face-to-face options, online courses, and an expansion of curricula beyond health careers.

Eight comments were received which were not germane to the request for input and did not identify an issue for potential inclusion as a State Policy Priority. We respond to the comments as follows:

- Thank you for your advocacy for our military families. It is both valued

and recognized. Thank you very much for your contributions.

Each fiscal year, the DoD considers numerous vital state policy issues, with the aim of selecting those that hold the most promise for positively impacting the lives of Service members and their families. It is within this competitive and discerning framework that we evaluate, research, and assess all proposed state policy solutions to resolve challenges for military families.

We are committed to a rigorous examination of these issues, among others. Our process is designed to ensure that we advance the most impactful and viable initiatives to support our military families effectively.

As always, our team at the Defense-State Liaison Office, who manage state government relations for the Office of the Secretary of Defense on personnel and readiness issues, stand ready to fully support state policymakers and the military community. Thank you once again for bringing these important issues to our attention.

Dated: August 1, 2024.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024-17412 Filed 8-6-24; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 8615-049]

Fiske Hydro, Inc.; Notice of Application for Surrender of License Accepted for Filing, Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Surrender of License.

b. *Project No:* P-8615-049.

c. *Date Filed:* September 20, 2023.

d. *Applicant:* Fiske Hydro, Inc.

e. *Name of Project:* Fiske Mill Hydroelectric Project.

f. *Location:* The project is located on the Ashuelot River, in the town of Hinsdale, Cheshire County, New Hampshire.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.

h. *Applicant Contact:* Cameron MacLeod, 47 Warwick Road, Orange, MA 01364, microhydro@comcast.net, (610) 310-5539.

i. *FERC Contact*: Diana Shannon, (202) 502–6136, diana.shannon@ferc.gov.

j. *Cooperating agencies*: With this notice, the Commission is inviting Federal, State, local, and Tribal agencies with jurisdiction and/or special expertise with respect to environmental issues affected by the proposal, that wish to cooperate in the preparation of any environmental document, if applicable, to follow the instructions for filing such requests described in item k below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of any environmental document cannot also intervene. See 94 FERC ¶ 61,076 (2001).

k. *Deadline for filing comments, motions to intervene, and protests*: August 30, 2024.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, and protests using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support at FERCOnlineSupport@ferc.gov, (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, MD 20852. The first page of any filing should include the docket number P–8615–049. Comments emailed to Commission staff are not considered part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

l. *Description of Request*: The applicant proposes to surrender its project license. Certain project works

are not operable, and the applicant states the cost of needed repairs to the generating equipment is significant and infeasible. To surrender the project, the applicant proposes to: (1) disconnect the generating units from the utility interconnection point; (2) disconnect the turbine drive shafts, and offer the equipment for sale; (3) install service lines to provide power for future dam operation and security needs; (4) close the intake structure at the north abutment; (5) remove transformers; (6) remove any hydraulic fluids from project equipment; and (7) lock and secure the powerhouse. The turbine-generator units may remain in place until sold. No major physical changes to any project features are planned and no ground disturbance would occur under this proposal. The dam would remain in place.

m. *Locations of the Application*: This filing may be viewed on the Commission's website at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1–866–208–3676 or email FERCOnlineSupport@ferc.gov, for TTY, call (202) 502–8659. Agencies may obtain copies of the application directly from the applicant.

n. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

o. *Comments, Protests, or Motions to Intervene*: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

p. *Filing and Service of Documents*: Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address,

and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

q. The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202)502–6595 or OPP@ferc.gov.

Dated: July 31, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024–17393 Filed 8–6–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP24–923–000.

Applicants: Iroquois Gas Transmission System, L.P.

Description: 4(d) Rate Filing: 7.31.24 Negotiated Rates—Koch Energy Services, LLC R–7755–08 to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5031.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24–924–000.

Applicants: Granite State Gas Transmission, Inc.

Description: 4(d) Rate Filing: Revised tariff records in Original Volume No. 1 of its FERC Gas Tariff to be effective 9/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5033.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24–925–000.

Applicants: West Texas Gas Utility, LLC.

Description: Annual Purchased Gas Cost Reconciliation Report of West Texas Gas Utility, LLC.

Filed Date: 7/31/24.

Accession Number: 20240731-5036.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-926-000.

Applicants: Eastern Gas Transmission and Storage, Inc.

Description: 4(d) Rate Filing: EGTS—Revision Clarifying Incremental Electric Power Costs to be effective 9/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5038.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-927-000.

Applicants: Enable Mississippi River Transmission, LLC.

Description: Compliance filing: MRT RP20-131 and RP20-212, et seq. Cost and Revenue Study Compliance Filing to be effective N/A.

Filed Date: 7/31/24.

Accession Number: 20240731-5041.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-928-000.

Applicants: MountainWest Overthrust Pipeline, LLC.

Description: Annual Fuel Gas Reimbursement Report of MountainWest Overthrust Pipeline, LLC.

Filed Date: 7/31/24.

Accession Number: 20240731-5043.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-929-000.

Applicants: El Paso Natural Gas Company, L.L.C.

Description: 4(d) Rate Filing: Negotiated Rate Agreements Update (Hartree 614700 615843 610670 Aug 2024) to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5044.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-930-000.

Applicants: Kern River Gas Transmission Company.

Description: 4(d) Rate Filing: 2024 BP, Concord, Constellation TSA Term Amendments to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5048.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-931-000.

Applicants: Honeoye Storage Corporation.

Description: Compliance filing: HSC 2024 Rate Case Compliance Filing to be effective 9/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5054.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-932-000.

Applicants: Kern River Gas Transmission Company.

Description: 4(d) Rate Filing: 2024 KRF-1 Form of Service Exhibit A Filing to be effective 9/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5057.

Comment Date: 5 p.m. ET 8/12/24.

Docket Numbers: RP24-933-000.

Applicants: National Fuel Gas Supply Corporation.

Description: 4(d) Rate Filing: Negotiated Rate—Citadel Energy Marketing to be effective 9/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731-5070.

Comment Date: 5 p.m. ET 8/12/24.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/docs-filing/efiling/filing-req.pdf>. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: July 31, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-17398 Filed 8-6-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24-500-000]

Florida Gas Transmission Company, LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on July 19, 2024, Florida Gas Transmission Company, LLC (FGT), 1300 Main St., Houston, Texas 77002, filed in the above referenced docket, a prior notice request pursuant to sections 157.205, 157.208, 157.210, and 157.211 of the Commission's regulations under the Natural Gas Act (NGA), and FTG's blanket certificate issued in Docket No. CP82-553-000, for authorization to increase certificated mainline capacity, and to construct, modify, own, maintain and operate interstate natural gas delivery point and appurtenant facilities, consisting of an additional alternate feed connection and a meter station upgrade; appurtenant facility maintenance replacement on a compressor unit at FGT's existing Compressor Station 10 (CS 10) and other appurtenant facilities as needed. All of the above facilities are located in St. Helena Parish, Louisiana and Perry County, Mississippi (Livingston Parish Project). The project will allow FGT to transport incremental certificated firm transportation capacity up to 4.0 million cubic feet per day (MMcf/d) to the existing City of Walker Meter Station delivery point to be upgraded by FGT, and to be utilized by the City of Walker, La (City of Walker, Customer, or Shipper) primarily for residential use through the City of Walker gas system. The estimated cost for the project is \$985,000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at (202) 502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

Any questions concerning this request should be directed to Blair Lichtenwalter, Senior Director of Certificates, Florida Gas Transmission Company, LLC, 1300 Main St., Houston, Texas, 77002, at (713) 989-2605, or blair.lichtenwalter@energytransfer.com.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on September 30, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202)502-6595 or OPP@ferc.gov.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,¹ any person² or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for

authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,³ and must be submitted by the protest deadline, which is September 30, 2024. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁴ and the regulations under the NGA⁵ by the intervention deadline for the project, which is September 30, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to/intervene.asp>.

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission

considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before September 30, 2024. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP24-000-000 in your submission.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Protest", "Intervention", or "Comment on a Filing"; or⁶

(2) You can file a paper copy of your submission by mailing it to the address below. Your submission must reference the Project docket number CP24-500-000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other method: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of submissions (option 1 above) and has eFiling staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: Blair Lichtenwalter, Senior Director of Certificates, Florida Gas Transmission Company, LLC, 1300 Main St., Houston, Texas, 77002, or by blair.lichtenwalter@energytransfer.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the

⁶ Additionally, you may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project.

¹ 18 CFR 157.205.

² Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

³ 18 CFR 157.205(e).

⁴ 18 CFR 385.214.

⁵ 18 CFR 157.10.

service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at www.ferc.gov using the “eLibrary” link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Dated: July 31, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–17396 Filed 8–6–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–2625–000]

Mordor ES2 LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Mordor ES2 LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of

future issuances of securities and assumptions of liability, is August 20, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502–8371, TTY (202) 502–8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or OPP@ferc.gov.

Dated: July 31, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–17394 Filed 8–6–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER24–2624–000]

Mordor ES1 LLC ; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Mordor ES1 LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 20, 2024.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all

interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (<http://www.ferc.gov>). From the Commission's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field.

User assistance is available for eLibrary and the Commission's website during normal business hours from FERC Online Support at 202-502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Dated: July 31, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-17395 Filed 8-6-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13123-031]

Eagle Crest Energy Company; Notice of Availability of Environmental Assessment

The EA contains Commission staff's analysis of the potential environmental effects of the proposed amendment, alternatives to the proposed action, and concludes that the proposed amendment with appropriate environmental protective measures, would not constitute a major federal action that would significantly affect the quality of the human environment.

The EA may be viewed on the Commission's website at <http://www.ferc.gov> using the "elibrary" link. Enter the docket number (P-13123) in the docket number field to access the document. For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov or toll-free at 1-866-208-3676, or for TTY, (202) 502-8659.

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

All comments must be filed by August 31, 2024.

The Commission strongly encourages electronic filing. Please file comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. For assistance, please contact FERC Online Support. In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include docket number P-13123-031.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

For further information, contact Shawn Halerz at 202-502-6360 or Shawn.Halerz@ferc.gov.

Dated: July 31, 2024.

Debbie-Anne A. Reese,
Acting Secretary.

[FR Doc. 2024-17392 Filed 8-6-24; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG24-244-000.
Applicants: Ray Ranch Solar LLC.
Description: Ray Ranch Solar LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 7/30/24.

Accession Number: 20240730-5147.
Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: EG24-245-000.
Applicants: Twin Lakes Solar LLC.
Description: Twin Lakes Solar LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 7/30/24.
Accession Number: 20240730-5148.
Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: EG24-246-000.
Applicants: Duane Arnold Solar II, LLC.

Description: Duane Arnold Solar II, LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.
Filed Date: 7/31/24.

Accession Number: 20240731-5034.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: EG24-247-000.
Applicants: 69SV 8me LLC.
Description: 69SV 8me LLC submits Notice of Self-Certification of Exempt Wholesale Generator Status.

Filed Date: 7/31/24.
Accession Number: 20240731-5156.
Comment Date: 5 p.m. ET 8/21/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER23-861-001.
Applicants: California Independent System Operator Corporation.
Description: Compliance filing: 2024-07-31 Compliance Filing of Effective Date—TCA—Citizen S-Line to be effective 6/12/2024.

Filed Date: 7/31/24.
Accession Number: 20240731-5090.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24-2149-002.
Applicants: Entergy Arkansas, LLC.
Description: Tariff Amendment:

Union Electric WDS Agreement to be effective 8/1/2024.

Filed Date: 7/31/24.
Accession Number: 20240731-5105.
Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24-2408-001.
Applicants: Duke Energy Florida, LLC, Duke Energy Carolinas, LLC.
Description: Tariff Amendment: Duke Energy Florida, LLC submits tariff filing

per 35.17(b); DEF—Amendment to Pending Revisions to Attachment J to Joint OATT (LGIP/LGIA) to be effective 9/1/2024.

Filed Date: 7/30/24.

Accession Number: 20240730–5153.

Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: ER24–2431–001.

Applicants: Duke Energy Progress, LLC, Duke Energy Carolinas, LLC.

Description: Tariff Amendment: Duke Energy Progress, LLC submits tariff filing per 35.17(b); DEC–DEP Amendment to Pending Revisions to Attachment K to Joint OATT to be effective 9/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5073.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2626–000.

Applicants: California Independent System Operator Corporation.

Description: 205(d) Rate Filing: 2024–07–30 First Amended Generator Scheduling Agreement—WAPA to be effective 11/1/2024.

Filed Date: 7/30/24.

Accession Number: 20240730–5164.

Comment Date: 5 p.m. ET 8/20/24.

Docket Numbers: ER24–2627–000.

Applicants: Pacific Gas and Electric Company.

Description: 205(d) Rate Filing: Q2 2024 Quarterly Filing of City and County of San Francisco's WDT SA (SA 275) to be effective 6/30/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5000.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2628–000.

Applicants: Gravel Pit Solar, LLC.

Description: Baseline eTariff Filing: Filing of Co-Tenancy and Shared Facilities Agreement to be effective 9/11/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5021.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2629–000.

Applicants: DESRI Gravel Pit Construction Borrower, L.L.C.

Description: Baseline eTariff Filing: Filing of Co-Tenancy and Shared Facilities Agreement to be effective 9/11/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5022.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2630–000.

Applicants: Gravel Pit Solar III, LLC.

Description: Initial rate filing: Filing of Co-Tenancy and Shared Facilities Agreement to be effective 9/11/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5023.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2631–000.

Applicants: Gravel Pit Solar IV, LLC.

Description: Initial rate filing: Filing of Co-Tenancy and Shared Facilities Agreement to be effective 9/11/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5024.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2632–000.

Applicants: DESRI Gravel Pit Construction Borrower, L.L.C.

Description: Initial rate filing: Filing of Shared Facilities Agreement and Request for Waivers to be effective 9/11/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5026.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2633–000.

Applicants: Avista Corporation.

Description: 205(d) Rate Filing: Avista RS T1238 Glendive Wind Cert of Concurrence to be effective 6/18/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5068.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2634–000.

Applicants: Avista Corporation.

Description: 205(d) Rate Filing: Avista RS T1239 Glendive Wind Cert of Concurrence to be effective 6/18/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5071.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2635–000.

Applicants: AlbertaEx, L.P.

Description: Compliance filing: Notification of Non-Material Change in Status and MBR Tariff Changes to be effective 9/30/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5074.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2636–000.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: 205(d) Rate Filing: ISO New England Inc. submits tariff filing per 35.13(a)(2)(iii): 135th Agreement Amending NEPOOL Agreement & Participants Agreement Amendment #13 to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5075.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2637–000.

Applicants: Middletown Coke Company, LLC.

Description: Compliance filing: Middletown Coke Tariff Filing July 31 2024 to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5078.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2638–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Amended ISA, Service Agreement No. 6031; AB2–136 to be effective 9/30/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5089.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2639–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: 205(d) Rate Filing: Alabama Power Company submits tariff filing per 35.13(a)(2)(iii): Centaurus Solar Amended and Restated LGIA Filing to be effective 7/24/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5103.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2640–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Original WMPA, Service Agreement No. 7318; AG1–469 to be effective 7/2/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5104.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2641–000.

Applicants: Bayou Cove Peaking Power, LLC.

Description: 205(d) Rate Filing: Normal filing 2024 to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5106.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2642–000.

Applicants: PJM Interconnection, L.L.C.

Description: 205(d) Rate Filing: Original WMPA Service Agreement No. 7316, AF2–054 to be effective 7/2/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5108.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2643–000.

Applicants: Arizona Public Service Company.

Description: 205(d) Rate Filing: Rate Schedule No. 217, Exhibit B.BKE–LIB to be effective 10/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5113.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2644–000.

Applicants: Big Cajun I Peaking Power LLC.

Description: 205(d) Rate Filing: Normal filing 2024 to be effective 8/1/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5124.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2645–000.

Applicants: Cottonwood Energy Company LP.

Description: 205(d) Rate Filing:
Normal filing 2024 to be effective 8/1/
2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5136.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2646–000.

Applicants: Louisiana Generating
LLC.

Description: 205(d) Rate Filing:
Normal filing 2024 to be effective 8/1/
2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5141.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2647–000.

Applicants: PJM Interconnection,
L.L.C.

Description: 205(d) Rate Filing:
Original GIA, Service Agreement No.
7317, AF1–237 to be effective 7/2/2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5146.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2648–000.

Applicants: Granite Shore Power.

Description: 205(d) Rate Filing:
Normal filing 2024 to be effective 8/1/
2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5148.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2649–000.

Applicants: GSP Merrimack LLC.

Description: 205(d) Rate Filing:
Normal filing 2024 to be effective 8/1/
2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5152.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2650–000.

Applicants: GSP Newton LLC.

Description: 205(d) Rate Filing:
Normal filing 2024 to be effective 8/1/
2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5155.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2651–000.

Applicants: GSP Schiller LLC.

Description: 205(d) Rate Filing:
Normal filing 2024 to be effective 8/1/
2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5164.

Comment Date: 5 p.m. ET 8/21/24.

Docket Numbers: ER24–2652–000.

Applicants: GSP White Lake LLC.

Description: 205(d) Rate Filing:
Normal filing 2024 to be effective 8/1/
2024.

Filed Date: 7/31/24.

Accession Number: 20240731–5165.

Comment Date: 5 p.m. ET 8/21/24.

Take notice that the Commission
received the following electric securities
filings:

Docket Numbers: ES24–44–000.

Applicants: Wheeling Power
Company.

Description: Application Under
Section 204 of the Federal Power Act for
Authorization to Issue Securities of
Wheeling Power Company.

Filed Date: 7/29/24.

Accession Number: 20240729–5195.

Comment Date: 5 p.m. ET 8/19/24.

Docket Numbers: ES24–45–000;
ES24–46–000; ES24–47–000; ES24–48–
000; ES24–49–000; ES24–50–000; ES24–
51–000.

Applicants: National Grid Generation
LLC, New England Power Company,
New England Hydro-Transmission
Electric Company, Inc., Niagara
Mohawk Power Corporation, Nantucket
Electric Company, Massachusetts
Electric Company, National Grid USA.

Description: Application Under
Section 204 of the Federal Power Act for
Authorization to Issue Securities of
National Grid USA, et al. under ES24–
45 et al.

Filed Date: 7/30/24.

Accession Number: 20240730–5185.

Comment Date: 5 p.m. ET 8/20/24.

The filings are accessible in the
Commission's eLibrary system ([https://
elibrary.ferc.gov/idmws/search/
fercgensearch.asp](https://elibrary.ferc.gov/idmws/search/fercgensearch.asp)) by querying the
docket number.

Any person desiring to intervene, to
protest, or to answer a complaint in any
of the above proceedings must file in
accordance with Rules 211, 214, or 206
of the Commission's Regulations (18
CFR 385.211, 385.214, or 385.206) on or
before 5:00 p.m. Eastern time on the
specified comment date. Protests may be
considered, but intervention is
necessary to become a party to the
proceeding.

eFiling is encouraged. More detailed
information relating to filing
requirements, interventions, protests,
service, and qualifying facilities filings
can be found at: [http://www.ferc.gov/
docs-filing/efiling/filing-req.pdf](http://www.ferc.gov/docs-filing/efiling/filing-req.pdf). For
other information, call (866) 208–3676
(toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public
Participation (OPP) supports meaningful
public engagement and participation in
Commission proceedings. OPP can help
members of the public, including
landowners, environmental justice
communities, Tribal members and
others, access publicly available
information and navigate Commission
processes.

For public inquiries and assistance
with making filings such as
interventions, comments, or requests for
rehearing, the public is encouraged to
contact OPP at (202) 502–6595 or [OPP@
ferc.gov](mailto:OPP@ferc.gov).

Dated: July 31, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024–17399 Filed 8–6–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–494–000]

Black Bayou Gas Storage, LLC; Notice of Application and Establishing Intervention Deadline

Take notice that on July 17, 2024,
Black Bayou Gas Storage, LLC (Black
Bayou), 229 Heymann Blvd., Lafayette,
Louisiana 70503, filed an application
under section 7c of the Natural Gas Act
(NGA), and Part 157 of the
Commission's regulations requesting
authorization for its Black Bayou
Storage Project (Project). Black Bayou
proposes to construct a salt dome
natural gas storage facility in Cameron
and Calcasieu Parishes, Louisiana
consisting of: (1) 4 salt storage caverns,
with a total working gas capacity of 34.7
Bcf; (2) a 44,000 gas-driven
reciprocating engine compressor station;
(3) two 27.1-mile-long, 24-inch-diameter
bidirectional header pipelines
connecting the caverns to multiple
interstate pipelines; (4) 10 meter
stations; and (5) appurtenances.

Black Bayou further requests: (1) Part
157, Subpart F and Part 284, Subpart G
blanket certificates; (2) authorization to
charge market-based rates for its
proposed interstate storage services and
hub services; (3) approval of its pro
forma tariff; and (4) waiver of certain
Commission regulations, all as more
fully set forth in the application which
is on file with the Commission and open
for public inspection.

In addition to publishing the full text
of this document in the **Federal
Register**, the Commission provides all
interested persons an opportunity to
view and/or print the contents of this
document via the internet through the
Commission's Home Page ([http://
www.ferc.gov](http://www.ferc.gov)). From the Commission's
Home Page on the internet, this
information is available on eLibrary.
The full text of this document is
available on eLibrary in PDF and
Microsoft Word format for viewing,
printing, and/or downloading. To access
this document in eLibrary, type the
docket number excluding the last three
digits of this document in the docket
number field.

User assistance is available for
eLibrary and the Commission's website

during normal business hours from FERC Online Support at (202) 502-6652 (toll free at 1-866-208-3676) or email at ferconlinesupport@ferc.gov, or the Public Reference Room at (202) 502-8371, TTY (202) 502-8659. Email the Public Reference Room at public.referenceroom@ferc.gov.

Any questions regarding the proposed project should be directed to Tad Lalande, Chief Executive Officer, Black Bayou Gas Storage, LLC, 229 Heymann Blvd., Lafayette, Louisiana 70503, by phone at (337) 541-1200, or by email at TLalande@blackbayouenergyhub.com.

Pursuant to section 157.9 of the Commission's Rules of Practice and Procedure,¹ within 90 days of this Notice the Commission staff will either: complete its environmental review and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or environmental assessment (EA) for this proposal. The filing of an EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all Federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Water Quality Certification

Black Bayou stated that a water quality certificate under section 401 of the Clean Water Act is required for the project from the Louisiana Department of Environmental Quality. When available, Black Bayou should submit to the Commission a copy of the request for certification for the Commission authorization, including the date the request was submitted to the certifying agency, and either (1) a copy of the certifying agency's decision or (2) evidence of waiver of water quality certification.

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file comments on the project, you can protest the filing, and you can file a motion to intervene in the proceeding. There is no fee or cost for filing comments or intervening. The deadline for filing a motion to

intervene is 5:00 p.m. Eastern Time on August 21, 2024. How to file protests, motions to intervene, and comments is explained below.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502-6595 or OPP@ferc.gov.

Comments

Any person wishing to comment on the project may do so. Comments may include statements of support or objections, to the project as a whole or specific aspects of the project. The more specific your comments, the more useful they will be.

Protests

Pursuant to sections 157.10(a)(4)² and 385.211³ of the Commission's regulations under the NGA, any person⁴ may file a protest to the application. Protests must comply with the requirements specified in section 385.2001⁵ of the Commission's regulations. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

To ensure that your comments or protests are timely and properly recorded, please submit your comments on or before August 21, 2024.

There are three methods you can use to submit your comments or protests to the Commission. In all instances, please reference the Project docket number CP24-494-000 in your submission.

(1) You may file your comments electronically by using the eComment feature, which is located on the Commission's website at www.ferc.gov under the link to Documents and Filings. Using eComment is an easy method for interested persons to submit brief, text-only comments on a project;

(2) You may file your comments or protests electronically by using the eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and

Filings. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Comment on a Filing"; or

(3) You can file a paper copy of your comments or protests by mailing them to the following address below. Your written comments must reference the Project docket number (CP24-494-000).

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426
To file via any other courier: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of comments (options 1 and 2 above) and has eFiling staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Persons who comment on the environmental review of this project will be placed on the Commission's environmental mailing list, and will receive notification when the environmental documents (EA or EIS) are issued for this project and will be notified of meetings associated with the Commission's environmental review process.

The Commission considers all comments received about the project in determining the appropriate action to be taken. However, the filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding. For instructions on how to intervene, see below.

Interventions

Any person, which includes individuals, organizations, businesses, municipalities, and other entities,⁶ has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure⁷ and the regulations under the NGA⁸ by the intervention deadline

¹ 18 CFR 157.9.

² 18 CFR 157.10(a)(4).

³ 18 CFR 385.211.

⁴ Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

⁵ 18 CFR 385.2001.

⁶ 18 CFR 385.102(d).

⁷ 18 CFR 385.214.

⁸ 18 CFR 157.10.

for the project, which is August 21, 2024. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at <https://www.ferc.gov/resources/guides/how-to-intervene.asp>.

There are two ways to submit your motion to intervene. In both instances, please reference the Project docket number CP24-494-000 in your submission.

(1) You may file your motion to intervene by using the Commission's eFiling feature, which is located on the Commission's website (www.ferc.gov) under the link to Documents and Filings. New eFiling users must first create an account by clicking on "eRegister." You will be asked to select the type of filing you are making; first select "General" and then select "Intervention." The eFiling feature includes a document-less intervention option; for more information, visit <https://www.ferc.gov/docs-filing/efiling/document-less-intervention.pdf>; or

(2) You can file a paper copy of your motion to intervene, along with three copies, by mailing the documents to the address below. Your motion to intervene must reference the Project docket number CP24-494-000.

To file via USPS: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426

To file via any other courier: Debbie-Anne A. Reese, Acting Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852

The Commission encourages electronic filing of motions to intervene (option 1 above) and has eFiling staff available to assist you at (202) 502-8258 or FercOnlineSupport@ferc.gov.

Protests and motions to intervene must be served on the applicant either by mail or email at: Tad Lalande, Chief Executive Officer, Black Bayou Gas Storage, LLC, 229 Heymann Blvd., Lafayette, Louisiana 70503 or at TLalande@blackbayouenergyhub.com. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be downloaded from the

service list at the eService link on FERC Online. Service can be via email with a link to the document.

All timely, unopposed⁹ motions to intervene are automatically granted by operation of Rule 214(c)(1).¹⁰ Motions to intervene that are filed after the intervention deadline are untimely, and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations.¹¹ A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208-FERC, or on the FERC website at www.ferc.gov using the "eLibrary" link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to www.ferc.gov/docs-filing/esubscription.asp.

Intervention Deadline: 5:00 p.m. Eastern Time on August 21, 2024.

Dated: July 31, 2024.

Debbie-Anne A. Reese,

Acting Secretary.

[FR Doc. 2024-17397 Filed 8-6-24; 8:45 am]

BILLING CODE 6717-01-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2011-0374; FRL-12147-01-OCSPP]

Pesticides; Emergency Order Suspending the Registrations of All Pesticide Products Containing Dimethyl Tetrachloroterephthalate (DCPA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: The Environmental Protection Agency (EPA or Agency) is issuing an Emergency Order directing the suspension of all registrations issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for pesticide products containing the active ingredient dimethyl tetrachloroterephthalate (DCPA), also marketed under the trade name Dacthal. EPA has determined that continued sale, distribution, or use of DCPA products during the time required to cancel such products would pose an imminent hazard and that an emergency exists that does not permit EPA to hold a hearing before suspending such products. These determinations are based primarily on a risk of thyroid hormone perturbations in the fetuses of female bystanders and workers who apply DCPA or who enter treated fields after application. EPA has concerns that pregnant individuals may be currently exposed to DCPA at levels higher than those that cause fetal thyroid hormone disruption, but at which no thyroid effects would occur in the pregnant individual. The downstream effects of such hormone perturbations in the fetus may include low birth weight and irreversible and life-long impacts to children exposed in-utero, such as impaired brain development and motor skills. While the sole registrant of DCPA products, AMVAC Chemical Corporation (AMVAC), has attempted to address these concerns, EPA has determined that there is no combination of practicable mitigations under which DCPA use can continue without presenting an imminent hazard. Set forth below are the substantive bases for these determinations and the procedures that affected registrants must follow to obtain a hearing on or otherwise challenge these determinations.

DATES: This Emergency Order is issued and effective immediately upon signature. The sole affected registrant has also been notified by certified mail. Any request by the registrant for a

⁹ The applicant has 15 days from the submittal of a motion to intervene to file a written objection to the intervention.

¹⁰ 18 CFR 385.214(c)(1).

¹¹ 18 CFR 385.214(b)(3) and (d).

hearing on the issue of whether an imminent hazard exists must be received by the Clerk of the EPA Office of Administrative Law Judges (OALJ). A copy of the Emergency Order has been filed with the OALJ Clerk.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2011–0374, is available online at <https://www.regulations.gov>. Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Jean Overstreet, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: 202–566–2425; email address: overstreet.anne@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, farm worker and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

B. What action is the Agency taking?

EPA is issuing an Emergency Order directing the suspension of all registrations for pesticide products containing the active ingredient dimethyl tetrachloroterephthalate (DCPA), also marketed under the trade name Dacthal. See Unit II.

C. What is the Agency’s authority for taking this action?

The Emergency Order is issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, pursuant to section 6(c)(3) (7 U.S.C. 136d(c)(3)). See Unit IV.

D. What is DCPA?

DCPA is a benzoic acid herbicide (Herbicide Resistance Action Committee/Weed Science Society of America Group 3) which inhibits cell division of root tips in target plants. It controls annual grasses and broadleaf weeds before they emerge in a variety of agricultural crops. DCPA is registered for agricultural uses, including on *Allium* species, *Brassica* species, cucurbits, root vegetables, fruiting vegetables, strawberry, sod and nursery ornamental production. Non-agricultural uses of DCPA include non-residential grass/turf including golf courses and athletic fields. While these turf uses are considered non-residential because the treated turf is not a home lawn, there is still the potential for residential post-application exposures as a result of application to these use sites. The registered end-use product may be applied by handheld, ground, aerial, and chemigation equipment.

E. Why is EPA issuing this Emergency Order?

EPA has determined that the further sale, distribution, and use of DCPA as an herbicide would pose an imminent hazard during the period required to conduct administrative hearings concerning cancellation. EPA has further determined that an emergency exists with respect to all DCPA products which does not permit it to hold a hearing concerning its determination of imminent hazard before acting to prohibit further sale, distribution, and use of such products.

EPA has evaluated the available information concerning the risks and benefits associated with continued use of DCPA during the time required for a cancellation hearing. Based on this information, EPA has determined that the risks of continued use during this period outweigh the benefits and that registered DCPA products therefore pose an imminent hazard. The Agency has determined that this imminent hazard constitutes an emergency, such that sale, distribution, and use of all DCPA products must be suspended during the pendency of any expedited hearing held under FIFRA section 6(c)(2).

EPA’s findings concerning the existence of an imminent hazard and an emergency are summarized in Unit V., and Unit VI. then provides in greater detail the evidence and analyses upon which these findings are based.

II. Emergency Order

This Emergency Order suspends the registration of all pesticide products which contain DCPA (see Table 1). EPA has determined that continued registration of DCPA products during the time required to conduct a cancellation proceeding would likely result in unreasonable adverse effects on the environment (which, according to FIFRA section 2(j), includes “man and other animals living therein”) and therefore poses an imminent hazard. EPA has also determined that there is a substantial likelihood that the continued sale, distribution, or use of DCPA products during the pendency of a suspension hearing would result in serious harm and therefore that an emergency exists that does not permit EPA to hold a hearing before suspending such products. Accordingly, EPA is issuing this Emergency Order immediately suspending all registrations of DCPA products. The substantive rationale for these determinations is explained below.

TABLE 1—PESTICIDE PRODUCTS SUBJECT TO ORDER

Product	EPA Reg. No.	Registrant	Active ingredient
Dacthal Flowable Herbicide	5481–487	AMVAC	Dimethyl tetrachloroterephthalate (DCPA).
Dacthal W–75 Herbicide	W1050002	AMVAC	Dimethyl tetrachloroterephthalate (DCPA).
Technical Chlorthal Dimethyl	5481–495	AMVAC	Dimethyl tetrachloroterephthalate (DCPA).

Pursuant to FIFRA section 6(c)(3), EPA hereby suspends the registration of each pesticide product containing DCPA as identified in Table 1. Effective immediately, no person in any state may distribute, sell, offer for sale, hold for sale, ship, deliver for shipment, or receive and (having so received) deliver

or offer to deliver to any person any pesticide product containing DCPA. Additionally, in accordance with FIFRA section 6(a)(1), EPA has elected not to permit the continued use of existing stocks, consistent with its policies applicable to cancellations where the Agency has identified significant risk

concerns. See 56 FR 29362, 29367, June 26, 1991 (FRL–3845–4). Generally, the Agency will not permit continued distribution, sale, or use of a cancelled pesticide that raises risk concerns, absent a showing that the benefits of such use exceed the risks. The same facts supporting the imminent hazard

determination in this Emergency Order weigh heavily against allowing any sale, distribution, or use of DCPA during cancellation proceedings. Accordingly, this Emergency Order expressly prohibits any person from using any pesticide product containing DCPA for any purpose. However, EPA will allow continued distribution of existing stocks of DCPA for the express purpose of returning any DCPA product to the registrant of such products. EPA intends to issue a notice of intent to cancel the same DCPA products (identified in Table 1) within the next 90 days, pursuant to FIFRA section 6(c)(3).

III. Background

Based on indications that DCPA likely has effects on thyroid function in rats, (e.g., DCPA Reregistration Eligibility Decision, 64 FR 40370, July 26, 1999 (FRL-6087-4)), EPA determined that additional information was necessary for the Agency to complete its statutorily-required Registration Review of DCPA under FIFRA section 3(g). Accordingly, in 2013 EPA issued a data call-in (DCI) under FIFRA section 3(c)(2)(B) to the sole registrant of DCPA products, AMVAC, requiring the registrant to submit a number of studies, including a comparative thyroid assay (CTA). The Agency required the CTA to evaluate the potential impact (hazard) of DCPA exposure on thyroid hormone homeostasis and thyroid function in the developing organism. AMVAC submitted a dose range-finding report for the CTA in May 2021 as a first step towards satisfying the DCI requirement. However, by itself, this report was insufficient to satisfy the DCI. In April 2022, the Agency filed a Notice of Intent to Suspend the DCPA technical (manufacturing use) product, pursuant to FIFRA section 3(c)(2)(B). See *In re FIFRA Section 3(c)(2)(B) Notice of Intent to Suspend Dimethyl Tetrachloroterephthalate (DCPA) Technical Registration*, OALJ Docket No. FIFRA-HQ-2022-0002 (EPA 2022).

AMVAC subsequently submitted a definitive CTA in August 2022. The results of the CTA indicated that very low levels of DCPA cause thyroid hormone perturbations in fetal rats. *DCPA—Data Evaluation Record (DER) of a submitted definitive study to fulfill the Comparative Thyroid Assay (CTA) study requirement* (EPA 2023), available at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0080>. The level of exposure at which fetal hormone perturbations was observed (1 mg/kg/day) is at least 10-fold lower than the dose that did not cause adverse thyroid effects in maternal animals (10 mg/kg/day) in the

CTA, and lower than levels at which EPA estimates human users of DCPA are currently being exposed (maximum estimated exposure of 2.42 mg/kg/day for occupational handlers). See May 2023 ORE Assessment at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0081>.

In the fetus of exposed pregnant humans, thyroid hormone perturbations, such as those observed in the CTA, can lead to downstream health problems such as low birth weight, impaired brain development, decreased Intelligence Quotient (IQ), impaired motor skills, and decreased bone deposition (Chan, S; Kilby, MD. Thyroid hormone and central nervous system development. *Journal of Endocrinology*. April 1, 2000. 165:1–8; Fisher, DA. The importance of early management in optimizing IQ in infants with congenital hypothyroidism. *The Journal of Pediatrics*. March 2000. 136:274–274; Morreale de Escobar, G; Obregón, MJ; Sescobar del Rey, F. Is neuropsychological development related to maternal hypothyroidism or to maternal hypothyroxinemia? *The Journal of Clinical Endocrinology and Metabolism*. November 1, 2000. 85:3975–3987; Zoeller, RT; Rovet, J. Timing of thyroid hormone action in the developing brain: clinical observations and experimental findings. *Journal of Neuroendocrinology*. October 20, 2004. 16:809–818). Based on the CTA data for DCPA, these effects are not expected in exposed adults, but rather in children born to individuals exposed to DCPA during pregnancy and might not always be obvious in affected children at the time of birth. The health problems associated with thyroid hormone perturbations have long-lasting consequences for children exposed before birth that—when later identified—would not likely be recognized as resulting from prior pesticide exposure. *Id.*

In May 2023, an occupational and residential exposure (ORE) assessment was conducted based on the two DCPA end-use products registered at that time [EPA Reg. Nos. 5481–487 (a liquid formulation) and 5481–490 (a wettable powder formulation)]. See 88 FR 89447, December 27, 2023 (FRL-11590-01–OCSPP) (final cancellation order for EPA Reg. No. 5481–490). Risks of concern were identified for multiple scenarios, including occupational scenarios (handler and post-application), residential post-application scenarios, and non-occupational post-application bystander spray drift scenarios. Occupational handler scenarios were of concern assuming label-prescribed personal

protective equipment (PPE), and even assuming maximum PPE and/or engineering controls. Occupational post-application scenarios were of concern on the day of application (the current label required restricted entry interval of 12 hours) and even past 30 day after application. It should be noted that available data for DCPA indicates that while DCPA residues decline on treated foliage after application, residues that are present even out 40 days post-application can result in risks of concern. For bystander spray drift scenarios, risks were of concern up to and greater than 300 feet from the field edge.

These risks of concern indicate that individuals, either using DCPA products as currently registered, working in areas/fields treated with DCPA, or present near areas where DCPA is being used can be exposed to DCPA at levels greater than the level at which no adverse effects were observed in rat fetuses in the CTA. In some situations, pregnant individuals are likely being exposed to DCPA at levels greater than the level at which adverse effects were observed in the study. EPA is concerned that exposure at these levels could result in adverse effects to the fetuses of the pregnant individuals being exposed. Although the registrant has presently unilaterally promised to halt the sale and distribution of DCPA (until EPA approves new labels incorporating the registrant's proposed mitigations), DCPA products that were sold or distributed prior to this voluntary cessation remain in the hands of growers, and the Agency has no mechanism to enforce the voluntary cessation. DCPA is used year-round on certain crops, so EPA believes that these exposures of concern are likely to be occurring at present. Succinctly, EPA believes that the continued use of DCPA products will allow for people, particularly pregnant individuals, to be unknowingly exposed to DCPA at levels that result in a risk of concern and in some cases, are equal to or greater than those that result in fetal thyroid hormone perturbations in the CTA and the life-long health effects that may result from those perturbations.

In addition to assessing the risks posed by continued registration or use of DCPA, the Agency also assessed all currently registered uses of the pesticide to conduct a “rough and ready balancing” of health risks against economic benefits. *Love v. Thomas*, 858 F.2d 1347, 1361–62 (9th Cir. 1988). DCPA's main benefits are its broad spectrum of weed control and its safety to the crop when applied as a band of spray within rows of crops (“banded

within rows”) at planting in direct-seeded production of *Brassicas* and registered *Alliums*. Weed control prior to crop emergence is important in these crops, especially in *Alliums*, as these crops are slow to emerge and vulnerable to early season weed competition.

DCPA has high benefits for growers of specialty *Brassica* crops (e.g., bok choy, collards and kale), which have fewer alternative pre-emergence herbicides than major *Brassica* crops (e.g., broccoli, brussels sprouts, cabbage, cauliflower). Without DCPA, growers of specialty *Brassica* crops could incur significant additional costs. DCPA has medium benefits for growers of direct-seeded major *Brassicas*, who have access to alternative herbicides and other options. DCPA provides low benefits for growers of transplanted major *Brassicas*, who have adequate alternatives available to replace DCPA. In *Alliums*, DCPA has high benefits for green onions and leeks in California due to a lack of registered preemergence herbicides for those uses. DCPA has low benefits in dry bulb onion and shallots where growers can replace DCPA with other alternatives. DCPA has low benefits in all other registered uses, and data available to EPA indicate that actual herbicide applications for these uses are limited. Though growers of *Brassica* and *Allium* crops may be substantially impacted, these crops are internationally traded, and the global price is unlikely to increase. If the global price does not increase, growers will be unable to pass cost increases on to the consumer, thus this Emergency Order is likely to result in negligible impact at the consumer level. For more information, see *Assessment of Dimethyl Tetrachloroterephthalate (DCPA) (PC: 078701) Use, Usage, and Benefits*, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0088>.

Between EPA’s issuance of the May 2023 ORE Assessment and April 2024, the Agency and AMVAC discussed how to limit exposures to DCPA. AMVAC voluntarily cancelled all but two of its DCPA products [(EPA Reg. Nos. 5481–495 (technical product) and 5481–487 (liquid end-use product)] pursuant to FIFRA Section 6(f). 88 FR 89447, December 27, 2023 (FRL–11590–01–OCSPP) (final cancellation order). These product cancellations limited registered end-use products to only one liquid formulation (a Special Local Need (SLN) registration in Wisconsin remains active (WI050002), but will imminently be cancelled pursuant to FIFRA Section 4 due to AMVAC’s failure to pay the required maintenance fees). Further, in July 2023, the registrant requested to

voluntarily cancel uses on turf from its remaining product. While these voluntary cancellations would eliminate residential post-application exposures to DCPA from activities on and around turf (including golf courses and athletic fields), the currently available product labels have not been revised—due to the remaining issues not addressed by the proposed mitigations—and still allow for these uses.

AMVAC submitted additional proposals in April 2024 and May 2024 to address the identified risk to handlers, post-application workers and residential bystanders that still remained even after cancelling the products identified above and proposing cancellation of the turf uses. These additional proposals include limiting the amount of product individual handlers are allowed to use, only permitting banded applications, limiting applications over the top of crops to reduce the post-application exposure potential, and requiring buffers around agricultural applications to address risks in residential areas from spray drift. In April 2024, AMVAC informed EPA that the company had voluntarily ceased sale and distribution of all Dacthal Flowable Herbicide (the only remaining end-use product) in the company’s possession until the Agency approved product labels addressing the risks described in the May 2023 ORE Assessment. Although the registrant has presently unilaterally promised to halt the sale and distribution of DCPA, DCPA products that were sold or distributed prior to this voluntary cessation remain in the hands of growers. DCPA is used year-round on certain crops, so EPA believes that exposures of concern likely continue to occur.

While the voluntary steps identified above may reduce the risks of concern identified for DCPA, according to the Agency’s analysis, these steps would not adequately address all of the identified risks of concern, leaving the current approved product label in use. As noted in the May 2023 ORE Assessment, use under the current approved product label can result in pregnant individuals being unknowingly exposed to DCPA at levels greater than the level at which adverse effects were observed in the CTA. EPA is concerned that exposure at these levels could result in adverse effects to the fetuses of the pregnant individuals being exposed. There are unknown amounts of existing DCPA product in the hands of users which may lead to the serious and significant health outcomes described in this Emergency Order. Additional explanation as to why

the proposed mitigations do not address the risks of concern or alleviate the imminent hazard from continued DCPA use is provided in Unit VII., below. Due to the concerns summarized, EPA does not believe that the risks identified in this Emergency Order can be sufficiently mitigated through any means except cancellation and immediate suspension of all products containing DCPA. Accordingly, issuance of this Emergency Order is necessary.

IV. Legal Authority

A. Standards for Maintaining a Registration and Cancellation

FIFRA provides for federal regulation of pesticide distribution, sale, and use. 7 U.S.C. 136 *et seq.* Subject to limited exceptions, a pesticide may be distributed or sold in the United States only if it is registered by the EPA under FIFRA section 3(a). A registration is a license allowing a pesticide product to be sold and distributed for specified uses in accordance with specified use instructions, precautions, and other terms and conditions. Before EPA may register a pesticide under FIFRA, an applicant must show, among other things, that using the pesticide according to its specifications “will not generally cause unreasonable adverse effects on the environment.” FIFRA section 3(c)(5)(D). “Unreasonable adverse effects on the environment” is defined, in part, as “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of [the] pesticide.” FIFRA section 2(bb). This portion of the unreasonable adverse effects standard creates a “risk-benefit” standard wherein the EPA compares the risks presented from the use of a pesticide with the benefits from the use of the pesticide. The burden to demonstrate that a pesticide product satisfies the criteria for registration is at all times on the proponents of initial or continued registration. *Indus. Union Dept. v. Am. Petroleum Inst.*, 448 U.S. 607, 653 n. 61 (1980); *Env’tl. Defense Fund v. EPA*, 510 F.2d 1292, 1297, 1302 (D.C. Cir. 1975).

Whenever the Agency determines that the product no longer satisfies the statutory criteria for registration, it may issue a notice of intent to cancel the registration of a pesticide product under FIFRA section 6(b). In such notice, the Agency may specify particular modifications in the terms and conditions of registration, such as deletion of particular uses or revisions of labeling, as an alternative to cancellation. If a hearing is requested by an adversely affected person, the final

order concerning cancellation of the product is not issued until after a formal administrative hearing. FIFRA section 6(d). For purposes of this Emergency Order, and in conformity with the timetable for any cancellation hearing held pursuant to FIFRA section 6(b), EPA has assumed that a cancellation hearing concerning the registered DCPA products would require at least 18 months.

B. Suspension of a Pesticide Product

The suspension provisions in FIFRA section 6(c) give EPA the authority to take interim action until completion of the time-consuming procedures which may be required to reach a final cancellation decision. Under this authority, EPA may suspend the registration of a product and prohibit its distribution, sale, or use during cancellation proceedings upon a finding that the pesticide poses an “imminent hazard” to humans or the environment. FIFRA section 6(c)(1). Suspension is an interim remedy which enables the Agency to abate potential unreasonable adverse effects in advance of the full analysis of risks and benefits in a cancellation hearing. The function of suspension “is to make a preliminary assessment of evidence, and probabilities, not an ultimate resolution of difficult issues.” *Envtl. Defense Fund v. EPA*, 465 F.2d 528, 537 (D.C. Cir. 1972). FIFRA section 2(1) defines “imminent hazard” as “. . . a situation which exists when the continued use of a pesticide during the time required for cancellation proceedings would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered by the Secretary of the Interior under Public Law 91–135.”

As noted previously, “unreasonable adverse effects on the environment” means that the risks associated with use of a pesticide outweigh the benefits of its use. Thus, in order to find an “imminent hazard,” the Agency must determine that the risks appear to outweigh the benefits associated with continued registration during the period likely to be necessary to complete a cancellation proceeding. Courts addressing the suspension provisions of FIFRA section 6 have held that an imminent hazard exists if there is “a substantial likelihood that serious harm will be experienced during the year or two required in any realistic projection of the administrative [cancellation] process.” *Love*, 858 F.2d at 1350 (quoting *Envtl. Defense Fund v. EPA*, 465 F.2d at 540). Thus, courts interpreting the FIFRA section 6

suspension standard have made clear that an imminent hazard finding requires a greater degree of likelihood, immediacy, and severity of harm than is otherwise required to take cancellation action under FIFRA. In evaluating the nature and extent of information before the agency, courts have instructed EPA to consider:

- (1) The seriousness of the threatened harm;
- (2) The immediacy of the threatened harm;
- (3) The probability that the threatened harm will occur;
- (4) The benefits to the public of the continued use of the pesticide; and
- (5) The nature and extent of the information before the Agency at the time it makes a decision.

Dow Chem. Co. v. Blum, 469 F.Supp. 892, 902 (E.D. Mich. 1979).

C. Emergency Suspension

If the Administrator determines that: (1) A pesticide poses an imminent hazard, and (2) An emergency exists that does not permit the Administrator to hold a hearing before suspending the pesticide, FIFRA section 6(c)(3) provides that the Administrator may issue an Emergency Order immediately suspending registration of the pesticide.

The term “emergency” is not defined by FIFRA. In the case of emergency suspension, one court has found by analogy that suspension is appropriate if there is “a substantial likelihood that serious harm will be experienced during the three or four months required in any realistic projection of the administrative suspension process.” *Dow Chem. Co.*, 469 F.Supp. at 901. The Agency interprets FIFRA section 6(c)(3) to mean that, if the threat of harm to humans or the environment associated with continued sale, distribution, or use of a pesticide is sufficiently serious and immediate that the risks would be likely to outweigh the benefits during the time required for a suspension hearing, the registration of that pesticide may be suspended immediately. Thus, the determination whether an emergency exists is even more preliminary than the determination concerning the question of imminent hazard, and an Emergency Order is analogous to a temporary restraining order issued by a court while it is determining whether to issue a preliminary injunction. *Dow Chem. Co.*, 469 F.Supp. at 901.

An Emergency Order to suspend a registration may be issued without prior notice to affected registrants and is effective immediately upon issuance. In contrast to a notice of intent to suspend issued pursuant to FIFRA section 6(c)(1), there is no requirement that EPA

issue a notice of intent to cancel the registration or change the classification of that pesticide prior to or simultaneously with issuing an Emergency Order of suspension. The Agency may issue an Emergency Order of suspension, effective immediately, prior to issuing a notice of intent to cancel. However, if EPA does not issue a notice of intent to cancel within 90 days of issuing an Emergency Order of suspension, the Emergency Order of suspension will expire.

The Agency must notify the affected registrant that an Emergency Order of suspension has been issued and the registrant may request an expedited hearing by submitting a valid hearing request to the OALJ Clerk. If an expedited hearing is held concerning any product, the hearing is confined solely to the question of imminent hazard, and the Emergency Order of suspension remains in effect during the pendency of the expedited hearing. Following the expedited hearing, the Administrator issues a final order which may either retain, modify, or rescind the suspension. FIFRA section 6(c)(2).

The Administrator’s determination to issue an Emergency Order of suspension is also subject to immediate review in an appropriate United States district court. The only issues in any such review are whether the Emergency Order was arbitrary, capricious, or an abuse of discretion, and was issued in accordance with procedures established by law. FIFRA section 6(c)(4).

If a registrant does not request an expedited hearing concerning a particular product but does request a hearing concerning cancellation of that product, the Emergency Order of suspension remains in effect until the completion of the cancellation proceeding, unless the suspension is lifted, stayed, or otherwise modified by the Administrator or an appropriate federal court.

V. Findings Concerning Imminent Hazard and Emergency

This unit summarizes EPA’s findings concerning the existence of an imminent hazard and an emergency.

A. Findings Concerning Imminent Hazard

1. Nature and Extent of Information Before the Administrator

In evaluating the risks which DCPA would pose during the time needed to conduct a cancellation hearing, EPA has placed the greatest emphasis on the results of the CTA submitted to the Agency, which indicates that very low levels of DCPA (at least 10-fold lower

than a dose that did not cause adverse thyroid effects in maternal animals in the CTA) causes thyroid hormone perturbations in fetal rats. *DCPA—Data Evaluation Record (DER) of a submitted definitive study to fulfill the Comparative Thyroid Assay (CTA) study requirement* (EPA 2023), available at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0080>. The Agency required the CTA to evaluate the potential impact (hazard) of DCPA exposure on thyroid hormone homeostasis and thyroid function in the developing organism. Subsequent analysis of the CTA data by the Agency and review of registered end-use product labels as of May 2023, in combination with multiple other data sources, enabled the production of *DCPA Occupational and Residential Exposure Assessment for the Registration Review of DCPA* (May 18, 2023) (May 2023 ORE Assessment). This analysis indicates that current uses of DCPA may expose pregnant individuals to levels of the pesticide sufficient to cause adverse thyroid effects—with attendant lifelong health problems—in the fetuses of those individuals. There are still risk concerns even when taking into consideration the subsequent December 2023 product cancellations, the July 2023 voluntary use cancellation requests, and the registrant's voluntary cessation of the sale and distribution of DCPA.

EPA also took time to gather and evaluate essential and available data on the benefits associated with DCPA use. While this benefits assessment focused primarily on the heaviest current use patterns and locations, EPA also assessed DCPA use on a national level for all registered uses, to the extent that information was available to the Agency. Accordingly, as discussed in Unit VI. of this Emergency Order, EPA assessed DCPA's benefits as a preemergence treatment in crops with registered uses, primarily *Brassica* vegetables and *Alliums*, based on the observed usage of DCPA in these crops, weed control recommendations, and other information on DCPA's benefits from extension publications, pest management strategic plans, United States Department of Agriculture Office of Pest Management Policy (USDA OPMP), and a report from faculty at the University of California (UC) Davis on DCPA's benefits in California agriculture.

2. Seriousness of the Threatened Harm

In the CTA, decreased levels of the thyroid hormones T3 (triiodothyronine) and T4 (thyroxine) were observed in rats exposed to very low levels of DCPA (1

mg/kg/day). The level of exposure at which fetal hormone perturbations were observed is much lower than the level at which effects were observed in adult rats, and lower than levels at which EPA estimates human users of DCPA are currently being exposed. See May 2023 ORE Assessment at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0081>.

In the fetus of exposed pregnant humans, thyroid hormone perturbations, such as those observed in the CTA, can lead to downstream health problems such as low birth weight, impaired brain development, decreased IQ, impaired motor skills, and decreased bone deposition (Chan and Kilby, 2000; Fisher, 2000; Morreale, et al., 2000; Zoeller and Rovet, 2004). Based on the CTA data for DCPA, these effects are not expected in exposed adults, but rather in children born to individuals exposed to DCPA during pregnancy and might not always be obvious in affected children at the time of birth. Brief thyroid hormone perturbations in fetuses during critical stages of development may result in life-long consequences for children exposed before birth (e.g., impaired brain development, decreased IQ, and impaired motor skills) that—when later identified—would not likely be recognized as resulting from prior pesticide exposure. *Id.*

3. Immediacy of the Threatened Harm

EPA has determined that there are likely immediate, ongoing risks of concern presented by continued use of DCPA. Of primary concern, based on usage data, are the risks identified in the May 2023 ORE Assessment for occupational scenarios (handler and post-application) and non-occupational post-application bystander spray drift scenarios. Occupational handler scenarios were of concern assuming label-prescribed PPE, and even assuming maximum PPE and/or engineering controls. Occupational post-application scenarios were of concern on the day of application (the current label required restricted entry interval of 12 hours) and even past 30 days after application. It should be noted that available data for DCPA indicates that while DCPA residues decline on treated foliage after application, residues that are present more than 40 days post-application for some uses can result in risks of concern. For bystander spray drift scenarios, risks were of concern up to and greater than 300 feet from the field edge.

These risks of concern indicate that individuals, either using DCPA products as currently registered, working in

areas/fields treated with DCPA, or present near areas where DCPA is being used, can be unknowingly exposed to DCPA at levels greater than the level at which no adverse effects were observed in rat fetuses in the CTA, and in some situations, can be exposed to DCPA at levels greater than the level at which adverse effects were observed in the study. EPA is concerned that exposure at these levels could result in adverse effects to the fetuses of pregnant individuals being exposed. Although the registrant has presently unilaterally promised to halt the sale and distribution of DCPA (until EPA approves new labels incorporating the registrant's proposed mitigations), DCPA products that were sold or distributed prior to this voluntary cessation remain in the hands of growers and EPA has no mechanism to enforce this voluntary cessation. DCPA is used year-round on certain crops; EPA thus believes that these exposures of concern are likely occurring at present. To summarize, EPA believes that the continued use of DCPA products will allow for people, particularly pregnant individuals, to be unknowingly exposed to DCPA at levels that result in a risk of concern and in some cases, are equal to or greater than those that result in fetal thyroid hormone perturbations in the CTA and the life-long health effects that may result from those perturbations.

4. Probability That the Threatened Harm Will Occur

Based on EPA's analysis of the available evidence, the fetuses of pregnant individuals exposed to DCPA are at significant risk for adverse thyroid hormone changes. Without this Emergency Order, such exposures would continue during the time required to conduct a cancellation hearing. If the products were not suspended, use of DCPA could lawfully continue during the pendency of a cancellation hearing.

Although EPA considered AMVAC's statement that the company has voluntarily temporarily ceased sale and distribution of Dacthal Flowable Herbicide in the context of this determination, EPA still considers the probability of the harm in this situation sufficiently likely to justify this Emergency Order. While such voluntary steps would likely reduce the risks of concern identified for DCPA, the Agency has no means of assessing whether AMVAC is adhering to this temporary cessation of sale, neither EPA nor AMVAC has information concerning subsequent downstream distribution and use, and—in any event—there is no

mechanism under FIFRA through which EPA can enforce compliance with such voluntary measures. AMVAC could resume sale and distribution at any time, and application of DCPA products by end users is still allowed under current approved product labels.

EPA also considered, in the context of this determination, AMVAC's voluntary cancellation of all but two of its DCPA products (EPA Reg. Nos. 5481–495 and 5481–487; a SLN registration in Wisconsin remains active (WI050002), but will imminently be cancelled pursuant to FIFRA section 4 due to AMVAC's failure to pay the required maintenance fees) pursuant to FIFRA section 6(f). 88 FR 89447, December 27, 2023 (FRL–11590–01–OCSPP) (final cancellation order). Additionally, AMVAC submitted several revised proposed product labels from approximately July 2023 through May 2024, including its requests to cancel certain uses of DCPA. Of particular note, in July 2023 the registrant requested to voluntarily cancel remaining (non-residential) uses on turf from its remaining products. Accordingly, while risks of concern arising from turf uses are addressed in the May 2023 ORE Assessment, those risks are not part of the basis for this Emergency Order. However, the proposed product labels do not adequately address the risks of concern for continued DCPA use. Following the registrant's April and May proposals, EPA has determined that there is no combination of practicable mitigations under which DCPA use can continue without presenting an imminent hazard. Additional explanation as to why the proposed mitigations do not address the risks of concern or alleviate the imminent hazard from continued DCPA use is provided in Unit VII. of this Emergency Order. Due to the concerns described in this unit, EPA does not believe that the risks identified in this Emergency Order can be mitigated through any means except cancellation and immediate suspension of all products containing DCPA. Accordingly, issuance of this Emergency Order is necessary.

5. Benefits to the Public of the Continued Use of DCPA

While DCPA has high benefits for the growers of certain crops, EPA estimates that the suspension and cancellation of DCPA is likely to have negligible impacts to consumers of those crops. DCPA is registered for use in the production of *Brassica* (cole) vegetables (e.g., broccoli, cabbage, cauliflower, brussels sprouts), certain *Alliums* (onions, including dry bulb and various

green onions), certain cucurbit, root, and fruiting vegetables, strawberries, sod, and nursery ornamental plants. While DCPA is registered for non-agricultural turf uses, the registrant has requested cancellation of these uses; thus, these non-agricultural turf uses are not addressed here. DCPA is applied preemergent to the crop, and growers use DCPA for residual control of major broadleaf and grassy weeds, including common chickweed, common purslane, dodder, annual bluegrass, canarygrass, and barnyardgrass. DCPA's main benefits are its broad spectrum of weed control and its safety to the crop at planting in direct-seeded production of *Brassicas* and registered *Alliums*. Weed control prior to crop emergence is important in these crops, especially in *Alliums*, as these crops are slow to emerge and vulnerable to early-season weed competition.

DCPA has high benefits for growers of specialty *Brassica* crops (e.g., bok choy, collards, and kale), which have fewer alternative pre-emergence herbicides than major *Brassica* crops (e.g., broccoli, brussels sprouts, cabbage, cauliflower). In the absence of DCPA, growers of specialty *Brassica* crops would need to use a combination of alternative herbicides and hand-weeding labor to achieve the same level of control, at an additional cost to growers. Growers of specialty *Brassica* crops could lose up to 20% of gross revenue in the absence of DCPA due to lower yield resulting from less dense planting to avoid damage from hand-weeding, competition from uncontrolled weeds, or crop damage and increased labor costs resulting from increased hand-weeding.

DCPA has medium benefits for growers of direct-seeded major *Brassicas* who can acquire hand-weeding labor. In the absence of DCPA, growers of direct-seeded broccoli, brussels sprouts, cabbage, and cauliflower could replace DCPA with alternative preemergence herbicides and increased hand-weeding, facing estimated cost increases of \$40 per acre or 1% of gross revenue. If growers are unable to acquire the labor for increased hand-weeding, they would either have to switch to transplanting (as opposed to direct-seeding) and using oxyfluorfen, which is registered on *Brassicas* for transplanted broccoli, cabbage, and cauliflower only (growers of brussels sprouts can use napropamide), or else face yield loss. Both switching to transplanting with oxyfluorfen or using bensulide without additional hand-weeding may result in losses of over \$700 per acre or 9% of gross revenue.

In *Alliums*, DCPA has high benefits for green onions and leeks in California

due to a lack of registered preemergence herbicides for those uses. DCPA has low benefits in dry bulb onion and shallots where growers can replace DCPA with pendimethalin or a combination of bensulide and additional hand-weeding for sufficient control of early season weeds.

DCPA has low benefits in strawberry and the remaining cucurbit, fruiting, and root vegetables for which it is registered for use because extension publications do not recommend DCPA and/or recommend alternative preemergence herbicides; where surveyed, growers do not report using DCPA extensively on these crops. DCPA also has low benefits in sod and ornamental production as registered and recommended alternative herbicides are available on these use sites and growers do not report using DCPA.

In the use sites where there are high benefits from the use of DCPA, its absence could result in growers who rely on DCPA shifting to production of other crops. For registered *Brassica* and *Allium* crops, use of alternatives will likely result in increased treatment costs for growers, but these costs will have a negligible impact at the consumer level. The shift away from production of *Brassicas* could decrease U.S. production of *Brassica* crops; however, *Brassicas* are internationally traded crops, the total supply globally is unlikely to substantially decrease, and the global price for these commodities is unlikely to substantially increase. If the global price for these commodities does not increase, growers will be unable to pass cost increases from the absence of DCPA on to consumers. Thus, this Emergency Order is likely to result in negligible impact at the consumer level, but some growers of *Brassica* and *Allium* crops may be substantially impacted.

For additional details on the benefits of DCPA in registered use sites, see *Assessment of Dimethyl Tetrachloroterephthalate (DCPA) (PC: 078701) Use, Usage, and Benefits*, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0088>.

B. Findings Concerning Existence of an Emergency

The Agency has determined that an emergency exists such that sale, distribution, and use of all DCPA products must be suspended during the pendency of any expedited hearing. In order to find that an emergency exists, EPA must determine whether the threat of harm associated with continued sale, distribution, or use of DCPA products is sufficiently serious and immediate that

the risks outweigh the benefits during the time required for a suspension hearing. For purposes of this determination, and in conformity with the mandatory timetable for any hearing on the question of imminent hazard established by FIFRA section 6(c)(2) and 40 CFR part 164, subpart D, EPA assumes that a suspension hearing would require approximately four months. *Dow Chem. Co.*, 469 F.Supp. at 901.

Although EPA considered AMVAC's statement that the company has voluntarily ceased sale and distribution of Dacthal Flowable Herbicide in the context of this determination, EPA still considers the probability of the harm in this situation sufficiently likely to justify this Emergency Order. While such voluntary steps would likely reduce the risks of concern identified for DCPA, the Agency has no means of assessing whether AMVAC is adhering to this temporary cessation of sale, neither EPA nor AMVAC has information concerning subsequent downstream distribution and use, and—in any event—there is no mechanism under FIFRA through which EPA can enforce compliance with such voluntary measures. AMVAC could resume sale and distribution at any time, and application of DCPA products by end users is still allowed under current approved product labels.

In the absence of an emergency order, it appears that exposures to pregnant individuals resulting in adverse fetal thyroid effects could unknowingly occur as a result of lawful use during the time required for a suspension hearing. DCPA is registered and is typically used for weed control throughout the calendar year on a variety of crops, including *Allium* species, *Brassica* species, cucurbits, root vegetables, fruiting vegetables, and strawberry.

An immediate prohibition on use of DCPA products may cause some disruption, as users need to identify and obtain or implement alternatives. However, the Agency has concluded that alternative pesticides are available for most DCPA target pests and use sites, though there will be impacts on growers as they transition to combinations of alternative herbicides and hand weeding at an additional cost, and some *Brassica* and *Allium* growers that currently use DCPA may choose to cease production of these crops. Growers who have DCPA at the time the order is issued will not only have to obtain other weed control products, but they will also bear the burden of disposing of DCPA products. Based on the available evidence on risks and

benefits, EPA has determined that an emergency exists that does not permit the Agency to hold a hearing before suspending the registration of DCPA products. EPA has concluded that the risks of continued use are sufficiently serious and immediate to require immediate prohibition of all use of all pesticide products containing DCPA. EPA has also concluded that continued distribution or sale of DCPA products would be inconsistent with and frustrate enforcement of any prohibition on continued use of such products.

C. Waiver of Consultation With the Secretary of Agriculture and Submission to the FIFRA Scientific Advisory Panel

Although FIFRA section 6(b) generally requires prior review of and comment upon proposed notices of intent to cancel by the Secretary of Agriculture and the FIFRA Scientific Advisory Panel (SAP), FIFRA specifically provides the Administrator with the authority to waive such requirements and proceed in accordance with FIFRA section 6(c) whenever it finds that suspension of a pesticide registration is necessary to prevent an imminent hazard to human health. As described in this unit, EPA has found that immediate suspension of the registrations of pesticide products containing DCPA is necessary to prevent an imminent hazard to human health, and the Administrator hereby invokes the authority to waive the requirements for the Secretary of Agriculture and FIFRA SAP reviews.

VI. Analysis of Risk Posed by Continued Use of DCPA

As noted previously, in May 2023, an ORE assessment was conducted based on the two DCPA products registered at the time: EPA Reg. Nos. 5481–487 (a liquid formulation) and 5481–490 (a wettable powder formulation). The wettable powder product has since been voluntarily cancelled by AMVAC. Full details of inputs, assumptions and calculations are provided in the ORE Assessment. A summary of the exposure and risks identified in the May 2023 ORE Assessment are presented below. This summary takes into account the product cancellations that occurred in December 2023 (*i.e.*, the summary is only representative of the remaining liquid end-use product). While this product does allow for use on non-residential turf (including golf course and athletic fields), for which risks of concern were identified, a summary is not included here since those uses were requested for voluntary cancellation. The primary concern addressed by this Emergency Order is occupational risks

and non-occupational bystander drift risks.

A. Hazard Characterization

Any risk assessment begins with an evaluation of a chemical's properties that have the potential to cause adverse effects to humans. In evaluating toxicity or hazard, EPA reviews toxicity data, typically from studies with laboratory animals, to identify any adverse effects on the test subjects leading to the establishment of a Lowest Observed Adverse Effect Level (LOAEL) and a No Observed Adverse Effect Level (NOAEL). A Point of Departure (POD) is the dose that serves as the 'starting point' in extrapolating a risk to the human population. PODs are selected to be protective of the most sensitive adverse toxic effect for each exposure scenario and are chosen from toxicity studies that show clearly defined NOAELs or LOAELs, dose-response relationships, and relationships between the chemical exposure and effect. EPA will select separate PODs, as needed, for each expected exposure duration and route of exposure.

DCPA has low acute toxicity via the oral, dermal, and inhalation routes (Toxicity Category III–IV). DCPA is not a dermal sensitizer and is classified as Toxicity Categories III and IV for eye and skin irritation, respectively. Thyroid effects are the most sensitive endpoints in the DCPA toxicity database. Thyroid histological alterations and thyroid hormone perturbations were seen at all exposure durations and across lifestages. The decreased fetal thyroid hormone levels identified in the CTA are the basis for occupational and adult bystander assessments. Toxicological PODs for adults (including pregnant individuals) were selected for the following routes of exposure:

- Short- and intermediate-term dermal; and
- Short- and intermediate-term inhalation.

Although no adverse effects were observed up to the highest doses tested in the route-specific dermal and inhalation studies (1,000 mg/kg/day and 3.11 mg/L, respectively), increased quantitative susceptibility in the fetal life stage was observed in the definitive CTA in rats. Thus, an oral POD was selected for dermal and inhalation risk assessment because the dermal and inhalation toxicity studies did not evaluate the critical endpoint (thyroid hormone levels, thyroid weights or thyroid histopathology) or the fetal lifestage that were identified as the most sensitive endpoint and lifestage, respectively, in the DCPA database for

these exposure scenarios. The NOAEL of 0.1 mg/kg/day from the CTA served as the POD for evaluating short- and intermediate-term adult dermal and inhalation exposure scenarios. Although the POD for adults is based on the disruption of the thyroid hormones in rats, the 10X interspecies extrapolation factor is retained because the young (fetus) has been identified as the target life stage of concern and differences in the toxicodynamics for the developing thyroid function between juvenile rats and juvenile humans are not well understood. The level of concern (LOC) for adult dermal and inhalation exposure scenarios is 100 (10X interspecies extrapolation, 10X intraspecies variation, and 1X FQPA when applicable). For dermal exposure scenarios, a dermal absorption factor (DAF) of 15%, based on the results of an *in vivo* dermal absorption study (MRID 42651502), was applied to account for the amount of chemical absorbed through the skin. For the inhalation exposure scenario, toxicity via the inhalation route is assumed to be equivalent to oral exposure.

Since decreased fetal thyroid hormone levels (a female specific effect) is the endpoint for both the dermal and inhalation exposure scenarios, a body weight of 69 kg (representing females) was used in the dose calculations rather than 80 kg (representing males and females). This body weight was used for the ORE assessment because it accounts for the adverse effects to the fetal life stage and is protective of pregnant individuals.

Although a cancer assessment was also presented for DCPA in the May 2023 ORE Assessment, the concern for the Emergency Order are the non-cancer risks, specifically for the fetuses of exposed pregnant individuals. As such, only information related to the non-cancer risks for adults are further summarized here.

B. Occupational Exposure and Risk Estimates

1. Occupational Post-Application Exposure/Risk Estimates

EPA uses the term post-application to describe exposures that occur when individuals are present in an environment that has been previously treated with a pesticide (also referred to as re-entry exposure). Such exposures may occur when workers enter previously treated areas to perform job functions, including activities related to crop production, such as scouting for pests or harvesting. Post-application exposure levels vary over time and depend on such things as the type of

activity, the nature of the crop or target that was treated, the type of pesticide application, and the chemical's degradation properties. In addition, the timing of pesticide applications, relative to harvest activities for example, can greatly reduce the potential for post-application exposure.

A series of assumptions and exposure factors served as the basis for completing the occupational post-application risk assessments. Each assumption and factor are detailed in the May 2023 ORE Assessment. The algorithms used to estimate non-cancer exposure and dose for occupational post-application scenarios can be found in Appendix A of the May 2023 ORE Assessment. Occupational post-application non-cancer dermal risk estimates are of concern on the day of application (*i.e.*, 0-DAT "days after treatment") (*i.e.*, MOEs < LOC of 100) for all scenarios with MOEs ranging from 0.08 to 5.6. Some scenarios are no longer of concern from 20 to 31-DAT; however, most scenarios are still of concern greater than 30-DAT. The lowest MOEs are associated with activities that are likely to occur later in the season, when residues may be low but still present. These activities include scouting, hand harvesting, and moving hand-set irrigation in crops such as broccoli, brussels sprouts, cabbage, cauliflower, and onion. For these activities, there are still risks of concern at greater than 30-DAT. A full list of crops/activities and their associated risks are presented in the May 2023 ORE assessment.

A restricted entry interval (REI) can be established based on different sources of information considering both acute effects and also systemic effects. EPA considers both the acute toxicity categories for the active ingredient in a product and also the post-application risk assessment which may incorporate systemic effects from exposure to a pesticide product and establishes the REI based on the more protective duration.

Although active ingredients like DCPA that are classified as Category III or IV for acute dermal, eye irritation and primary skin irritation are assigned under 40 CFR 156.208(c)(2) a 12-hour REI (currently listed on registered product labels), short- and intermediate-term post-application risk estimates were of concern on 0-DAT (12 hours following application) for all activities with implications for re-entry risks of concern extending past 30 days.

2. Occupational Handler Exposure/Risk Estimates

EPA uses the term handlers to describe those individuals who are involved in the pesticide application process. EPA believes that there are distinct job functions or tasks related to applications and exposures can vary depending on the specifics of each task. The amount of chemical used in each application (*i.e.*, application rate and area treated or amount handled for the specific task), the kinds of equipment used, the target being treated, and the level of protection used by a handler can cause exposure levels to differ in a manner specific to each application event.

Based on the anticipated use patterns and current labeling, types of equipment and techniques that can potentially be used, occupational handler exposure is expected from the registered uses. A series of assumptions and exposure factors served as the basis for completing the occupational handler risk assessments. Each assumption and factor are detailed in the May 2023 ORE Assessment. The algorithms used to estimate non-cancer exposure and dose for occupational handlers can be found in Appendix A of the May 2023 ORE Assessment.

Estimates of dermal and inhalation exposure were calculated for various levels of personal protective equipment (PPE). Results are presented for the highest level of protection available for the particular scenario, which ranged from double layer of clothing (*i.e.*, coveralls over a long-sleeved shirt and long pants) and a PF10 respirator to engineering controls (*i.e.*, closed loading systems or closed cab tractors or cockpits). The current DCPA product labels direct mixers, loaders, applicators and other handlers to wear baseline attire (*i.e.*, long sleeve shirt, long pants, shoes and socks) as well as PPE including chemical- or water-resistant gloves.

Dermal and inhalation risk estimates were combined in this assessment, since the toxicological effects for these exposure routes were similar. Occupational handler non-cancer combined (dermal and inhalation) risk estimates are of concern (*i.e.*, MOEs < LOC of 100) when considering currently labelled PPE. Further, there are still risk estimates of concern for 37 out of 39 scenarios with engineering controls (*e.g.*, closed loading systems for mixer/loaders, closed cockpit or cab for aerial or groundboom applications) and/or maximum PPE (*i.e.*, double layer, gloves, respirators, etc.). Combined (dermal and inhalation) MOEs range

from 0.065 to 150. See Table 8.1.1 of the May 2023 ORE Assessment for the full list of occupational handler non-cancer exposure and risk estimates for DCPA.

C. Non-Occupational Spray Drift Exposure and Risk Estimates

The spray drift risk estimates are based on an estimated deposited residue concentration as a result of screening level agricultural application scenarios. DCPA is used on field crops, sod farms, and nurseries, and can be applied via groundboom and aerial equipment. The recommended drift scenario screening level options are as follows:

- Groundboom applications are based on the AgDrift model option for high boom height and using very fine to fine spray type using the 90th percentile results.
- Aerial applications are based on the use of AgDrift Tier 1 aerial model option for a fine to medium spray type and a series of other parameters which will be described in more detail below (e.g., wind vector assumed to be 10 mph in a downwind direction for entire application/drift event). (AgDrift allows for consideration of even finer spray patterns characterized as very fine to fine. However, this spray pattern was not selected as the common screening basis since it is used less commonly for most agriculture.)

Adult dermal exposures resulting from spray drift residues were estimated. Exposures were considered for 50 feet wide lawns where the nearest side of the property was directly adjoining the treated field (at field edge) and at varied distances up to 300 feet downwind of a treated field. The algorithms used to estimate exposure and dose for non-occupational spray drift can be found in Appendix C of the May 2023 ORE Assessment.

Results for the screening level scenarios are presented in Table 6.1.1 (adult risk estimates) of the May 2023 ORE Assessment and indicate that there are risks of concern at the field edge and at distances greater than 300 feet for some adult exposure scenarios (which includes exposures to pregnant individuals). For adults, dermal screening-level risk estimates were of concern at the field edge with MOEs ranging from 0.4–1 for all scenarios (dermal LOC = 100). The distance required for exposures to reach the LOC of 100 is >300 feet from the field edge.

VII. Analysis of Benefits Associated With Continued Use of DCPA

The Agency assessed DCPA's benefits as a preemergence treatment in the *Brassica* vegetables and *Alliums* for which there are registered uses based on

the observed usage of DCPA in these crops, weed control recommendations, and other information on DCPA's benefits from extension publications, pest management strategic plans, United States Department of Agriculture Office of Pest Management Policy (USDA OPMP), and a report from faculty at the University of California (UC), Davis, on DCPA's benefits in California agriculture.

EPA determined that DCPA is rarely used in registered use sites other than *Brassica* vegetables and *Alliums* because it provides little to no benefits to growers of those other registered use sites, it is not recommended for weed control in those sites, and/or other registered preemergence herbicides are preferred.

For more information on the benefits of DCPA usage (and to see supporting references), see *Assessment of Dimethyl Tetrachloroterephthalate (DCPA) (PC: 078701) Use, Usage, and Benefits*, available at <https://www.regulations.gov/document/EPA-HQ-OPP-2011-0374-0088>.

A. Benefits in Brassicas

Growers use DCPA, as directed by the product label, when planting seed (also referred to as direct seeding) and at transplant to provide residual control of weeds during the period between *Brassica* seeding and crop emergence, or during the establishment period for transplants. DCPA is applied banded within rows to reduce weed emergence around vulnerable seedlings. DCPA controls a broad range of annual broadleaf and grassy weeds prior to emergence, including several weeds identified by the University of California Integrated Pest Management (IPM) Program as problem weeds in *Brassica* production: i.e., weeds that compete with growing crops and reduce yield, pose a risk to workers, are prolific seed producers (leading to weed problems in subsequent crops), and/or for which no other herbicides are registered. Of these identified problem weeds, DCPA controls common chickweed and common purslane and provides partial control of little mallow, London rocket, burning nettle, nightshades, and sowthistles. Since *Brassica* vegetables can be produced year-round in California and DCPA is applied at planting/transplanting, applications of DCPA can and do occur in all months of the year. As noted previously, DCPA use is more prevalent for direct-seeded production than when growers use transplants. Direct-seeded *Brassicas* are more dependent on weed control than transplants because weeds

can more readily out-compete emerging seedlings than transplants.

The cost of herbicides used in *Brassicas* ranges widely, even herbicides targeting the same pests. DCPA (\$113/acre) is more expensive than other herbicides used in *Brassicas* (\$4/acre–\$90/acre) (Kynetec USA, Inc. 2022. "The AgroTrak® Study from Kynetec USA, Inc." iMap Software. Database Subset: 2017–2021. [Accessed February 2023]). Growers' willingness to pay a premium for DCPA suggests that DCPA cannot be easily replaced with other available herbicides in some applications.

In production of direct-seeded broccoli, Brussels sprouts, cabbage, and cauliflower, the most likely pre-emergent alternative to DCPA is bensulide. Bensulide can be applied without injuring the crop (crop-safe), and it allows for a number of rotational crops to be grown following *Brassicas*, but it does not control the full spectrum of weeds that DCPA controls. The next most likely alternative for these use sites is trifluralin: it is cheaper and has slightly better efficacy than bensulide, but it can be less crop-safe than bensulide, and it has a long (12-month) plant-back interval (PBI) for spinach, a common rotational crop. Trifluralin is not an alternative to DCPA in arid areas or during cold, wet winters due to the likelihood of crop injury. Neither bensulide nor trifluralin control the problem weeds little mallow, London rocket, or sowthistles; DCPA partially controls these weeds. If growers switch to bensulide or trifluralin to replace DCPA, the addition of hand-weeding may be necessary to replace early-season in-row weed control, as mechanical weeding and postemergence herbicides can damage emerging seedlings. Growers of direct-seeded broccoli, Brussels sprouts, cabbage, and cauliflower could also switch to transplanting in order to avoid the critical period for weed control between planting and emergence in direct-seeded production; this may also reduce hand-weeding labor needs from the loss of DCPA, though other labor costs may increase. Growers of direct-seeded broccoli, Brussels sprouts, cabbage, and cauliflower who do not have access to transplanting equipment and are unable to hire sufficient additional labor for increased hand-weeding may face substantial cost increases to either purchase or rent transplanting equipment or hire contract transplanters, or else suffer yield loss due to uncontrolled weeds.

In the absence of DCPA, growers who transplant broccoli, cabbage, and cauliflower could switch to oxyfluorfen

with few to no impacts on weed control, crop safety, or crop rotational programs. Oxyfluorfen, however, does not control common chickweed. Additional hand-weeding or a bensulide application may be necessary to replace in-row control of common chickweed. Oxyfluorfen is not registered for use on Brussels sprouts, but these growers can use napropamide, which is also less expensive and is effective against all problem weeds that DCPA is effective against. While napropamide has crop safety concerns and may not be an appropriate alternative for direct-seeded Brussels sprouts, growers who transplant Brussels sprouts can use napropamide without significant crop injury concerns. Napropamide also has long PBLs for several rotational crops; however, leafy greens, the typical rotational vegetables for Brassicas, can be planted following an early season napropamide application with little to no estimated impact to growers.

Growers of both direct-seeded and transplanted specialty *Brassica* may also replace DCPA with alternative pre-emergence herbicides such as bensulide and increased hand-weeding but could lose up to 20% of gross revenue in the absence of DCPA due to lower yield resulting from less dense planting to avoid damage from hand-weeding, competition from uncontrolled weeds, or crop damage and increased labor costs resulting from increased hand-weeding.

B. Benefits in Alliums

DCPA is recommended for weed management throughout the season; however, DCPA is the only herbicide that UC IPM recommends for application at seeding or transplant in onion, indicating its specific importance in early-season weed control in onion in California. Herbicide extension recommendations for states other than California generally do not recommend DCPA therefore the analysis for *Alliums* focuses on California. In onion, DCPA is used at seeding to provide residual control of weeds during the period between onion planting and emergence; DCPA can also be used at transplant. Preemergence weed control in onion is especially important because of the long time between onion seeding and emergence which permits weeds to outcompete the crop. DCPA is typically applied banded within rows to reduce weed emergence around vulnerable seedlings, and registered postemergence herbicides can only be applied after the crop and weeds have emerged. In the absence of DCPA, onion growers would need to use other preemergence herbicides combined with other weed

control or avoidance strategies, such as hand/mechanical weeding and growing onions from transplants, where feasible.

Herbicides that can be applied before crop emergence in onions and associated crops (shallot, leek) are bensulide, ethofumesate, flumioxazin, and pendimethalin; however, these herbicides are registered for different *Allium* crops than DCPA. Bensulide, ethofumesate, and flumioxazin are registered only for dry bulb onions including shallots; however, flumioxazin cannot be used in California. Pendimethalin is registered for all *Alliums*, but it is not registered at the state level for use in green onion or leek in California.

DCPA provides control or partial control for a wide spectrum of annual weeds in *Allium* spp. Of these weeds, several are problem weeds in California onion production: annual bluegrass, canarygrass, and dodder. While bensulide, ethofumesate, and pendimethalin are recommended for control of annual bluegrass and canarygrass in dry bulb onion and shallots, pendimethalin is the only preemergence herbicide besides DCPA that UC IPM recommends for control of dodder. Pendimethalin also has the broadest weed control spectrum of the potential alternatives, as it controls or partially controls all the weeds DCPA controls, while ethofumesate and bensulide have narrower control spectra. Additionally, onions are sensitive to crop injury from ethofumesate. If unable to use DCPA, affected dry bulb onion growers could use pendimethalin and likely face no reductions in weed control. However, pendimethalin cannot be used on green onions or leeks in California. Pendimethalin is already the recommended preemergence herbicide for green onions grown outside of California as it is cheaper, has better efficacy than DCPA, and performs better in the muck and mineral soils where most onions outside California are grown.

In the absence of DCPA, growers could transplant green onions to avoid the critical weed management period between onion seeding and emergence; however, transplanting is not currently a common practice in California onion production and may not be feasible for growers currently using DCPA. Green onions are densely planted, so transplanting can be infeasible for large-scale operations, and dense plantings can also make hand-weeding and mechanical cultivation difficult or impractical. If no preemergence herbicide options exist and transplanting is typically infeasible for

most onion growers who use DCPA, then growers would need to rely on other cultural weed management practices. Cultural weed management practices include using fields with low levels of weed pressure or using pre-irrigation before planting followed by shallow cultivation to reduce the emergence of weeds during crop emergence. Growers can also rotate onions with crops that have more effective registered herbicide options to reduce weed pressure before onions are planted. In all cases, the labor needs for green onion production would likely increase due to the lack of a preemergence herbicide.

In the absence of DCPA, dry bulb onion growers can use pendimethalin for early season weed control. Since pendimethalin provides the same level of preemergence weed control as DCPA, dry bulb onion growers will not face revenue loss from switching from DCPA to pendimethalin for early season weed control. Like dry bulb onion growers, shallot growers can also replace DCPA with pendimethalin for similar weed control without revenue loss. EPA expects that green onion and leek growers in California will face substantial impacts from the loss of DCPA due to a lack of registered preemergence herbicides; impacts include yield losses and increased labor for hand-weeding or other cultural weed management practices.

VIII. Risk Mitigation Measures

EPA has explored various mitigation measures to feasibly address the identified risks of concern to bystanders, occupational handlers, and occupational post-application workers. EPA requested public comment on the ORE Assessment on June 1, 2023, and received comments from various stakeholders including AMVAC. EPA has received various mitigation proposals from AMVAC beginning in July 2023, with each proposal further restricting DCPA registered uses, and a proposed draft product label submitted in April 2024. After EPA's extensive review and analysis of AMVAC's April 2024 mitigation proposal and considering all feasible mitigation measures, risks of concern remain for handlers and post-application workers exposed to DCPA and are documented in a revised ORE Assessment (*DCPA. Revised Occupational and Residential Exposure Assessment for the Registration Review of DCPA to Reflect Proposed Mitigation*, May 2, 2024) (Revised ORE Assessment). On May 7, 2024, AMVAC submitted another proposed draft product label incorporating additional restrictions to

address the remaining handler and post-application worker risks of concern. Similar to EPA's review of AMVAC's April 2024 proposal, EPA finds remaining risks of concern after considering all feasible mitigation measures.

A. Mitigation Proposals Prior to AMVAC's April 2024 Proposed Product Label

Prior to AMVAC's April 2024 proposed product label, AMVAC proposed a number of mitigation options, including restricting use patterns and reduced application rates, for DCPA to radish, Brassica (cole) leafy vegetables, and onions and restricting the formulation type (liquid formulation only). Mitigation was also proposed by AMVAC that would restrict application to groundboom and chemigation only and would require handlers to use engineering controls with gloves for all activities. In addition, REIs of 10 days and 21 days were proposed by AMVAC for post-application activities such as scouting and hand-set irrigation, respectively. For spray drift, AMVAC's proposed mitigations initially included a label requirement for medium/coarse droplets, use of a low boom, and a 150 ft buffer. However, risks of concern still remained for occupational handlers, occupational post-application workers and bystanders even after consideration of these mitigations.

B. Mitigations Proposed on AMVAC's April 2024 Product Label

In April 2024, AMVAC submitted an amended product label significantly reducing the use pattern and incorporating additional restrictions to address remaining risk concerns. On AMVAC's amended product label, many of the same restrictions noted above were incorporated, including the reduced application rate and requirement of engineering controls plus additional PPE. The following additional restrictions were proposed by AMVAC: applications only to radish and Brassica (cole) leafy vegetables, limitation of usage to CA and AZ, designation of the product as a restricted use pesticide (RUP), inclusion of a 200-foot buffer and low boom release height, restriction of handheld equipment applications, REIs for various activities ranging from 10 days to 21 days, restriction to banded ground applications, and restrictions on the amount of product handlers could use per day. These mitigations impact the occupational handler, occupational post-application worker, and bystander scenarios.

1. Analysis of AMVAC's Proposed Mitigations for Occupational Handlers

The restrictions of handheld equipment and the restriction to banded ground applications would result in only groundboom applications being allowed on the product label. Banded applications consist of a 12-inch band along a 24-inch row and would essentially reduce the application area by 50% because only half of the row is sprayed. Therefore, the banded groundboom scenarios assessed include a reduction in the area treated input from the default of 80 acres to 40 acres. This results in an increase in the combined (dermal + inhalation) MOEs, but not enough to reach the LOC of 100. MOEs range from 32 for applicators to 41 for mixers/loaders when considering banded applications.

Incorporating the additional restrictions on the amount of product that can be handled per day further reduces exposures and results in a combined MOE (dermal plus inhalation) of 98 for both mixers/loaders and applicators (LOC = 100). However, EPA does not typically approve labeling that restricts the amount of product that individual handlers are allowed to use for several reasons. First, there are various kinds of tasks individual handlers may need to do as part of an application, such as mixing the product, loading application equipment, using specific equipment, cleaning, repairing, or maintaining application equipment, and disposing of pesticides or materials with pesticide residue. These multiple activities can all lead to exposure, and make it difficult to adequately reduce exposure through a simple label restriction on the amount of a pesticide handled each day.

At present, there is also no mechanism in place through which users can track compliance with the proposed daily amount handled limitations. While AMVAC proposed to classify end use products containing DCPA as a RUP, which requires certain information to be retained concerning the application of a RUP (e.g., the total amount applied by a certified applicator and others under the certified applicator's direct supervision), the information required to be recorded does not include tracking the amounts of product individual handlers may use or the identity of handlers participating in an application.

Without a mechanism for reliably tracking the amounts of product handled per day, across different handling tasks such as mixing, loading and applying the pesticide, it would be very difficult to enforce this label

requirement. Without a way to provide clear limits for all handler tasks, and ensure compliance with a limit to the amount of product handled each day for each handler, EPA determined this mitigation measure would not adequately address these handler risks.

2. Analysis of AMVAC's Proposed Mitigations for Occupational Post-Application

AMVAC's April 2024 proposed product label limits use to cole crops and radish and only allows for applications over transplants for certain cole crops. Under AMVAC's April 2024 proposed product label, MOEs on the day of application (12 hours after application) are still of concern and MOEs continue to be of concern up until 28 or more days later.

3. Analysis of AMVAC's Proposed Mitigations for Bystanders

AMVAC proposed requiring a 200-foot buffer for a low boom height groundboom spray, which would result in no spray drift risks of concern for adults (including pregnant individuals) (all MOEs $\geq$ LOC of 30). Implementing this change proposed by AMVAC would address EPA's risk concerns for bystanders.

C. Mitigations Proposed on AMVAC's May 2024 Product Label

AMVAC's May 2024 proposed product label did not include additional mitigations to address the occupational handler nor the bystander scenarios. The same mitigations which addressed the bystander risks that were included on AMVAC's proposed April 2024 label were present on AMVAC's proposed May 2024 label. The same mitigations AMVAC proposed on the April 2024 label (i.e., restrictions on the amount of product handled per day) to address the occupational handler risks were present on AMVAC's proposed May 2024 label; however, as noted above, without a way to provide clear limits for all handler tasks, and ensure compliance with a limit to the amount of product handled each day for a handler, EPA determined this mitigation measure would not adequately address the handler risks.

AMVAC proposed additional mitigations to address the occupational post-application worker risks of concern. AMVAC's May 2024 proposed product label prohibits applications over transplanted crops, which would address the identified post-application risk concerns. Implementing AMVAC's proposed change would address EPA's risk concerns for occupational post-application workers.

While the proposed mitigations on AMVAC's May 2024 product label would address the risk concerns related to occupational post-application workers and bystanders, EPA still has concerns related to occupational handlers and does not feel that AMVAC's proposed mitigations will adequately address all of the identified risks of concern, leaving the current approved product label in use. As noted in the May 2023 ORE Assessment, use under the current approved product label can result in pregnant individuals being exposed to DCPA at levels greater than the level at which adverse effects were observed in the CTA. EPA has concerns that pregnant individuals may be exposed to DCPA at levels higher than those that cause fetal thyroid hormone disruption, but at which no thyroid effects would occur in the pregnant individual. There are unknown amounts of existing DCPA product in the hands of users which may lead to the serious and significant health outcomes described in this Emergency Order.

IX. Procedural Matters

With this Emergency Order the Agency has suspended the registrations of all pesticide products containing DCPA. The Emergency Order expressly prohibits any further sale, distribution, or use of any pesticide product containing DCPA, including federally registered products and products registered pursuant to FIFRA section 24(c) and 40 CFR 162.152. The registrant of products affected by the Emergency Order may request an expedited Agency hearing on the question of whether an imminent hazard exists. This unit explains how to request an expedited hearing, the consequences of requesting or not requesting an expedited hearing, and the procedures which will govern any expedited hearing in the event one is requested.

Alternatively, FIFRA section 6(c)(4) provides that a registrant—or other interested person, with the concurrence of the registrant—may seek immediate review of this Emergency Order in an appropriate district court. Such review shall be solely to determine whether the Emergency Order of suspension was arbitrary, capricious or an abuse of discretion, or whether the Emergency Order was issued in accordance with the procedures established by law. The registrant or other interested person need not request an expedited hearing pursuant to FIFRA section 6(c)(2) before seeking review in district court. *Love*, 858 F.2d at 1354.

A. Procedures for Requesting an Expedited Hearing

The registrant of a pesticide product containing DCPA may request an expedited hearing concerning the Agency's determination that an imminent hazard exists. Hearings must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR part 164. These procedures establish the following requirements:

(1) Each hearing request must specifically identify by registration or accession number each individual pesticide product concerning which a hearing is requested, 40 CFR 164.121(a)(3) and 164.22(a);

(2) Each hearing request must be accompanied by a document setting forth specific objections to the Agency's findings pertaining to the question of imminent hazard and state the factual basis for each such objection, 40 CFR 164.121(a)(3) and 164.22(a); and

(3) Each hearing request must be received by the Office of the Hearing Clerk, FIFRA section 6(c)(2); 40 CFR 164.121(a)(2) and 164.5(a).

Failure to comply with any one of these requirements will invalidate the request for a hearing.

Any person requesting a hearing is strongly encouraged to file such requests electronically via the EPA OALJ's E-filing system at: <https://yosemite.epa.gov/OA/EAB/EAB-ALJ/Upload.nsf/HomePage?ReadForm>. If a person opts to file by US mail or commercial delivery service, said party shall notify the OALJ Hearing Clerk *every time* it files a document, which must all be submitted to the following address: Office of Administrative Law Judges, U.S. Environmental Protection Agency, Attn: Mary Angeles, Headquarters Hearing Clerk, Mail Code 1900R, WJC East Mailroom 1309, 1200 Pennsylvania Avenue NW, Washington, DC 20460.

B. Effective Date of Emergency Order

This Emergency Order is effective immediately upon signature, regardless of whether a registrant requests an expedited hearing concerning the question of imminent hazard. If an expedited hearing is requested, this Emergency Order will remain in effect during any expedited hearing and consistent with the Administrator's final order on the issue of suspension. The final order to be issued by the Administrator or his delegate after any expedited hearing may retain the Emergency Order of suspension, modify it, or rescind it. Regardless of whether a registrant requests a hearing on this Emergency Order, the suspension shall

be lifted automatically if EPA fails to issue a Notice of Intent to Cancel for the DCPA products at issue within 90 days from issuance of this Emergency Order.

C. Hearing Procedures

If a registrant of a DCPA product submits a valid request for an expedited hearing, that hearing must commence within 5 days of receipt of the hearing request unless the registrant and the Agency agree that it will commence at a later time (FIFRA section 6(c)(2)). Valid requests received subsequently may be consolidated with requests received prior to commencement of the suspension hearing. Any suspension hearing will be limited to the question of whether an imminent hazard exists (FIFRA section 6(c)(1)) and no parties other than affected registrants and the Agency will be permitted to participate actively in the hearing (FIFRA section 6(c)(3)). However, other persons adversely affected may file proposed findings and conclusions and briefs in support thereof. 40 CFR 164.121(e)(3) and (j).

Once the presentation of evidence has been concluded, FIFRA section 6(c)(2) provides that the Administrative Law Judge will have 10 days to submit recommended findings and conclusions to the Administrator and the Administrator will have 7 days to issue a final order on the issue of suspension. Additional time requirements are set forth at 40 CFR 164.121(j).

D. Separation of Functions

EPA's Rules of Practice forbid anyone who may take part in deciding this case, at any stage of the proceeding, from discussing the merits of the proceeding *ex parte* with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of their representatives (40 CFR 164.7).

Accordingly, the following EPA offices, and the staffs thereof, are designated as the judicial staff to perform the judicial function of EPA in any administrative hearing on the issue of imminent hazard: The Presiding Officer, the Environmental Appeals Board, the Administrator, the Deputy Administrator, and the members of the staff in the immediate office of the Administrator and Deputy Administrator. None of the persons designated as the judicial staff may have any *ex parte* communication with the trial staff or any other interested person not employed by EPA on the merits of any of the issues involved in this proceeding, without fully complying

with the applicable regulations. 40 CFR 164.7.

Authority: 7 U.S.C. 136 *et seq.*

Dated: August 2, 2024.

Michael S. Regan,
Administrator.

[FR Doc. 2024–17431 Filed 8–6–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R07–SFUND–2024–0253; FRL–12014–01–R7]

Notice of Proposed Administrative Settlement Agreement and Covenant Not To Sue by Prospective Purchaser

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment.

SUMMARY: Notice is hereby given by the U.S. Environmental Protection Agency (EPA), Region 7, of a proposed prospective purchaser agreement, embodied in an Administrative Settlement Agreement and Covenant Not to Sue, with the city of St. Joseph, Missouri. This agreement pertains to a portion of the HPI Products, Inc. facility located at 424 S 8th Street (sometimes referred to as 408 S 8th Street), St. Joseph, Missouri.

DATES: Comments must be received on or before September 6, 2024.

ADDRESSES: The proposed settlement agreement is available for public inspection at EPA Region 7's office. A copy of the proposed agreement may also be obtained from Catherine Chiccine, EPA Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219, telephone number (913) 551–7917. You may send comments, identified by Docket ID No. EPA–R07–SFUND–2024–0253 to <https://www.regulations.gov>. Follow the online instructions for submitting comments. You may also send comments, identified by HPI Products Inc. Facility Public Comment, to Ms. Chiccine at the above address or electronically to Chiccine.catherine@epa.gov.

Instructions: All submissions received must include the Docket ID No. for this action. Comments received will be posted without change to <https://www.regulations.gov/>, including any personal information provided. For detailed instructions on sending comments and additional information on the process, see the “Written Comments” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT:

Catherine Chiccine, Assistant Regional Counsel, Office of Regional Counsel, U.S. Environmental Protection Agency Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number (913) 551–7917; email address chiccine.catherine@epa.gov.

SUPPLEMENTARY INFORMATION:

Written Comments

Submit your comments, identified by Docket ID No. EPA–R07–SFUND–2024–0253 at <https://www.regulations.gov>. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If CBI exists, please contact Ms. Chiccine. 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>.

Notice is hereby given by the U.S. Environmental Protection Agency, Region 7, of a proposed prospective purchaser agreement, embodied in an Administrative Settlement Agreement and Covenant Not to Sue, with the city of St. Joseph, Missouri. This agreement pertains to a portion of the former HPI Products, Inc. facility located at 424 S. 8th Street (sometimes referred to as 408 S. 8th Street), St. Joseph, Missouri. The city of St. Joseph, Missouri agrees to purchase the property for reuse and redevelopment and perform a response action. This project will result in a formerly contaminated property being restored to beneficial use by a community stakeholder.

The settlement includes a covenant by the EPA not to sue or take administrative action against the city of St. Joseph, Missouri, pursuant to sections 106 and 107(a) of CERCLA and section 7003 of RCRA. For thirty (30) days following the date of publication of this notice, the EPA will receive written comments relating to the settlement. The EPA will consider all comments

received and may modify or withdraw its consent to the settlement agreement if comments received disclose facts or considerations that indicate that the proposed settlement is inappropriate, improper, or inadequate. EPA's response to any comments received will be available for public inspection at EPA Region 7, 11201 Renner Boulevard, Lenexa, Kansas 66219.

Robert D. Jurgens,

Director, Superfund & Emergency Management Division, EPA Region 7.

[FR Doc. 2024–17465 Filed 8–6–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2022–0223; FRL–11828–02–OCSPP]

Chlorpyrifos; Final Cancellation Order for Certain Pesticide Registrations and Amendment of Certain Pesticide Registrations To Terminate Certain Uses

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA or Agency) hereby announces its final cancellation order for the cancellations and amendments to terminate uses voluntarily requested by the registrants and accepted by the Agency, of the products listed in Table 1 and Table 2 of Unit II., pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). This final cancellation order follows a notice in the **Federal Register** of April 3, 2024, that announced EPA's receipt of and sought comment on requests from the registrants in Table 3 of Unit II. to voluntarily cancel or amend these product registrations. In the April 3, 2024 notice, EPA indicated that it would issue a final cancellation order implementing the requests, unless the Agency received substantive comments within the comment period that would merit further review of these requests, or unless the registrants withdrew their requests. The Agency received two comments on the notice, which are summarized in Unit III.B. The registrants did not withdraw their requests for these voluntary cancellations and amendments. Accordingly, EPA hereby grants the requested cancellations and amendments to terminate uses as shown in this cancellation order. Any distribution, sale, or use of existing stocks of the products listed Table 1 and

Table 2 of Unit II are subject to the existing stocks provisions in this cancellation order and permitted only in accordance with the terms of this order.

DATES: The cancellations and amendments are effective August 7, 2024.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0223, is available at <https://www.regulations.gov>. Additional instructions on visiting the docket, along with more information about dockets generally, are available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Patricia Biggio, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 566–0700; email address: OPPChlorpyrifosInquiries@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this action apply to me?

This action is directed to the public in general and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members

of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action.

II. What action is the Agency taking?

This document announces the cancellations and amendments through termination of certain uses, as requested by registrants, of products registered under FIFRA section 3 (7 U.S.C. 136a). These registrations are listed in sequence by registration number in Table 1 and Table 2 of this unit.

TABLE 1—CHLORPYRIFOS REGISTRATIONS AMENDED TO TERMINATE USES

Registration No.	Product name	Company	Terminated Uses
81964–21	Chlorpyrifos 61.5% MUP	Chemstarr, LLC	Food processing plants (food and non-food areas). Food uses: Alfalfa; apple tree trunk; asparagus; <i>Brassica</i> (Cole) leafy vegetables: radish, rutabaga, turnip, cauliflower, broccoli, Brussels sprout, cabbage, Chinese cabbage, collards, kale, kohlrabi; citrus: calamondin, chironja, citrus citron, citrus hybrids, grapefruit, kumquat, lemon, lime, mandarin (tangerine), pummelo, Satsuma mandarin, sour orange, sweet orange, tangelo, tangor; corn (field and sweet); cotton; cranberry; legume vegetable: adzuki bean, bean, blackeyed pea, broad bean (dry and succulent), catjang, chickpea, cowpea, crowder pea, English pea, field bean, field pea, garden pea, grain lupin, green pea, guar, lima bean (dry and green), kidney bean, lablab bean, lentil, moth bean, mung bean, navy bean, pea, pigeon pea, pinto bean, rice bean, southern pea, sweet lupin, tepary bean, urd bean, white lupin, white sweet lupin; onion (dry bulb); peanut; peppermint; sorghum (grain sorghum (milo)); soybean; spearmint; sugar beet; sunflower; sweet potato; tree fruits: cherry, nectarine, peach, pear, plum, and prune; tree nuts: almonds, filbert, pecan and walnut; and wheat.
84229–20	Chlorpyrifos 4 EC	Tide International	

TABLE 2—CHLORPYRIFOS PRODUCT CANCELLATIONS

EPA registration No.	Product name	Company	Active ingredients
89459–72	Equil Chlorpyrifos ULV 1	Central Garden & Pet	Chlorpyrifos.
89459–73	Equil Chlorpyrifos ULV 2	Central Garden & Pet	Chlorpyrifos.

TABLE 3—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION OR TERMINATION OF USES

EPA company No.	Company name and address
81964	Chemstarr, LLC, Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct NW, Gig Harbor, WA 98332.
84229	Tide International USA, Inc., Agent Name: Pyxis Regulatory Consulting, Inc., 4110 136th Street Ct NW, Gig Harbor, WA 98332.
89459	Central Garden & Pet, 1501 E Woodfield Rd., Suite 200W, Schaumburg, IL 60173.

III. Public Comments

A. Brief History

In 2021, EPA issued a rule revoking chlorpyrifos tolerances on the grounds that they were not safe (86 FR 48315, August 30, 2021 (FRL–5993–04–OCSPP)). Once those tolerances expired

on February 28, 2022, use of pesticide products containing chlorpyrifos on food or feed crops would result in adulterated food, which cannot be sold in interstate commerce. After EPA alerted registrants of chlorpyrifos products of the lack of tolerances and the options for their products, several

registrants submitted requests to voluntarily cancel their registered chlorpyrifos products or amend their chlorpyrifos pesticide products to remove food uses.

In 2024, EPA announced the receipt of and sought comment on such requests from the registrants identified

in Table 3 of Unit II. (89 FR 23011, April 3, 2024 (FRL–11821–01–OCSP)). Since the registrants waived the 180-day comment period for these voluntary requests, EPA provided a 30-day comment period on the proposed requests, which closed on May 3, 2024.

B. Summary of Comments Received

EPA received two comments in response to the notice that published in the **Federal Register** of April 3, 2024. The comments are in the docket for this action and are briefly summarized here.

Neither of the comments specified the products listed in Table 1 or Table 2 of Unit II., but both comments were supportive of the cancellation of the pesticide. One commenter summarized studies found on the Breast Cancer Prevention Partners website. The other comment stated that the proposed provisions for using existing stocks for food uses until June 30, 2025 would subject workers, bystanders, and consumers to health risks, and were not consistent with FIFRA.

C. EPA Response to Comments

This cancellation action is responsive to registrants' requests to cancel specific products and specific uses. In response to both commenters, under FIFRA section 6(f), registrants may, at any time, seek to cancel their products or seek to amend their registrations to terminate specific uses. Under that provision of the statute, EPA provides an opportunity for public comment and then acts on the request. Cancellation of other products or uses that are not requested by the registrants occurs under other provisions of FIFRA, which is beyond the scope of this action and EPA's authority in FIFRA section 6(f).

In addition, in response to the comment submitted by Earthjustice, EPA has determined that the existing stocks provisions are not inconsistent with the purposes of FIFRA, given the limited amount of existing stocks and the limited time allowed for use of the existing stocks outlined in Unit VI.

Regarding the studies on the Breast Cancer Prevention Partners website referenced in the other submitted comment, the commenter may wish to submit this information for consideration during the next public comment period on the registration review of chlorpyrifos, when all currently registered uses of chlorpyrifos will be evaluated.

EPA determined that neither comment merited denial of the registrants' requests for cancellation and amendment.

IV. The Cancellation Order

Pursuant to FIFRA section 6(f) (7 U.S.C. 136d(f)(1)), EPA hereby approves the requested amendments to terminate uses and cancel the registrations identified in Table 1 and Table 2 of Unit II., respectively. Accordingly, the Agency hereby orders that the uses identified for the products listed in Table 1 of Unit II. are terminated, and the product registrations identified in Table 2 of Unit II. are cancelled.

The cancellations and amendments addressed in this Order are effective August 7, 2024. Any distribution, sale, or use of existing stocks of the products identified in Tables 1 and 2 of Unit II. in a manner inconsistent with any of the provisions for disposition of existing stocks set forth in Unit VI. will be a violation of FIFRA.

V. What is the Agency's authority for taking these actions?

Section 6(f)(1) of FIFRA (7 U.S.C. 136d(f)(1)) provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be cancelled or amended to terminate one or more registered uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register** and provide a public comment period. EPA must publish a notice in the **Federal Register** to take final action on such requests and respond to comments received.

VI. Provisions for Disposition of Existing Stocks

Existing stocks for the products identified in this document are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. EPA has determined that the following existing stocks provisions are not inconsistent with the purposes of FIFRA given the limited amount of existing stocks and the limited time allowed for use of the existing stocks outlined in this unit.

A. Products Listed in Table 1 of Unit II

- Sale and distribution of existing stocks of Chlorpyrifos 61.5% MUP (81964–21) will not be permitted after the final cancellation order is issued. Although the April 3, 2024 notice indicated that EPA intended to allow sale and distribution of this product until April 30, 2025, that date was intended to apply to end use products only and thus does not apply because this is a MUP. This will also help limit the amount of additional chlorpyrifos

end use products that can be produced from this MUP.

- Sale and distribution of existing stocks of Chlorpyrifos 4 EC (84229–20) will be permitted until April 30, 2025.

- Use of existing stocks of Chlorpyrifos 4 EC (84229–20) on food, food processing sites, and food manufacturing sites must be consistent with the product labeling and will be permitted until June 30, 2025.

- Use of existing stocks of Chlorpyrifos 61.5% MUP (81964–21) and Chlorpyrifos 4 EC (84229–20) for non-food purposes is permitted until existing stocks are exhausted, as long as such use is in accordance with the labeling.

After these dates, sale and distribution of existing stocks will be prohibited, except for export consistent with FIFRA section 17 (7 U.S.C. 136o), or for proper disposal in accordance with state regulations.

B. Products Listed in Table 2 of Unit II

The products listed in Table 2 of Unit II. bear labeling only for non-food use. Therefore, EPA is allowing sale and distribution of existing stocks of those products for one year after publication of the cancellation order. Thereafter, sale and distribution of existing stocks of the product will be prohibited, except for export consistent with FIFRA section 17 (7 U.S.C. 136o), or for proper disposal in accordance with state regulations.

Use of existing stocks is permitted until such stocks are exhausted, provided that use is consistent with the terms of the previously approved labeling on, or that accompanied, the cancelled products.

Authority: 7 U.S.C. 136 *et seq.*

Dated: August 2, 2024.

Jean Overstreet,

*Director, Pesticide Re-Evaluation Division,
Office of Pesticide Programs.*

[FR Doc. 2024–17453 Filed 8–6–24; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[FR ID 236862]

Deletion of Item From August 7, 2024 Open Meeting

August 1, 2024.

The following item has been deleted from the list of items scheduled for consideration at the Wednesday, August 7, 2024, Open Meeting. Item No. 5 was released by the Commission on August 1, 2024. The item was previously listed

in the Commission's Sunshine Notice on Wednesday, July 31, 2024.

Item No.	Bureau	Subject
5	ENFORCEMENT	<i>Title:</i> Enforcement Bureau Action. <i>Summary:</i> The Commission will consider an enforcement action.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2024-17429 Filed 8-6-24; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW,

Washington, DC 20551-0001, not later than September 6, 2024.

A. Federal Reserve Bank of Dallas (Karen Smith, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201-2272. Comments can also be sent electronically to Comments.applications@dal.frb.org:

1. *Producer Acquisition Corp.*, Beaumont, Texas; to become a bank holding company by acquiring Powell State Bank, Powell, Texas.

B. Federal Reserve Bank of Boston (Prabal Chakrabarti, Senior Vice President) 600 Atlantic Avenue, Boston, Massachusetts 02210-2204. Comments can also be sent electronically to BOS.SRC.Applications.Comments@bos.frb.org:

1. *Peoples Bancorp, MHC, Holyoke, Massachusetts*; to merge with SSB Community Bancorp MHC, and thereby indirectly acquire SSB Community Bancorp Inc. and Cornerstone Bank, all of Spencer, Massachusetts.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2024-17450 Filed 8-6-24; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at

<https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551-0001, not later than August 22, 2024.

A. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166-2034. Comments can also be sent electronically to Comments.applications@stls.frb.org:

1. *William A. Richelman, Gregory L. Richelman, Tracy D. Richelman, Shellie R. Astin, Donald L. Richelman, Elaine L. Richelman, and Mark A. Richelman, all of Campbell Hill, Illinois, and Jeffery A. Richelman, Perryville, Missouri*; to establish the Richelman Family Control Group, a group acting in concert; to retain voting shares of Campbell Hill Bancshares, Inc., and thereby indirectly retain voting shares of First State Bank of Campbell Hill, both of Campbell Hill, Illinois.

2. *The Edward C. Knop & Barbara B. Knop Living Trust, Edward C. Knop and Barbara B. Knop, Trustees, all of Clifton, Illinois; James E. Knop, Ely, Minnesota; Mary R. Knop Patterson, Williamsburg, Virginia; and John C. Knop, Apple Valley, Minnesota*; to establish the Knop Family Control Group, a group acting in concert, to retain voting shares of Campbell Hill Bancshares, Inc., and thereby indirectly retain voting shares of First State Bank of Campbell Hill, both of Campbell Hill, Illinois.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2024-17449 Filed 8-6-24; 8:45 am]

BILLING CODE P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090-0310; Docket No. 2024-0001; Sequence No. 7]

Information Collection; Nondiscrimination in Federal Financial Assistance for Real Property Recipients

AGENCY: The U.S. General Services Administration (GSA), Office of Civil Rights (OCR).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, and the Office of Management and Budget (OMB) regulations, GSA invites the public to comment on a revision to existing information collection 3090-0310, to add a Nondiscrimination in Federal Financial Assistance for Real Property Recipients form. This information is needed to facilitate nondiscrimination in GSA's Federal Financial Assistance Programs, consistent with Federal civil rights laws and regulations that apply to recipients of Federal financial assistance.

DATES: *Submit comments on or before:* October 7, 2024.

FOR FURTHER INFORMATION CONTACT: Lisa Lee Anderson, External Programs Branch Chief, OCR, at (202) 501-0767 or via email at civilrights@gsa.gov.

ADDRESSES: Submit comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, via <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link "Submit a Comment" that corresponds with "Information Collection 3090-0310, Nondiscrimination in Federal Financial Assistance Programs for Real Property Recipients". Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "Information Collection 3090-0310, Nondiscrimination in Federal Financial Assistance Programs for Real Property Recipients" on your attached document. If your comment cannot be submitted using [regulations.gov](http://www.regulations.gov), call or email the points of contact in the **FOR FURTHER**

INFORMATION CONTACT section of this document for alternate instructions.

Instructions: Please submit comments only and cite Information Collection 3090-0310, Nondiscrimination in Federal Financial Assistance for Real Property Recipients, in all correspondence related to this collection. Comments received generally will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two-to-three business days after submission to verify posting.

SUPPLEMENTARY INFORMATION:

A. Purpose

GSA has mission responsibilities related to monitoring and enforcing compliance with Federal civil rights laws and regulations that apply to Federal financial assistance programs administered by GSA. Specifically, those laws provide that no person on the ground of race, color, national origin, disability, sex, or age shall be excluded from participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program in connection with which Federal financial assistance is extended under laws administered in whole, or in part, by GSA.

These mission responsibilities generate the requirement to request and obtain certain data from recipients of Federal surplus real property conveyances under the Federal Public Benefit Conveyance Program for the purpose of determining compliance, such as the number of individuals that speak non-English languages encountered by the recipient's program(s) and how the recipient is addressing meaningful access for individuals that are Limited English Proficient; whether the recipients provide disability access in compliance with applicable laws and standards; whether there has been complaints or lawsuits filed against the recipient based on prohibited discrimination; whether there has been any findings of discrimination; and whether the recipient's facilities are accessible to qualified individuals with disabilities.

B. Annual Reporting Burden

Respondents: 75.

Responses per Respondent: 1.

Total Responses: 75.

Hours per Response: 2.

Total Burden Hours: 150.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals:

Requesters may obtain a copy of the information collection documents from the GSA Regulatory Secretariat Division by calling 202-501-4755 or emailing GSARegSec@gsa.gov. Please cite OMB Control No. 3090-0310, Nondiscrimination in Federal Financial Assistance Programs for Real Property Recipients, in all correspondence.

Lois Mandell,

*Director, Regulatory Secretariat Division,
General Services Administration. Regulatory
Secretariat Division, General Services
Administration.*

[FR Doc. 2024-17451 Filed 8-6-24; 8:45 am]

BILLING CODE 6820-34-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10237 and
CMS-R-308]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of

this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 7, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-10237 Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits

CMS-R-308 State Children's Health Insurance Program and Supporting Regulations

Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain

approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor.

The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Revision of a currently approved information collection; *Title of Information Collection:* Applications for Part C Medicare Advantage, 1876 Cost Plans, and Employer Group Waiver Plans to Provide Part C Benefits; *Use:* Collection of this information is mandated by the Code of Federal Regulations, MMA, and CMS regulations at 42 CFR part 422, subpart K, in "Application Procedures and Contracts for Medicare Advantage Organizations." In addition, the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) further amended titles XVII and XIX of the Social Security Act.

This information collection includes the process for organizations wishing to provide healthcare services under MA plans. These organizations must complete an application annually (if required), file a bid, and receive final approval from CMS. The MA application process has two options for applicants that include (1) request for new MA product or (2) request for expanding the service area of an existing product. CMS utilizes the application process as the means to review, assess and determine if applicants are compliant with the current requirements for participation in the MA program and to make a decision related to contract award. This collection process is the only mechanism for organizations to complete the required MA application process. *Form Number:* CMS-10237 (OMB control number: 0938-0935); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not for-profits and Federal Government; *Number of Respondents:* 500; *Number of Responses:* 500; *Total Annual Hours:* 9,173. (For policy

questions regarding this collection contact Jackie Ford at 410-786-7767 or Jacqueline.Ford@cms.hhs.gov).

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* State Children's Health Insurance Program and Supporting Regulations; *Use:* States must submit title XXI plans and amendments for approval by the Secretary. We use the plan and its subsequent amendments to determine if the state has met the requirements of title XXI. Information provided in the state plan, state plan amendments, and from the other information we are collecting will be used by advocacy groups, beneficiaries, applicants, other governmental agencies, providers groups, research organizations, health care corporations, health care consultants. States will use the information collected to assess state plan performance, health outcomes and an evaluation of the amount of substitution of private coverage that occurs as a result of the subsidies and the effect of the subsidies on access to coverage. *Form Number:* CMS-R-308 (OMB control number: 0938-0841); *Frequency:* Yearly, once, and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 16,024,071; *Total Annual Hours:* 803,280. (For policy questions regarding this collection contact Joyce Jordan at 410-786-3413.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-17467 Filed 8-6-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-R-48]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995

(PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by October 7, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: _____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS-R-48 Hospital Conditions of Participation (CoPs) and Supporting Regulations

Under the PRA (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collections

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Hospital Conditions of Participation (CoPs) and Supporting Regulations; *Use:* The purpose of this package is to request from the Office of Management and Budget (OMB) approval of the reinstatement with change of the information collection request associated with OMB control number: 0938-0328.

The information collection requirements described herein are needed to implement the Medicare and Medicaid Conditions of Participation (CoPs) for a total of 5,132 facilities that includes: 4,994 accredited and non-accredited hospitals and 138 Critical Access Hospitals (CAHs) with Distinct Part Units (DPUs); specifically, 119 CAHs with psychiatric DPUs and 19 CAHs with rehabilitation DPUs. The information collection requirements for the 1,245 CAHs without DPUs (1,383 total CAHs less 138 CAHs with DPUs) are covered under OMB control number: 0938-1043 (CMS-10239).

As previously stated, this notice is related to a reinstatement of the information collection request that expired on 11/30/2017. The previous iteration of this OMB control number 0938-0328 (approved November 14, 2014) had a burden of 14,424,655 annual hours. For this requested reinstatement, with changes, the adjusted annual hourly burden for industry is 3,566,521 hours at an annual cost of \$310,989,894. The decrease in

burden hours is primarily due to the fact that many of the information collections that were previously required as CoPs by CMS are now customary and usual industry practice and would take place in the absence of the Medicare and Medicaid programs. In addition, where possible, CMS reduced the burden of CoPs with prior information collections. For example, the burden for individual hospitals that are part of a multi-hospital system was reduced by allowing a multi-hospital system, which represent approximately 70% of hospitals today, to develop a unified Quality Assessment and Performance Improvement (QAPI) program rather than requiring each hospital in the system to maintain separate programs and reporting requirements.

This reinstatement also reflects a change in how the annual burden costs for information collection requirements for Hospital CoPs are calculated. In prior submissions, the fully loaded wage estimates applied only an additional 33% to the hourly wage to account for fringe benefits. This reinstatement applies an additional 100% to the median hourly wage to reflect the costs more accurately to hospitals for compliance with the current CoPs.

Additional changes reflected in this reinstatement are some of the information collections were placed on participating hospitals as CoPs during the recent COVID-19 Public Health Emergency (PHE), specifically regarding collecting and reporting data on incidents and hospital management of infection diseases. The burden of many of these information collections were accounted for in other OMB submissions, such as the "*Unified Hospital Data Surveillance System (U.S. Healthcare COVID-19 Collection)*" (OMB control number 0990-0478), and some of these collections ended or were revised after HHS declared the end of the COVID-19 PHE in April 2024. As a result, this reinstatement does not include information collection requirements that have expired, and only includes the annual burden and costs to participating hospitals and CAHs with DPUs for information collections that have remained as CoPs after the COVID-19 PHE ended. In addition, in anticipation of an upcoming final rule titled "*Medicare and Medicaid Programs and the Children's Health Insurance Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2025 Rates; Quality Programs Requirements; and Other Policy Changes,*" this package includes burden

estimates for additional information collection requirements that CMS is adding as CoPs in the interest of public health and ensuring resiliency in the U.S. health care system. The aforementioned final rule, CMS–1808–F (RIN 0938–AV34), is currently on public display at the Office of the Federal Register and scheduled for publication on August 28, 2024.

Finally, this reinstatement incorporates additional information collection requirements associated with a number of new CoPs for hospitals and CAHs regarding obstetrical services which are outlined in detail in the July 2024 proposed rule titled “Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities” (89 FR 59186). *Form Number:* CMS–R–48 (OMB control number: 0938–0328); *Frequency:* Yearly; *Affected Public:* Private Sector (Business or other for-profit); *Number of Respondents:* 4,664; *Total Annual Responses:* 2,647,647; *Total Annual Hours:* 3,566,521 (For policy questions regarding this collection contact Claudia Molinar at 410–786–8445).

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–17484 Filed 8–2–24; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10874 and CMS–R–285]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS’ intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency’s functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 6, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT:

William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section

3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* New collection (Request for a new OMB control number); *Title of Information Collection:* Part D Drug Management Program (DMP); *Use:* Section 1860D–4(c)(5)(A) of the Social Security Act requires that Part D sponsors have a DMP for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs). The information in this collection of information request is necessary for sponsor conformance with DMP requirements at § 423.153(f), including communicating with prescribers and pharmacies, informing beneficiaries that they have been identified as a PARB or ARB, and informing beneficiaries and CMS whether a beneficiary’s access to FADs will be restricted to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale claim edit. Part D sponsors will use the standardized and model documents to communicate with providers, enrollees, and other sponsors. Specifically, Part D sponsors may use the Model Part D Drug Management Program Prescriber Inquiry Letter to inform providers that their patient’s pattern of use or history of use of FADs is potentially unsafe and has prompted a case management review under the plan’s DMP. Part D sponsors must use the standardized Initial Notice and Second Notice, or Alternate Second Notice, to inform enrollees, following identification by CMS’s OMS and subsequent case management, whether the beneficiaries have been identified as being potentially at risk or at risk for abuse or misuse of FADs. Part D sponsors may use the Model Part D Drug Management Program Sponsor Information Transfer Memorandum to communicate to a gaining sponsor the enrollee’s history of misuse or abuse of FADs; *Form Number:* CMS–10874 (OMB control number: 0938–1465); *Frequency:* Yearly and once; *Affected Public:* Private sector; *Number of Respondents:* 319; *Number of Responses:* 62,248; *Total Annual Hours:* 152,585. (For policy questions regarding this

collection contact Valerie Yingling at 667-290-8657.)

2. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Medicare Request for Retirement Benefit Information; *Use:* Medicare Premium Part A is a voluntary program that is financed from premium payments by enrollees together with contributions from funds appropriated by the Federal Government. Form CMS-R-285, "Medicare Request for Retirement Benefit Information," is used to obtain information regarding whether a beneficiary currently purchasing Medicare Premium Part A coverage is receiving retirement payments based on State or local government employment, how long the claimant worked for the State or local government employer, and whether the former employer or pension plan is subsidizing the individual's Part A premium.

Form CMS-R-285 provides the necessary information regarding the prior state or local government employment to process the individual's request for premium Part A reduction based on their employment by a state or local government. The form is completed by the state or local government employer on behalf of the individual seeking the Medicare premium reduction. The SSA, CMS' agent for processing Medicare enrollments and premium amount determinations, will use this information to help determine whether a beneficiary meets the requirements for reduction of the Part A premium. The form is owned by CMS but not completed by CMS staff. *Form Number:* CMS-R-285 (OMB control number: 0938-0769); *Frequency:* Once; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 500; *Total Annual Responses:* 500; *Total Annual Hours:* 125. (For policy questions regarding this collection contact Candace Carter at 410-786-8446.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-17468 Filed 8-6-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10695]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by September 6, 2024.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Quality Payment Program/Merit-Based Incentive Payment System (MIPS) Surveys and Feedback Collections; *Use:* The purpose of this submission is to request approval for generic clearance of a program of survey and feedback collections supporting the Quality Payment Program which includes the Merit-Based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (AAPMs). MIPS is a program for certain eligible clinicians that makes Medicare payment adjustments based on performance on quality, cost and other measures and activities, and that consolidates components of three precursor programs—the Physician Quality Reporting system (PQRS), the Value Modifier (VM), and the Medicare Electronic Health Record (EHR) Incentive Program for eligible professionals. AAPMs are a track of the Quality Payment Program that offer incentives for achieving threshold levels of payments or patients in Advanced APMs or Other Payer Advanced APMs. Under the AAPM path, eligible clinicians may become Qualifying APM Participants (QPs) and are excluded from MIPS. Partial Qualifying APM Participants (Partial QPs) may opt to report and be scored under MIPS.

This generic clearance will cover a program of surveys and feedback collections designed to strategically obtain data and feedback from MIPS

eligible clinicians, third-party intermediaries, Medicare beneficiaries, and any other audiences that would support the Agency in improving MIPS or the Quality Payment Program. The specific collections we intend to conduct are: Human Centered Design (HCD) User Testing Volunteer Sign-Up Survey; HCD User Satisfaction, Product Usage, and Benchmarking Surveys; and Physician Compare (and/or successor website) User Testing. *Form Number:* CMS-10695 (OMB control number: 0938-1399); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions and Individuals; *Number of Respondents:* 630,300; *Total Annual Responses:* 630,300; *Total Annual Hours:* 61,035. (For policy questions regarding this collection, contact Renee O'Neill at 410-786-8821.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024-17411 Filed 8-6-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-0001]

Enhancing Diversity in Therapeutics Development for Pediatric Patients; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Enhancing Diversity in Therapeutics Development for Pediatric Patients." The aim of the public workshop is to explore strategies to increase the enrollment of historically underrepresented populations in pediatric clinical trials and to help improve the strength and generalizability of the evidence for the intended use population.

DATES: The public workshop will be held on September 6, 2024, from 9 a.m. to 5 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993-0002. Entrance for the registered public

workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/about-fda/visitor-information>. The workshop will also be streamed online.

FOR FURTHER INFORMATION CONTACT: Julie Levin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6481, Silver Spring, MD 20993, 202-567-7565, or ONDPublicMTGSupport@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Clinical trials in children are essential for obtaining data on the safety and effectiveness of medical products in children and to protect children from the risks associated with exposure to medical products that may be unsafe or ineffective for their intended uses in children. In some therapeutic areas, participation in clinical trials may be an important component of a participant's clinical care. Pediatric drug development programs should consider the clinical and demographic factors that impact the generalizability of study results with respect to the patient population that will use the product once it is approved.

II. Topics for Discussion at the Public Workshop

FDA, in collaboration with the University of Maryland Center of Excellence in Regulatory Science and Innovation, is convening a 1-day workshop to explore strategies for enrolling historically underrepresented populations in pediatric clinical trials. The specific topics to be covered include, but are not limited to, the following:

- Understanding the current state and challenges of pediatric clinical trial participation;
- Understanding metrics for assessing representative clinical study enrollment, including considerations of disease prevalence and incidence across subgroups of the pediatric population; and
- Discussing key elements of a strategy to include a more representative population, including trial design and methodological considerations, community engagement, recruitment and retention practices, and other related topics.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following

website: <https://www.fda.gov/drugs/news-events-human-drugs/adept-9-public-workshop-enhancing-diversity-therapeutics-development-pediatric-patients-09062024>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop in person must register by August 23, 2024, at 5 p.m. Eastern Time; virtual attendees may register by September 6, 2024, at 9 a.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 8:15 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Julie Levin at 202-567-7565 or ONDPublicMTGSupport@fda.hhs.gov no later than August 16, 2024.

Streaming Webcast of the Public Workshop: This public workshop will also be streamed virtually via Zoom. A link will be provided via email to registered participants. If you have never attended a Zoom event before, test your connection at <https://zoom.us/test>. Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop is available, it will be accessible on the workshop website.

(Notice of this meeting is given pursuant to 21 CFR 10.65.)

Dated: July 22, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-16365 Filed 8-6-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Health Resources and Services Administration****Agency Information Collection****Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process**

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than October 7, 2024.

ADDRESSES: Submit your comments to paperwork@hrsa.gov or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, Maryland, 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project, email paperwork@hrsa.gov or call Joella Roland, the HRSA Information Collection Clearance Officer, at (301) 443-3983.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: 340B Drug Pricing Program; Initiation of the Administrative Dispute Resolution Process, OMB No. 0906-xxxx—New.

Abstract: Section 602 of Public Law 102-585, the Veterans Health Care Act of 1992, created the 340B Drug Pricing Program in section 340B of the Public Health Service (PHS) Act. The Secretary of HHS (Secretary) has delegated the authority to administer the 340B Drug Pricing Program to the HRSA Administrator, who has further delegated authority to the Office of Pharmacy Affairs (OPA), within HRSA, which oversees the 340B Drug Pricing Program. Eligible covered entity types are defined in section 340B(a)(4) of the PHS Act, as amended. Section 340B(a)(1) of the PHS Act instructs HHS to enter into pharmaceutical pricing

agreements with manufacturers of covered outpatient drugs. Under section 1927(a)(5)(A) of the Social Security Act, a manufacturer must enter into an agreement with the Secretary that complies with section 340B of the PHS Act to receive payments from Medicaid or Medicare Part B for the manufacturer's covered outpatient drugs. When a manufacturer signs a pharmaceutical pricing agreement, it agrees that the prices charged for covered outpatient drugs to covered entities will not exceed statutorily defined 340B ceiling prices. Such prices are based on quarterly pricing reports that manufacturers must provide to the Secretary which are calculated and verified by HRSA.

Section 340B(d)(3) to the PHS Act requires HHS to promulgate regulations establishing and implementing a binding 340B Administrative Dispute Resolution (ADR) process for certain disputes arising under the 340B Drug Pricing Program. Pursuant to the statute, the 340B ADR process is intended to resolve (1) claims by covered entities that they have been overcharged for covered outpatient drugs by manufacturers and (2) claims by manufacturers, after a manufacturer has conducted an audit as authorized by section 340B(a)(5)(C) of the PHS Act, that a covered entity has violated the prohibition on diversion or duplicate discounts.

On April 19, 2024, HRSA published the 340B Drug Pricing Program; Administrative Dispute Resolution Regulation Final Rule (340B ADR Final Rule) (89 FR 28643 (Apr. 19, 2024)) (to be codified at 42 CFR part 10)). The 340B ADR Final Rule provides the requirements for filing a 340B ADR claim. The 340B ADR Final Rule requires the submission of a 340B ADR claim within 3 years of the date of the alleged violation and specifies that it is a remedy open to all manufacturers and covered entities that participate in the 340B Drug Pricing Program. To initiate the 340B ADR process, a petitioner will email OPA's designated mailbox with its 340B ID or Labeler code and contact information, the 340B ID or Labeler code and contact information of the opposing party, and a brief description of the claim. Once a petition is filed, OPA reviews the petition to make sure the claim meets the requirements for the 340B ADR process, including whether: (1) the claim alleges a violation of an overcharge, duplicate discount, or diversion; (2) the claim has been filed within 3 years of the alleged violation; and (3) the petitioner has engaged in good faith efforts to resolve the claim. Both the petitioner and opposing party

will be required to upload certain documentation to a secure 340B ADR workspace in the 340B OPA Information System to substantiate the claim. After an initial review of the claim and any supporting documentation, OPA staff will determine whether the requirements for filing a claim have been met, and if the claim is deemed complete, OPA will notify the parties. If the claim is deemed complete and all filing requirements are met, the claim will be assigned to a 340B ADR Panel. If the claim does not meet the filing requirements, OPA will dismiss the claim. Specific details concerning the 340B ADR Panel and requirements for filing a claim are outlined in the 340B ADR Final Rule and can be reviewed at <https://www.hrsa.gov/opa/340b-administrative-dispute-resolution>.

This information collection request is limited to the initiation of the 340B ADR process and the uploading of the related documents. Filing a claim though the 340B ADR process is a remedy open to all manufacturers and covered entities that participate in the 340B Drug Pricing Program, which can constitute a standardized federal information collection. Once the claim is assigned to a 340B ADR Panel for review, these subsequent steps, which encompass the 340B ADR process itself and ensuing correspondence with the parties involved in the process, are exempt from Paperwork Reduction Act requirements, pursuant to the Paperwork Reduction Act exception listed at 44 U.S.C. 3518(c), which exempts administrative actions or investigations involving an agency against specific individuals or entities.

Need and Proposed Use of the Information: HRSA is requesting approval for the initiation of the 340B ADR process and uploading of the related documents outlined in the 340B ADR Final Rule. The 340B ADR process is conducted pursuant to the requirements under section 340B(d)(3) of the PHS Act, which requires the establishment and implementation of the 340B ADR process for certain disputes arising under the 340B Drug Pricing Program. HRSA uses the information gathered in the 340B ADR initiation process to determine if the claim submitted meets the statutory requirements for filing a 340B claim and accessing the 340B ADR process.

Likely Respondents: Covered entities and manufacturers and organizations representing these groups.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. 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. To estimate the burden to initiate the 340B ADR process, HRSA reviewed the amount of petitions received under a prior 340B ADR process and estimated the amount of time it took petitioners to initiate the

340B ADR process up until the claim was assigned to a 340B ADR Panel for review. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized Burden Hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
340B Claim Submission	10	1	10	2.5	25
Total	10		10		25

HRSA specifically requests comments on: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–17380 Filed 8–6–24; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; 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 General Medical Sciences Special Emphasis Panel; Review of Center of Biomedical Research Excellence—COBRE (P20) Phase-2 Applications.

Date: November 21–22, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Manas Chattopadhyay, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12N, Bethesda, Maryland 20892, 301–827–5320, manasc@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–17408 Filed 8–6–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Initial Review Group; Kidney, Urologic and Hematologic Diseases D Study Section.

Date: October 15–17, 2024.

Time: 5:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jason D. Hoffert, Ph.D., Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney, National Institute of Health, 6707 Democracy Boulevard, Rm. 7343, Bethesda, MD 20817, 301–496–9010, hoffertj@nidk.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–17376 Filed 8–6–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Proteogenomic Approaches in Tauopathies.

Date: October 23, 2024.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, 5601 Fishers Ln, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Ivan Tadeu Rebutini, Ph.D., Scientific Review Officer, National Institute of Aging, National Institute of Health, 7201 Wisconsin Ave, Rm 100, Bethesda, MD 20814, (301) 555-1212, ivan.rebutini@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17415 Filed 8-6-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; U01Alzheimer's Disease Drug Development.

Date: October 10, 2024.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 5601 Fishers Lane, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Mariel Jais, M.D., Ph.D., Scientific Review Officer, National Institute of Aging, 7201 Wisconsin Avenue, Rm.

2E400, Bethesda, MD 20814, (301) 594-2614, mariel.jais@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17377 Filed 8-6-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; 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 Center for Advancing Translational Sciences Special Emphasis Panel; NCATS CTSA Training Grants Review Meeting.

Date: September 17-18, 2024.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Washingtonian Ballroom (Salon G), Gaithersburg, MD 20878 (In-Person and Virtual Meeting).

Contact Person: Nakia C. Brown, Ph.D., Scientific Review Officer, Office of Grants Management and Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 9609 Medical Center Drive, Room 1E504, Bethesda, MD 20892, (301) 827-4905, brownnac@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B-Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 1, 2024.

David W. Freeman,

Supervisory Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17407 Filed 8-6-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Review of Institutional Training Grants (T32) in Digestive Diseases and Nutrition.

Date: November 1, 2024.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Tori Stone, Ph.D., Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney, National Institute of Health, 6707 Democracy Boulevard, Bethesda, MD 20892, (301) 827-0994, tori.stone@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17373 Filed 8-6-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; NIDDK RC2 Application Review.

Date: September 19, 2024.

Time: 12:00 p.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cheryl Nordstrom, Ph.D., MPH, Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney, National Institute of Health, 6707 Democracy Blvd., Rm. 7013, Bethesda, MD 20892, 301-402-6711, cheryl.nordstrom@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17375 Filed 8-6-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute on Aging; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; GxE and ADRD Risk.

Date: October 11, 2024.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, 5601 Fishers Ln., Rockville, MD 20852 (Virtual Meeting).

Contact Person: Lisa-Marie Tisdale Rowell, Ph.D., Scientific Review Officer, National Institute of Aging, National Institute of Health, 6701 Rockledge Drive, Room 1007G, Bethesda, MD 20892, (301) 594-5622, wigfallt@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17404 Filed 8-6-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR-22-069: High Impact, Interdisciplinary Science in NIDDK Research Areas (RC2).

Date: September 6, 2024.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Lan Tian, Ph.D., Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, 6707 Democracy Boulevard, Bethesda, MD 20892-5452, (301) 496-7050, lan.tian@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17374 Filed 8-6-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**National Institutes of Health****Office of the Director, National Institutes of Health; Notice of Partially Closed Meeting**

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Council of Councils.

This will be a hybrid meeting held in-person and virtually and will be partially 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. Registration is not required to attend the open portions of this meeting and 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: Council of Councils.

Date: September 12-13, 2024.

Open: September 12, 2024, 9:00 a.m. to 11:15 a.m.

Agenda: Welcome and Opening Remarks; Announcements and NIH Program Updates.

Place: National Institutes of Health, Building 35A, 35 Convent Drive, Rooms 620/630/640, Bethesda, MD 20892 (In Person and Virtual).

Closed: September 12, 2024, 12:00 p.m. to 2:00 p.m.

Agenda: Review of Grant Applications.

Place: National Institutes of Health, Building 35A, 35 Convent Drive, Rooms 620/630/640, Bethesda, MD 20892 (In Person and Virtual).

Open: September 12, 2024, 2:15 p.m. to 3:45 p.m.

Agenda: Presentations and Other Business of the Committee.

Place: National Institutes of Health Building 35A, 35 Convent Drive, Rooms 620/630/640, Bethesda, MD 20892 (In Person and Virtual).

Open: September 13, 2024, 9:00 a.m. to 12:35 p.m.

Agenda: Welcome; Announcements; Presentations; and Other Business of the Committee.

Place: National Institutes of Health, Building 35A, 35 Convent Drive, Rooms 620/630/640, Bethesda, MD 20892 (In Person and Virtual).

Contact Person: Franziska Grieder, D.V.M., Ph.D., Executive Secretary, Council of Councils, Director, Office of Research Infrastructure Programs, Division of Program Coordination, Planning, and Strategic Initiatives, Office of the Director, NIH, 6701 Democracy Boulevard, Room 948, Bethesda, MD 20892, GriederF@mail.nih.gov, 301-435-0744.

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 Council of Council's home page at <http://dpcpsi.nih.gov/council/> where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan

Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: July 31, 2024.

Bruce A George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-17409 Filed 8-6-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2024-0336]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625-0017

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625-0017, Various International Agreement Safety Certificates and Documents; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before September 6, 2024.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG-2024-0336]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>.

Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG-6P), ATTN:

PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593-7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202-475-3528, fax 202-372-8405, or email hqs-dg-m-cg-61-pii@uscg.mil for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG-2024-0336, and must be received by September 6, 2024.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents

mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the <https://www.reginfo.gov>, comment-submission web page. OIRA posts its decisions on ICRs online at <https://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0017.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (89 FR 43863, May 20, 2024) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Various International Agreement Safety Certificates and Documents.

OMB Control Number: 1625–0017.

Summary: These Coast Guard-issued forms are used as evidence of compliance with the International Convention for Safety of Life at Sea, 1974 (SOLAS) by certain U.S. vessels on international voyages. Without the proper certificates or documents, a U.S. vessel could be detained in a foreign port.

Need: SOLAS applies to all mechanically propelled cargo vessels of 500 or more gross tons (GT), and to all mechanically propelled passenger vessels carrying more than 12 passengers that engage in international voyages. SOLAS and title 46 CFR 2.01–25 list certificates and documents that may be issued to vessels.

Forms:

- CG–967, Exemption Certificate
- CG–968, Passenger Ship Safety Certificate
- CG–968A, Record of Equipment for the Passenger Ship Safety Certificate (Form P)

- CG–969, Notice of Completion of Examination for Safety Certificate
- CG–3347, Cargo Ship Safety Equipment Certificate
- CG–3347B, Record of Equipment for the Cargo Ship Safety Equipment Certificate (Form E)
- CG–4359, Cargo Ship Safety Construction Certificate
- CG–4360, International Ship Security Certificate
- CG–4361, Interim International Ship Security Certificate
- CG–5643, Safety Management Certificate
- CG–5679, High-Speed Craft Safety Certificate
- CG–5679A, Record of Equipment for High-Speed Craft Safety Certificate
- CG–5680, Permit to Operate High-Speed Craft
- CG–6038, Continuous Synopsis Record (CSR) Document Number _____ for the ship with IMO Number: _____
- CG–6038A, Amendments to the Continuous Synopsis Record (CSR) Document Number _____ for the ship with IMO Number: _____
- CG–16170, Polar Ship Certificate
- CG–16170A, Record of Equipment for the Polar Ship Certificate

Respondents: Owners and operators of SOLAS vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 69 hours to 55 hours a year, due to a decrease in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.*, chapter 35, as amended.

Dated: August 2, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–17459 Filed 8–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0334]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0103

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an

Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0103, Mandatory Ship Reporting System for the Northeast and Southeast Coasts of the United States; without change. Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before September 6, 2024.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2024–0334]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>.

Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email hqs-dg-m-cg-61-pii@uscg.mil for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2024–0334, and must be received by September 6, 2024.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the <https://www.reginfo.gov>, comment-submission web page. OIRA posts its decisions on ICRs online at <https://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0103.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (89 FR 43864, May 20, 2024) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Mandatory Ship Reporting System for the Northeast and Southeast Coasts of the United States.

OMB Control Number: 1625–0103.

Summary: The information is needed to reduce the number of ship collisions with endangered northern right whales. Coast Guard rules at 33 CFR part 169 establish two mandatory ship-reporting systems off the northeast and southeast coasts of the United States.

Need: The collection involves ships' reporting by radio to a shore-based authority when entering the area covered by the reporting system. The ship will receive, in return, information to reduce the likelihood of collisions between themselves and northern right whales—an endangered species—in the areas established with critical-habitat designation.

Forms: None.

Respondents: Operators of certain vessels.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden remains 137 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.*, chapter 35, as amended.

Dated: August 2, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–17461 Filed 8–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0337]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–0043

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR),

abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs (OIRA), requesting an extension of its approval for the following collection of information: 1625–0043, Ports and Waterways Safety; without change.

Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before September 6, 2024.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number [USCG–2024–0337]. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>.

Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email hqs-dg-m-cg-61-pii@uscg.mil for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary

for the proper performance of Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2024–0337, and must be received by September 6, 2024.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the <https://www.reginfo.gov>, comment-submission web page. OIRA posts its decisions on ICRs online at <https://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625–0043.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day

notice (89 FR 43866, May 20, 2024) required by 44 U.S.C. 3506(c)(2). That notice elicited no comments. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Ports and Waterways Safety—Title 33 CFR Subchapter P.

OMB Control Number: 1625–0043.

Summary: This collection of information allows the master, owner, or agent of a vessel affected by these rules to request a deviation from the requirements governing navigation safety equipment to the extent that there is no reduction in safety.

Need: Provisions in Title 33 CFR Subchapter P, allow any person directly affected by the rules in that subchapter to request a deviation from any of the requirements as long as it does not compromise safety. This collection enables the Coast Guard to evaluate the information the respondent supplies, to determine whether it justifies the request for a deviation.

Forms: None.

Respondents: Master, owner, or agent of a vessel.

Frequency: On occasion.

Hour Burden Estimate: The estimated burden has decreased from 2,033 hours to 1,463 hours a year, due to a decrease in the estimated annual number of responses.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.*, chapter 35, as amended.

Dated: August 2, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–17463 Filed 8–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2024–0335]

Collection of Information Under Review by Office of Management and Budget; OMB Control Number 1625–NEW

AGENCY: Coast Guard, DHS.

ACTION: Thirty-day notice requesting comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 the U.S. Coast Guard is forwarding an Information Collection Request (ICR), abstracted below, to the Office of Management and Budget (OMB), Office of Information and Regulatory Affairs

(OIRA), requesting an extension of its approval for the following collection of information: 1625–NEW, Coast Guard Junior Reserve Officers' Training Corps (JROTC) Host School Application; without change.

Our ICR describes the information we seek to collect from the public. Review and comments by OIRA ensure we only impose paperwork burdens commensurate with our performance of duties.

DATES: You may submit comments to the Coast Guard and OIRA on or before September 6, 2024.

ADDRESSES: Comments to the Coast Guard should be submitted using the Federal eRulemaking Portal at <https://www.regulations.gov>. Search for docket number USCG–2024–0335. Written comments and recommendations to OIRA for the proposed information collection should be sent within 30 days of publication of this notice to <https://www.reginfo.gov/public/do/PRAMain>.

Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

A copy of the ICR is available through the docket on the internet at <https://www.regulations.gov>. Additionally, copies are available from: COMMANDANT (CG–6P), ATTN: PAPERWORK REDUCTION ACT MANAGER, U.S. COAST GUARD, 2703 MARTIN LUTHER KING JR. AVE. SE, STOP 7710, WASHINGTON, DC 20593–7710.

FOR FURTHER INFORMATION CONTACT: A.L. Craig, Office of Privacy Management, telephone 202–475–3528, fax 202–372–8405, or email hqs-dg-m-cg-61-pii@uscg.mil for questions on these documents.

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

This notice relies on the authority of the Paperwork Reduction Act of 1995; 44 U.S.C. 3501 *et seq.*, chapter 35, as amended. An ICR is an application to OIRA seeking the approval, extension, or renewal of a Coast Guard collection of information (Collection). The ICR contains information describing the Collection's purpose, the Collection's likely burden on the affected public, an explanation of the necessity of the Collection, and other important information describing the Collection. There is one ICR for each Collection.

The Coast Guard invites comments on whether this ICR should be granted based on the Collection being necessary for the proper performance of

Departmental functions. In particular, the Coast Guard would appreciate comments addressing: (1) the practical utility of the Collection; (2) the accuracy of the estimated burden of the Collection; (3) ways to enhance the quality, utility, and clarity of information subject to the Collection; and (4) ways to minimize the burden of the Collection on respondents, including the use of automated collection techniques or other forms of information technology. These comments will help OIRA determine whether to approve the ICR referred to in this Notice.

We encourage you to respond to this request by submitting comments and related materials. Comments to Coast Guard or OIRA must contain the OMB Control Number of the ICR. They must also contain the docket number of this request, USCG–2024–0335, and must be received by September 6, 2024.

Submitting Comments

We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted.

We accept anonymous comments. All comments to the Coast Guard will be posted without change to <https://www.regulations.gov> and will include any personal information you have provided. For more about privacy and submissions to the Coast Guard in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). For more about privacy and submissions to OIRA in response to this document, see the <https://www.reginfo.gov>, comment-submission web page. OIRA posts its decisions on ICRs online at <https://www.reginfo.gov/public/do/PRAMain> after the comment period for each ICR. An OMB Notice of Action on each ICR will become available via a hyperlink in the OMB Control Number: 1625—NEW.

Previous Request for Comments

This request provides a 30-day comment period required by OIRA. The Coast Guard published the 60-day notice (89 FR 43865 May 20, 2024)

required by 44 U.S.C. 3506(c)(2). That notice received five comments unrelated to the Collection. Accordingly, no changes have been made to the Collection.

Information Collection Request

Title: Coast Guard Junior Reserve Officers' Training Corps (JROTC) Host School Application.

OMB Control Number: 1625—NEW.

Summary: The Coast Guard is mandated under 14 U.S.C. 320 to establish and maintain not fewer than 1 Coast Guard JROTC Units in every Coast Guard District by December 31, 2025. The JROTC program is governed under the provisions of 10 U.S.C. Chapter 102. The information on this Host School Application will be used to help determine whether the applying school will be selected to host a Coast Guard JROTC unit. If the school is selected, the information will be used to establish and manage the unit.

Need: The information is needed to help determine whether the applying school will be selected to host a Coast Guard JROTC unit. If the school is selected, the information will be used to establish and manage the unit. The Coast Guard is mandated under 14 U.S.C. 320 to establish and maintain not fewer than one Coast Guard JROTC Units in every Coast Guard District by Dec 31, 2025. The JROTC program is governed under the provisions of 10 U.S.C. Chapter 102.

Forms:

- Host School Application for USCG JROTC Unit (CG–1533)

Respondents: School officials applying on behalf of a secondary school, public or private, that wish to apply to host a Coast Guard JROTC unit.

Frequency: Applicants need only apply once unless their application information needs to be updated.

Hour Burden Estimate: The estimated burden is 25 hours a year.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. *et seq.*, chapter 35, as amended.

Dated: August 2, 2024.

Kathleen Claffie,

Chief, Office of Privacy Management, U.S. Coast Guard.

[FR Doc. 2024–17460 Filed 8–6–24; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–HQ–MB–2024–0093;
FXMB1231099BPP0–245–FF09M22000;
OMB Control Number 1018–0067]

Agency Information Collection Activities; Approval Procedures for Nontoxic Shot and Shot Coatings

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection without change.

DATES: Interested persons are invited to submit comments on or before October 7, 2024.

ADDRESSES: Send your comments on the information collection request (ICR) by one of the following methods (please reference “1018–0067” in the subject line of your comments):

- *Internet (preferred):* <https://www.regulations.gov>. Follow the instructions for submitting comments on Docket No. FWS–HQ–MB–2024–0093.
- *U.S. mail:* Service Information Collection Clearance Officer, U.S. Fish and Wildlife Service, 5275 Leesburg Pike, MS: PRB (JAO/3W), Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT:

Madonna L. Baucum, Service Information Collection Clearance Officer, by email at Info_Coll@fws.gov, or by telephone at (703) 358–2503. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act (PRA; 44 U.S.C. 3501 *et seq.*) and its implementing regulations at 5 CFR part 1320, all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other

Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

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

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

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

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

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: The Migratory Bird Treaty Act (MBTA; 16 U.S.C. 703 *et seq.*) prohibits the unauthorized take of migratory birds and authorizes the Secretary of the Interior to regulate take of migratory birds in the United States. Under this authority, we control the hunting of migratory game birds through regulations in 50 CFR part 20. On January 1, 1991, we banned lead shot for hunting waterfowl and coots in the United States.

This is a non-form collection. Regulations at 50 CFR 20.134 outline the application and approval process for new types of nontoxic shot. When considering approval of a candidate material as nontoxic, we must ensure that it is not hazardous in the

environment and that secondary exposure (ingestion of spent shot or its components) is not a hazard to migratory birds. To make that decision, we require each applicant to provide information about the solubility and toxicity of the candidate material. Additionally, for law enforcement purposes, a noninvasive field detection device must be available to distinguish candidate shot from lead shot. This information constitutes the bulk of an application for approval of nontoxic shot. The Director uses the data in the application to decide whether to approve a material as nontoxic.

Title of Collection: Approval Procedures for Nontoxic Shot and Shot Coatings (50 CFR 20.134).

OMB Control Number: 1018–0067.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Businesses that produce and/or market approved nontoxic shot types or nontoxic shot coatings.

Total Estimated Number of Annual Respondents: 1.

Total Estimated Number of Annual Responses: 1.

Estimated Completion Time per Response: 3,200 hours.

Total Estimated Number of Annual Burden Hours: 3,200 hours.

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

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: \$26,630 (\$1,630 application processing fee and \$25,000 for solubility testing).

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2024–17457 Filed 8–6–24; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX24EE000101100]

Public Meeting of the National Geospatial Advisory Committee

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act (FACA) of 1972, the U.S. Geological Survey (USGS) is publishing this notice to announce that a Federal advisory committee meeting of the National Geospatial Advisory Committee (NGAC) will take place and is open to members of the public.

DATES: The meeting will be held on Wednesday, October 16, 2024, from 9 a.m. to 5 p.m.; and on Thursday, October 17, 2024, from 9 a.m. to 4 p.m. eastern standard time.

ADDRESSES: The meeting will be held in the South Penthouse Conference Room of the Department of the Interior Building, 1849 C Street NW, Washington, DC. Members of the public may attend the meeting in person or can attend via webinar. Instructions for registration to attend the meeting will be posted at www.fgdc.gov/ngac. Comments can be sent by email to gs-faca@usgs.gov.

FOR FURTHER INFORMATION CONTACT: Mr. Josh Delmonico, Federal Geographic Data Committee (FGDC), USGS, by mail at 12201 Sunrise Valley Drive, MS 590, Reston, VA 20192; by email at jdelmonico@usgs.gov; or by telephone at (703) 648–5752.

Individuals in the United States who are deaf, blind, 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: This meeting is being held under the provisions of the FACA of 1972 (5 U.S.C. ch. 10), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR part 102–3.

Purpose of the Meeting: The NGAC provides advice and recommendations to the FGDC related to management of federal and national geospatial programs, the development of the National Spatial Data Infrastructure (NSDI), and the implementation of the Geospatial Data Act (GDA) of 2018 and the Office of Management and Budget Circular A–16. The NGAC reviews and comments on geospatial policy and management issues and provides a forum to convey views representative of non-federal stakeholders in the geospatial community. The NGAC is one of the primary ways that the FGDC collaborates with its broad network of partners. Additional information about the NGAC is available at: www.fgdc.gov/ngac.

Agenda Topics:

- FGDC Update
- Landsat Advisory Group
- 3D Elevation Program
- GDA
- NSDI
- GeoPlatform
- Standards and Data Access
- Public Comment

Meeting Accessibility/Special Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, language translation services, 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. Seating for in-person attendees may be limited due to room capacity. Webinar/conference line instructions will be provided to registered attendees prior to the meeting.

Public Disclosure of Comments: There will be an opportunity for public comment during each day of the meeting. Depending on the number of people who wish to speak and the time available, the time for individual comments may be limited. Written comments may also be sent to the NGAC for consideration. To allow for full consideration of information by NGAC members, written comments must be provided to Josh Delmonico (see **FOR FURTHER INFORMATION CONTACT**) at least three (3) business days prior to the meeting. Any written comments received will be provided to NGAC members before the meeting.

Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you may ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. ch. 10.

Kenneth Shaffer,

Deputy Executive Director, Federal Geographic Data Committee.

[FR Doc. 2024–17456 Filed 8–6–24; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management**

[WAOR106084175, WAOR 056583]

Public Land Order No. 7946; Extension of Public Land Order No. 7608 for Chief Joseph Dam Additional Units Project, Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Public Land Order.

SUMMARY: This Order extends the duration of the withdrawal created by Public Land Order (PLO) No. 7608 for an additional 20-year period. Subject to valid existing rights, PLO No. 7608 withdrew 400.27 acres of public lands from settlement, sale, location, or entry under the general land laws, including the United States mining laws, and transferred jurisdiction over those lands to the United States Department of the Army, Corps of Engineers, for the Chief Joseph Dam Additional Units Project for a period of 20 years.

DATES: This Order takes effect on August 7, 2024.

FOR FURTHER INFORMATION CONTACT:

Luke Poff, Realty Specialist, BLM Oregon/Washington State Office, (503) 808–6249, by email at lpoff@blm.gov. For the United States Army Corps of Engineers (USACE), contact Cindy Luciano, Civil Works Program Manager, USACE Seattle District, (206) 316–4376, or by email at Cindy.L.Luciano@usace.army.mil. Individuals in the United States who are deaf, blind, 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 purpose of this extension is to continue to reserve the use of the land for the USACE's water management responsibilities at Chief Joseph Dam, which includes water impoundment and storage, management of grazing, wildlife habitat and mitigation areas, recreation, fire protection, public access, cultural resources, and realty actions. The extension will be under the terms and conditions agreed upon between the USACE and the Bureau of Land Management and may be revised by consent of both parties.

Order

By virtue of the authority vested in the Secretary of the Interior by Section

204(d) of the Federal Land Policy and Management Act of 1976, 43 U.S.C. 1714(d), it is ordered as follows:

1. PLO No. 7608 (69 FR 48253), which withdrew 400.27 acres of public lands from settlement, sale, location, or entry under the general land laws, including the United States mining laws, and transferred jurisdiction over those lands to the United States Department of the Army, Corps of Engineers, is hereby extended for an additional 20-year period. The following lands are affected by this Order:

Willamette Meridian, Washington

T. 29 N., R. 26 E.,
Sec. 9, SW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 30, lot 2.
T. 30 N., R. 26 E.,
Sec. 25, NW $\frac{1}{4}$ NE $\frac{1}{4}$;
Sec. 35, SW $\frac{1}{4}$ SE $\frac{1}{4}$.
T. 30 N., R. 27 E.,
Sec. 28, SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 29, NE $\frac{1}{4}$ NW $\frac{1}{4}$;
Sec. 34, SW $\frac{1}{4}$ NW $\frac{1}{4}$ and NE $\frac{1}{4}$ SW $\frac{1}{4}$.
T. 30 N., R. 28 E.,
Sec. 9, SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 14, NE $\frac{1}{4}$ SW $\frac{1}{4}$.
The areas described aggregate 400.27 acres.

2. This withdrawal will expire 20 years from the effective date of this order unless, as a result of a review conducted prior to the expiration date pursuant to Section 204(f) of the Federal Land Policy and Management Act, the Secretary determines that the withdrawal shall be further extended.

(Authority: 43 U.S.C. 1714)

Robert T. Anderson,

Solicitor.

[FR Doc. 2024–17381 Filed 8–6–24; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management**

[BLM_NM_FRN_MO4500180435]

Public Meetings of the Southern New Mexico Resource Advisory Council, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976, as amended, and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management's (BLM) Southern New Mexico Resource Advisory Council (RAC) will meet as indicated below.

DATES: The Southern New Mexico RAC will participate in a field tour on

Monday, September 16, 2024, from 8 a.m. to approximately 4 p.m. Mountain Time (MT). The RAC will then hold an in-person meeting, with a virtual participation option, on Tuesday, September 17, 2024, from 8 a.m. to 4 p.m. MT, with public comments accepted at 3:30 p.m.

The RAC will participate in a field tour on Thursday, January 23, 2025, from 8 a.m. to approximately 4 p.m. MT. The RAC will then hold an in-person meeting, with a virtual participation option, on Friday, January 24, 2025, from 8 a.m. to 4 p.m. MT, with public comments accepted at 3:30 p.m.

ADDRESSES: The September 16, 2024, field tour will commence and conclude at the BLM Roswell Field Office, 2909 West Second St., Roswell, New Mexico 88201–1287. The September 17, 2024, meeting will take place at the Roswell Field Office.

The January 23, 2025, field tour will commence and conclude at the BLM Socorro Field Office, 901 South Highway 85, Socorro, NM 87801–4168. The January 24, 2025, meeting will take place at the Socorro Field Office.

A virtual participation option is available on the Zoom Webinar platform. To register for the September 17 meeting, go to https://blm.zoomgov.com/webinar/register/WN_KQuXociiSi2T4cG1_q0jNQ. To register for the Jan. 24 meeting, go to https://blm.zoomgov.com/webinar/register/WN_hg9JTuxDQ7yG_dENBsP4YA.

FOR FURTHER INFORMATION CONTACT:

Wendy Brown, BLM Pecos District Office, 2909 West Second Street, Roswell, New Mexico 88201–1287; telephone: 575–627–0259; email: wabrown@blm.gov. Individuals in the United States who are deaf, blind, 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 can use relay services offered within their respective country to make international calls to the accessibility point-of-contact in the United States.

For sign language interpretation services, language translation services, assistive listening devices, or other reasonable accommodations, please contact the individual listed above at least 7 business days before the meeting to ensure there is sufficient time to process the request. The Department of the Interior manages accommodation requests on a case-by-case basis.

SUPPLEMENTARY INFORMATION: The 12-member Southern New Mexico RAC advises the Secretary of the Interior, through the BLM New Mexico State

Director, on planning and management of public land resources located within the jurisdictional boundaries of the RAC.

The September 16, 2024, field tour will include restoration/reclamation project sites in the Roswell Field Office, the Lesser Prairie Chicken Dunes Sagebrush Lizard Area of Critical Environmental Concern and adjoining areas, and recreational areas within the Field Office.

Planned meeting agenda items for the September 17, 2024, meeting include Albuquerque District updates with programs and major actions overviews; Las Cruces District updates with programs and major actions overviews (including an update on the Gila Box Riparian National Conservation Area); Pecos District updates with programs and major actions overviews; a presentation on dark skies designations; a presentation on the BLM Conservation and Landscape Health Rule (also known as the Public Lands Rule); and a discussion of land access issues in southern New Mexico.

The January 23, 2025, field tour will give the RAC the opportunity to see the Box Recreation Area and the Datil Well Recreation Campground.

Planned meeting agenda items for the January 24, 2025, meeting include Albuquerque District updates with programs and major actions overviews (including a presentation on the proposed Datil Well Recreation Area Campground fee increases); Las Cruces District updates with programs and major actions overviews; Pecos District updates with programs and major actions overviews (including a presentation on proposed fee increases for the Rob Jagers Campground, Valley of Fires Recreation Area, Haystack Mountain Off-Highway Vehicle Area, and Mescalero Sands Off-Highway Vehicle Area); an oil and gas industry presentation by a ConocoPhillips representative; a discussion of land access issues in southern New Mexico; and votes on proposed recreation and campground fee increases.

Final agendas will be posted 2 weeks in advance of the meetings on the RAC web page at: www.blm.gov/get-involved/resource-advisory-council/near-you/new-mexico/southern-rac.

All meetings and field tours are open to the public, but members of the public who wish to participate in the field tours must provide their own transportation and meals.

Public Comment Procedures: The BLM welcomes comments from all interested parties. There will be a half-hour public comment period during the September 17, 2024, meeting beginning

at 3:30 p.m. MT and during the January 24, 2025, meeting beginning at 3:15 p.m. MT for any interested members of the public who wish to address the Southern New Mexico RAC. Written comments pertaining to this meeting may be submitted in advance to the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Please include “RAC Comment” in your submission. Depending on the number of persons wishing to speak, the time for individual comments may be limited. Before including an address, phone number, email address, or other personal identifying information in any comment, please be aware that all comments—including personal identifying information—may be made publicly available at any time. While requests can be made to withhold personal identifying information from public review, BLM cannot guarantee it will be able to do so.

Detailed meeting minutes for the Southern New Mexico RAC are maintained in the BLM Roswell Field Office and in the BLM Socorro Field Office (see **ADDRESSES**). Meeting minutes will be available for public inspection and reproduction during regular business hours within 90 days following the meeting. Minutes will also be posted on the RAC web page at <https://www.blm.gov/get-involved/resource-advisory-council/near-you/new-mexico/southern-rac>.

(Authority: 43 CFR 1784.4–1)

James Stovall,

BLM Pecos District Manager.

[FR Doc. 2024–17440 Filed 8–6–24; 8:45 am]

BILLING CODE 4331–23–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM AK FRN MO4500172161; AA–12372, F–22452, F–22460, F–22494, F–22521, F–22777, F–22779, F–22780, F–22781]

Alaska Native Claims Selection

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of decision approving lands for conveyance.

SUMMARY: The Bureau of Land Management (BLM) hereby provides constructive notice that it will issue an appealable decision approving conveyance of the surface and subsurface estates in certain lands to Doyon, Limited, an Alaska Native regional corporation, pursuant to the Alaska Native Claims Settlement Act of 1971 (ANCSA), as amended.

DATES: Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the time limits set out in the **SUPPLEMENTARY INFORMATION** section.

ADDRESSES: You may obtain a copy of the decision from the Bureau of Land Management, Alaska State Office, 222 West Seventh Avenue, #13, Anchorage, Alaska 99513-7504.

FOR FURTHER INFORMATION CONTACT: Rolando R. Masvidal, Land Law Examiner, BLM Alaska State Office, 907-271-4687, or rmasvidal@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point of contact in the United States.

SUPPLEMENTARY INFORMATION: As required by 43 CFR 2650.7(d), notice is hereby given that the BLM will issue an appealable decision to Doyon, Limited. The decision approves conveyance of the surface and subsurface estates in certain lands pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601, *et seq.*), as amended. A portion of the lands are located within the Koyukuk National Wildlife Refuge and the Central Yukon River Valley, in the following townships, and aggregate 169.97 acres: T. 16 N., R. 26 W., Fairbanks Meridian; T. 7 N., R. 16 E., Kateel River Meridian (KRM); T. 6 S., R. 21 E., KRM; T. 6 S., R. 22 E., KRM; T. 6 S., R. 23 E., KRM; T. 13 N., R. 24 E., KRM; T. 12 N., R. 26 E., KRM; T. 22 N., R. 60 W., Seward Meridian.

The decision addresses public access easements, if any, to be reserved to the United States pursuant to Sec. 17(b) of ANCSA (43 U.S.C. 1616(b)), in the lands approved for conveyance. The BLM will also publish notice of the decision once a week for four consecutive weeks in the "Fairbanks Daily News-Miner" newspaper. Any party claiming a property interest in the lands affected by the decision may appeal the decision in accordance with the requirements of 43 CFR part 4 within the following time limits:

1. Unknown parties, parties unable to be located after reasonable efforts have been expended to locate, parties who fail or refuse to sign their return receipt, and parties who receive a copy of the decision by regular mail, which is not certified, return receipt requested, shall

have until September 6, 2024 to file an appeal.

2. Parties receiving service of the decision by certified mail shall have 30 days from the date of receipt to file an appeal.

Parties who do not file an appeal in accordance with the requirements of 43 CFR part 4 shall be deemed to have waived their rights. Notices of appeal transmitted by facsimile will not be accepted as timely filed.

Rolando R. Masvidal,
Land Law Examiner, Adjudication Section.

[FR Doc. 2024-17406 Filed 8-6-24; 8:45 am]

BILLING CODE 4331-10-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_WY_FRN_MO4500180547]

Notice of Public Meeting, Wyoming Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Land Policy and Management Act of 1976 and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management's (BLM) Wyoming Resource Advisory Council (Council) will meet as follows.

DATES: The Council will hold a meeting on September 18, 2024, from 8:30 a.m. to 4:30 p.m. Mountain Time (MT) and a field tour on September 19, 2024, from 9:00 a.m. to approximately 4:00 p.m. MT. A virtual participation option will be available. The meeting and field tour are open to the public.

ADDRESSES: The September 18 meeting will be held, and the September 19 field tour will commence and conclude, at the Sublette County Library, 155 S Tyler Ave, Pinedale, WY 82941. Individuals that prefer to participate virtually must register in advance. Registration information and the final agenda will be posted two weeks in advance of the meeting on the Council's web page at <https://www.blm.gov/get-involved/resource-advisory-council/near-you/wyoming>.

FOR FURTHER INFORMATION CONTACT: Allegra Keenoo, BLM Wyoming State Office, telephone: (307) 775-6318, email: akeenoo@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services.

Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. Please make requests in advance for sign language interpreter services, assistive listening devices, language translation services, or other reasonable accommodations. We ask that you contact the person listed above at least 14 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.

SUPPLEMENTARY INFORMATION: The Council provides recommendations to the Secretary of the Interior concerning the planning and management of the public land resources located within the State of Wyoming. Agenda topics for the September 18, 2024, meeting may include district and field manager updates and presentations on the final Rock Springs Resource Management Plan (RMP), if available, the Greater Sage Grouse RMP Amendments, the Foundation for America's Public Lands, wild horse gathers, rule implementation, the Blueprint for 21st Century Outdoor Recreation Plan, and other resource management issues the Council may raise. The Council will participate in a field tour on September 19, 2024, to view projects within the Pinedale Field Office. Members of the public are welcome on field tours but must provide their own transportation and meals.

A public comment period will be offered September 18, 2024, at 2:45 p.m. Depending on the number of persons wishing to speak and the time available, the amount of time for oral comments may be limited. Written comments for the Council may be sent electronically in advance of the scheduled meeting to the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. All comments received will be provided to the Council. 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.

Detailed minutes for Council meetings will be maintained in the BLM Wyoming State Office. Minutes will also be posted to the Council's web page at

<https://www.blm.gov/get-involved/resource-advisory-council/near-you/wyoming>.

Authority: 43 CFR 1784.4–2.

Andrew Archuleta,
BLM Wyoming State Director.

[FR Doc. 2024–17421 Filed 8–6–24; 8:45 am]

BILLING CODE 4331–16–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[MO4500180461]

Notice of Proposed Reinstatement of Terminated Oil and Gas Lease NMNM105679576, New Mexico

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Mineral Leasing Act of 1920, Mewbourne Oil Company timely filed a petition for reinstatement of competitive oil and gas lease NMNM105679576 (legacy serial number NMNM 115404) in Eddy County, New Mexico. The lessee paid the required rentals accruing from the date of termination. No lease was issued that affect these lands. The Bureau of Land Management (BLM) proposes to reinstate the lease.

FOR FURTHER INFORMATION CONTACT: Julieann Serrano, Supervisory Land Law Examiner, Branch of Adjudication, Bureau of Land Management New Mexico State Office, 301 Dinosaur Trail, Santa Fe, New Mexico 87508, (505) 954–2149, jserrano@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The lessees agree to new lease terms for rentals and royalties of \$20 per acre, or fraction thereof, per year, and 20 percent, respectively. The lessee agrees to additional or amended stipulations. The lessee paid the \$500 administration fee for the reinstatement of the lease and \$151 cost for publishing this Notice.

The lessee met the requirements for reinstatement of the lease per sections 31 (d) and (e) of the Mineral Leasing Act of 1920 (30 U.S.C. 188). The BLM is proposing to reinstate the lease effective March 1, 2006, and an extension for one year from the date the lease is reinstated

in accordance with 43 CFR 3108.23(d) subject to: the original terms and conditions of the lease; additional and amended stipulations; increased rental of \$20 per acre; increased royalty of 20 percent; and a one-year lease extension. Authority: 30 U.S.C. 188 (e)(4) and 43 CFR 3108.23.

Julieann Serrano,

Supervisory Land Law Examiner, Branch of Adjudication.

[FR Doc. 2024–17379 Filed 8–6–24; 8:45 am]

BILLING CODE 4331–23–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–38485; PPWOCRADIO, 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 27, 2024, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by August 22, 2024.

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 27, 2024. 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.

DISTRICT OF COLUMBIA

District of Columbia

Old Korean Legation, 1500 13th Street NW (15 Logan Circle NW), Washington, SG100010773

ILLINOIS

Cook County

Royalton Hotel (Residential Hotels in Chicago, 1910–1930), 1810 W Jackson Boulevard, Chicago, MP100010782
Werner Brothers Storage Warehouse No. 6, 7613 N Paulina Street, Chicago, SG100010783

Macon County

Garfield School, 1077 W Grand Avenue, Decatur, SG100010784

KENTUCKY

Fayette County

Lexington Hospitality Motor Inn, 2143 North Broadway Street, Lexington, SG100010762

Franklin County

Green Hill Cemetery, Intersection of East Main Street (U.S. 60) and Atwood Avenue, Frankfort, SG100010763

Jefferson County

Chickasaw Neighborhood Historic District, Bounded by Broadway, Louis Coleman Jr. Drive, Ohio River, the southern boundary of Chickasaw Park and the Paducah and Louisville Railroad, Louisville, SG100010764

The KFC White House Building, 1441 Gardiner Lane, Louisville, SG100010765
Lynnview Historic District, Roughly bounded by Preston Hwy. on the west, Gilmore Ln. on the south, Breitenstein Ave. on the east, and Evergreen Cemetery to the north, Lynnview, SG100010766

Southern Heights-Beechmont District (Boundary Increase), (South Louisville MRA), Roughly bounded by W Southern Heights to the north, S 3rd St. to the east, Southern Parkway, Brookline Ave., Belleview Ave., and Bluegrass Ave. to the south, and on the south, and Cliff Ave. on the west, Louisville, BC100010767

Lee County

Beattyville Historic District, Main Street, Hwy. 11, Locust St., Center St., River Drive, Lumber Street, Madison Street,

Railroad Street, Elm Street, Walnut Street, Bradford Street, Beattyville, SG100010769

Pike County

Pikeville Commercial Historic District (Boundary Increase), (Pikeville MRA), Roughly bounded by Hambley Boulevard, South Auxier Avenue, Main Street, and Huffman Avenue, Pikeville, BC100010771

MICHIGAN

Presque Isle County

Rogers Theater, 257 North 3rd Street, Rogers City, SG100010780

MISSISSIPPI

Union County

New Albany Historic District, Roughly bounded to the north by properties fronting the north side of Mississippi Street; to the east 1 by properties fronting the east side of North and Garfield Streets; to the south by Standish Street and properties fronting the south side of Ford Street, New Albany, SG100010772

OHIO

Cuyahoga County

E.F. Hauserman Co. Administration, Engineering & Research Building, 5711 Grant Avenue, Cuyahoga Heights, SG100010756

OKLAHOMA

Blaine County

Dusbabek Filling Station, 101 N Main Street, Okeene, SG100010776

Garfield County

Booker T. Washington School, 801 Pastor Alfred Baldwin Jr. Way, Enid, SG100010777
Covington Jail (Calabooses (Tiny Jails) in Oklahoma 1904–1940 MPS), 514 W Main St., Covington, MP100010778

Tillman County

Tipton Orphans Home, 1000 North Broadway Avenue, Tipton, SG100010779

PENNSYLVANIA

Delaware County

Pennock E. Sharpless House, 684 Concord Road, Glen Mills, SG100010758

Susquehanna County

Silver Lake Schoolhouse #1 (Educational Resources of Pennsylvania MPS), 1340 Wilkes Barre Turnpike, Montrose, MP100010759

TEXAS

Comal County

Faust-Frueholz House and Medical Building, 305 South Seguin Avenue, New Braunfels, SG100010760

Ellis County

West Marvin Avenue-Patrick Street Historic District, Roughly bounded by North Spencer Street to the west, the rear property lines of the resources fronting the north side of West Marvin Avenue to the north, Ferris Avenue to the east, and Water

Street and West Parks Avenue to the south, Waxahachie, SG100010757

WISCONSIN

Winnebago County

Baumann Block, 1124–1128 Oregon Street, Oshkosh, SG100010774

An owner objection received for the following resource(s):

KENTUCKY

Hart County

Horse Cave Residential Historic District, Roughly bounded by Maple Ave., Guthrie St., Walthall St., Cemetery St., Hart Ave., College St., E Kathleen Ave., Horse Cave, SG100010781

Additional documentation has been received for the following resource(s):

KENTUCKY

Jefferson County

Southern Heights-Beechmont District (Additional Documentation), (South Louisville MRA), Roughly bounded by Southern Pkwy., 6th St., Ashland, and Southern Heights Aves., Louisville, AD83002736

Pike County

Pikeville Commercial Historic District (Additional Documentation), (Pikeville MRA), Main St. and Division Ave., Pikeville, AD84001916

NEBRASKA

Douglas County

Benson Commercial Historic District (Additional Documentation), (Streetcar-Era Commercial Development in Omaha, Nebraska MPS), Centered along Maple St. between North 59th and North 63rd Sts., Omaha, AD100005766

Authority: Section 60.13 of 36 CFR part 60.

Sherry A. Frear,

Chief, National Register of Historic Places/
National Historic Landmarks Program.

[FR Doc. 2024–17434 Filed 8–6–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On July 29, 2024, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Middle District of North Carolina in the lawsuit entitled *United States v. Rudy’s Performance Parts, Inc. and Aaron Rudolf*, Civil Action No. 1:22–cv–00495.

The proposed Consent Decree settles the claims in the Complaint filed on June 29, 2022, which alleges that Defendants violated section 203(a) of

the CAA (42 U.S.C. 7522(a) by manufacturing, selling, offering to sell, and installing aftermarket automotive products that bypass, defeat, or render inoperative motor vehicle emission controls and by failing to provide information requested by EPA. The Consent Decree settles the action by requiring Defendants to pay a \$7 million penalty and comply with various measures detailed in the Consent Decree that are designed to present CAA violations from re-occurring.

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. Rudy’s Performance Parts, Inc. and Aaron Rudolf*, D.J. Ref. No. 90–5–2–1–11963. 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: <https://www.justice.gov/enrd/consent-decrees>. If you require assistance accessing Consent Decree, you may request assistance by email or by mail to the addresses provided above for submitting comments.

Jeffrey Sands,

Deputy Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2024–17420 Filed 8–6–24; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

223rd Meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans; Notice of Meeting

Pursuant to the authority contained in section 512 of the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1142, the 223rd open meeting of the Advisory Council on Employee Welfare and Pension Benefit Plans (also

known as the ERISA Advisory Council) will be held on September 10–12, 2024. On Tuesday, September 10, 2024, the meeting will begin at 1 p.m. and end at approximately 4:30 p.m. (ET). On Wednesday, September 11, 2024, the meeting will begin at 9 a.m. and end at approximately 6 p.m. (ET), with a one-hour break for lunch. On Thursday, September 12, 2024, the meeting will begin at 9 a.m. and end at approximately 3 p.m. (ET), with a one-hour break for lunch.

The three-day meeting will take place at the U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210 in Room 6, C5320. The meeting will also be accessible via teleconference and some participants, as well as members of the public, may elect to attend virtually. Instructions for public teleconference access will be available on the ERISA Advisory Council's web page at <https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/erisa-advisory-council> approximately one week prior to the meeting.

The purpose of the open meeting is for Advisory Council members to hear testimony from invited witnesses and to receive an update from the Employee Benefits Security Administration (EBSA).

The Advisory Council is studying the following topics: (1) Making Welfare Plan Claims and Appeals Procedures More Accessible to Participants, and (2) Lifetime Income and Qualified Defined Investment Alternatives (QDIAs). Descriptions of these topics are available on the ERISA Advisory Council's web page at <https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/erisa-advisory-council>.

Organizations or members of the public wishing to submit a written statement on any of the matters before the Advisory Council may do so on or before Tuesday, September 3, 2024, to George Pantazopoulos, Executive Secretary, ERISA Advisory Council. Statements should be transmitted electronically as an email attachment in text or pdf format to ERISAAAdvisoryCouncil@dol.gov. Statements transmitted electronically that are included in the body of the email will not be accepted. Relevant statements received on or before Tuesday, September 3, 2024, will be included in the record of the meeting and made available through the EBSA Public Disclosure Room. No deletions, modifications, or redactions will be made to the statements received as they are public records. **Warning:** Do not include any personally identifiable or

confidential business information that you do not want publicly disclosed.

Individuals or representatives of organizations interested in addressing the ERISA Advisory Council at the public meeting must submit a written request to the Executive Secretary on or before Tuesday, September 3, 2024, via email to ERISAAAdvisoryCouncil@dol.gov. Requests to address the Council must include: (1) the name, title, organization, address, email address, and telephone number of the individual who would appear; (2) if applicable, the name of the organization(s) whose views would be represented; and (3) a concise summary of the statement that would be presented. Each individual or organization will be given 10 minutes to address the Council and should be prepared to answer questions regarding their written and oral statements. An agenda for the meeting, including a schedule of testimony from invited witnesses and a schedule of members of the public who will address the Council, will be posted on the ERISA Advisory Council's web page at <https://www.dol.gov/agencies/ebsa/about-ebsa/about-us/erisa-advisory-council> no later than September 5, 2024. The number of public commenters that address the Council may be limited based on the number of requests that are received. In that event, the broadest array of viewpoints on all aspects of the matters under consideration by the Advisory Council will be represented and all written statements received will be included in the public record.

Individuals who need special accommodations should contact the Executive Secretary on or before Tuesday, September 3, 2024, via email to ERISAAAdvisoryCouncil@dol.gov or by telephoning (202) 693–8654.

For more information about the meeting, contact the Executive Secretary at the address or telephone number above.

Signed at Washington, DC, this 1st day of August, 2024.

Lisa M. Gomez,

Assistant Secretary, Employee Benefits Security Administration.

[FR Doc. 2024–17464 Filed 8–6–24; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–24–0017; NARA–2024–050]

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](https://www.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 23, 2024.

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-24-0017/document>. This is a direct link to the schedules posted in the docket for this notice on [regulations.gov](https://www.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](https://www.regulations.gov) and on submitting comments, see their FAQs at <https://www.regulations.gov/faq>.

If you are unable to comment via [regulations.gov](https://www.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 Defense, Department of the Army, Career Acquisition Management Portal (CAMP) Master File (DAA-AU-2024-0004).

2. HHS, Food and Drug Administration, Criminal Investigation Records of the Office of Criminal Investigations and the Office of Internal Affairs (DAA-0088-2024-0005).

3. HHS, Office of the Secretary, Records of the Office of Evaluation and Inspections (OEI) of the Inspector General (IG) of Health and Human Services (DAA-0468-2024-0003).

4. Department of Justice, Executive Office of US Trustees, Recordings of 341 Meetings (DAA-0060-2022-0018).

5. Central Intelligence Agency, Agency-wide, Due Diligence Records (DAA-0263-2023-0003).

6. National Credit Union Administration, Office of External Affairs and Communications, Web

Content Records (DAA-0413-2023-0006).

7. Southeastern Power Administration, Agency-wide, Legal and Legislative Program (DAA-0388-2024-0008).

William P. Fischer,

Acting Chief Records Officer for the U.S. Government.

[FR Doc. 2024-17416 Filed 8-6-24; 8:45 am]

BILLING CODE 7515-01-P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification request received and permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of a requested permit modification issued.

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: The National Science Foundation (NSF), as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95-541, 45 CFR part 670), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection.

Description of Permit Modification Requested: The Foundation issued a permit (ACA 2023-004) to Steve Emslie on July 26, 2022. The issued permit allows for take and harmful interference associated with research examining ecological responses in diet and foraging behavior of the Adelie penguin (*Pygoscelis adeliae*) in Antarctica. The permit holder may collect up to 150 ancient and modern penguin tissues per year at active and abandoned penguin colonies in the Ross Sea region. Ice-free areas would be surveyed and sampled through excavations 1x1 m in size, of sediment and rock in penguin colonies, and bones, feathers, eggshell, and whole

carcasses would be salvaged. The permit holder may collect salvaged whole or partial seabird carcasses, up to 10 of each species per year, of native Antarctic birds found dead on beaches, at seabird colonies, at McMurdo and Palmer stations, or on any U.S. Antarctic Program (USAP) vessel. The applicant may enter ASPAs 104, 105, 106, 121, 124, 159, 161, 165.

Now the applicant proposes a modification to the permit to add access to ASPA 178—Inexpressible Island and Seaview Bay, Ross Sea to continue diet and foraging behavior research. The activities are consistent with the management plan for the ASPA.

The ACA Permit Officer has reviewed the modification request and has determined that the amendment is not a material change to the permit, and it will have a less than a minor or transitory impact.

Dates: July 26, 2022 to December 31, 2025.

The permit modification was issued on June 25, 2024.

Kimiko S. Bowens-Knox,

Program Analyst, Office of Polar Programs.

[FR Doc. 2024–17437 Filed 8–6–24; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permits 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; 603–292–4479; email: ACApermits@nsf.gov.

SUPPLEMENTARY INFORMATION: On June 18, 2024, the National Science Foundation published a notice in the **Federal Register** of permit applications received. The permits were issued on the following dates:

1. Link Olson, Permit No. 2025–001, July 19, 2024
2. Jesse Naiman, Permit No. 2025–002, July 30, 2024

On June 26, 2024, the National Science Foundation published a notice in the **Federal Register** of permit applications received. The permits were issued on the following dates:

1. Birgitte McDonald, Permit No. 2025–003, July 30, 2024

Kimiko S. Bowens-Knox,

Program Analyst, Office of Polar Programs.

[FR Doc. 2024–17436 Filed 8–6–24; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permit Modification Received Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit modification request received and permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish a notice of requests to modify permits issued to conduct activities regulated under the Antarctic Conservation Act of 1978. NSF has published regulations under the Antarctic Conservation Act in the Code of Federal Regulations. This is the required notice of a requested permit modification issued.

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: The National Science Foundation (NSF), as directed by the Antarctic Conservation Act of 1978 (Pub. L. 95–541, 45 CFR part 670), as amended by the Antarctic Science, Tourism and Conservation Act of 1996, has developed regulations for the establishment of a permit system for various activities in Antarctica and designation of certain animals and certain geographic areas as requiring special protection.

Description of Permit Modification Requested:

The Foundation issued a permit (ACA 2023–034) to Leidos Innovations Group, Antarctic Support Contract on January 27, 2024. The issued permit allows the applicant to enter Antarctic Specially Protected Areas 105, 106, 113, 121, 123, 124, 131, 137, 138, 149, 154, 172, 175 to support National Science Foundation (NSF) environmental management responsibilities under Annex V of the Protocol on Environmental Protection to the Antarctic Treaty.

Now the applicant proposes a modification to the permit to add access to ASPA 116—New College Valley, Caughley Beach, Cape Bird, Ross Island to support activities related to a review of the management plan for the ASPA. The activities are consistent with the existing activities authorized under the permit.

The ACA Permit Officer has reviewed the modification request and has determined that the amendment is not a material change to the permit, and it will have a less than a minor or transitory impact.

Dates: February 1, 2023 to January 31, 2028.

The permit modification was issued on July 30, 2024.

Kimiko S. Bowens-Knox,

Program Analyst, Office of Polar Programs.

[FR Doc. 2024–17433 Filed 8–6–24; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2024–0040]

Information Collection: Facility Security Clearance and Safeguarding of National Security Information and Restricted Data

AGENCY: Nuclear Regulatory Commission.

ACTION: Renewal of existing information collection; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment on the renewal of Office of Management and Budget (OMB) approval for an existing collection of information. The information collection is entitled, “Facility Security Clearance and Safeguarding of National Security Information and Restricted Data.”

DATES: Submit comments by October 7, 2024. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration only for comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2024–0040. Address questions about Docket IDs in [Regulations.gov](https://www.regulations.gov) to Stacy Schumann; telephone: 301–415–0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* David Cullison, Office of the Chief Information Officer, Mail Stop: T–6 A10M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

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: David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: Infocollects.Resource@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2024-0040 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC-2024-0040.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The supporting statement, burden spreadsheet, and NRC Form 405F are available in ADAMS under Accession Nos. ML24081A183, ML24081A185, and ML24081A186.

- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

- *NRC's Clearance Officer:* A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, David Cullison, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-2084; email: Infocollects.Resource@nrc.gov.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include

Docket ID NRC-2024-0040, in your comment submission.

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at <https://www.regulations.gov> and entered into ADAMS. Comment submissions are not routinely edited 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 comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35), the NRC is requesting public comment on its intention to request the OMB's approval for the information collection summarized below.

1. *The title of the information collection:* 10 CFR part 95, “Facility Security Clearance and Safeguarding of National Security Information and Restricted Data.”
2. *OMB approval number:* 3150-0047.
3. *Type of submission:* Extension.
4. *The form number, if applicable:* NRC Form 405F.
5. *How often the collection is required or requested:* When new facility clearance requests are received, existing facility clearances are terminated, and when respondents make changes reportable under the rule—including a mandatory submission every 5 years.
6. *Who will be required or asked to respond:* NRC-regulated facilities and their contractors who require access to, and possession of NRC classified information.
7. *The estimated number of annual responses:* 156 (136 reporting responses + 20 recordkeepers).
8. *The estimated number of annual respondents:* 20.
9. *The estimated number of hours needed annually to comply with the information collection requirement or request:* 940 (784 hours reporting + 156 recordkeeping).

10. *Abstract:* The NRC-regulated facilities and their contractors who are authorized to access and possess classified matter are required to provide

information and maintain records to ensure an adequate level of protection is provided to NRC classified information and material.

III. Specific Requests for Comments

The NRC is seeking comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility? Please explain your answer.
2. Is the estimate of the burden of the information collection accurate? Please explain your answer.
3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?
4. How can the burden of the information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

Dated: August 1, 2024.

For the Nuclear Regulatory Commission.

David Cullison,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2024-17372 Filed 8-6-24; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-255; NRC-2024-0130]

Holtec Decommissioning International, LLC, and Holtec Palisades, LLC; Palisades Nuclear Plant; Applications for Amendments to Renewed Facility Operating License Involving Proposed No Significant Hazards Considerations and Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment requests; opportunity to comment, request a hearing, and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC or the Commission) received and is considering issuance of four amendments to Renewed Facility Operating License (RFOL) No. DPR-20, that were requested by Holtec Decommissioning International, LLC (HDI), on behalf of Holtec Palisades, LLC, to support the potential reauthorization of power operations at the Palisades Nuclear Plant (PNP). For each amendment request, the NRC proposes to determine that they involve

no significant hazards consideration (NSHC). Because potential parties may deem it necessary to obtain access to sensitive unclassified non-safeguards information (SUNSI) and safeguards information (SGI) to meet Commission requirements for intervention, the NRC is issuing an order imposing procedures to obtain access to SUNSI and SGI for contention preparation by persons who file a hearing request or petition for leave to intervene.

DATES: Comments must be filed by September 6, 2024. A request for a hearing or petition for leave to intervene must be filed by October 7, 2024. Any potential party as defined in section 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR) who believes access to SUNSI and/or SGI is necessary to respond to this notice must request document access by August 19, 2024.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website.

- *Federal rulemaking website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2024–0130. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

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

FOR FURTHER INFORMATION CONTACT: Marlayna Doell, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–3178; email: Marlayna.Doell@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2024–0130 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2024–0130.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to PDR.Resource@nrc.gov. The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

- *NRC’s PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC–2024–0130 in your comment submission.

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

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

II. Background

A. Background

PNP consists of a single pressurized-water reactor located in Covert Township, Michigan, along the

shoreline of Lake Michigan. Originally licensed for operation on March 24, 1971, the NRC issued a renewed operating license for PNP on January 17, 2007, with the renewed operating license term expiring on March 24, 2031.

On June 13, 2022, Entergy Operations, Inc., the licensee who operated the facility prior to transfer of control of the PNP license to HDI and Holtec Palisades, LLC, submitted certifications that it had permanently ceased operations of PNP and permanently removed fuel from the reactor vessel in accordance with paragraph 10 CFR 50.82(a)(1). When the NRC docketed the certifications, the PNP RFOL No. DPR–20 no longer authorized operation of the reactor, or emplacement or retention of fuel into the reactor vessel, as provided by 10 CFR 50.82(a)(2).

HDI is seeking to return PNP to power operations and has submitted several requests for NRC approval to support allowing the resumption of power operations through March 24, 2031, the end of the renewed facility operating license term under PNP RFOL No. DPR–20. These requests include four license amendment requests, which are the subject of this notice, a license transfer request, and an exemption request. The hearing opportunity for the license transfer request is being addressed by a separate notice published in today’s issue of the **Federal Register**. Consistent with the Atomic Energy Act of 1954, as amended, and NRC regulations, the NRC is not publishing a notice of opportunity for hearing on the exemption request.

B. License Amendment Requests

The NRC is considering issuance of amendments to RFOL No. DPR–20 that were requested by HDI, on behalf of Holtec Palisades, LLC, to support reauthorization of commercial power operations at PNP. These license amendment requests are the subject of this notice and are listed in tabular form in Section III of this document.

Before any issuance of the proposed license amendments, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and the NRC’s regulations. Pursuant to Section 189a.(2) of the Act, the NRC is publishing this notice. The Act requires the Commission to publish notice of any amendments issued or proposed to be issued, and grants the Commission the authority to issue and make immediately effective any amendment to an operating license or combined license, as applicable, upon a determination by the Commission that such amendment involves no significant hazards consideration, notwithstanding

the pendency before the Commission of a request for a hearing from any person.

The scope of this notice is limited to comments, requests for a hearing, and petitions for leave to intervene related to the four proposed license amendment requests listed in tabular form in Section III of this document. The proposed direct transfer of the PNP license from HDI to Palisades Energy, LLC, is available for comment, as well as the opportunity to request a hearing and petition for leave to intervene, in a separate notice published in today's issue of the **Federal Register**.

The NRC staff also notes that, although the four amendment requests state that a categorical exclusion applies to the requested amendments, the NRC staff is not relying on a categorical exclusion for these actions but is instead preparing an environmental assessment (EA) to evaluate the environmental impacts from the proposed Federal actions related to reauthorizing power operations at PNP, which include the license amendment requests. The NRC's decision to prepare an EA and additional detail about the environmental review are discussed in the NRC's notice of intent to prepare an EA and conduct scoping, published on June 27, 2024 (89 FR 53659).

III. Notice of Consideration of Issuance of Amendments to Renewed Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The Commission has made a proposed determination that the four amendment requests listed in this notice involve no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendments would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated, or (2) create the possibility of a new or different kind of accident from any accident previously evaluated, or (3) involve a significant reduction in a margin of safety. The basis for this proposed determination for each amendment request is included in the license amendment requests as referenced in tabular form in Section III of this document.

The Commission is seeking public comments on these proposed determinations. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determinations.

Normally, the Commission will not issue the amendments until the expiration of 60 days after the date of publication of this notice. The Commission may issue any of these license amendments before expiration of the 60-day period provided that its final determination is that the amendment involves no significant hazards consideration. In addition, the Commission may issue any of these amendments prior to the expiration of the 30-day comment period if circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in prevention of resumption of operation of the facility. If the Commission takes action on any of these amendments prior to the expiration of either the comment period or the notice period, it will publish a notice of issuance in the **Federal Register**. If the Commission makes a final no significant hazards consideration determination for any of these amendments, any hearing will take place after issuance. The Commission expects that the need to take this action on any amendment before 60 days have elapsed will occur very infrequently.

A. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by any of these actions may file a request for a hearing and petition for leave to intervene (petition) with respect to that action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

If a hearing is requested and the Commission has not made a final determination on the issue of no significant hazards consideration, the Commission will make a final determination on the issue of no significant hazards consideration, which

will serve to establish when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of the amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

A State, local governmental body, federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 60 days from the date of publication of this notice. Alternatively, a State, local governmental body, federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (<https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053>) and on the NRC's public website at <https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate>.

B. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions in adjudicatory proceedings is located in the "Electronic Information Exchange System Adjudicatory User's Guide" (ADAMS Accession No. ML23150A083) and on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>.

To comply with the procedural requirements of E-Filing, at least 10

days prior to the filing deadline, the participant should contact the Office of the Secretary by email at Hearing.Docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the

NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's

electronic hearing docket, which is publicly available at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as previously described, click "cancel" when the link requests certificates and you will be automatically directed to the NRC's electronic hearing docket where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The following table provides the topic and dates of each application, ADAMS accession number(s), and location in the application of HDI's proposed NSHC determination for each of the license amendment requests that support resumption of commercial power operation at PNP. For further details with respect to these license amendment applications, see the applications for amendment, publicly available portions of which are available for public inspection in ADAMS. For additional direction on accessing information related to these documents, see the "Obtaining Information and Submitting Comments" section of this document.

Request to Revise Operating License and Technical Specifications to Support Resumption of Power Operations

Application Date	December 14, 2023.
Supplement Date	July 9, 2024.
ADAMS Accession Nos	ML23348A148 and ML24191A422.
Location in Application of NSHC	Pages 91-94 of the Enclosure.
Brief Description of Amendment	The proposed amendments would revise the renewed facility operating license, including the permanently defueled technical specifications and the environmental protection plan, to support the resumption of power operations at PNP.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jason Day, General Counsel, Holtec Decommissioning International, LLC, 1 Holtec Boulevard, Camden, NJ 08104.
NRC Project Manager, Telephone Number	Marlayna Doell, 301-415-3178.

Request to Revise the Administrative Technical Specifications to Support Resumption of Power Operations

Application Date	February 9, 2024.
Supplement Date	July 31, 2024.
ADAMS Accession Nos	ML24040A089 and ML24213A082.
Location in Application of NSHC	Pages 19-21 of the Enclosure.
Brief Description of Amendment	The proposed amendment would revise selected sections of the permanently defueled technical specifications to support the resumption of power operations at PNP.
Proposed Determination	NSHC.

Name of Attorney for Licensee, Mailing Address	Jason Day, General Counsel, Holtec Decommissioning International, LLC, 1 Holtec Boulevard, Camden, NJ 08104.
NRC Project Manager, Telephone Number	Marlayna Doell, 301-415-3178.

Request to Revise the Palisades Emergency Plan to Support Resumption of Power Operations

Application Date	May 1, 2024.
Supplement Date	July 24, 2024.
ADAMS Accession No	ML24122C666 and ML24206A187.
Location in Application of NSHC	Pages 28-29 of the Enclosure.
Brief Description of Amendment	The proposed amendment would revise the PNP Site Emergency Plan and emergency classification scheme to support the resumption of power operations at PNP.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jason Day, General Counsel, Holtec Decommissioning International, LLC, 1 Holtec Boulevard, Camden, NJ 08104.
NRC Project Manager, Telephone Number	Justin Poole, 301-415-2048.

Request to Update the Main Steam Line Break Analysis Methodology for Palisades

Application Date	May 24, 2024.
ADAMS Accession No	ML24145A145.
Location in Application of NSHC	Pages 6-8 of the Enclosure.
Brief Description of Amendment	The proposed amendment would allow the use of the Framatome Inc. Topical Report EMF-2310, Revision 1, Supplement 2P-A, Revision 0, "SRP Chapter 15 Non-LOCA Methodology for Pressurized Water Reactors," for application of the Biasi Critical Heat Flux correlation in the Post-Scram Main Steam Line Break (MSLB) Analysis at PNP, which supports the resumption of power operations at PNP.
Proposed Determination	NSHC.
Name of Attorney for Licensee, Mailing Address	Jason Day, General Counsel, Holtec Decommissioning International, LLC, 1 Holtec Boulevard, Camden, NJ 08104.
NRC Project Manager, Telephone Number	Justin Poole, 301-415-2048.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information and Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI and SGI. Requirements for access to SGI are primarily set forth in 10 CFR parts 2 and 73. Nothing in this Order is intended to conflict with the SGI regulations.

B. Within 10 days after publication of this notice of opportunity for hearing, any potential party who believes access to SUNSI and/or SGI is necessary to respond to this notice may request such access. A "potential party" is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI and/or SGI submitted later than 10 days after publication will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI, SGI, or both to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Licensing, Hearings, and Enforcement, Office of the General Counsel, U.S. Nuclear Regulatory Commission,

Washington, DC 20555-0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email addresses for the Office of the Secretary and the Office of the General Counsel are Hearing.Docket@nrc.gov and RegsOgcMailCenter.Resource@nrc.gov, respectively.¹ The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice.

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1).

(3) If the request is for SUNSI, the identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

¹ While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's "E-Filing Rule," the initial request to access SUNSI and/or SGI under these procedures should be submitted as described in this paragraph.

(4) If the request is for SGI, the identity of each individual who would have access to SGI if the request is granted, including the identity of any expert, consultant, or assistant who will aid the requestor in evaluating the SGI. In addition, the request must contain the following information:

(a) A statement that explains each individual's "need to know" the SGI, as required by 10 CFR 73.2 and 10 CFR 73.22(b)(1). Consistent with the definition of "need to know" as stated in 10 CFR 73.2, the statement must explain:

(i) Specifically, why the requestor believes that the information is necessary to enable the requestor to proffer and/or adjudicate a specific contention in this proceeding;² and

(ii) The technical competence (demonstrable knowledge, skill, training or education) of the requestor to effectively utilize the requested SGI to provide the basis and specificity for a proffered contention. The technical competence of a potential party or its counsel may be shown by reliance on a

² Broad SGI requests under these procedures are unlikely to meet the standard for need to know; furthermore, NRC staff redaction of information from requested documents before their release may be appropriate to comport with this requirement. These procedures do not authorize unrestricted disclosure or less scrutiny of a requestor's need to know than ordinarily would be applied in connection with an already-admitted contention or non-adjudicatory access to SGI.

qualified expert, consultant, or assistant who satisfies these criteria.

(b) A completed Form SF-85, "Questionnaire for Non-Sensitive Positions," for each individual who would have access to SGI. The completed Form SF-85 will be used by the Office of Administration to conduct the background check required for access to SGI, as required by 10 CFR part 2, subpart C, and 10 CFR 73.22(b)(2), to determine the requestor's trustworthiness and reliability. For security reasons, Form SF-85 can only be submitted electronically through the National Background Investigation Services e-App system, a secure website that is owned and operated by the Defense Counterintelligence and Security Agency (DCSA). To obtain online access to the form, the requestor should contact the NRC's Office of Administration at 301-415-3710.³

(c) A completed Form FD-258 (fingerprint card), signed in original ink, and submitted in accordance with 10 CFR 73.57(d). Copies of Form FD-258 will be provided in the background check request package supplied by the Office of Administration for each individual for whom a background check is being requested. The fingerprint card will be used to satisfy the requirements of 10 CFR part 2, subpart C, 10 CFR 73.22(b)(1), and Section 149 of the Atomic Energy Act of 1954, as amended, which mandates that all persons with access to SGI must be fingerprinted for a Federal Bureau of Investigation identification and criminal history records check.

(d) A check or money order payable in the amount of \$310.00⁴ to the U.S. Nuclear Regulatory Commission for each individual for whom the request for access has been submitted, and

(e) If the requestor or any individual(s) who will have access to SGI believes they belong to one or more of the categories of individuals in 10 CFR 73.59 that are exempt from the criminal history records check and background check requirements, the requestor should also provide a statement identifying which exemption the requestor is invoking and explaining the requestor's basis for believing that the exemption applies. While processing the request, the Office of Administration, Personnel Security Branch, will make a final determination

whether the claimed exemption applies. Alternatively, the requestor may contact the Office of Administration for an evaluation of their exemption status prior to submitting their request. Persons who are exempt from the background check are not required to complete the SF-85 or Form FD-258; however, all other requirements for access to SGI, including the need to know, are still applicable.

Note: Copies of documents and materials required by paragraphs C.(4)(b), (c), and (d) of this Order must be sent to the following address: U.S. Nuclear Regulatory Commission, Office of Administration, ATTN: Personnel Security Branch, Mail Stop: TWFN-07D04M, 11555 Rockville Pike, Rockville, MD 20852.

These documents and materials should *not* be included with the request letter to the Office of the Secretary, but the request letter should state that the forms and fees have been submitted as required.

D. To avoid delays in processing requests for access to SGI, the requestor should review all submitted materials for completeness and accuracy (including legibility) before submitting them to the NRC. The NRC will return incomplete packages to the sender without processing.

E. Based on an evaluation of the information submitted under paragraphs C.(3) or C.(4), as applicable, the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI and/or a need to know the SGI requested.

F. For requests for access to SUNSI, if the NRC staff determines that the requestor has satisfied both E.(1) and E.(2), the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order⁵ setting forth terms and conditions to prevent the unauthorized or inadvertent

disclosure of SUNSI by each individual who will be granted access to SUNSI.

G. For requests for access to SGI, if the NRC staff determines that the requestor has satisfied both E.(1) and E.(2), the Office of Administration will then determine, based upon completion of the background check, whether the proposed recipient is trustworthy and reliable, as required for access to SGI by 10 CFR 73.22(b). If the Office of Administration determines that the individual or individuals are trustworthy and reliable, the NRC will promptly notify the requestor in writing. The notification will provide the names of approved individuals as well as the conditions under which the SGI will be provided. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order⁶ by each individual who will be granted access to SGI.

H. Release and Storage of SGI. Prior to providing SGI to the requestor, the NRC staff will conduct (as necessary) an inspection to confirm that the recipient's information protection system is sufficient to satisfy the requirements of 10 CFR 73.22. Alternatively, recipients may opt to view SGI at an approved SGI storage location rather than establish their own SGI protection program to meet SGI protection requirements.

I. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI and/or SGI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of opportunity for hearing), the petitioner may file its SUNSI and/or SGI contentions by that later deadline.

J. Review of Denials of Access.

(1) If the request for access to SUNSI and/or SGI is denied by the NRC staff either after a determination on standing and requisite need, or after a determination on trustworthiness and reliability, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

³ The requestor will be asked to provide the requestor's full name, social security number, date and place of birth, telephone number, and email address. After providing this information, the requestor usually should be able to obtain access to the online form within one business day.

⁴ This fee is subject to change pursuant to the DCSA's adjustable billing rates.

⁵ Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer, or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

⁶ Any motion for Protective Order or draft Non-Disclosure Agreement or Affidavit for SGI must be filed with the presiding officer, or the Chief Administrative Judge if the presiding officer has not yet been designated, within 180 days of the deadline for the receipt of the written access request.

(2) Before the Office of Administration makes a final adverse determination regarding the trustworthiness and reliability of the proposed recipient(s) for access to SGI, the Office of Administration, in accordance with 10 CFR 2.336(f)(1)(iii), must provide the proposed recipient(s) any records that were considered in the trustworthiness and reliability determination, including those required to be provided under 10 CFR 73.57(e)(1), so that the proposed recipient(s) have an opportunity to correct or explain the record.

(3) The requestor may challenge the NRC staff's adverse determination regarding access to SUNSI or with respect to standing or need to know for SGI by filing a challenge within 5 days of receipt of that determination with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if this individual is unavailable, another administrative judge or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has

been designated to rule on information access issues, with that officer.

(4) The requestor may challenge the Office of Administration's final adverse determination with respect to trustworthiness and reliability for access to SGI by filing a request for review in accordance with 10 CFR 2.336(f)(1)(iv).

(5) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

K. Review of Grants of Access. A party other than the requestor may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if this individual is unavailable, another administrative judge or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.⁷

L. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI and/or SGI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated: August 1, 2024.

For the Nuclear Regulatory Commission.

Carrie Safford,

Secretary of the Commission.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION AND SAFEGUARDS INFORMATION IN THIS PROCEEDING

Day	Event/activity
0	Publication of Federal Register notice of opportunity for hearing, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) and/or Safeguards Information (SGI). SUNSI requests should include information: (i) supporting the standing of a potential party identified by name and address and (ii) describing the requestor's need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding. SGI requests should include information: (i) supporting the standing of a potential party identified by name and address; (ii) describing why the information is necessary to enable the requestor to proffer and/or adjudicate a specific contention in the adjudicatory proceeding; (iii) demonstrating technical competence of the requestor to use the SGI to provide the basis and specificity for a proffered contention; and (iv) including the application and fee for the fingerprint/background check.
60	Deadline for submitting petition for intervention containing: (i) demonstration of standing and (ii) all contentions whose formulation does not require access to SUNSI and/or SGI (+25 Answers to petition for intervention; +7 requestor/petitioner reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows (1) need for SUNSI and/or (2) need to know SGI. (For SUNSI, NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents). If NRC staff makes the finding of need to know for SGI and likelihood of standing, NRC staff begins background check (including fingerprinting for a criminal history records check), information processing (preparation of redactions or review of redacted documents), and readiness inspections.
25	If NRC staff finds no "need" for SUNSI and/or no "need to know" for SGI, or no likelihood of standing, the deadline for requestor/petitioner to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds "need" for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Agreement or Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement or Affidavit for SUNSI.

⁷ Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR

46562, August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as

applicable), but not to the initial SUNSI and/or SGI request submitted to the NRC staff under these procedures.

ATTACHMENT 1—GENERAL TARGET SCHEDULE FOR PROCESSING AND RESOLVING REQUESTS FOR ACCESS TO SENSITIVE UNCLASSIFIED NON-SAFEGUARDS INFORMATION AND SAFEGUARDS INFORMATION IN THIS PROCEEDING—Continued

Day	Event/activity
190	(Receipt +180) If NRC staff finds standing, need to know for SGI, and trustworthiness and reliability, deadline for NRC staff to file motion for Protective Order and draft Non-Disclosure Agreement or Affidavit (or to make a determination that the proposed recipient of SGI is not trustworthy or reliable). <i>Note:</i> Before the Office of Administration makes a final adverse determination regarding access to SGI, the proposed recipient must be provided an opportunity to correct or explain information.
205	Deadline for petitioner to seek reversal of a final adverse NRC staff trustworthiness or reliability determination under 10 CFR 2.336(f)(1)(iv).
A	If access granted: issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Agreements or Affidavits. Access provided to SUNSI and/or SGI consistent with decision issuing the protective order.
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI and/or SGI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of opportunity for hearing), the petitioner may file its SUNSI and/or SGI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI and/or SGI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2024–17359 Filed 8–6–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION**[Docket Nos. 50–255 and 72–007; NRC–2024–0128]****Holtec Decommissioning International, LLC, Holtec Palisades, LLC, and Palisades Energy, LLC; Palisades Nuclear Plant and the Palisades Independent Spent Fuel Storage Installation; Consideration of Approval of Transfer of Licenses and Conforming Amendment****AGENCY:** Nuclear Regulatory Commission.**ACTION:** Application for direct transfer of license; opportunity to comment, request a hearing, and petition for leave to intervene.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) received and is considering approval of an application filed on December 6, 2023, by Holtec Decommissioning International, LLC (HDI), on behalf of itself, Holtec Palisades, LLC, and Palisades Energy, LLC (collectively, the Applicants), regarding the proposed transfer of control of Renewed Facility Operating License (RFO) No. DPR–20 for the Palisades Nuclear Plant (PNP) and the general license for the Palisades Independent Spent Fuel Storage Installation (ISFSI). HDI and Holtec Palisades, LLC, are the current license holders. The application seeks NRC approval of the direct transfer of control of PNP RFO No. DPR–20 and the Palisades ISFSI general license from

HDI to Palisades Energy, LLC (the proposed new licensed operator). The NRC is also considering amending the RFO for administrative purposes to reflect the proposed transfer. The application contains sensitive unclassified non-safeguards information (SUNSI).

DATES: Submit comments by September 6, 2024. A request for a hearing must be filed by August 27, 2024. Any person who has requested, or who may intend to request, a hearing or petition to intervene in this proceeding, who believes access to SUNSI is necessary to respond to this notice must follow the instructions in Section VI of the **SUPPLEMENTARY INFORMATION** section of this notice.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal rulemaking website:

- Federal rulemaking website: Go to <https://www.regulations.gov> and search for Docket ID NRC–2024–0128. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: Stacy.Schumann@nrc.gov. For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Email comments to:* Hearing.Docket@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at 301–415–1677.

- *Fax comments to:* Secretary, U.S. Nuclear Regulatory Commission at 301–415–1101.

- *Mail comments to:* Secretary, U.S. Nuclear Regulatory Commission,

Washington, DC 20555–0001, ATTN: Rulemakings and Adjudications Staff.

- *Hand deliver comments to:* 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. eastern time (ET) Federal workdays; telephone: 301–415–1677.

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

FOR FURTHER INFORMATION CONTACT: Marlayna Doell, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3178; email: Marlayna.Doell@nrc.gov.

SUPPLEMENTARY INFORMATION:**I. Obtaining Information and Submitting Comments***A. Obtaining Information*

Please refer to Docket ID NRC–2024–0128 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking Website:* Go to <https://www.regulations.gov> and search for Docket ID NRC–2024–0128.

- *NRC’s Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at <https://www.nrc.gov/reading-rm/adams.html>. To begin the search, select “Begin Web-based ADAMS Search.” For problems with ADAMS, please contact the NRC’s Public Document Room (PDR)

reference staff at 1-800-397-4209, at 301-415-4737, or by email to PDR.Resource@nrc.gov. The license transfer application dated December 6, 2023, and supplemental letter dated May 23, 2024, are available in ADAMS under Accession Nos. ML23340A161 and ML24144A106, respectively.

- **NRC's PDR:** The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to PDR.Resource@nrc.gov or call 1-800-397-4209 or 301-415-4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal rulemaking website (<https://www.regulations.gov>). Please include Docket ID NRC-2024-0128 in your comment submission.

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

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

II. Introduction

A. Background

PNP consists of a single pressurized-water reactor located in Covert Township, Michigan, along the shoreline of Lake Michigan. Originally licensed for operation on March 24, 1971, the NRC issued a renewed operating license for PNP on January 17, 2007, with the renewed operating license term expiring on March 24, 2031.

On June 13, 2022, Entergy Operations, Inc., the licensee who operated the facility prior to transfer of control of the PNP license to HDI and Holtec Palisades, LLC, submitted certifications

that it had permanently ceased operations of PNP and permanently removed fuel from the reactor vessel in accordance with paragraph 50.82(a)(1) of title 10 of the *Code of Federal Regulations* (10 CFR). When the NRC docketed the certifications, the PNP RFOL No. DPR-20 no longer authorized operation of the reactor, or emplacement or retention of fuel into the reactor vessel, as provided by 10 CFR 50.82(a)(2).

HDI is seeking to return PNP to power operations and has submitted several requests for NRC approval to support allowing the resumption of power operations through March 24, 2031, the end of the renewed facility operating license term under PNP RFOL No. DPR-20. These requests include the license transfer application, which is the subject of this notice, and four license amendment requests. The hearing opportunity for the four license amendment requests is being addressed by a separate notice published in today's issue of the **Federal Register**.

B. Transfer Request

The NRC is considering the issuance of an order under 10 CFR 50.80 approving the direct transfer of control of RFOL No. DPR-20 for PNP and the general license for the Palisades ISFSI, from HDI to Palisades Energy, LLC, which would be the new licensed operator. The application states that this proposed transfer of operating authority would be conditioned on HDI's receipt of the NRC approvals necessary to resume full-power operation of PNP. Thus, implementation of the proposed direct transfer of control of the license, would make Palisades Energy, LLC, responsible for the operation and maintenance of PNP as licensed for full-power reactor operation. The proposed transfer would also involve the issuance of a conforming license amendment.

According to the application, HDI is requesting NRC approval to transfer operational authority to Palisades Energy, LLC, and to vest in Palisades Energy, LLC, exclusive control of operation and maintenance of PNP. Palisades Energy, LLC, is an indirect, wholly owned subsidiary of Holtec International, formed, staffed, and resourced by Holtec International specifically for power operations of PNP. As described in the application, Palisades Energy, LLC, will be resourced with the appropriate operational experience and the programmatic expertise to conduct licensed power operations activities at PNP. Holtec Palisades, LLC, will remain the licensed owner, the beneficiary of the PNP decommissioning trust fund, and the

party to the Standard Contract for Disposal of Spent Nuclear Fuel. No changes are being made to the Big Rock Point license, which will remain owned by Holtec Palisades, LLC, and operated by HDI. No physical changes to the Palisades Nuclear Plant or Palisades ISFSI are being proposed in the transfer application.

The scope of this notice is limited to comments, requests for a hearing, and petitions for leave to intervene related to the proposed direct transfer of control of the PNP RFOL No. DPR-20 and the Palisades ISFSI general license from HDI to Palisades Energy, LLC. The four license amendment requests associated with potential reauthorization of power operations at PNP are available for comment, as well as the opportunity to request a hearing and petition for leave to intervene, in a separate notice published in today's issue of the **Federal Register**.

The NRC staff also notes that, although the transfer application states that a categorical exclusion applies to the proposed transfer, the NRC staff is not relying on a categorical exclusion for this action but is instead preparing an environmental assessment (EA) to evaluate the environmental impacts from the proposed Federal actions related to reauthorizing power operations at PNP, which include the proposed license transfer. The NRC's decision to prepare an EA and additional detail about the environmental review are discussed in the NRC's notice of intent to prepare an EA and conduct scoping, published on June 27, 2024 (89 FR 53659).

The NRC's regulations at 10 CFR 50.80 state that no license for a production or utilization facility, or any right thereunder, shall be transferred, directly or indirectly, through transfer of control of the license, unless the Commission gives its consent in writing. The Commission will approve an application for the transfer of a license if the Commission determines that the proposed transferee is qualified to hold the license, and that the transfer is otherwise consistent with applicable provisions of law, regulations, and orders issued by the Commission.

Before issuance of the proposed conforming license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended, and the Commission's regulations.

As provided in 10 CFR 2.1315, unless otherwise determined by the Commission with regard to a specific application, the Commission has determined that any amendment to the license of a utilization facility, or to the

license of an ISFSI, which does no more than conform the license to reflect the transfer action involves no significant hazards consideration and no genuine issue as to whether the health and safety of the public will be significantly affected. No contrary determination has been made with respect to this specific license amendment application. In light of the generic determination reflected in 10 CFR 2.1315, no public comments with respect to significant hazards considerations are being solicited, notwithstanding the general comment procedures contained in 10 CFR 50.91.

III. Opportunity to Comment

Within 30 days from the date of publication of this notice, persons may submit written comments regarding the license transfer application, as provided for in 10 CFR 2.1305. The Commission will consider and, if appropriate, respond to these comments, but such comments will not otherwise constitute part of the decisional record. Comments should be submitted as described in the ADDRESSES section of this document.

IV. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 20 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 20 days from the date of publication of this notice in accordance with the filing instructions in the "Electronic Submissions (E-Filing)" section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

A State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 20 days from the date of publication of this notice. Alternatively, a State, local governmental body, Federally recognized Indian Tribe, or agency

thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (<https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053>) and on the NRC's public website at <https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate>.

V. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local governmental body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions in adjudicatory proceedings is located in the "Electronic Information Exchange System Adjudicatory User's Guide" (ADAMS Accession No. ML23150A083) and on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at Hearing.Docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals/getting-started.html>. After a digital ID certificate is obtained and a docket created, the participant must submit

adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website at <https://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public website at <https://www.nrc.gov/site-help/e-submittals.html>, by email to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, except Federal holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)-(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at <https://adams.nrc.gov/ehd>, unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-

issued digital ID certificate as previously described, click “cancel” when the link requests certificates and you will be automatically directed to the NRC’s electronic hearing docket where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the **Federal Register** and served on the parties to the hearing.

For further details with respect to this application, see the application dated December 6, 2023 (ADAMS Accession No. ML23340A161), as supplemented on May 23, 2024 (ADAMS Accession No. ML24144A106).

VI. Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Any person who desires access to proprietary, confidential commercial information that has been redacted from the application should contact the applicant by telephoning Jason Day, HDI General Counsel, at 856-797-0900, extension 3688, or J.Day@holtec.com for the purpose of negotiating a confidentiality agreement or a proposed protective order with the applicant. If no agreement can be reached, persons who desire access to this information may file a motion with the Secretary and addressed to the Commission that requests the issuance of a protective order.

Dated: August 1, 2024.

For the Nuclear Regulatory Commission.

Jeffrey A. Whited,

Chief, Plant Licensing Branch 3, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2024-17332 Filed 8-6-24; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR WASTE TECHNICAL REVIEW BOARD

Board Meeting

The U.S. Nuclear Waste Technical Review Board will hold a hybrid (in-person/virtual) public meeting on August 29, 2024.

Board meeting: August 29, 2024—The U.S. Nuclear Waste Technical Review Board will hold a hybrid (in-person/virtual) meeting in North Augusta, South Carolina, on Thursday, August 29, 2024, to review information on the U.S. Department of Energy’s (DOE) management and plans for disposal of DOE spent nuclear fuel (SNF) and to receive program updates from DOE’s Office of Nuclear Energy (DOE-NE).

Pursuant to its authority under section 5051 of Public Law 100-203, Nuclear Waste Policy Amendments Act (NWPAA) of 1987, the U.S. Nuclear Waste Technical Review Board will hold a hybrid (in-person/virtual) meeting in North Augusta, South Carolina, on Thursday, August 29, 2024, to review information on the U.S. Department of Energy’s (DOE) management and plans for disposal of DOE spent nuclear fuel (SNF). The meeting will begin with a program update from DOE’s Office of Nuclear Energy (DOE-NE) on its reprioritization of storage, transportation, and disposal research and development (R&D) activities. One speaker will also provide an update on DOE-NE’s federal consolidated interim storage facility for commercial SNF and consent-based siting efforts.

The hybrid (in-person/virtual) meeting will be held at the Crowne Plaza North Augusta at 1060 Center Street in North Augusta, South Carolina. The hotel telephone number is 803-349-8400. The hotel website is <https://www.ihg.com/crowneplaza/hotels/us/en/north-augusta/aikna/hoteldetail>. On Thursday, August 29, the meeting will begin at 8:00 a.m. Eastern Daylight Time (EDT) and is scheduled to adjourn at approximately 5:00 p.m. EDT. DOE speakers will provide an overview of DOE SNF storage, transportation, and plans for disposal. Other speakers will describe DOE’s Office of Environmental Management (DOE-EM) SNF technology development activities. Additional speakers will report on SNF management activities at the Savannah River Site including current SNF storage, the accelerated basin de-inventory project, and management alternatives for stored SNF after completion of the de-inventory project. Speakers will describe SNF management activities at the Idaho

National Laboratory, including the Idaho Road-Ready SNF Demonstration. A detailed meeting agenda will be available on the Board’s website at www.nwtrb.gov approximately one week before the meeting.

The meeting will be open to the public, and there will be an opportunity for public comment at the end of the meeting. Those attending the meeting in person and wishing to provide oral comments are encouraged to sign-in using the Public Comment Register at the check-in table near the entrance to the meeting room. Oral commenters will be taken in the order in which they signed in. Public comments may also be submitted during the meeting via the online meeting viewing platform, using the “Comment for the Record” form. Comments submitted online during the day of the meeting may be read into the record by Board staff during the public comment period if time allows. Depending on the number of speakers and online comments, a time limit on individual remarks may be set. Written comments of any length may be submitted to the Board staff by mail or electronic mail. Comments received in writing will be included in the meeting record, which will be posted on the Board’s website. An archived recording of the meeting will be available on the Board’s website following the meeting, and a transcript of the meeting will be available on the website by November 1, 2024.

The Board is an independent federal agency in the Executive Branch. It was established in the Nuclear Waste Policy Amendments Act of 1987 (Pub. L. 100-203) to perform ongoing evaluation of the technical and scientific validity of U.S. Department of Energy activities related to developing and implementing a program for the management and disposal of spent nuclear fuel and high-level radioactive waste, in accordance with the terms of the Nuclear Waste Policy Act of 1982. Board members serve part-time and are appointed by the President from a list of nominees submitted by the National Academy of Sciences. The Board reports its findings, conclusions, and recommendations to Congress and the Secretary of Energy. Board reports, correspondence, congressional testimony, meeting transcripts, and related materials are posted on the Board’s website.

For information regarding the meeting, contact Mr. Christopher Burk at burk@nwtrb.gov, or by phone at 703-235-4486, or Dr. Bret Leslie at leslie@nwtrb.gov, or by phone at 703-235-9132. For information on meeting logistics, contact Ms. Davonya Barnes at barnes@nwtrb.gov, or by phone at 703-

235–9141. All three may be reached by mail at 2300 Clarendon Boulevard, Suite 1300, Arlington, VA 22201–3367; or by fax at 703–235–4495.

Dated: August 1, 2024.

Neysa M. Slater-Chandler,
Director of Administration, U.S. Nuclear
Waste Technical Review Board.

[FR Doc. 2024–17383 Filed 8–6–24; 8:45 am]

BILLING CODE 6820-AM-P

POSTAL REGULATORY COMMISSION

[Docket Nos. CP2021–43; MC2024–459 and CP2024–466; MC2024–468 and CP2024–475; MC2024–469 and CP2024–476; MC2024–470 and CP2024–477]

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 9, 2024.

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):* CP2021–43; *Filing Title:* USPS Notice of Amendment to Parcel Select Contract 44, Filed Under Seal; *Filing Acceptance Date:* August 1, 2024; *Filing Authority:* 39 CFR 3035.105; *Public Representative:* Arif Hafiz; *Comments Due:* August 9, 2024.

2. *Docket No(s):* MC2024–459 and CP2024–466; *Filing Title:* USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 41 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 1, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Katalin K. Clendenin; *Comments Due:* August 9, 2024.

3. *Docket No(s):* MC2024–468 and CP2024–475; *Filing Title:* USPS Request to Add Parcel Select Contract 60 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 1, 2024; *Filing*

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).

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 9, 2024.

4. *Docket No(s):* MC2024–469 and CP2024–476; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 191 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 1, 2024; *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 9, 2024.

5. *Docket No(s):* MC2024–470 and CP2024–477; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 192 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 1, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Arif Hafiz; *Comments Due:* August 9, 2024.

This Notice will be published in the **Federal Register**.

Jennie L. Jbara,

Primary Certifying Official.

[FR Doc. 2024–17476 Filed 8–6–24; 8:45 am]

BILLING CODE 7710-FW-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100635; File No. 4–551]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing and Order Approving and Declaring Effective an Amendment to the Plan for the Allocation of Regulatory Responsibilities Among NYSE American LLC, Cboe BZX Exchange, Inc., the Cboe EDGX Exchange, Inc., Cboe C2 Exchange, Inc., Cboe Exchange, Inc., Nasdaq ISE, LLC, Financial Industry Regulatory Authority, Inc., NYSE Arca, Inc., The Nasdaq Stock Market LLC, BOX Exchange LLC, Nasdaq BX, Inc., Nasdaq PHLX LLC, Miami International Securities Exchange, LLC, Nasdaq GEMX, LLC, Nasdaq MRX, LLC, MIA X PEARL, LLC, MIA X Emerald, LLC, MIA X Sapphire, and MEMX LLC Concerning Options-Related Market Surveillance

August 1, 2024.

Notice is hereby given that the Securities and Exchange Commission (“Commission”) has issued an Order,

pursuant to Section 17(d) of the Securities Exchange Act of 1934 (“Act”),¹ approving and declaring effective an amendment to the plan for allocating regulatory responsibility (“Plan”) filed on July 31, 2024, pursuant to Rule 17d–2 of the Act,² by NYSE American LLC (“NYSE American”), Cboe BZX Exchange, Inc., (“BZX”), the Cboe EDGX Exchange, Inc. (“EDGX”), Cboe C2 Exchange, Inc. (“C2”), Cboe Exchange, Inc. (“Cboe”), Nasdaq ISE, LLC (“ISE”), Financial Industry Regulatory Authority, Inc. (“FINRA”), NYSE Arca, Inc. (“Arca”), The NASDAQ Stock Market LLC (“Nasdaq”), BOX Exchange LLC (“BOX”), NASDAQ BX, Inc. (“BX”), NASDAQ PHLX LLC (“PHLX”), Miami International Securities Exchange, LLC (“MIAX”), Nasdaq GEMX, LLC (“Gemini”), Nasdaq MRX, LLC (“Mercury”), MIAX PEARL, LLC (“MIAX PEARL”), and MIAX Emerald, LLC (MIAX Emerald), MIAX Sapphire, LLC (“MIAX Sapphire”), and MEMX LLC (“MEMX”) (collectively, “Participating Organizations” or “parties”).

I. Introduction

Section 19(g)(1) of the Act,³ among other things, requires every self-regulatory organization (“SRO”) registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO’s own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d)⁴ or Section 19(g)(2)⁵ of the Act. Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO (“common members”). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act⁶ was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.⁷ With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the

responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.⁸ Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority (“DEA”) to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.⁹ When an SRO has been named as a common member’s DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO’s obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.¹⁰ Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors, to foster cooperation and coordination among the SROs, to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system, and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On December 11, 2007, the Commission declared effective the

Participating Organizations’ Plan for allocating regulatory responsibilities pursuant to Rule 17d–2.¹¹ On April 11, 2008, the Commission approved an amendment to the Plan to include NASDAQ as a participant.¹² On October 9, 2008, the Commission approved an amendment to the Plan to clarify that the term Regulatory Responsibility for options position limits includes the examination responsibilities for the delta hedging exemption.¹³ On February 25, 2010, the Commission approved an amendment to the Plan to add Bats and C2 as SRO participants and to reflect the name changes of the American Stock Exchange LLC to the NYSE Amex LLC, and the Boston Stock Exchange, Inc. to the NASDAQ OMX BX, Inc.¹⁴ On May 11, 2012, the Commission approved an amendment to the Plan to add BOX as a participant to the Plan.¹⁵ On December 5, 2012, the Commission approved an amendment to the Plan to add MIAX as a participant to the Plan.¹⁶ On July 26, 2013, the Commission approved an amendment to the Plan to add Topaz Exchange, LLC as a Participant to the Plan.¹⁷ On October 29, 2015, the Commission approved an amendment to add EDGX as a Participant to the Plan and to change the name of Topaz Exchange, LLC to ISE Gemini, LLC.¹⁸ On February 16, 2016, the Commission approved an amendment to add ISE Mercury, LLC as a Participant to the Plan.¹⁹ On February 2, 2017, the Commission approved an amendment to add MIAX PEARL as a Participant to the Plan.²⁰ On February 11, 2019, the Commission approved an amendment to add MIAX Emerald as a Participant to

¹¹ See Securities Exchange Act Release No. 56941 (December 11, 2007), 72 FR 71723 (December 18, 2007) (File No. 4–551).

¹² See Securities Exchange Act Release No. 57649 (April 11, 2008), 73 FR 20976 (April 17, 2008) (File No. 4–551).

¹³ See Securities Exchange Act Release No. 58765 (October 9, 2008), 73 FR 62344 (October 20, 2008) (File No. 4–551).

¹⁴ See Securities Exchange Act Release No. 61588 (February 25, 2010), 75 FR 9970 (March 4, 2010) (File No. 4–551).

¹⁵ See Securities Exchange Act Release No. 66975 (May 11, 2012), 77 FR 29712 (May 18, 2010) (File No. 4–551).

¹⁶ See Securities Exchange Act Release No. 68362 (December 5, 2012), 77 FR 73719 (December 11, 2012) (File No. 4–551).

¹⁷ See Securities Exchange Act Release No. 70052 (July 26, 2013), 78 FR 46665 (August 1, 2013) (File No. 4–551).

¹⁸ See Securities Exchange Act Release No. 76310 (October 29, 2015), 80 FR 68354 (November 4, 2015) (File No. 4–551).

¹⁹ See Securities Exchange Act Release No. 77149 (February 16, 2016), 81 FR 8781 (February 22, 2016) (File No. 4–551).

²⁰ See Securities Exchange Act Release No. 79930 (February 2, 2017), 82 FR 9807 (February 8, 2017) (File No. 4–551).

¹ 15 U.S.C. 78q(d).

² 17 CFR 240.17d–2.

³ 15 U.S.C. 78s(g)(1).

⁴ 15 U.S.C. 78q(d).

⁵ 15 U.S.C. 78s(g)(2).

⁶ 15 U.S.C. 78q(d)(1).

⁷ See Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

⁸ 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

⁹ See Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

¹⁰ See Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

the Plan.²¹ On November 23, 2022, the Commission approved a proposed amendment to the Plan to add MEMX as a Participant to the Plan, to reflect name changes of certain Participating Organizations, and update rule references.²²

The Plan is designed to reduce regulatory duplication for common members by allocating regulatory responsibility for certain options-related market surveillance matters among the Participating Organizations. Generally, under the Plan, a Participating Organization will serve as the Designated Options Surveillance Regulator (“DOSR”) for each common member assigned to it and will assume regulatory responsibility with respect to that common member’s compliance with applicable common rules for certain accounts. When an SRO has been named as a common member’s DOSR, all other SROs to which the common member belongs will be relieved of regulatory responsibility for that common member, pursuant to the terms of the Plan, with respect to the applicable common rules specified in Exhibit A to the Plan.

III. Proposed Amendment to the Plan

On July 31, 2024, the parties submitted a proposed amendment to the Plan. The primary purpose of the amendment is to add MIAX Sapphire as a Participant to the Plan. The text of the proposed amended 17d–2 plan is as follows (additions are *italicized*; deletions are [bracketed]):

* * * * *

AGREEMENT BY AND AMONG NYSE AMERICAN LLC, CBOE BZX EXCHANGE, INC., CBOE EDGX EXCHANGE INC., BOX EXCHANGE LLC, NASDAQ BX, INC., CBOE C2 EXCHANGE, INC., CBOE EXCHANGE, INC., NASDAQ ISE, LLC, NASDAQ GEMX, LLC, NASDAQ MRX, LLC, FINANCIAL INDUSTRY REGULATORY AUTHORITY, INC., NYSE ARCA, INC., THE NASDAQ STOCK MARKET LLC, NASDAQ PHLX LLC, MIAMI INTERNATIONAL SECURITIES EXCHANGE, LLC, MIA X PEARL, LLC, MIA X EMERALD, LLC, *MIA X SAPPHIRE, LLC*, AND MEMX LLC PURSUANT TO RULE 17d–2 UNDER THE SECURITIES EXCHANGE ACT OF 1934

This agreement (this “Agreement”), by and among NYSE American LLC

(“NYSE American”), Cboe BZX Exchange, Inc., (“BZX”), the Cboe EDGX Exchange, Inc. (“EDGX”), Cboe C2 Exchange, Inc. (“C2”), Cboe Exchange, Inc. (“Cboe”), Nasdaq ISE, LLC (“ISE”), Financial Industry Regulatory Authority, Inc. (“FINRA”), NYSE Arca, Inc. (“Arca”), The Nasdaq Stock Market LLC (“Nasdaq”), BOX Exchange LLC (“BOX”), Nasdaq BX, Inc. (“BX”), Nasdaq PHLX LLC (“PHLX”), Miami International Securities Exchange, LLC (“MIAX”), Nasdaq GEMX, LLC (“GEMX”), Nasdaq MRX, LLC (“MRX”), MIA X PEARL, LLC (“MIA X PEARL”), MIA X Emerald, LLC (“MIA X Emerald”), *MIA X Sapphire, LLC* (“MIA X Sapphire”), and MEMX LLC (“MEMX”), is made the 10th day of October 2007, and as amended the 31st day of March 2008, the 1st day of October 2008, the 3rd day of February 2010, the 25th day of April 2012, the 19th day of November 2012, the 30th day of May 2013, the 16th day of October 2015, the 29th day of January 2016, the 23rd day of January 2017, the 8th day of January 2019, [and] the 18th[th] day of October 2022, *and the 19th day of July 2024*, pursuant to Section 17(d) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and Rule 17d–2 thereunder (“Rule 17d–2”), which allows for a joint plan among self-regulatory organizations (“SROs”) to allocate regulatory obligations with respect to brokers or dealers that are members of two or more of the parties to this Agreement (“Common Members”). NYSE American, BZX, C2, Cboe, EDGX, Gemini, ISE, Mercury, FINRA, Arca, Nasdaq, BOX, BX, PHLX, MIAX, MIA X PEARL, MIA X Emerald, *MIA X Sapphire*, and MEMX, are collectively referred to herein as the “Participants” and individually, each a “Participant.” This Agreement shall be administered by a committee known as the Options Surveillance Group (the “OSG” or “Group”), as described in Section V hereof. Unless defined in this Agreement or the context otherwise requires, the terms used herein shall have the meanings assigned thereto by the Exchange Act and the rules and regulations thereunder.

Whereas, the Participants desire to eliminate regulatory duplication with respect to SRO market surveillance of Common Member¹ activities with regard to certain common rules relating to listed options (“Options”); and

Whereas, for this purpose, the Participants desire to execute and file

this Agreement with the Securities and Exchange Commission (the “SEC” or “Commission”) pursuant to Rule 17d–2.

Now, therefore, in consideration of the mutual covenants contained in this Agreement, the Participants agree as follows:

I. Except as otherwise provided in this Agreement, each Participant shall assume Regulatory Responsibility (as defined below) for the Common Members that are allocated or assigned to such Participant in accordance with the terms of this Agreement and shall be relieved of its Regulatory Responsibility as to the remaining Common Members. For purposes of this Agreement, a Participant shall be considered to be the Designated Options Surveillance Regulator (“DOSR”) for each Common Member that is allocated to it in accordance with Section VII.

II. As used in this Agreement, the term “Regulatory Responsibility” shall mean surveillance, investigation and enforcement responsibilities relating to compliance by the Common Members with such Options rules of the Participants as the Participants shall determine are substantially similar and shall approve from time to time, insofar as such rules relate to market surveillance (collectively, the “Common Rules”). For the purposes of this Agreement the list of Common Rules is attached as Exhibit A hereto, which may only be amended upon unanimous written agreement by the Participants. The DOSR assigned to each Common Member shall assume Regulatory Responsibility with regard to that Common Member’s compliance with the applicable Common Rules for certain accounts.² A DOSR may perform its Regulatory Responsibility or enter an agreement to transfer or assign such responsibilities to a national securities exchange registered with the SEC under Section 6(a) of the Exchange Act or a national securities association registered with the SEC under Section 15A of the Exchange Act. A DOSR may not transfer or assign its Regulatory Responsibility to an association registered for the limited purpose of regulating the activities of members who are registered as brokers or dealers in security futures products.

The term “Regulatory Responsibility” does not include, and each Participant shall retain full responsibility with respect to:

² Certain accounts shall include customer (“C” as classified by the Options Clearing Corporation (“OCC”)) and firm (“F” as classified by OCC) accounts, as well as other accounts, such as market maker accounts as the Participants shall, from time to time, identify as appropriate to review.

²¹ See Securities Exchange Act Release No. 85097 (February 11, 2019), 84 FR 4871 (February 19, 2019) (File No. 4–551).

²² See Securities Exchange Act Release No. 96383 (November 23, 2022), 87 FR 73569 (November 30, 2022) (File No. 4–551).

¹ In the case of the BX and BOX, members are those persons who are Options Participants (as defined in the BOX Exchange LLC Rules and NASDAQ BX, Inc. Rules).

(a) surveillance, investigative and enforcement responsibilities other than those included in the definition of Regulatory Responsibility;

(b) any aspects of the rules of a Participant that are not substantially similar to the Common Rules or that are allocated for a separate surveillance purpose under any other agreement made pursuant to Rule 17d-2. Any such aspects of a Common Rule will be noted as excluded on Exhibit A.

With respect to options position limits, the term Regulatory Responsibility shall include examination responsibilities for the delta hedging exemption. Specifically, the Participants intend that FINRA will conduct examinations for delta hedging for all Common Members that are members of FINRA notwithstanding the fact that FINRA's position limit rule is, in some cases, limited to only firms that are not members of an options exchange (*i.e.*, access members). In such cases, FINRA's examinations for delta hedging options position limit violations will be for the identical or substantively similar position limit rule(s) of the other Participant(s). Examinations for delta hedging for Common Members that are non-FINRA members will be conducted by the same Participant conducting position limit surveillance. The allocation of Common Members to DOSRs for surveillance of compliance with options position limits and other agreed to Common Rules is provided in Exhibit B. The allocation of Common Members to DOSRs for examinations of the delta hedging exemption under the options position limits rules is provided in Exhibit C.

III. Each year within 30 days of the anniversary date of the commencement of operation of this Agreement, or more frequently if required by changes in the rules of a Participant, each Participant shall submit to the other Participants, through the Chair of the OSG, an updated list of Common Rules for review. This updated list may add Common Rules to Exhibit A, shall delete from Exhibit A rules of that Participant that are no longer identical or substantially similar to the Common Rules, and shall confirm that the remaining rules of the Participant included on Exhibit A continue to be identically or substantially similar to the Common Rules. Within 30 days from the date that each Participant has received revisions to Exhibit A from the Chair of the OSG, each Participant shall confirm in writing to the Chair of the OSG whether that Participant's rules listed in Exhibit A are Common Rules.

IV. Apparent violation of another Participant's rules discovered by a

DOSR, but which rules are not within the scope of the discovering DOSR's Regulatory Responsibility, shall be referred to the relevant Participant for such action as is deemed appropriate by that Participant.

Notwithstanding the foregoing, nothing contained herein shall preclude a DOSR in its discretion from requesting that another Participant conduct an investigative or enforcement proceeding ("Proceeding") on a matter for which the requesting DOSR has Regulatory Responsibility. If such other Participant agrees, the Regulatory Responsibility in such case shall be deemed transferred to the accepting Participant and confirmed in writing by the Participants involved. Additionally, nothing in this Agreement shall prevent another Participant on whose market potential violative activity took place from conducting its own Proceeding on a matter. The Participant conducting the Proceeding shall advise the assigned DOSR. Each Participant agrees, upon request, to make available promptly all relevant files, records and/or witnesses necessary to assist another Participant in a Proceeding.

V. The OSG shall be composed of one representative designated by each of the Participants (a "Representative"). Each Participant shall also designate one or more persons as its alternate representative(s) (an "Alternate Representative"). In the absence of the Representative, the Alternate Representative shall assume the powers, duties and responsibilities of the Representative. Each Participant may at any time replace its Representative and/or its Alternate Representative to the Group.³ A majority of the OSG shall constitute a quorum and, unless otherwise required, the affirmative vote of a majority of the Representatives present (in person, by telephone or by written consent) shall be necessary to constitute action by the Group.

The Group will have a Chair, Vice Chair and Secretary. A different Participant will assume each position on a rotating basis for a one-year term. In the event that a Participant replaces a Representative who is acting as Chair, Vice Chair or Secretary, the newly appointed Representative shall assume the position of Chair, Vice Chair, or Secretary (as applicable) vacated by the Participant's former Representative. In the event a Participant cannot fulfill its duties as Chair, the Participant serving as Vice Chair shall substitute for the Chair and complete the subject unfulfilled term. All notices and other

³ A Participant must give notice to the Chair of the Group of such a change.

communications for the OSG are to be sent in care of the Chair and, as appropriate, to each Representative.

VI. The OSG shall determine the times and locations of Group meetings, provided that the Chair, acting alone, may also call a meeting of the Group in the event the Chair determines that there is good cause to do so. To the extent reasonably possible, notice of any meeting shall be given at least ten business days prior to the meeting date. Representatives shall always be given the option of participating in any meeting telephonically at their own expense rather than in person.

VII. No less frequently than every two years, in such manner as the Group deems appropriate, the OSG shall allocate Common Members that conduct an Options business among the Participants ("Allocation"), and the Participant to which a Common Member is allocated will serve as the DOSR for that Common Member. Any Allocation shall be based on the following principles, except to the extent all affected Participants consent to one or more different principles:

(a) The OSG may not allocate a Common Member to a Participant unless the Common Member is a member of that Participant.

(b) To the extent practicable, Common Members that conduct an Options business shall be allocated among the Participants of which they are members in such manner as to equalize as nearly as possible the allocation among such Participants, provided that no Common Members shall be allocated to FINRA. For example, if sixteen Common Members that conduct an Options business are members only of three Participants, none of which is FINRA, those Common Members shall be allocated among the three Participants such that no Participant is allocated more than six such members and no Participant is allocated less than five such members. If, in the previous example, one of the three Participants is FINRA, the sixteen Common Members would be allocated evenly between the remaining Participants, so that the two non-FINRA Participants would be allocated eight Common Members each.

(c) To the extent practicable, Allocation shall take into account the amount of Options activity conducted by each Common Member in order to most evenly divide the Common Members with the largest amount of activity among the Participants of which they are members. Allocation will also take into account similar allocations pursuant to other plans or agreements to which the Common Members are party

to maintain consistency in oversight of the Common Members.⁴

(d) To the extent practicable, Allocation of Common Members to Participants will be rotated among the applicable Participants such that a Common Member shall not be allocated to a Participant to which that Common Member was allocated within the previous two years. The assignment of DOSRs pursuant to the Allocation is attached as Exhibit B hereto, and will be updated from time to time to reflect Common Member Allocation changes.

(e) The Group may reallocate Common Members from time-to-time, as it deems appropriate.

(f) Whenever a Common Member ceases to be a member of its DOSR, the DOSR shall promptly inform the Group, which shall review the matter and allocate the Common Member to another Participant.

(g) A DOSR may request that a Common Member to which it is assigned be reallocated to another Participant by giving 30 days written notice to the Chair of the OSG. The Group, in its discretion, may approve such request and reallocate the Common Member to another Participant.

(h) All determinations by the Group with respect to Allocation shall be made by the affirmative vote of a majority of the Participants that, at the time of such determination, share the applicable Common Member being allocated; a Participant shall not be entitled to vote on any Allocation relating to a Common Member unless the Common Member is a member of such Participant.

VIII. Each DOSR shall conduct routine surveillance reviews to detect violations of the applicable Common Rules by each Common Member allocated to it with a frequency (daily, weekly, monthly, quarterly, semi-annually or annually as noted on Exhibit A) not less than that determined by the Group. The other Participants agree that, upon request, relevant information in their respective files relative to a Common Member will be made available to the applicable DOSR. In addition, each Participant shall provide, to the extent not otherwise already provided, information pertaining to its surveillance program that would be relevant to FINRA or the Participant(s) conducting routine examinations for the delta hedging exemption.

At each meeting of the OSG, each Participant shall be prepared to report on the status of its surveillance program

for the previous quarter and any period prior thereto that has not previously been reported to the Group. In the event a DOSR believes it will not be able to complete its Regulatory Responsibility for its allocated Common Members, it will so advise the Group in writing promptly. The Group will undertake to remedy this situation by reallocating the subject Common Members among the remaining Participants. In such instance, the Group may determine to impose a regulatory fee for services provided to the DOSR that was unable to fulfill its Regulatory Responsibility.

IX. Each Participant will, upon request, promptly furnish a copy of the report or applicable portions thereof relating to any investigation made pursuant to the provisions of this Agreement to each other Participant of which the Common Member under investigation is a member.

X. Each Participant will routinely populate a common database, to be accessed by the Group relating to any formal regulatory action taken during the course of a Proceeding with respect to the Common Rules concerning a Common Member.

XI. Any written notice required or permitted to be given under this Agreement shall be deemed given if sent by certified mail, return receipt requested, to any Participant to the attention of that Participant's Representative, to the Participant's principal place of business or by email at such address as the Representative shall have filed in writing with the Chair.

XII. The costs incurred by each Participant in discharging its Regulatory Responsibility under this Agreement are not reimbursable. However, any of the Participants may agree that one or more will compensate the other(s) for costs incurred.

XIII. The Participants shall notify the Common Members of this Agreement by means of a uniform joint notice approved by the Group. Each Participant will notify the Common Members that have been allocated to it that such Participant will serve as DOSR for that Common Member.

XIV. This Agreement shall be effective upon approval of the Commission. This Agreement may only be amended in writing duly approved by each Participant. All amendments to this Agreement, excluding changes to Exhibits A, B and C, must be filed with and approved by the Commission.

XV. Any Participant may manifest its intention to cancel its participation in this Agreement at any time upon providing written notice to (i) the Group six months prior to the date of such

cancellation, or such other period as all the Participants may agree, and (ii) the Commission. Upon receipt of the notice the Group shall allocate, in accordance with the provisions of this Agreement, those Common Members for which the canceling Participant was the DOSR. The canceling Participant shall retain its Regulatory Responsibility and other rights, privileges and duties pursuant to this Agreement until the Group has completed the reallocation as described above, and the Commission has approved the cancellation.

XVI. The cancellation of its participation in this Agreement by any Participant shall not terminate this Agreement as to the remaining Participants. This Agreement will only terminate following notice to the Commission, in writing, by the then Participants that they intend to terminate the Agreement and the expiration of the applicable notice period. Such notice shall be given at least six months prior to the intended date of termination, or such other period as all the Participants may agree. Such termination will become effective upon Commission approval.

XVII. Participation in the Group shall be strictly limited to the Participants and no other party shall have any right to attend or otherwise participate in the Group except with the unanimous approval of all Participants. Notwithstanding the foregoing, any national securities exchange registered with the SEC under Section 6(a) of the Act or any national securities association registered with the SEC under section 15A of the Act may become a Participant to this Agreement provided that: (i) such applicant has adopted rules substantially similar to the Common Rules, and received approval thereof from the SEC; (ii) such applicant has provided each Participant with a signed statement whereby the applicant agrees to be bound by the terms of this Agreement to the same effect as though it had originally signed this Agreement and (iii) an amended agreement reflecting the addition of such applicant as a Participant has been filed with and approved by the Commission.

XVIII. This Agreement is wholly separate from the multiparty Agreement made pursuant to Rule 17d-2 by and among [the NYSE American LLC,] the Cboe BZX Exchange, Inc., BOX Exchange LLC, [the C2 Exchange, Inc., the] Cboe Exchange, Inc., *Cboe C2 Exchange, Inc.*, [the] Nasdaq ISE, LLC, Financial Industry Regulatory Authority, Inc., *Miami International Securities Exchange, LLC*, *NYSE American LLC*, *NYSE Arca, Inc.*, The

⁴ For example, if one Participant was allocated a Common Member by another regulatory group that Participant would be assigned to be the DOSR of that Common Member, unless there is good cause not to make that assignment.

Nasdaq Stock Market LLC, *Nasdaq BX, Inc.*, *Nasdaq PHLX LLC*, [the New York Stock Exchange, LLC, the NYSE Arca, Inc., the Nasdaq BX, Inc., the Nasdaq PHLX LLC, Miami International Securities Exchange, LLC,] Nasdaq GEMX, LLC, [Nasdaq MRX, LLC,] Cboe EDGX Exchange, Inc., *Nasdaq MRX, LLC*, MIAx PEARL, LLC, [and] MIAx Emerald, LLC, and *MEMX LLC* involving the allocation of regulatory responsibilities with respect to common members for compliance with common rules relating to the conduct by broker-dealers of accounts for listed options or index warrants approved by the SEC on [February 12, 2019] *October 18, 2022*, and as may be amended from time to time.

Limitation of Liability

No Participant nor the Group nor any of their respective directors, governors, officers, employees or representatives shall be liable to any other Participant

in this Agreement for any liability, loss or damage resulting from or claimed to have resulted from any delays, inaccuracies, errors or omissions with respect to the provision of Regulatory Responsibility as provided hereby or for the failure to provide any such Regulatory Responsibility, except with respect to such liability, loss or damages as shall have been suffered by one or more of the Participants and caused by the willful misconduct of one or more of the other Participants or its respective directors, governors, officers, employees or representatives. No warranties, express or implied, are made by the Participants, individually or as a group, or by the OSG with respect to any Regulatory Responsibility to be performed hereunder.

Relief From Responsibility

Pursuant to Section 17(d)(1)(A) of the Exchange Act and Rule 17d-2, the Participants join in requesting the

Commission, upon its approval of this Agreement or any part thereof, to relieve the Participants that are party to this Agreement and are not the DOSR as to a Common Member of any and all Regulatory Responsibility with respect to the matters allocated to the DOSR.

* * * * *

This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all such counterparts shall together constitute one and the same Agreement.

In Witness Whereof, the Participants hereto have executed this Agreement as of the date and year first above written.

EXHIBIT A

Options Surveillance Group 17d-2 Agreement COMMON RULES as of [October 18, 2022] *July 19, 2024*

VIOLATION I: EXPIRING EXERCISE DECLARATIONS (EED)—FOR LISTED AND FLEX EQUITY OPTIONS

SRO	Description of rule	Exchange rule No.	Frequency of review
BZX	Exercise of Options Contracts	Rule 23.1	At Expiration.
BOX	Exercise of Options Contracts	Rule 9000	At Expiration.
C2	Exercise of Options Contracts	Ch. 6, Sec. B	At Expiration.
Cboe	Exercise of Options Contracts	Rule 6.20(a)–(d), I&P .01–.07	At Expiration.
EDGX	Exercise of Options Contracts	Rule 23.1	At Expiration.
FINRA	Exercise of Options Contracts	Rule 2360(b)(23)	At Expiration.
ISE	Exercise of Options Contracts	Options 6B, Section 1	At Expiration.
GEMX	Exercise of Options Contracts	Options 6B, Section 1	At Expiration.
MRX	Exercise of Options Contracts	Options 6B, Section 1	At Expiration.
MIAx	Exercise of Options Contracts	Rule 700	At Expiration.
MIAx PEARL	Exercise of Options Contracts	Rule 700	At Expiration.
MIAx Emerald	Exercise of Options Contracts	Rule 700	At Expiration.
MIAx Sapphire	Exercise of Options Contracts	Rule 700	At Expiration.
MEMX	Exercise of Options Contracts	Rule 23.1	At Expiration.
Nasdaq	Exercise of Options Contracts	Options 6B, Section 1	At Expiration.
Nasdaq BX	Exercise of Options Contracts	Options 6B, Section 1	At Expiration.
Nasdaq PHLX	Exercise of Equity Options Contracts	Options 6B, Section 1	At Expiration.
NYSE Arca	Exercise of Options Contracts	Rule 6.24–O	At Expiration.
NYSE American	Exercise of Options Contracts	Rule 980	At Expiration.

VIOLATION II: POSITION LIMITS (PL)—FOR LISTED EQUITY OPTIONS

SRO	Description of rule (for review as they apply to PL)	Exchange rule No.	Frequency of review
BZX	Position Limits	Rule 18.7	Daily.
	Exemptions from Position	Rule 18.8	As Needed.
	Liquidation Positions	Rule 18.11	As Needed.
BOX	Position Limits	Rule 3120	Daily.
	Exemptions from Position Limits	Rule 3130	As Needed.
	Liquidation Positions	Rule 3160	As Needed.
C2	Position Limits	Ch. 8	Daily.
	Liquidation of Positions	Ch. 8	As Needed.
Cboe	Position Limits	Rule 8.30	Daily.
	Liquidation of Positions	Rule 8.44	As Needed.
EDGX	Position Limits	Rule 18.7	Daily.
	Exemptions from Position	Rule 18.8	As Needed.
	Liquidation Positions	Rule 18.11	As Needed.
FINRA	Position Limits	Rule 2360(b)(3)	Daily.
	Liquidation of Positions and Restrictions on Access	Rule 2360(b)(6)	As Needed.
ISE	Position Limits	ISE Options 9, Section 13	Daily.
	Exemptions from Position Limits	ISE Options 9, Section 14	As Needed.
	Liquidating Positions	ISE Options 9, Section 17	As Needed.
GEMX	Position Limits	GEMX Options 9, Section 13	Daily.
	Exemptions from Position Limits	GEMX Options 9, Section 14	As Needed.
	Liquidating Positions	GEMX Options 9, Section 17	As Needed.
MRX	Position Limits	MRX Options 9, Section 13	Daily.
	Exemptions from Position Limits	MRX Options 9, Section 14	As Needed.

VIOLATION II: POSITION LIMITS (PL)—FOR LISTED EQUITY OPTIONS—Continued

SRO	Description of rule (for review as they apply to PL)	Exchange rule No.	Frequency of review
MIAX	Liquidating Positions	MRX Options 9, Section 17	As Needed.
MIAX	Position Limits	Rule 307	Daily.
MIAX	Exemptions from Position Limits	Rule 308	As Needed.
MIAX Pearl	Liquidating Positions	Rule 311	As Needed.
MIAX Pearl	Position Limits	Rule 307	Daily.
MIAX Pearl	Exemptions from Position Limits	Rule 308	As Needed.
MIAX Emerald	Liquidating Positions	Rule 311	As Needed.
MIAX Emerald	Position Limits	Rule 307	Daily.
MIAX Emerald	Exemptions from Position Limits	Rule 308	As Needed.
MIAX Sapphire	Liquidating Positions	Rule 311	As Needed.
MIAX Sapphire	Position Limits	Rule 307	Daily.
MIAX Sapphire	Exemptions from Position Limits	Rule 308	As Needed.
MEMX	Liquidating Positions	Rule 311	As Needed.
MEMX	Position Limits	Rule 18.7	Daily.
MEMX	Exemptions from Position	Rule 18.8	As Needed.
Nasdaq	Liquidation Positions	Rule 18.11	As Needed.
Nasdaq	Position Limits	NOM Options 9, Section 13	Daily.
Nasdaq	Exemptions from Position Limits	NOM Options 9, Section 14	As Needed.
Nasdaq BX	Liquidation Positions	NOM Options 9, Section 17	As Needed.
Nasdaq BX	Position Limits	BX Options 9, Section 13	Daily.
Nasdaq BX	Exemptions from Position Limits	BX Options 9, Section 14	As Needed.
Nasdaq PHLX	Liquidation Positions	BX Options 9, Section 17	As Needed.
Nasdaq PHLX	Position Limits	PHLX Options 9, Section 13	Daily.
NYSE Arca	Liquidation of Position	PHLX Options 9, Section 17	As Needed.
NYSE American	Position Limits	Rule 6.8–O	Daily.
NYSE American	Liquidation of Position	Rule 6.7–O	As Needed.
NYSE American	Position Limits	Rule 904	Daily.
NYSE American	Liquidating Positions	Rule 907	As Needed.

VIOLATION III: LARGE OPTIONS POSITION REPORT (LOPR)—FOR LISTED AND FLEX EQUITY OPTIONS AND ETF OPTIONS

SRO	Description of rule (for review as they apply to LOPR)	Exchange rule No.	Frequency of review
BZX	Reports Related to Position Limits	Rule 18.10	Yearly.
BOX	Reports Related to Position Limits	Rule 3150	Yearly.
C2	Reports Related to Position Limits	Ch. 8	Yearly.
C2	Reports Related to Position Limits	Ch. 8	Yearly.
C2	Reports Related to Position Limits	Ch. 8	Yearly.
Cboe	Reports Related to Position Limits	Ch. 8	Yearly.
Cboe	Reports Related to Position Limits	Rule 8.43(a)	Yearly.
Cboe	Reports Related to Position Limits	Rule 8.43(b)	Yearly.
Cboe	Reports Related to Position Limits	Rule 8.43(d)	Yearly.
EDGX	Reports Related to Position Limits	Rule 18.10	Yearly.
FINRA	Options	Rule 2360(b)(5)	Yearly.
ISE	Reports Related to Options Position Limits	ISE Options 9, Section 16—Reports Related to Options Position Limits.	Yearly.
GEMX	Reports Related to Options Position Limits	GEMX Options 9, Section 16—Reports Related to Options Position Limits.	Yearly.
MRX	Reports Related to Options Position Limits	MRX Options 9, Section 16—Reports Related to Options Position Limits.	Yearly.
MIAX	Reports Related to Position Limits	Rule 310	Yearly.
MIAX PEARL	Reports Related to Position Limits	Rule 310	Yearly.
MIAX Emerald	Reports Related to Position Limits	Rule 310	Yearly.
MIAX Sapphire	Reports Related to Position Limits	Rule 310	Yearly.
MEMX	Reports Related to Position Limits	Rule 18.10	Yearly.
Nasdaq	Reports Related to Options Position Limits	NOM Options 9, Section 16—Reports Related to Options Position Limits.	Yearly.
Nasdaq BX	Reports Related to Options Position Limits	BX Options 9, Section 16—Reports Related to Options Position Limits.	Yearly.
Nasdaq PHLX	Reporting of Options Positions	PHLX Options 6E, Section 2—Reporting of Options Positions, PHLX Options 9, Section 13—Position Limits.	Yearly.
NYSE Arca	Reporting of Options Positions	Rule 6.6–O	Yearly.
NYSE American	Reporting of Options Positions	Rule 906	Yearly.

VIOLATION IV: OPTIONS CLEARING CORPORATION (OCC) ADJUSTMENT PROCESS

SRO	Description of rule (as they apply to OCC adjustments/by-laws article V, section 1 .01(a) and .02)	Exchange rule No.	Frequency of review
BZX	Adherence to Law	Rule 18.1	Yearly.
BOX	Adherence to Law	Rule 3010	Yearly.
C2	Adherence to Law	Ch. 8	Yearly.
Cboe	Adherence to Law	Rule 8.2	Yearly.
EDGX	Adherence to Law	Rule 18.1	Yearly.
FINRA	Violation of By-Laws and Rules of FINRA or The OCC.	Rule 2360(b)(21)	Yearly.
ISE	Adherence to Law	ISE Options 9, Section 2	Yearly.
GEMX	Adherence to Law	GEMX Options 9, Section 2	Yearly.

VIOLATION IV: OPTIONS CLEARING CORPORATION (OCC) ADJUSTMENT PROCESS—Continued

SRO	Description of rule (as they apply to OCC adjustments/by-laws article V, section 1 .01(a) and .02)	Exchange rule No.	Frequency of review
MRX	Adherence to Law	MRX Options 9, Section 2	Yearly.
MIAX	Adherence to Law	Rule 300	Yearly.
MIAX PEARL	Adherence to Law	Rule 300	Yearly.
MIAX Emerald	Adherence to Law	Rule 300	Yearly.
MIAX Sapphire	Adherence to Law	Rule 300	Yearly.
MEMX	Adherence to Law	Rule 18.1	Yearly.
Nasdaq	Adherence to Law	NOM Options 9, Section 2	Yearly.
Nasdaq BX	Adherence to Law	BX Options 9, Section 2	Yearly.
Nasdaq PHLX	Violation of By-Laws And Rules Of OCC	PHLX Options 9, Section 24	Yearly.
NYSE Arca	Adherence to Law and Good Business Practice	Rule 11.1	Yearly.
NYSE American	Business Conduct	Rule 16	Yearly.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. 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 4–551 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 4–551. 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 plan that are filed with the Commission, and all written communications relating to the proposed plan 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 plan also will be available for inspection and copying at the principal offices of NYSE American, BZX, C2, Cboe, EDGX,

Gemini, ISE, Mercury, FINRA, Arca, Nasdaq, BOX, BX, PHLX, MIAX, MIAX PEARL, MIAX Emerald, MIAX Sapphire, and MEMX. 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 4–551 and should be submitted on or before August 28, 2024.

V. Discussion

The Commission finds that the proposed Amended Plan is consistent with the factors set forth in Section 17(d) of the Act²² and Rule 17d–2(c) thereunder²³ in that the proposed Amended Plan is necessary or appropriate in the public interest and for the protection of investors, fosters cooperation and coordination among SROs, and removes impediments to and fosters the development of the national market system. The Commission continues to believe that the Plan, as proposed to be amended, is an achievement in cooperation among the SRO participants. The Plan, as amended, will reduce unnecessary regulatory duplication by allocating to the designated SRO the responsibility for certain options-related market surveillance matters that would otherwise be performed by multiple SROs. The Plan promotes efficiency by reducing costs to firms that are members of more than one of the SRO participants. In addition, because the SRO participants coordinate their regulatory functions in accordance with the Plan, the Plan promotes, and will

continue to promote, investor protection. Under paragraph (c) of Rule 17d–2, the Commission may, after appropriate notice and comment, declare a plan, or any part of a plan, effective. In this instance, the Commission believes that appropriate notice and comment can take place after the proposed amendment is effective. The primary purpose of the amendment is to add MIAX Sapphire as a Participant. By declaring it effective today, the amended Plan can become effective and be implemented without undue delay. In addition, the Commission notes that the prior version of this Plan was published for comment, and the Commission did not receive any comments thereon.²⁴ Finally, the Commission does not believe that the amendment to the Plan raises any new regulatory issues that the Commission has not previously considered.

VI. Conclusion

This order gives effect to the amended Plan submitted to the Commission that is contained in File No. 4–551.

It is further ordered that those SRO participants that are not the DOSR as to a particular common member are relieved of those regulatory responsibilities allocated to the common member's DOSR under the amended Plan to the extent of such allocation.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024–17387 Filed 8–6–24; 8:45 am]

BILLING CODE 8011–01–P

²⁴ See Securities Exchange Act Release No. 96383 (November 23, 2022), 87 FR 73569 (November 30, 2022) (File No. 4–551).

²⁵ 17 CFR 200.30–3(a)(34).

²² 15 U.S.C. 78q(d).

²³ 17 CFR 240.17d–2(c).

SECURITIES AND EXCHANGE COMMISSION**[Investment Company Act Release No. 35289; File No. 812-15496]****Fidus Investment Corporation, et al.**

August 2, 2024.

AGENCY: Securities and Exchange Commission (“Commission” or “SEC”).**ACTION:** Notice.

Notice of application for an order under sections 17(d) and 57(i) of the Investment Company Act of 1940 (the “Act”) and rule 17d-1 under the Act to permit certain joint transactions otherwise prohibited by sections 17(d) and 57(a)(4) of the Act and rule 17d-1 under the Act.

Summary of Application: Applicants request an order to permit certain business development companies and closed-end management investment companies to co-invest in portfolio companies with each other and with certain affiliated investment entities.

Applicants: Fidus Investment Corporation, Fidus Credit Opportunities L.P., Fidus Equity Opportunities Fund, L.P., Fidus Mezzanine Capital, L.P., Fidus Mezzanine Capital II, L.P., Fidus Mezzanine Capital III, L.P., Fidus Mezzanine Capital IV, L.P., Fidus Investment Advisors, LLC, and Fidus Capital Advisors, LLC.

Filing Dates: The application was filed on August 11, 2023, and amended on November 22, 2023, May 16, 2024 and July 23, 2024.

Hearing or Notification of Hearing: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing on any application by emailing the SEC’s Secretary at Secretarys-Office@sec.gov and serving the Applicants with a copy of the request by email, if an email address is listed for the relevant Applicant below, or personally or by mail, if a physical address is listed for the relevant Applicant below. Hearing requests should be received by the Commission by 5:30 p.m. on, August 27, 2024, and should be accompanied by proof of service on the Applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0-5 under the Act, hearing requests should state the nature of the writer’s interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission’s Secretary at Secretarys-Office@sec.gov.

ADDRESSES: The Commission: Secretarys-Office@sec.gov. Applicants: Edward H. Ross, at eross@fidusinv.com; and Steven B. Boehm, Esq., Anne G. Oberndorf, Esq. and Payam Siadatpour, Esq., Eversheds Sutherland (US) LLP, at anneoberndorf@eversheds-sutherland.us.

FOR FURTHER INFORMATION CONTACT: Laura L. Solomon, Senior Counsel, or Kyle R. Ahlgren, Branch Chief, at (202) 551-6825 (Division of Investment Management, Chief Counsel’s Office).

SUPPLEMENTARY INFORMATION: For Applicants’ representations, legal analysis, and conditions, please refer to Applicants’ third amended and restated application, dated July 23, 2024, which may be obtained via the Commission’s website by searching for the file number at the top of this document, or for an Applicant using the Company name search field, on the SEC’s EDGAR system.

The SEC’s EDGAR system may be searched at <http://www.sec.gov/edgar/searchedgar/legacy/companysearch.html>. You may also call the SEC’s Public Reference Room at (202) 551-8090.

For the Commission, by the Division of Investment Management, under delegated authority.

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-17446 Filed 8-6-24; 8:45 am]

BILLING CODE 8011-01-P**SECURITIES AND EXCHANGE COMMISSION****[Release No. 34-100632; File No. SR-MSRB-2024-06]****Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MSRB’s Real-Time Transaction Reporting System and Price Dissemination Information Facility To Retire the Transmission Control Protocol Secure Socket Connection**

August 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Exchange Act”) ¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 30, 2024, the Municipal Securities Rulemaking Board (“MSRB”) 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 MSRB. 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 MSRB filed with the Commission a proposed rule change to amend the MSRB’s Real-Time Transaction Reporting System and Price Dissemination Information Facility (“IF-1”) to consolidate access by subscribers to the real-time transaction data residing within the Real-Time Transaction Reporting System (“RTRS”) through a web service and to fully retire the Transmission Control Protocol secure socket connection (“TCP secure socket connection”) (the “proposed rule change”).

The MSRB has filed the proposed rule change under Section 19(b)(3)(A)(iii) of the Exchange Act ³ and Rule 19b-4(f)(6) ⁴ thereunder, as a noncontroversial rule change that renders the proposed rule change effective upon filing. The MSRB will announce the operative date of the proposed rule change, which would be no earlier than 30 days following the filing of the proposed rule change with the Commission, in a regulatory notice to be published on the MSRB website. The operative date will be the earlier of nine months following the filing date or the day by which all subscribers are deemed to have discontinued the use of the TCP secure socket connection. During the period leading to the operative date, the MSRB will no longer permit new subscribers to establish new connectivity to RTRS using the TCP secure socket connection.

The text of the proposed rule change is available on the MSRB’s website at <https://msrb.org/2024-SEC-Filings>, at the MSRB’s principal office, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the 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

¹ 15 U.S.C. 78s(b)(1).² 17 CFR 240.19b-4.³ 15 U.S.C. 78s(b)(3)(A)(iii).⁴ 17 CFR 240.19b-4(f)(6).

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

MSRB Rule G–14, on transaction reporting, requires brokers, dealers and municipal securities dealers (“dealers”), and associated persons to report executed transactions in municipal securities to RTRS, with limited exceptions. The MSRB disseminates trade reporting information from RTRS to subscribers through certain data subscription feeds.⁵ One subscription feed offered by the MSRB is the Real-Time Transaction Data Subscription Service (the “Real-Time Subscription”). Currently, subscribers to the Real-Time Subscription may connect to RTRS to obtain real-time data through one of two methods: a TCP secure socket connection, a broadcast service, referred to in IF–1 as a “TCP secure socket connection” and referred to by subscribers as the TCP secure socket interface, and a secure web Application Programming Interface connection, referred to in IF–1 as the “web service”.⁶

The MSRB has utilized a socket service-based technology since the introduction of RTRS in 2005, with the current version consisting of the TCP secure socket connection. The MSRB later added the web service in 2018 as an additional connectivity option to obtain real time transaction data through the Real-Time Subscription.⁷ Since then, the TCP secure socket connection has become less reliable than the web service, with greater susceptibility for individual subscribers to experience sporadic temporary connection problems.⁸ In some cases, this can require the intervention of information technology support resources from both the MSRB and individual subscribers for troubleshooting and resolving such issues when they arise.

⁵ The MSRB also disseminates trade reporting information free of charge to the general public through the MSRB’s centralized Electronic Municipal Market Access (EMMA[®]) website. EMMA[®] is a registered trademark of the MSRB.

⁶ See IF–1, *MSRB Real-Time Transaction Data Subscription Service, Access to Real-Time Service and Replay Files*.

⁷ See Exchange Act Release No. 83038 (Apr. 12, 2018), 83 FR 17200 (Apr. 18, 2018), (File No. MSRB–2018–02) available at <https://www.msrb.org/sites/default/files/MSRB-2018-02-Fed-Reg.pdf>.

⁸ These connectivity issues are confined to TCP socket service subscribers only and are not related to RTRS, EMMA[®], or any other MSRB system.

The MSRB has determined to consolidate access by subscribers to the Real-Time Subscription through the web service and to retire the older TCP secure socket connection. The purpose of the proposed rule change is to amend IF–1 to remove the reference to the TCP secure socket connection therein to reflect its retirement. Current subscribers using the TCP secure socket connection that wish to continue receiving the real-time transaction data subscription would need to migrate to the web service. The MSRB expects that, upon migration, these subscribers would experience improvements in the consistency and reliability of receiving trade data information in real-time.

The MSRB would announce the operative date of the proposed rule change, which would be no earlier than 30 days following the filing of the proposed rule change with the Commission, in a regulatory notice to be published on the MSRB website. The operative date will be the earlier of nine months following the filing date or the day by which all subscribers are deemed to have discontinued the use of the TCP secure socket connection. The MSRB intends to engage in outreach efforts to impacted subscribers to support the transition from the TCP secure socket connection to the web service.

Lastly, the proposed rule change also includes minor language changes to improve the readability and technical accuracy of the rule. These changes include adding the word “disseminated” to better describe the mechanics of the Real-Time Subscription, adding the article “a” to clarify the use of a single connection, and changing “connecting with RTRS” to “connected to RTRS” to more accurately describe the connection between the web service and RTRS.

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2) of the Exchange Act,⁹ which provides that the MSRB shall propose and adopt rules to effect the purposes of the Exchange Act with respect to, among other matters, transactions in municipal securities effected by dealers. Section 15B(b)(2)(C) of the Exchange Act¹⁰ further provides that the MSRB’s rules shall 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,

⁹ 15 U.S.C. 78o–4(b)(2).

¹⁰ 15 U.S.C. 78o–4(b)(2)(C).

and facilitating transactions in municipal securities and municipal financial products, to remove impediments to and perfect the mechanism of a free and open market in municipal securities and municipal financial products, and, in general, to protect investors, municipal entities, obligated persons, and the public interest.

The proposed rule change would improve subscribers’ experience using the Real-Time Subscription to receive trade data. As noted above, the TCP secure socket connection has become less reliable than the web service, with greater susceptibility for individual subscribers to experience sporadic temporary connection problems and requiring the intervention and resources of information technology support resources from both the MSRB and individual subscribers for resolving such issues. By consolidating subscriber connection to only the web service, the MSRB can also streamline technical support for the web service and provide an improved user experience for subscribers.¹¹ As a result, the MSRB believes that subscribers will benefit from a common connection with more efficient technical support and faster resolution when any issues arise.

These improvements in the resiliency and efficiency of the Real-Time Subscription will further remove impediments to and perfect the mechanism of a free and open market in municipal securities by making it more likely that subscribers to the Real-Time Subscription receive continuous transaction information. Therefore, the MSRB believes that the proposed rule change satisfies the applicable requirements of Section 15B(b)(2)(C) of the Exchange Act.¹²

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15B(b)(2)(C) of the Exchange Act¹³ requires that MSRB rules not be designed to impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act. The MSRB does not believe the proposed rule change to amend IF–1 would result in any burden on competition. Therefore, the MSRB does not believe the proposed rule change would result in any burden on competition that is not

¹¹ Using the web service exclusively would also allow the MSRB to perform more efficient maintenance and information technology deployments during business hours, thereby enhancing business continuity in addition to subscriber experience.

¹² 15 U.S.C. 78o–4(b)(2)(C).

¹³ *Id.*

necessary or appropriate in furtherance of the purposes of the Exchange Act. In determining whether these standards have been met, the MSRB is guided by the MSRB's Policy on the Use of Economic Analysis in MSRB Rulemaking.¹⁴ The proposed rule change consists of revisions to remove language relating to the TCP secure socket connection to obtain trade reporting data from RTRS.

The proposed rule change is of a technical nature. This proposed rule change to IF-1 would remove references to the "TCP secure socket connection" for access to RTRS data to correspond to the MSRB's planned retirement of that connection for a subset of subscribers. Subscribers presently using the TCP secure socket connection would need to convert to web service for messaging with RTRS. However, with the introduction of a more modern technology infrastructure, issues for individual subscribers using the TCP secure socket connection have increased, and MSRB staff has spent time and resources troubleshooting problems and restoring connectivity to individual subscribers. The MSRB expects that such efforts would need to be continued on a longer-term basis so long as the TCP secure socket connection is available. Subscribers using the TCP secure socket connection are burdened with the higher level of service disruptions and inquiries to MSRB support staff as compared to subscribers through the web service.

By retiring the TCP secure socket connection, the MSRB is expected to focus its resources on one method of connection, therefore improving the reliability, availability, and supportability of the Real-Time Subscription. This in turn will benefit the current TCP secure socket connection users with a more reliable connection if they choose to continue their Real-Time Subscription and migrate to the web service. The MSRB

believes the proposed rule change, while requiring some initial adjustments by subscribers who currently use the TCP secure socket connection to rewrite, or retrofit, their code for the use of the web service, would reduce connection problems for subscribers and therefore improve market efficiency in the longer term. The proposed rule change would not modify the MSRB's administration of RTRS in collecting and disseminating information to the EMMA[®] website publicly for transactions in the municipal securities market. Accordingly, the MSRB does not believe that the proposed rule change would result in any burden on competition that is not necessary or appropriate in furtherance of the Exchange Act.¹⁵

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 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: (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 Exchange Act¹⁶ and Rule 19b-4(f)(6)¹⁷ 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 Exchange Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Exchange 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-MSRB-2024-06 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR-MSRB-2024-06. 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 10:00 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-2024-06 and should be submitted on or before August 28, 2024.

For the Commission, pursuant to delegated authority.¹⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-17384 Filed 8-6-24; 8:45 am]

BILLING CODE 8011-01-P

¹⁴ See Policy on the Use of Economic Analysis in MSRB Rulemaking, available at <https://www.msrb.org/Policy-Use-Economic-Analysis-MSRB-Rulemaking>. In evaluating whether there was any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act, the MSRB was guided by its principles that required the MSRB to consider costs and benefits of a rule change, its impact on efficiency, capital formation and competition, and the main reasonable alternative regulatory approaches. For those rule changes which the MSRB files for immediate effectiveness under Section 19(b)(3)(A) of the Exchange Act (15 U.S.C. 78s(b)(3)(A)), including information facility rule filings, while not subject to the policy, the MSRB usually focuses its examination exclusively on the burden of competition on regulated entities, but may also include any additional economic analysis that the MSRB believes may inform the rulemaking process based on the facts and circumstances.

¹⁵ 15 U.S.C. 78o-4(b)(2)(C).

¹⁶ 15 U.S.C. 78s(b)(3)(A).

¹⁷ 17 CFR 240.19b-4(f)(6).

¹⁸ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100634; File No. SR–NYSEARCA–2024–62]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Rule 7.31–E

August 1, 2024.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”)² and Rule 19b–4 thereunder,³ notice is hereby given that on July 25, 2024, NYSE Arca, Inc. (“NYSE Arca” or the “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 modify Rule 7.31–E regarding MPL-ALO Orders. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31–E regarding MPL-ALO Orders.

Rule 7.31–E(d)(3) defines a Mid-Point Liquidity Order (“MPL Order”) as a Limit Order to buy (sell) that is not

displayed and does not route, with a working price at the lower (higher) of the midpoint of the PBBO or its limit price. An MPL Order is ranked Priority 3—Non-Display Orders, is valid for any session, and does not participate in auctions.

Rule 7.31–E(d)(3)(A) provides that an MPL Order to buy (sell) must be designated with a limit price in the MPV for the security and will be eligible to trade at the working price of the order.

Rule 7.31–E(d)(3)(B) provides that if there is no PBB, PBO, or the PBBO is locked or crossed, both an arriving and resting MPL Order will wait for a PBBO that is not locked or crossed before being eligible to trade. If a resting MPL Order to buy (sell) trades with an MPL Order to sell (buy) after there is an unlocked or uncrossed PBBO, the MPL Order with the later working time will be the liquidity-removing order.

Rule 7.31–E(d)(3)(C) provides that an Aggressing MPL Order to buy (sell) will trade at the working price of resting orders to sell (buy) when such resting orders have a working price at or below (above) the working price of the MPL Order. Resting MPL Orders to buy (sell) will trade against all Aggressing Orders to sell (buy) priced at or below (above) the working price of the MPL Order.

Rule 7.31–E(d)(3)(D) provides that an MPL Order may be designated IOC (“MPL-IOC Order”). Subject to such IOC instructions, an MPL-IOC Order will follow the same trading and priority rules as an MPL Order, except that an MPL-IOC Order will be rejected if there is no PBBO or the PBBO is locked or crossed. An MPL-IOC Order cannot be designated ALO or with a Non-Display Remove Modifier.

Rule 7.31–E(d)(3)(E) and the subparagraphs thereunder define the MPL-ALO Order, which is an MPL Order designated with an ALO Modifier.⁴ An Aggressing⁵ MPL-ALO Order to buy (sell) will trade at the working price of resting orders to sell (buy) when such resting orders have a working price below (above) the less aggressive of the midpoint of the PBBO or the limit price of the MPL-ALO Order, but will not trade with resting orders to sell (buy) priced equal to the

less aggressive of the midpoint of the PBBO or the limit price of the MPL-ALO Order (Rule 7.31–E(d)(3)(E)(i)). If an MPL-ALO Order to buy (sell) cannot trade with a same-priced resting order to sell (buy), a subsequently arriving order to sell (buy) eligible to trade at the working price of the MPL-ALO Order will trade ahead of a resting order to sell (buy) that is not displayed at that price; if such resting order to sell (buy) is displayed, the MPL-ALO Order to buy (sell) will not be eligible to trade at that price (Rule 7.31–E(d)(3)(E)(ii)). An MPL-ALO Order may not be designated with a Non-Display Remove Modifier (Rule 7.31–E(d)(3)(E)(iii)).

Proposed Rule Change

Currently, Aggressing MPL-ALO Orders to buy (sell) may trade with resting orders priced below (above) the less aggressive of the midpoint of the PBBO or the limit price of the MPL-ALO Order (*i.e.*, priced below (above) the MPL-ALO Order’s working price), regardless of the amount of price improvement the Aggressing MPL-ALO Order would receive. The Exchange proposes to amend Rule 7.31–E(d)(3)(E)(i) to provide that an Aggressing MPL-ALO Order would only be eligible to trade with resting orders when it would receive price improvement over the MPL-ALO Order’s working price of at least one MPV. This proposed change would not impact non-Aggressing MPL-ALO Orders (*e.g.*, MPL-ALO Orders resting on the Exchange Book). A non-Aggressing MPL-ALO Order would continue to provide liquidity at its working price unless it would not be eligible to trade as outlined in Rules 7.31–E(d)(3)(E)(ii)(a) and (b), as amended below.

The Exchange next proposes to amend Rule 7.31–E(d)(3)(E)(ii) to provide that an MPL-ALO Order not eligible to trade as described in proposed Rule 7.31–E(d)(3)(E)(i) would be ranked in the NYSE Arca Book at its working price and would not trade at that price if it would lock or cross displayed interest or cross non-displayed interest on the NYSE Arca Book. Specifically, the Exchange proposes to add new Rules 7.31–E(d)(3)(E)(ii)(a) and (b) to provide that resting MPL-ALO Orders would not be eligible to trade (a) at a price equal to or above (below) any sell (buy) orders that are displayed and that have a working price equal to or below (above) the working price of the MPL-ALO Order, or (b) at a price above (below) any sell (buy) orders that are not displayed and that have a working price below (above) the working price of the MPL-ALO Order. The Exchange notes

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ An ALO Order is a Non-Routable Limit Order that, unless it receives price improvement, will not remove liquidity from the NYSE Arca Book. See NYSE Arca Rule 7.31–E(e)(2).

⁵ An “Aggressing Order” is a buy (sell) order that is or becomes marketable against sell (buy) interest on the Exchange Book. A resting order may become an Aggressing Order if its working price changes, if the PBBO or NBBO is updated, because of changes to other orders on the Exchange Book, or when processing inbound messages. See Rule 7.36–E(a)(5).

that the circumstances under which such orders would not be able to trade are consistent with the Exchange's existing priority and ranking rules.

The Exchange further proposes to renumber current Rule 7.31–E(d)(3)(E)(ii) as Rule 7.31–E(d)(3)(E)(iii) and to amend the text of the rule to provide that if an MPL-ALO Order to buy (sell) cannot trade with a same-priced resting order to sell (buy) that is not displayed, a subsequently arriving order to sell (buy) eligible to trade at the working price of the MPL-ALO Order will trade ahead of such resting order to sell (buy). This proposed change is not intended to change the meaning of the rule, but rather to clarify that, if an MPL-ALO Order is resting at the same price as resting non-displayed interest, a subsequently arriving order that is eligible to trade with that MPL-ALO Order would, as currently, be permitted to trade ahead of such interest. The Exchange further proposes to delete the last sentence of current Rule 7.31–E(d)(3)(E)(ii), which provides that an MPL-ALO Order would not be eligible to trade at the price of a displayed resting order to buy (sell), as duplicative of proposed Rule 7.31–E(d)(3)(E)(ii)(a) described above.

The following example demonstrates how an arriving Aggressing MPL-ALO Order would trade or be ranked on the NYSE Arca Book, as proposed:

- Assume the PBBO⁶ is \$10.00 × \$10.05 (midpoint is \$10.025). On the NYSE Arca Book, there is a Limit Order to sell 90 shares at \$10.02 (“Order 1”) and an MPL Order to sell 100 shares at \$10.00 (“Order 2”). Order 1 is displayed at its working price of \$10.02. Order 2 is non-displayed and has a working price at the midpoint, \$10.025.
- Order 3 is an incoming MPL-ALO Order to buy 100 shares at \$10.05. Order 3, as an Aggressing MPL-ALO Order, would not trade with either Order 1 or Order 2 because it would receive less than \$0.01 price improvement over the midpoint. Pursuant to proposed Rule 7.31–E(d)(3)(E)(ii), Order 3 would be ranked on the NYSE Arca Book at its working price, \$10.025 (which is the midpoint, as the working price of an MPL-ALO Order to buy is the lower of the midpoint or the order's limit price).
- Order 4 is an incoming MPL-IOC Order to sell 100 shares at \$10.00. Order 4 would not trade with Order 3 (which

is now ranked on the NYSE Arca Book at its working price) at \$10.025 per proposed Rule 7.31–E(d)(3)(E)(ii)(a) because an execution at that price would be at a price above displayed interest on the NYSE Arca Book (Order 1 at \$10.02). Order 4, as an IOC Order, would be cancelled because it does not execute.

- Assume Order 1 is cancelled, and Order 5 is an incoming MPL-IOC Order to sell 100 shares at \$10.00. Order 5 would trade with Order 3 (where Order 3 is the liquidity provider) at \$10.025, consistent with proposed Rule 7.31–E(d)(3)(E)(iii), because the trade would execute at a price that is not above the price of any displayed or non-displayed interest on the NYSE Arca Book, although it would be at the same price as Order 2 (non-displayed interest on the NYSE Arca Book).⁷

The following example demonstrates how an MPL-ALO Order that is resting on the NYSE Arca Book and subsequently becomes an Aggressing MPL-ALO Order (in this example, when the PBBO is updated) would trade, as proposed:

- Assume the PBBO is \$10.00 × \$10.05 (midpoint is \$10.025). Order 1 is a non-displayed Limit Order to sell 100 shares at \$10.03, resting on the NYSE Arca Book at its working price of \$10.03. Order 2 is an MPL-ALO Order to buy 100 shares at \$10.05. Order 2 is resting non-displayed on the NYSE Arca Book at its working price of \$10.025 (which is the midpoint, as the working price of an MPL-ALO Order to buy is the lower of the midpoint or the order's limit price).
- Assume the PBBO updates to \$10.03 × \$10.05 (midpoint is \$10.04). Order 2 reprices to the new midpoint, \$10.04, and becomes an Aggressing Order because its working price has changed and the PBBO has updated. Order 2 will trade as an Aggressing Order (as the liquidity taker) with Order 1 at \$10.03 because it would receive \$0.01 price improvement over its working price.

Finally, the Exchange proposes to renumber current Rule 7.31–E(d)(3)(E)(iii) as Rule 7.31–E(d)(3)(E)(iv) to reflect the addition of the new rule text described above, without any changes to the text of the rule.

The Exchange believes that the proposed change, which would allow an

Aggressing MPL-ALO Order to trade only when it would receive price improvement over its working price of at least one MPV, would promote higher-quality executions for ETP Holders and provide ETP Holders with greater certainty regarding the amount of price improvement such executions would receive, thereby encouraging increased order flow to the Exchange and enhanced opportunities for order execution for all market participants. The Exchange notes that evaluating the economic benefit of an execution is not a novel concept on equity exchanges.⁸ Accordingly, the Exchange believes that this proposed change, which would consider the amount of price improvement that an Aggressing MPL-ALO Order would receive upon execution, would offer ETP Holders a similar benefit to that available on at least one other equity exchange for an order type similar to the MPL-ALO Order and could thus promote competition among equity exchanges.

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update, which, subject to effectiveness of this proposed rule change, will be no later than in the fourth quarter of 2024.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,⁹ in general, and furthers the objectives of Section 6(b)(5),¹⁰ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed change would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and protect investors and the public interest because allowing an Aggressing MPL-ALO Order to trade only when it would receive price improvement over its working price of at least one MPV

⁶ “Best Protected Bid” or “PBB” means the highest Protected Bid, “Best Protected Offer” or “PBO” means the lowest Protected Offer, and “Protected Best Bid and Offer” or “PBBO” means the Best Protected Bid and the Best Protected Offer. See Rule 1.1 (NBBO, Best Protected Bid, Best Protected Offer, Protected Best Bid and Offer (PBBO)).

⁷ As noted above, Rule 7.31–E(d)(3)(E)(iii), as amended, reflects current Rule 7.31–E(d)(3)(E)(ii), which provides that an MPL-ALO Order that is resting at the same price as resting non-displayed interest would be permitted to trade with a subsequently arriving order that is eligible to trade with that MPL-ALO Order, ahead of the non-displayed interest.

⁸ See, e.g., Nasdaq Stock Market LLC, Equity 4, Rule 4702(b)(5)(A) (defining the Midpoint Peg Post-Only Order, which is priced at the midpoint between the NBBO and will execute upon entry only in circumstances where economically beneficial to the party entering such order).

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

would promote higher-quality executions for ETP Holders, thereby encouraging increased order flow to the Exchange and enhanced trading opportunities for all market participants. The Exchange also believes that the proposed conforming changes to Rule 7.31–E(d)(3)(E) would remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and protect investors and the public interest by clarifying how Aggressing MPL–ALO Orders that would not be eligible to trade based on the amount of price improvement would be ranked and would trade once resting, in accordance with the Exchange’s priority and ranking rules. Finally, the Exchange notes that considering the economic benefit of an execution is not a novel concept and believes that this proposed change would remove impediments to, and perfect the mechanism of, a free and open market and a national market system by providing ETP Holders with greater certainty as to the amount of price improvement they would receive when an Aggressing MPL–ALO Order executes, as well as by promoting competition among equity exchanges.¹¹

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 proposed rule change would amend Exchange rules to permit Aggressing MPL–ALO Orders to trade only when they would receive price improvement of at least one MPV over their working price, thereby providing a minimum amount of price improvement for ETP Holders entering such orders. To the extent the proposed rule change promotes higher-quality executions on the Exchange, the proposed change could encourage increased order flow to the Exchange and facilitate additional trading opportunities for all market participants. In addition, at least one other equity exchange considers the economic benefit to the entering party when evaluating whether a similar order type may trade, and the Exchange’s proposal would thus promote competition among exchanges by providing a minimum amount of price improvement to Aggressing MPL–ALO Orders.¹² The Exchange also believes that, to the extent the proposed change would increase opportunities for order execution, the proposed change would

promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

C. Self-Regulatory Organization’s Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹³ and Rule 19b–4(f)(6)¹⁴ thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)¹⁵ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),¹⁶ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange is requesting the waiver because it will allow the Exchange to implement the proposed change as soon as the associated technology is available, which is anticipated to be less than 30 days from the date of this filing. The Exchange believes the proposed change would provide member organizations with greater certainty regarding the amount of price improvement their Aggressing MPL–ALO Orders would receive, thereby promoting higher-quality executions and encouraging increased order flow to the Exchange for the benefit of all market participants. For these reasons, and because the proposed

rule change does not raise any novel legal or 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 30-day operative delay and designates the proposal operative upon filing.¹⁷

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission’s internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR–NYSEARCA–2024–62 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.
- All submissions should refer to file number SR–NYSEARCA–2024–62. 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

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 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.

¹⁵ 17 CFR 240.19b–4(f)(6).

¹⁶ 17 CFR 240.19b–4(f)(6)(iii).

¹⁷ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule’s impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹¹ See note 8, *supra*.

¹² See note 8, *supra*.

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEARCA-2024-62 and should be submitted on or before August 28, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-17386 Filed 8-6-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100637; File No. SR-DTC-2024-007]

Self-Regulatory Organizations; The Depository Trust Company; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the DTC Operational Arrangements (Necessary for Securities To Become and Remain Eligible for DTC Services)

August 1, 2024.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder,² notice is hereby given that on July 26, 2024, The Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the clearing agency. DTC filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to DTC Operational Arrangements (Necessary for Securities to Become and Remain Eligible for DTC Services) (the "OA")⁵ to (i) insert, consolidate and update the procedures for an Agent processing a reorganizations event, offer, or solicitation (each, an "Offer") through the DTC Automated Tender Offer Program ("ATOP")⁶ system or Automated Subscription Offer Program ("ASOP")⁷ system in order to better align with current processing, and (ii) make related technical and clarifying changes relating to Offers processed through ATOP (an "ATOP-eligible Offer") or ASOP (an "ASOP-eligible Offer"), as described in greater detail below.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the clearing agency included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The clearing agency has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the DTC Operational Arrangements (Necessary for Securities to Become and Remain Eligible for DTC Services) (the "OA") to (i) insert,

⁵ Available at www.dtcc.com/-/media/Files/Downloads/legal/issue-eligibility/eligibility/operational-arrangements.pdf. Each term not otherwise defined herein has its respective meaning as set forth in the OA, the Rules, By-Laws and Organization Certificate of DTC (the "Rules") and the Reorganizations Service Guide (the "Reorganizations Guide"), available at www.dtcc.com/legal/rules-and-procedures.

⁶ For the history of ATOP, see Securities Exchange Act Release Nos. 26538 (Feb. 13, 1989), 54 FR 7316 (Feb. 17, 1989) (SR-DTC-88-19); 27139 (Aug. 14, 1989), 54 FR 34841 (Aug. 22, 1989) (SR-DTC-88-19); 29168 (May 7, 1991), 56 FR 22742 (May 16, 1991) (SR-DTC-91-04); 30678 (May 7, 1992), 57 FR 20541 (May 13, 1992) (SR-DTC-91-11); and 32645 (July 16, 1993), 58 FR 39585 (SR-DTC-92-12).

⁷ For more information about ASOP, see Securities Exchange Act Release No. 35108 (Dec. 16, 1994), 59 FR 67356 (Dec. 29, 1994) (SR-DTC-94-15).

consolidate and update the procedures for an Agent processing a reorganizations event, offer, or solicitation (each, an "Offer") through the DTC Automated Tender Offer Program ("ATOP") system or Automated Subscription Offer Program ("ASOP") system in order to better align with current processing, and (ii) make related technical and clarifying changes relating to Offers processed through ATOP (an "ATOP-eligible Offer") or ASOP (an "ASOP-eligible Offer"), as described below.

(i) Background

ATOP is an instruction processor initially developed by DTC in 1988 to automate the manner in which tender and exchange offers are processed through DTC. When an Agent processes an Offer through ATOP, Participants are able to (i) submit instructions or elections for the Offer without needing to provide a letter of transmittal⁸ or a notice of guaranteed delivery⁹ to the Agent, which will instead receive an electronic message transmitted by DTC through the ATOP system with respect to each instruction and election, and (ii) tender the subject securities directly from the Participant's account into the Agent's account maintained by DTC for purposes of the ATOP-eligible Offer or ASOP-eligible Offer ("Agent ATOP/ASOP Account"). ATOP can be used in connection with any corporate action event that DTC deems appropriate, including, but not limited to, tenders and exchanges, cash conversions, and event processing of mergers with elections.¹⁰

ASOP is an instruction processing system similar to ATOP that was developed by DTC around 1994 to automate the manner in which rights subscription offers are processed

⁸ The letter of transmittal is the basic instrument for effecting transfer of tendered securities. It is the document by which a security holder of the subject company's securities, as applicable, accepts the invitation to tender or offer to purchase; offers to sell the subject company's shares to the bidder; appoints the depository as the agent to receive and hold tendered securities; and guarantees to deliver the subject company's securities to or actually deposits the subject company's securities with the depository.

⁹ A notice of guaranteed delivery, sometimes called a "protect," is a document submitted to the tender agent prior to the expiration of the tender offer whereby the holder submitting the notice guarantees delivery of securities (a "cover" of the protect) after the expiration of the tender offer but before the expiration of the protection period.

¹⁰ See Securities Exchange Act Release Nos. 56538 (Sep. 26, 2007), 72 FR 56409 (Oct. 3, 2007) (SR-DTC-2007-09); 62119 (May 18, 2010), 75 FR 29374 (May 25, 2010) (SR-DTC-2010-08); 69597 (May 16, 2013), 78 FR 30382 (May 22, 2013) (SR-DTC-2013-06); and 81096 (July 7, 2017), 82 FR 32406 (July 13, 2017) (SR-DTC-2017-011).

¹⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b-4(f)(6).

through DTC. When an Agent processes an Offer through ASOP, a Participant can (i) submit subscription instructions without providing a subscription form, letter of transmittal, or a notice of guaranteed delivery to the Agent, which instead receives an electronic message transmitted by DTC through the ASOP system with respect to each instruction and election from DTC, and (ii) tender the subject rights directly from the Participant's account into the Agent ATOP/ASOP Account and authorize DTC to debit the payment from Participant's account and credit the payment to the Agent's account. When the underlying securities are distributed by the Agent, DTC credits the securities to the account of the Participant.

Currently, in order to make an Offer eligible for ATOP or ASOP, the agent for the Offer must have entered into a corresponding agreement ("Master Agreement") with DTC and been approved by DTC to process Offers as an ATOP Agent or an ASOP Agent, as applicable. The ATOP Agent Master Agreement and ASOP Agent Master Agreement provide, in relevant part, that the Agent agrees that (i) the delivery by DTC of an electronic message transmitted through the ATOP or ASOP system, with respect to each instruction and election (an "Agent Message"), will satisfy the terms of each Offer made eligible for ATOP or ASOP (as applicable) as to the execution and delivery of a subscription form, letter of transmittal or a notice of guaranteed delivery, as the case may be, in the form of the subscription form, letter of transmittal or notice of guaranteed delivery required by the Offer by the Participant identified in such Agent's Message, and (ii) the agreement set forth above will be enforceable against the offeror in each Offer made eligible for ATOP or ASOP (as applicable) by the Participant identified in such Agent's Message. For each ATOP-eligible Offer or ASOP-eligible Offer, the Agent is required to electronically agree to a Letter of Agreement ("LOA") that relates specifically to that Offer and contains additional terms, conditions, and requirements with respect to the Offer. ATOP Agents and ASOP Agents are also provided with a copy of the ATOP Agent procedures and ASOP Agent procedures, respectively. The procedures, which were originally drafted around 1989 and revised from time to time, outline the procedures and the technical operations of ATOP and ASOP.¹¹

(ii) Proposed Rule Change

DTC currently provides the ATOP Agent procedures and the ASOP Agent procedures to the ATOP Agent and ASOP Agent, as applicable, upon onboarding. However, DTC has come to understand that when the Agent later makes additional Offers ATOP-eligible or ASOP-eligible, as the case may be, the Agent might not have the applicable procedures readily accessible or might not be familiar with current processes. In addition, on the basis of its interactions with ATOP Agents and ASOP Agents, DTC has determined that the clarification and update of certain elements of the procedures would enhance Agents' understanding and facility with the process. Further, since there is considerable overlap between ATOP Agents and ASOP Agents, DTC determined that it is duplicative to continue to have two separate agreements and procedures for ATOP and ASOP processing.

Therefore, in order to make the Agent's procedures for ATOP and ASOP more streamlined, transparent, and reflective of current processes, DTC would discontinue use of standalone procedures and proposes to amend the OA to (i) insert consolidated and updated procedures for Agents that are processing ATOP-eligible Offers or ASOP-eligible Offers, and (ii) make related technical and clarifying changes relating to ATOP-eligible Offers or ASOP-eligible Offers.

A. Deletion of Current Language

Pursuant to the proposed rule change, DTC would delete the following:

1. Delete the second paragraph in Section VI.D because cut-off times would be addressed in the text of the proposed rule change.
2. Delete Section VI.D.2 because rights offers would be addressed in the text of the proposed rule change.
3. Delete Section VI.D.4.a and the text beginning "With regard to tender/exchange offers" through "Agent is required to approve and adhere to all requirements represented in the LOA which includes, but is not limited to, the following:" because processing of tender/exchange offers would be more fully described in the text of the proposed rule change.

B. Heading

Above the paragraph beginning with "At least one business day prior to payment and allocation of entitlements by DTC," DTC is proposing to insert a new Section VI.D.3 with the title "DTC's

Automated Tender Offer Program ("ATOP") and DTC's Automated Subscription Offer Program ("ASOP")."

C. Becoming an ATOP/ASOP Agent

DTC is proposing to add a new subsection VI.D.3.a with the heading "Becoming an ATOP/ASOP Agent." Currently, the requirements for an Agent to become an ATOP or ASOP Agent are reflected in the ATOP Agent procedures and the ASOP Agent procedures, respectively. The new subsection would reflect the new consolidated designation of an Agent as an ATOP/ASOP Agent, which would be permitted to make an Offer ATOP or ASOP eligible. Specifically, in order to make an Offer eligible to be processed through ATOP or ASOP, an Agent must be an agent approved as an ATOP/ASOP Agent.

To become an ATOP/ASOP Agent, the Agent must (i) obtain the proper connectivity to access the ATOP and ASOP functions as may be required by DTC, and (ii) execute a DTC OA Agent Letter, if the Agent does not already have one on file with DTC; and (iii) execute an Automated Tender Offer (ATOP) and Automated Subscription Offer Program (ASOP) Agent Master Agreement ("ATOP/ASOP Master Agreement"), if the Agent does not already have one on file at DTC.¹²

Two footnotes will be inserted to clarify when an Agent will be required to sign a new OA Letter and/or a new ATOP/ASOP Master Agreement. The footnotes would state as follows: "All Agents must have a signed OA Agent Letter on file at DTC prior to making any Offer eligible for either ATOP or ASOP. All Agents must have a signed ATOP/ASOP Master Agreement on file at DTC prior to making any Offer eligible for either ATOP or ASOP. Any Agent that had previously signed an ATOP Master Agreement and/or ASOP Master Agreement prior to August 1, 2024, will be required to execute a new ATOP/ASOP Master Agreement. DTC may, in its sole discretion, decline to make an Offer eligible for ATOP or ASOP if the Agent does not have an ATOP/ASOP Master Agreement on file with DTC."

Pursuant to the proposed rule change, OA would provide that the DTC Rules, including, without limitation, the OA, as may be amended from time to time, and the LOA for the particular Offer will govern the rights and obligations of the Agent in respect of each ATOP-eligible Offer or ASOP-eligible Offer, as the case may be. In addition, the OA would

¹¹ See e.g., Securities Exchange Release Nos. 26757 (Apr. 21, 1989); 54 FR 18619 (May 1, 1989)

(SR-DTC-88-19); 33797 (Mar. 22, 1994); 59 FR 14696 (Mar. 29, 1994) (SR-DTC-93-11).

¹² As noted above, this would be a change from the current structure, where an Agent has to be approved as an ATOP Agent or an ASOP Agent under separate agreements.

provide that by executing the ATOP/ASOP Master Agreement, the Agent acknowledges and agrees that:

1. The transmission by DTC of an Agent's Message shall satisfy the terms of:¹³

a. each ATOP-eligible Offer as to the execution and delivery of a letter of transmittal, a notice of guaranteed delivery, or other form of instruction, election, or acceptance, as the case may be, in the form of the letter of transmittal, notice of guaranteed delivery, or other form of instruction, election, or acceptance required by the Offer by the Participant identified in such Agent's Message;

b. each ASOP-eligible Offer as to the execution and delivery of a subscription form, a notice of guaranteed delivery, other form of instruction, election, or acceptance, as the case may be, in the form of the subscription form, notice of guaranteed delivery, or other form of instruction, election or acceptance required by the Offer by the Participant identified in such Agent's Message.

2. The delivery of securities from the account of the Participant identified in the Agent's Message to the Agent's account maintained by DTC for purposes of the Offer ("Agent ATOP/ASOP Account") shall satisfy the terms of each Offer as to the surrender of securities required by the Offer by the Participant identified in the Agent's Message.

3. Notwithstanding anything to the contrary, for purposes of making a determination of the timeliness of an instruction, election, or acceptance and, if applicable, the tender of securities, the date and time of a Participant's submission of any instruction, election, or acceptance to DTC through ATOP or ASOP (as reflected in the Transaction ID or Subscription ID), and not the date and time of the transmission of the Agent's Message by DTC to the Agent, shall govern. A footnote would be inserted to state that "By way of example, but without limitation, for purposes of determining the timeliness of a Participant's instruction and/or tender in connection with an Offer, the Participant's instruction is deemed to have been timely received by, and, if applicable, the securities timely tendered to, the Agent when the date and time of the submission of a Participant's instruction to DTC (as reflected in the Transaction ID or Subscription ID of the completed transaction) is prior to the applicable

cutoff/expiration date and time, even if the transaction does not complete and/or an Agent's Message is not transmitted until after the applicable cutoff/expiration date and time for the Offer."

4. The agreements set forth in the preceding paragraphs 1–3 are enforceable against the offeror of an ATOP-eligible Offer or ASOP-eligible Offer by the Participant(s) identified in the applicable Agent's Message.

5. Prior to making an Offer eligible for ATOP or ASOP, the Agent shall have obtained authorization by the offeror of the Offer to make the acknowledgements and agreements in the preceding paragraphs 1–4.

6. The Agent must inspect all Agent's Messages promptly upon receipt and to immediately escalate any questions to the appropriate DTC contacts identified in the OA and in the LOA for the specific Offer.

7. If the Agent believes that the acceptance of an Offer (including acceptance by notice of guaranteed delivery and cover of protect instructions) and/or the tender of securities reflected in an Agent's Message is deficient for some reason, it is the sole responsibility of the Agent to promptly notify the affected Participant directly to resolve the issue and/or request that the Participant enter a withdrawal of its acceptance. The Agent must also promptly notify DTC about the deficiency by emailing the DTC contacts listed in the OA and in the LOA for the specific Offer.

8. The Agent acknowledges and agrees that if there are any events or amendments that occur during the life of the Offer, the Agent must immediately notify DTC, and confirm DTC's receipt of the notice. DTC may revoke the eligibility of an Offer, including, without limitation, in the event that the terms of the Offer are amended, or if DTC becomes aware of a fact, factor, or circumstance and determines, in its sole discretion, that it is not practical or feasible for DTC to provide services in respect of the Offer.

9. The Agent will ensure that DTC has, at all times, up-to-date contact information for the Agent, including, but not limited to, for senior management and operational personnel.

D. ATOP Eligibility or ASOP Eligibility of an Offer

DTC is proposing to insert a new subsection VI.D.3.b. with the heading "ATOP Eligibility or ASOP Eligibility of an Offer." Pursuant to the proposed rule change, this section would reflect the current procedure on how an Agent can make an Offer ATOP-eligible or ASOP-eligible and would add transparency to

DTC's discretion to decline to process any Offer and to the ATOP and ASOP cutoff times for instructions, after which the ATOP/ASOP Agent would need to process instructions outside of DTC.

The proposed new subsection would first remind Agents and Issuers that DTC has discretion to decline to process any Offer, and DTC's acceptance of a particular Offer in one case does not set a precedent for future Offers. All Agents and Issuers with a proposed non-standard Offer that could require special processing must confirm with DTC whether the particular Offer can be processed on the ATOP or ASOP platform before including references to, or instructions or directions for, ATOP or ASOP processing in any documentation or filings. The new subsection would then explain that to make an Offer ATOP-eligible or ASOP-eligible, the Agent must send the offering announcement, including the source document, and a completed DTC questionnaire to DTC within the timeframes and in the manner described in the OA. DTC may require the Agent to provide additional documentation if needed. For an ASOP-eligible Offer, the Agent will also be required to provide the "Agent Wire Instructions Letter" for which DTC is to send the subscription payments.

Once DTC's receipt and review of the documentation and information is complete, DTC will post the terms of the Offer on ATOP or ASOP, as the case may be, viewable by the Agent only. Within one business day of posting, the Agent must review and approve the details of the Offer and to approve the terms of the LOA for the Offer by entering an acknowledgement in ATOP or ASOP, as applicable. Any delays by the Agent may impact the timeliness of opening the Offer to participants. If the Agent reviews the details of the Offer and the terms of the LOA and disagrees with one or more terms or details, the Agent must notify DTC of its disagreement by entering the LOA rejection and the reason for the rejection in ATOP or ASOP, as applicable, and by email to the DTC contacts listed in the LOA. DTC, at its option, may work with the Agent to modify the terms and details and resolve any differences with the Agent. DTC will not make an Offer available to Participants unless all approvals have been received from the Agent.

The proposed subsection would also note that when making an Offer ATOP-eligible or ASOP-eligible, DTC will confirm with the Agent the actual expiration date/time for the Offer and the DTC cutoff date/time for the Offer. For Offers in which the offering

¹³ The following footnote reference would be added: "The Agent's Message is the electronic message that is generated and transmitted to the Agent through ATOP or ASOP with respect to each Participant instruction and election."

documentation (i) allows for holders to participate in the Offer (*i.e.*, submit instructions) on the expiration date until a time later than the DTC cutoff time of 6:00 p.m. ET for equities or 5:00 p.m. ET for debt (*e.g.*, Offers with an actual expiration time of 11:59 p.m. ET on expiration date), or (ii) reflects an Offer expiration time on expiration date that is earlier than 5:00 p.m. ET on expiration date (*e.g.*, an Offer with an 11:00 a.m. ET expiration time on expiration date), in which case DTC's cutoff date and time for such Offer will typically be at 6:00 p.m. ET for equities or 5:00 p.m. ET for debt on the business day prior to the actual expiration date. DTC will neither accept nor facilitate any instructions through ATOP/ASOP after the stated DTC cutoff date/time, and DTC has no responsibility or obligation to do so. After DTC cutoff date/time, the Agent will be responsible for administering protects and cover of protects. The Agent must make itself available to Participants and have the capabilities to handle protect instructions, tenders of securities, and payments directly with Participants. Further, if the Agent is not the tendering security's transfer agent it is the responsibility of the Agent to coordinate with the transfer agent to receive the tendered securities from Participants and/or to deliver the security entitlement (if applicable) to Participants upon payment.

E. ATOP-Eligible Offers

DTC is proposing to insert a new subsection VI.D.3.c. with the heading "ATOP-eligible Offers." As previously noted, pursuant to the proposed rule change, DTC would discontinue its practice of providing standalone ATOP Agent procedures and would insert clarified and updated ATOP procedures in the OA. This new subsection would provide such updated procedures in order to provide enhanced transparency and to reflect current processes relating to ATOP-eligible Offers.

F. Use of ATOP

DTC is proposing to insert a new subsection VI.D.3.c. (i) with the heading "Use of ATOP." Pursuant to the proposed rule change, to enhance the transparency of possible uses of the ATOP platform, this subsection would briefly explain that ATOP can be used for processing any Offer as DTC may deem appropriate, and that the procedures and requirements may differ for ATOP-eligible Offers that are not standard tender and exchange Offers and/or require special or manual processing.

The new proposed subsection would reflect the existing language that with regard to certain Offers, such as tenders and exchanges and mergers with elections, ATOP procedures and systems must be used for all elections (*e.g.*, original acceptances, withdrawals of acceptances, notices of guaranteed deliveries, conditional acceptances). Use of ATOP for these purposes is an eligibility requirement for securities that are the subject of such Offers unless it is communicated by the Issuer or Agent to DTC and determined by DTC that certain conditions preclude the use of DTC's processors for a particular event, or preclude DTC from allocating entitlements for an Offer (*e.g.*, restricted securities that cannot be made DTC eligible).

The proposed subsection will also note that the subsequent description of ATOP processing is for standard processing of a tender or exchange Offer on ATOP, but that ATOP may be used for processing any Offer as DTC may deem appropriate. Accordingly, certain processes and requirements may differ and, when applicable, will be communicated to the Agent by DTC in writing and/or in a rider to the ATOP/ASOP Master Agreement and/or in the LOA for the specific Offer. For illustration, a footnote would be added as follows: "By way of example, but without limitation, in order to make a voting solicitation Offer eligible for ATOP, the Agent must have a signed voting addendum to the ATOP/ASOP Master Agreement on file at DTC."

The text of the proposed subsection would continue to explain that, in addition, for such Offers, including, but not limited to, Offers that require special or manual processing, the Agent and Issuer may be required to provide additional written instructions and indemnifications from the Agent and Issuer and to pay additional processing fees. Unless otherwise agreed between the parties, payment of such fees is due upon receipt of an invoice from DTC, prior to DTC's announcement of the Offer.

G. Participant Acceptance and Surrender of Securities Through ATOP

DTC is proposing to insert a new subsection VI.D.3.c.(ii) titled "Participant Acceptances and Surrender of Securities Through ATOP" to provide transparency into how instructions are inputted and processed through ATOP.

Pursuant to the proposed rule change, this subsection would briefly summarize how the ATOP system processes Participant instructions, stating that when a Participant submits an instruction to DTC for an ATOP-

eligible Offer, such as an acceptance and surrender of securities, acceptance by submission of a notice of guaranteed delivery (a "protect"), or a surrender of securities to cover a notice of guaranteed delivery (a "cover of a protect") through ATOP, the ATOP system will typically (x) process the Participant submission, and, in the case of an acceptance with surrender of securities or a cover of a protect, effect a book-entry delivery of the Participant's subject position in the securities to the Agent ATOP/ASOP Account, (y) enter information about the submission (including the time of the Participant's submission into DTC) into ATOP and transmit an Agent's Message to the Agent that indicates the Participant's acceptance of the ATOP-eligible Offer or its instruction to cover a protect, as the case may be, and, to the extent applicable, reflects the book-entry delivery of the securities into the Agent ATOP/ASOP Account.

H. Withdrawal of Acceptances

DTC proposes to insert a new subsection VI.D.3.c.(iii) titled "Withdrawal of Acceptances (including acceptances by notice of guaranteed delivery or instructions to cover the protect)" to provide transparency into how withdrawals may be processed through ATOP. Pursuant to the proposed rule change, this subsection would briefly describe the process for a Participant to withdraw its acceptance or cover instruction.

The proposed subsection would provide that if permitted under the terms of the ATOP-eligible Offer, Participants can submit an instruction for a partial or full withdrawal of their acceptance of an ATOP-eligible Offer. When a Participant submits a withdrawal request, the ATOP System will transmit a message ("Withdrawal Message") to the Agent indicating the withdrawal instruction submitted by the Participant. The Agent is required to inspect all Withdrawal Messages upon receipt to verify the validity of the withdrawal request. No later than 30 minutes after the instruction cutoff time on the day of the withdrawal instruction, the Agent must take one of the following actions: (i) if the Agent determines to accept the withdrawal, the Agent must transmit an acceptance ("Withdrawal Acceptance") to DTC through ATOP; or (ii) if the Agent determines to reject the request, the Agent must transmit a rejection ("Withdrawal Rejection") to DTC through ATOP.

The proposed subsection would also provide that the Agent's failure to timely accept or reject a pending

Withdrawal Message can prevent the ATOP-eligible Offer from being balanced with DTC and delay any payments due to Participants pursuant to the ATOP-eligible Offer and note that an Agent cannot partially accept or reject a withdrawal instruction.

The proposed subsection would also clarify that if the withdrawal instruction relates to securities delivered to the Agent ATOP/ASOP Account in connection with the acceptance of the ATOP-eligible Offer, the Withdrawal Acceptance shall constitute an authorization from the Agent to DTC to deliver by book-entry from the Agent ATOP/ASOP Account to the account of the Participant submitting the withdrawal instruction the securities that are the subject of the Participant's withdrawal instruction. Upon receipt of such a Withdrawal Acceptance, DTC will affect a book-entry delivery returning the securities to the Participant from the Agent ATOP/ASOP Account. If the withdrawal request relates to an acceptance of the ATOP-eligible Offer by notice of guaranteed delivery, the Withdrawal Acceptance constitutes an authorization from the Agent to DTC to reduce the quantity of securities to which the Notice of Guaranteed Delivery relates by the quantity of securities that are subject to the withdrawal instruction.

I. After Expiration of an ATOP-Eligible Offer

DTC is proposing to add a new subsection VI.D.3.c.(iv) titled "After Expiration of an ATOP-eligible Offer," which would include the existing enumerated list of requirements. DTC would also make grammatical changes, correct typos, and add the following sentence into No. 2 in the list: "Agent must reconcile balances with DTC at least one business day prior to the allocation of entitlements, and must receive DTC confirmation prior to wiring funds to DTC." The purpose of this requirement is to prevent agents from overpaying or underpaying DTC, which would delay the allocation to Participants.

J. ASOP-Eligible Offers

DTC is proposing to insert a new subsection VI.D.3.d. with the heading "ASOP-eligible Offers." As previously noted, pursuant to the proposed rule change, DTC would discontinue its practice of providing standalone ASOP Agent procedures and would insert clarified and updated ASOP procedures in the OA. This new subsection would provide such updated procedures in order to provide enhanced transparency

and to reflect current processes relating to ASOP-eligible Offers.

K. ASOP-Eligible Offer Processing

DTC is proposing to insert subsection VI.D.3.d.(i), titled "ASOP-eligible Offer Processing," to enhance the transparency of possible uses of the ASOP platform. This subsection would generally describe the possible uses for ASOP, and what may be required from the Agent and Issuer for Offers that require special or manual processing.

Pursuant to the proposed rule filing, this subsection would state that in the case of rights offerings, DTC's ASOP procedures and systems must be used to process subscription exercise activities, including the submission of instructions for basic subscriptions, the exercise of oversubscriptions, sales of rights, and notices of guaranteed deliveries, and all related activities. Use of ASOP for these purposes is an eligibility requirement for securities that are the subject of rights offers. However, ASOP can be used for processing any corporate action as DTC may deem appropriate. Accordingly, certain processes and requirements may differ and, when applicable, will be communicated to the Agent by DTC in writing and/or in a rider to the ATOP/ASOP Master Agreement and/or in the LOA. In addition, for such Offers, including, but not limited to, Offers that require special or manual processing, the Agent and Issuer may be required to provide additional written instructions and indemnifications from the Agent and Issuer and to pay additional processing fees. Unless otherwise agreed between the parties, payment of such fees is due upon receipt of an invoice from DTC, prior to DTC's announcement of the Offer.

L. Participant Acceptances of the ASOP-Eligible Offer and Surrender of Rights Through ASOP

DTC is proposing to insert subsection VI.D.3.d.(ii) under the "ASOP-eligible Offers" subsection with the heading "Participant Acceptances of the ASOP-eligible Offer and Surrender of Rights through ASOP," to provide transparency into how instructions are inputted and processed through ATOP.

Pursuant to the proposed rule change, this subsection would briefly summarize how the ASOP system processes Participant instructions, stating that when a Participant submits an instruction to DTC for an ASOP-eligible Offer, such as an acceptance and surrender of rights, acceptance by submission of a notice of guaranteed delivery (protect), or a surrender of securities to cover a notice of

guaranteed delivery (cover of a protect), through ASOP, the ASOP system will typically (x) process the Participant submission, and in the case of an acceptance with surrender of rights or cover of a protect, effect a book-entry delivery of the Participant's subject position in the rights from Participant's account to the Agent ATOP/ASOP Account, (y) debit the required subscription payment from the Participant's account and credit the payment to the Agent ATOP/ASOP Account,¹⁴ (z) enter information about the submission (including the time of the Participant's submission into DTC) into ASOP and transmit an Agent's Message to the Agent that indicates the Participant's acceptance of the ASOP-eligible Offer and reflects the crediting of the required subscription payment to the Agent ATOP/ASOP Account, and, to the extent applicable, the book-entry delivery of the rights into the Agent ATOP/ASOP Account.

The subscription payment indicated on the Agent's Message is typically credited to the Agent ATOP/ASOP Account on the same day, except where the Agent agrees to, or the Terms and Conditions of the Offer provides for, different procedures with respect to payment. Once the funds are credited to the Agent ATOP/ASOP Account, the funds are usually wired to the Agent on the following business day.

M. Instructions To Surrender and Sell Rights Through ASOP

DTC is proposing to insert subsection VI.D.3.d. (iii) under the "ASOP-eligible Offers" subsection with the heading "Instructions to Surrender and Sell Rights Through ASOP," which would briefly describe the process through which a Participant could submit instructions to sell rights through ASOP.

Pursuant to the proposed rule change, the subsection would state that for any ASOP-eligible Offer on which the Agent accepts instructions to sell rights, when a Participant submits instructions to sell rights through the Agent by means of ASOP, the ASOP system will typically (x) process the Participant submission, (y) effect a book-entry delivery of the Participant's position in the subject rights from the Participant's account to the Agent ATOP/ASOP Account, (z) enter information about the submission (including the time of the Participant's submission into DTC) into ASOP, and transmit an Agent's Message to the Agent that indicates the Participant's instruction to sell rights and reflects the

¹⁴ Depending on the terms of the Offer, the subscription payment may be debited at the end of the Offer.

book-entry delivery of the rights into the Agent ATOP/ASOP Account.

2. Statutory Basis

Section 17A(b)(3)(F) of the Act¹⁵ requires, in part, that the Rules be designed to promote the prompt and accurate clearance and settlement of securities transactions. As described above, the proposed rule change to amend the OA would (i) insert consolidate and updated procedures, including for an enhanced Master Agreement, for ATOP/ASOP Agents, and (ii) make related technical and clarifying changes relating to ATOP-eligible Offers or ASOP-eligible Offers. DTC believes that these proposed changes would make the Agent's procedures for ATOP and ASOP more streamlined, transparent, and reflective of current processes, thereby allowing Agents to more efficiently and effectively process corporate action events and associated securities transactions. Based on the foregoing, DTC believes that the proposed rule change is designed to promote the prompt and accurate clearance and settlement of securities transactions, consistent with Section 17A(b)(3)(F) of the Act, cited above.

(B) Clearing Agency's Statement on Burden on Competition

DTC believes that the proposed rule change to amend the OA to (i) insert consolidated and updated procedures, including for an enhanced Master Agreement, for ATOP/ASOP Agents, and (ii) make related technical and clarifying changes relating to ATOP-eligible Offers or ASOP-eligible Offers will not have any impact on competition.¹⁶ The proposed rule change would provide procedures that are more accessible, transparent, and reflective of current processes and would apply to all ATOP/ASOP Agents equally. Any additional efforts required on the part of Agents would be merely administrative, such as entering a new Master Agreement. In light of the foregoing, DTC does not believe that the proposed rule change would impose a burden on competition.¹⁷

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

DTC has not received or solicited any written comments relating to this proposal. If any written comments are received, they would be publicly filed

as an Exhibit 2 to this filing, as required by Form 19b-4 and the General Instructions thereto.

Persons submitting comments are cautioned that, according to Section IV (Solicitation of Comments) of the Exhibit 1A in the General Instructions to Form 19b-4, the Commission does not edit personal identifying information from comment submissions. Commenters should submit only information that they wish to make available publicly, including their name, email address, and any other identifying information.

All prospective commenters should follow the Commission's instructions on how to submit comments, *available at* www.sec.gov/regulatory-actions/how-to-submit-comments. General questions regarding the rule filing process or logistical questions regarding this filing should be directed to the Main Office of the Commission's Division of Trading and Markets at tradingandmarkets@sec.gov or 202-551-5777.

DTC reserves the right to not respond to any comments received.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

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 and Rule 19b-4(f)(6) thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or

- Send an email to rule-comments@sec.gov. Please include File Number SR-DTC-2024-007 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR-DTC-2024-007. 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 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of DTC and on DTCC's website (<https://dtcc.com/legal/sec-rule-filings.aspx>). Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR-DTC-2024-007 and should be submitted on or before August 28, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-17389 Filed 8-6-24; 8:45 am]

BILLING CODE 8011-01-P

¹⁵ 15 U.S.C. 78q-1(b)(3)(F).

¹⁶ 15 U.S.C. 78q-1(b)(3)(I).

¹⁷ *Id.*

¹⁸ 17 CFR 200.30-3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–100636; File No. 4–618]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing and Order Approving and Declaring Effective an Amendment to the Plan for the Allocation of Regulatory Responsibilities Between Cboe BZX Exchange, Inc., Cboe BYX Exchange, Inc., BOX Exchange LLC, Cboe Exchange, Inc., Cboe C2 Exchange, Inc., NYSE Chicago, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., Long-Term Stock Exchange, Inc., MEMX LLC, Nasdaq ISE, LLC, Nasdaq GEMX, LLC, Nasdaq MRX, LLC, Investors Exchange LLC, Miami International Securities Exchange, LLC, MIAx PEARL, LLC, MIAx Emerald, LLC, MIAx Sapphire, LLC, The Nasdaq Stock Market LLC, Nasdaq BX, Inc., Nasdaq PHLX LLC, NYSE National, Inc., New York Stock Exchange LLC, NYSE American LLC, and NYSE Arca, Inc. Concerning Covered Regulation NMS and Consolidated Audit Trail Rules

August 1, 2024.

Notice is hereby given that the Securities and Exchange Commission (“Commission”) has issued an Order, pursuant to Section 17(d) of the Securities Exchange Act of 1934 (“Act”),¹ approving and declaring effective an amendment to the plan for allocating regulatory responsibility (“Plan”) filed on July 31, 2024, pursuant to Rule 17d–2 of the Act,² by Cboe BZX Exchange, Inc. (“BZX”), Cboe BYX Exchange, Inc. (“BATS Y”), BOX Exchange LLC (“BOX”), Cboe Exchange, Inc. (“Cboe”), Cboe C2 Exchange, Inc. (“C2”), NYSE Chicago, Inc. (“CHX”), Cboe EDGA Exchange, Inc. (“EDGA”), Cboe EDGX Exchange, Inc. (“EDGX”), Financial Industry Regulatory Authority, Inc. (“FINRA”), Long-Term Stock Exchange, Inc. (“LTSE”), MEMX LLC (“MEMX”), Nasdaq ISE, LLC (“ISE”), Nasdaq GEMX, LLC (“GEMX”), Nasdaq MRX, LLC (“MRX”), Investors Exchange LLC (“IEX”), Miami International Securities Exchange, LLC (“MIAx”), MIAx PEARL, LLC (“MIAx PEARL”), MIAx Emerald, LLC (“MIAx Emerald”), MIAx Sapphire, LLC (“MIAx Sapphire”), The Nasdaq Stock Market LLC (“Nasdaq”), Nasdaq BX, Inc. (“BX”), Nasdaq PHLX LLC (“PHLX”), NYSE National, Inc. (“NYSE National”), New York Stock Exchange

LLC (“NYSE”), NYSE American LLC (“NYSE American”), and NYSE Arca, Inc. (“NYSE Arca”) (each, a “Participating Organization,” and, together, the “Participating Organizations” or the “Parties”). This Agreement amends and restates the agreement by and among the Participating Organizations approved by the Commission on June 10, 2020.³

I. Introduction

Section 19(g)(1) of the Act,⁴ among other things, requires every self-regulatory organization (“SRO”) registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO’s own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d) or Section 19(g)(2) of the Act.⁵ Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO (“common members”). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act⁶ was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.⁷ With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.⁸ Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority (“DEA”) to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO

rules.⁹ When an SRO has been named as a common member’s DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO’s obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.¹⁰ Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for appropriate notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors; to foster cooperation and coordination among the SROs; to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system; and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On December 3, 2010, the Commission approved the SRO participants’ plan for allocating regulatory responsibilities pursuant to Rule 17d–2.¹¹ On October 29, 2015, the Commission approved an amended plan that added Regulation NMS Rules 606, 607, and 611(c) and (d) and added additional Participating Organizations that are options markets to the Plan.¹² On August 11, 2016, the Commission approved an amended plan that added IEX and ISE Mercury as Participating

³ See Securities Exchange Act Release No. 89042, 85 FR 36450 (June 16, 2020).

⁴ 15 U.S.C. 78s(g)(1).

⁵ 15 U.S.C. 78q(d) and 15 U.S.C. 78s(g)(2), respectively.

⁶ 15 U.S.C. 78q(d)(1).

⁷ See Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

⁸ 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

⁹ See Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

¹⁰ See Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

¹¹ See Securities Exchange Act Release No. 63430, 75 FR 76758 (December 9, 2010).

¹² See Securities Exchange Act Release No. 76311, 80 FR 68377 (November 4, 2015).

¹ 15 U.S.C. 78q(d).

² 17 CFR 240.17d–2.

Organizations.¹³ On February 2, 2017, the Commission approved an amended plan that added MIAX PEARL as a Participating Organization.¹⁴ On February 4, 2019, the Commission approved an amended plan that added MIAX Emerald as a Participating Organization and reflected name changes of certain Participating Organizations.¹⁵ On July 25, 2019, the Commission approved an amended plan that added LTSE as a Participating Organization and reflected name changes of certain Participating Organizations.¹⁶ On March 12, 2020, the Commission approved an amended plan that added Rule 613 under the Act and the rules of each Participating Organization related to Rule 613 listed on Exhibit A to the Plan, and reflected the name change of Nasdaq PHLX, Inc. to Nasdaq PHLX LLC.¹⁷ On June 10, 2020, the Commission approved a proposed amendment to the Plan to add MEMX as a Participant to the Plan.¹⁸

The proposed 17d–2 Plan is intended to reduce regulatory duplication for firms that are members of more than one Participating Organization.¹⁹ The Plan provides for the allocation of regulatory responsibility according to whether the covered rule pertains to NMS stocks or NMS securities. For covered rules that pertain to NMS stocks (*i.e.*, Rules 607, 611, and 612), FINRA serves as the “Designated Regulation NMS Examining Authority” (“DREA”) for common members that are members of FINRA and assumes certain examination and enforcement responsibilities for those members with respect to specified Regulation NMS rules. For common members that are not members of FINRA, the member’s DEA serves as the DREA and “Designated CAT Surveillance Authority” (“DCSA”), provided that the DEA exchange operates a national securities exchange or facility that trades NMS stocks and the common member is a member of such exchange or facility. Section 2(c) of the Plan contains a list of principles that are applicable to the allocation of common members in cases not specifically addressed in the Plan. An exchange that does not trade NMS

stocks would have no regulatory authority for covered Regulation NMS rules pertaining to NMS stocks. For covered rules that pertain to NMS securities, and thus include options (*i.e.*, Rule 606, Rule 613 and the SRO Covered CAT Rules), the Plan provides that the DREA will be the same as the DREA for the rules pertaining to NMS stocks and will serve as the DCSA. For common members that are not members of an exchange that trades NMS stocks, the common member would be allocated according to the principles set forth in Section 2(c) of the Plan.

The text of the Plan delineates the proposed regulatory responsibilities with respect to the Parties. Included in the proposed Plan is an exhibit (the “Covered Rules”) that lists the federal securities laws, rules, and regulations, for which the applicable DREA would bear examination and enforcement responsibility, and for which the applicable DCSA would bear surveillance, investigation, and enforcement responsibility, under the Plan for common members of the Participating Organization and their associated persons.

Specifically, the applicable DREA assumes examination and enforcement responsibility, and the applicable DCSA assumes surveillance, investigation, and enforcement responsibility, relating to compliance by common members with the Covered Rules. Covered Rules do not include the application of any rule of a Participating Organization, or any rule or regulation under the Act, to the extent that it pertains to violations of insider trading activities, because such matters are covered by a separate multiparty agreement under Rule 17d–2.²⁰ Under the Plan, Participating Organizations retain full responsibility for surveillance and enforcement with respect to trading activities or practices involving their own marketplace.²¹

III. Proposed Amendment to the Plan

On July 31, 2024, the parties submitted a proposed amendment to the Plan. The primary purpose of the amendment is to add MIAX Sapphire as a Participant to the Plan.

The text of the proposed amended 17d–2 Plan is as follows (additions are in *italics*; deletions are in [brackets]):

* * * * *

²⁰ See Securities Exchange Act Release No. 88948 (May 26, 2020), 85 FR 33239 (June 1, 2020) (File No. 4–566) (notice of filing and order approving and declaring effective an amendment to the insider trading 17d–2 plan).

²¹ See paragraph 3 of the Plan.

Agreement for the Allocation of Regulatory Responsibility for the Covered Regulation NMS and Consolidated Audit Trail Rules Pursuant to § 17(d) of the Securities Exchange Act of 1934, 15 U.S.C. 78q(d), and Rule 17d–2 Thereunder

This agreement (the “Agreement”) by and among Cboe BZX Exchange, Inc. (“Cboe BZX”), Cboe BYX Exchange, Inc. (“[BATS Y] Cboe BYX”), BOX Exchange LLC (“BOX”), Cboe Exchange, Inc. (“Cboe Options”), Cboe C2 Exchange, Inc. (“Cboe C2”), NYSE Chicago, Inc. (“CHX”), Cboe EDGA Exchange, Inc. (“Cboe EDGA”), Cboe EDGX Exchange, Inc. (“Cboe EDGX”), Financial Industry Regulatory Authority, Inc. (“FINRA”), MEMX LLC (“MEMX”), Nasdaq ISE, LLC (“ISE”), Nasdaq GEMX, LLC (“GEMX”), Nasdaq MRX, LLC (“MRX”), Investors Exchange LLC (“IEX”), Miami International Securities Exchange, LLC (“MIAX”), MIAX PEARL, LLC (“MIAX PEARL”), MIAX Emerald, LLC (“MIAX Emerald”), MIAX Sapphire, LLC (“MIAX Sapphire”), The Nasdaq Stock Market LLC (“Nasdaq”), Nasdaq BX, Inc. (“BX”), Nasdaq PHLX LLC (“PHLX”), NYSE National, Inc. (“NYSE National”), New York Stock Exchange LLC (“NYSE”), NYSE American LLC (“NYSE American”), NYSE Arca, Inc. (“NYSE Arca”) and Long-Term Stock Exchange, Inc. (“LTSE”) (each, a “Participating Organization,” and, together, the “Participating Organizations”), is made pursuant to § 17(d) of the Securities Exchange Act of 1934 (the “Act” or “SEA”), 15 U.S.C. 78q(d), and Rule 17d–2 thereunder, which allow for plans to allocate regulatory responsibility among self-regulatory organizations (“SROs”). Upon approval by the Securities and Exchange Commission (“Commission” or “SEC”), this Agreement shall amend and restate the agreement by and among the Participating Organizations approved by the SEC on [March 12] June 10, 2020.

Whereas, the Participating Organizations desire to: (a) foster cooperation and coordination among the SROs; (b) remove impediments to, and foster the development of, a national market system; (c) strive to protect the interest of investors; (d) eliminate duplication in their examination and enforcement of (i) SEA Rules 606, 607, 611, 612 and 613 (the “Covered Regulation NMS Rules”) and (ii) rules of each Participating Organization related to SEA Rule 613 listed on Exhibit A hereto (“SRO Covered CAT Rules,” together with the Covered Regulation NMS Rules, collectively, the “Covered Rules”) and (e) eliminate duplication in their surveillance, examination,

¹³ See Securities Exchange Act Release No. 78552, 81 FR 54905 (August 17, 2016).

¹⁴ See Securities Exchange Act Release No. 79928, 82 FR 9814 (February 8, 2017).

¹⁵ See Securities Exchange Act Release No. 85046, 84 FR 2643 (February 7, 2019).

¹⁶ See Securities Exchange Act Release No. 86470, 84 FR 37363 (July 31, 2019).

¹⁷ See Securities Exchange Act Release No. 88366, 85 FR 15238 (March 17, 2020).

¹⁸ See Securities Exchange Act Release No. 89042, 85 FR 36450 (June 16, 2020).

¹⁹ The proposed 17d–2 Plan refers to these members as “Common Members.”

investigation and enforcement of SEA Rule 613 and the SRO Covered CAT Rules;

Whereas, the Participating Organizations are interested in allocating regulatory responsibilities with respect to broker-dealers that are members of more than one Participating Organization (the “Common Members”) relating to the examination and enforcement of the Covered Rules and the surveillance, examination, investigation and enforcement of SEA Rule 613 and the SRO Covered CAT Rules; and

Whereas, the Participating Organizations will request regulatory allocation of these regulatory responsibilities by executing and filing with the SEC this plan for the above stated purposes pursuant to the provisions of § 17(d) of the Act, and Rule 17d–2 thereunder, as described below.

Now, therefore, in consideration of the mutual covenants contained hereafter, and other valuable consideration to be mutually exchanged, the Participating Organizations hereby agree as follows:

1. Assumption of Surveillance Responsibility. The Designated CAT Surveillance Authority (the “DCSA”) shall assume surveillance, investigation and enforcement responsibility relating to compliance by Common Members with SEA Rule 613 and the SRO Covered CAT Rules listed on Exhibit A (“Surveillance Responsibility”). Included in the Surveillance Responsibility assumed hereunder the DCSA shall perform investigations and enforcement resulting from reports and metrics concerning potentially non-compliant CAT reporting generated by the Plan Processor for the National Market System Plan Governing the Consolidated Audit Trail and as provided for in the Monitoring CAT Reporter Compliance Policy (dated August 13, 2019 and as amended from time to time) relating to Common Members. FINRA shall serve as DCSA for Common Members that are members of FINRA. The DREA allocated below shall serve as DCSA for Common Members that are not members of FINRA.

2. Assumption of Examination Responsibility. The Designated Regulation NMS Examining Authority (the “DREA”) shall assume examination and enforcement responsibilities relating to compliance by Common Members with the Covered Rules to which the DREA is allocated responsibility (“Examination Responsibility”). A list of the Covered Rules is attached hereto as Exhibit A.

a. For Covered Regulation NMS Rules Pertaining to “NMS stocks” (as defined in Regulation NMS) (*i.e.*, Rules 607, 611 and 612): FINRA shall serve as DREA for Common Members that are members of FINRA. The Designated Examining Authority (“DEA”) pursuant to SEA Rule 17d–1 shall serve as DREA (and accordingly as DCSA as provided in paragraph 1 above) for Common Members that are not members of FINRA, provided that the DEA operates a national securities exchange or facility that trades NMS stocks and the Common Member is a member of such exchange or facility. For all other Common Members, the Participating Organizations shall allocate Common Members among the Participating Organizations (other than FINRA) that operate a national securities exchange that trades NMS stocks based on the principles outlined below and the Participating Organization to which such a Common Member is allocated shall serve as the DREA for that Common Member. (A Participating Organization that operates a national securities exchange that does not trade NMS stocks has no regulatory responsibilities related to Covered Regulation NMS Rules [pertaining] *pertaining* to NMS stocks and will not serve as DREA for such Covered Regulation NMS Rules.)

b. For Covered Regulation NMS Rules Pertaining to “NMS securities” (as defined in Regulation NMS) (*i.e.*, Rule 606 and Rule 613) and the SRO Covered CAT Rules listed on Exhibit A hereto, the DREA shall be the same as the DREA for Covered Regulation NMS Rules pertaining to NMS stocks (and shall serve as the DCSA in paragraph 1 above). For Common Members that are not members of a national securities exchange that trades NMS stocks and thus have not been appointed a DREA under paragraph a., the Participating Organizations shall allocate the Common Members among the Participating Organizations (other than FINRA) that operate a national securities exchange that trades NMS securities based on the principles outlined below and the Participating Organization to which such a Common Member is allocated shall serve as the DREA for that Common Member with respect to Covered Regulation NMS Rules pertaining to NMS securities. The allocation of Common Members to DREAs (including FINRA) and accordingly to serve as DCSA in paragraph 1 above for all Covered Rules is provided in Exhibit B.

c. For purposes of this paragraph 2, any allocation of a Common Member to a Participating Organization other than

as specified in paragraphs a. and b. above shall be based on the following principles, except to the extent all affected Participating Organizations consent to one or more different principles and any such agreement to different principles would be deemed an amendment to this Agreement as provided in paragraph 24:

i. The Participating Organizations shall not allocate a Common Member to a Participating Organization unless the Common Member is a member of that Participating Organization.

ii. To the extent practicable, Common Members shall be allocated among the Participating Organizations of which they are members in such a manner as to equalize, as nearly as possible, the allocation among such Participating Organizations.

iii. To the extent practicable, the allocation will take into account the amount of NMS stock activity (or NMS security activity, as applicable) conducted by each Common Member in order to most evenly divide the Common Members with the largest amount of activity among the Participating Organizations of which they are a members. The allocation will also take into account similar allocations pursuant to other plans or agreements to which the Participating Organizations are party to maintain consistency in oversight of the Common Members.¹

iv. The Participating Organizations may reallocate Common Members from time-to-time and in such manner as they deem appropriate consistent with the terms of this Agreement.

v. Whenever a Common Member ceases to be a member of its DREA (including FINRA), the DREA shall promptly inform the Participating Organizations, who shall review the matter and reallocate the Common Member to another Participating Organization.

vi. The DEA or DREA (including FINRA) may request that a Common Member be reallocated to another Participating Organization (including the DEA or DREA (including FINRA)) by giving 30 days written notice to the Participating Organizations. The Participating Organizations shall promptly consider such request and, in their discretion, may approve or disapprove such request and if approved, reallocate the Common

¹ For example, if one Participating Organization was allocated responsibility for a particular Common Member pursuant to a separate Rule 17d–2 Agreement, that Participant Organization would be assigned to be the DREA of that Common Member, unless there is good cause not to make that assignment.

Member to such Participating Organization.

vii. All determinations by the Participating Organizations with respect to allocations shall be by the affirmative vote of a majority of the Participating Organizations that, at the time of such determination, share the applicable Common Member being allocated; a Participating Organization shall not be entitled to vote on any allocation related to a Common Member unless the Common Member is a member of such Participating Organization.

d. The Participating Organizations agree that they shall conduct meetings among them as needed for the purposes of ensuring proper allocation of Common Members and identifying issues or concerns with respect to the regulation of Common Members. To promote consistency in connection with regulation of Common Members, the Participating Organizations further agree to conduct meetings to discuss the overarching principles as to how Covered Rules, in particular SEA Rule 613 and the SRO Covered CAT Rules, should be surveilled, examined, investigated and enforced. On an ongoing basis, the Participating Organizations agree to consult with and solicit input from the Participating Organizations regarding their surveillance, examination, investigation and enforcement programs regarding SEA Rule 613 and the SRO Covered CAT Rules. In particular, FINRA will consult with Participating Organizations prior to finalizing its disposition and sanctions guidelines with respect to violations of SEA Rule 613 and the SRO Covered CAT Rules. Further, in the period preceding the full implementation of CAT for equities and options securities, FINRA will consult with other Participating Organizations prior to finalizing dispositions other than no further action that involve their Common Members.

e. By signing this Agreement, the Participating Organizations hereby certify that the list of SRO Covered CAT Rules listed on Exhibit A hereto are correct and are identical or substantially similar to each other.

f. Each year following the commencement date of operation of this Agreement, or more frequently if required by changes in any of the SRO Covered CAT Rules, each Participating Organization shall submit an updated list of SRO Covered CAT Rules to FINRA for review which shall (1) add SRO Covered CAT Rules not included in the current list of SRO Covered CAT Rules that are substantially similar to each other; (2) delete SRO Covered CAT Rules included in the current list that

are no longer substantially similar; and (3) confirm that the remaining rules on the current list of SRO Covered CAT Rules continue to be substantially similar. FINRA shall review each Participating Organization's annual certification and confirm whether FINRA agrees with the submitted certified and updated list of SRO Covered CAT Rules. The DREA/DCSA shall not have Regulatory Responsibility for any provision in a SRO Covered CAT Rule provision requiring a member of a Participating Organization to provide notice, reports or any other filings directly to a Participating Organization.

3. Scope of Responsibility. Notwithstanding anything herein to the contrary, it is explicitly understood that the terms "Surveillance Responsibility" and "Examination Responsibility" (collectively referred to herein as the "Regulatory Responsibility") do not include any responsibilities beyond those concerning the Covered Rules, and each of the Participating Organizations shall retain full responsibility for, examination, surveillance and enforcement with respect to trading activities or practices involving its own marketplace unless otherwise allocated pursuant to a separate Rule 17d-2 Agreement. The allocation of DCSA Responsibility to a Participating Organization shall not limit another Participating Organization's ability to utilize data from the Consolidated Audit Trail to perform examination, surveillance, investigative, enforcement or other regulatory work concerning potential or identified violations of statutes or rules other than the SRO Covered CAT Rules.

4. No Retention of Regulatory Responsibility. The Participating Organizations do not contemplate the retention of any responsibilities with respect to the regulatory activities being assumed by the DREA/DCSA under the terms of this Agreement. Nothing in this Agreement will be interpreted to prevent a DREA/DCSA from entering into Regulatory Services Agreement(s) to perform its Regulatory Responsibility.

5. No Charge. A DREA/DCSA shall not charge Participating Organizations for performing the Regulatory Responsibility under this Agreement.

6. Applicability of Certain Laws, Rules, Regulations or Orders. Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the SEC. To the extent such statute, rule, or order is inconsistent with one or more provisions of this Agreement, the statute, rule, or order shall supersede the provision(s) hereof to the extent necessary to be properly effectuated and

the provision(s) hereof in that respect shall be null and void.

7. Customer Complaints. If a Participating Organization receives a copy of a customer complaint relating to a DREA's/DCSA's Regulatory Responsibility as set forth in this Agreement, the Participating Organization shall promptly forward to such DREA/DCSA a copy of such customer complaint. It shall be such DREA's/DCSA's responsibility to review and take appropriate action in respect to such complaint.

8. Parties to Make Personnel Available as Witnesses. Each Participating Organization shall make its personnel available to the DREA/DCSA to serve as testimonial or non-testimonial witnesses as necessary to assist the DREA/DCSA in fulfilling the Regulatory Responsibility allocated under this Agreement. The DREA/DCSA shall provide reasonable advance notice when practicable and shall work with a Participating Organization to accommodate reasonable scheduling conflicts within the context and demands as the entity with ultimate regulatory responsibility. The Participating Organization shall pay all reasonable travel and other expenses incurred by its employees to the extent that the DREA/DCSA requires such employees to serve as witnesses, and provide information or other assistance pursuant to this Agreement.

9. Sharing of Work-Papers, Data and Related Information.

a. Sharing. A Participating Organization shall make available to the DREA/DCSA information necessary to assist the DREA/DCSA in fulfilling the Regulatory Responsibility assumed under the terms of this Agreement. Such information shall include *any* information collected by a Participating Organization in the course of performing its regulatory obligations under the Act, including information relating to an on-going disciplinary investigation or action against a member, the amount of a fine imposed on a member, financial information, or information regarding proprietary trading systems gained in the course of examining a member ("Regulatory Information"). This Regulatory Information shall be used by the DREA/DCSA solely for the purposes of fulfilling the DREA's/DCSA's Regulatory Responsibility.

b. No Waiver of Privilege. The sharing of documents or information between the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges relating to the discovery of documents or information.

10. Special or Cause Examinations and Enforcement Proceedings. Nothing in this Agreement shall restrict or in any way encumber the right of a Participating Organization to conduct special or cause examinations of a Common Member, or take enforcement proceedings against a Common Member as a Participating Organization, in its sole discretion, shall deem appropriate or necessary.

11. Dispute Resolution Under this Agreement.

a. Negotiation. The Participating Organizations will attempt to resolve any disputes through good faith negotiation and discussion, escalating such discussion up through the appropriate management levels until reaching the executive management level. In the event a dispute cannot be settled through these means, the Participating Organizations shall refer the dispute to binding arbitration.

b. Binding Arbitration. All claims, disputes, controversies, and other matters in question between the Participating Organizations to this Agreement arising out of or relating to this Agreement or the breach thereof that cannot be resolved by the Participating Organizations will be resolved through binding arbitration. Unless otherwise agreed by the Participating Organizations, a dispute submitted to binding arbitration pursuant to this paragraph shall be resolved using the following procedures:

(i) The arbitration shall be conducted in a city selected by the DREA/DCSA in which it maintains a principal office or where otherwise agreed to by the Participating Organizations in accordance with the Commercial Arbitration Rules of the American Arbitration Association and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof; and

(ii) There shall be three arbitrators, and the chairperson of the arbitration panel shall be an attorney. The arbitrators shall be appointed in accordance with the Commercial Arbitration Rules of the American Arbitration Association.

12. Limitation of Liability. As between the Participating Organizations, no Participating Organization, including its respective directors, governors, officers, employees and agents, will be liable to any other Participating Organization, or its directors, governors, officers, employees and agents, for any liability, loss or damage resulting from any delays, inaccuracies, errors or omissions with respect to its performing or failing to perform regulatory

responsibilities, obligations, or functions, except: (a) as otherwise provided for under the Act; (b) in instances of a Participating Organization's gross negligence, willful misconduct or reckless disregard with respect to another Participating Organization; or (c) in instances of a breach of confidentiality obligations owed to another Participating Organization. The Participating Organizations understand and agree that the regulatory responsibilities are being performed on a good faith and best effort basis and no warranties, express or implied, are made by any Participating Organization to any other Participating Organization with respect to any of the responsibilities to be performed hereunder. This paragraph is not intended to create liability of any Participating Organization to any third party.

13. SEC Approval.

a. The Participating Organizations agree to file promptly this Agreement with the SEC for its review and approval. FINRA shall file this Agreement on behalf, and with the explicit consent, of all Participating Organizations.

b. If approved by the SEC, the Participating Organizations will notify their members of the general terms of the Agreement and of its impact on their members.

14. Subsequent Parties; Limited Relationship. This Agreement shall inure to the benefit of and shall be binding upon the Participating Organizations hereto and their respective legal representatives, successors, and assigns. Nothing in this Agreement, expressed or implied, is intended or shall: (a) confer on any person other than the Participating Organizations hereto, or their respective legal representatives, successors, and assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement, (b) constitute the Participating Organizations hereto partners or participants in a joint venture, or (c) appoint one Participating Organization the agent of the other.

15. Assignment. No Participating Organization may assign this Agreement without the prior written consent of the DREAs/DCSAs performing Regulatory Responsibility on behalf of such Participating Organization, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that any Participating Organization may assign the Agreement to a corporation controlling, controlled by or under common control with the Participating Organization without the prior written

consent of such Participating Organization's DREAs/DCSAs. No assignment shall be effective without Commission approval.

16. Severability. Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

17. Termination. Any Participating Organization may cancel its participation in the Agreement at any time upon the approval of the Commission after 180 days written notice to the other Participating Organizations (or in the case of a change of control in ownership of a Participating Organization, such other notice time period as that Participating Organization may choose). The cancellation of its participation in this Agreement by any Participating Organization shall not terminate this Agreement as to the remaining Participating Organizations.

18. General. The Participating Organizations agree to perform all acts and execute all supplementary instruments or documents that may be reasonably necessary or desirable to carry out the provisions of this Agreement.

19. Written Notice. Any written notice required or permitted to be given under this Agreement shall be deemed given if sent by certified mail, return receipt requested, or by a comparable means of electronic communication to each Participating Organization entitled to receipt thereof, to the attention of the Participating Organization's representative at the Participating Organization's then principal office or by email.

20. Confidentiality. The Participating Organizations agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations under this Agreement, provided, however, that each Participating Organization may disclose such documents or information as may be required to comply with applicable regulatory requirements or requests for information from the SEC. Any Participating Organization disclosing confidential documents or information in compliance with applicable regulatory or oversight requirements will request confidential treatment of such information. No

Participating Organization shall assert regulatory or other privileges as against the other with respect to Regulatory Information that is required to be shared pursuant to this Agreement.

21. **Regulatory Responsibility.** Pursuant to Section 17(d)(1)(A) of the Act, and Rule 17d-2 thereunder, the Participating Organizations request the SEC, upon its approval of this Agreement, to relieve the Participating Organizations which are participants in this Agreement that are not the DREA or DCSA as to a Common Member of any and all responsibilities with respect to the matters allocated to the DREA or DCSA pursuant to this Agreement for purposes of §§ 17(d) and 19(g) of the Act.

22. **Governing Law.** This Agreement shall be deemed to have been made in the State of New York, and shall be construed and enforced in accordance with the law of the State of New York, without reference to principles of conflicts of laws thereof. Each of the Participating Organizations hereby consents to submit to the jurisdiction of the courts of the State of New York in connection with any action or proceeding relating to this Agreement.

23. **Survival of Provisions.** Provisions intended by their terms or context to survive and continue notwithstanding delivery of the regulatory services by the DREA/DCSA and any expiration of this Agreement shall survive and continue.

24. **Amendment.**

a. This Agreement may be amended to add a new Participating Organization, provided that such Participating Organization does not assume regulatory responsibility, by an amendment executed by all applicable DREAs/DCSAs and such new Participating Organization. All other Participating Organizations expressly consent to allow such DREAs/DCSAs to jointly add new Participating Organizations to the Agreement as provided above. Such DREAs/DCSAs will promptly notify all Participating Organizations of any such amendments to add a new Participating Organization.

b. All other amendments must be approved by each Participating Organization. All amendments, including adding a new Participating Organization but excluding changes to Exhibit B, must be filed with and approved by the Commission before they become effective.

25. **Effective Date.** The Effective Date of this Agreement will be the date the SEC declares this Agreement to be effective pursuant to authority conferred by § 17(d) of the Act, and Rule 17d-2 thereunder.

26. **Counterparts.** This Agreement may be executed in any number of counterparts, including facsimile, each of which will be deemed an original, but all of which taken together shall constitute one single agreement among the Participating Organizations.

* * * * *

EXHIBIT A

Covered Rules

Covered Regulation NMS Rules

SEA Rule 606—Disclosure of Order Routing Information.*

SEA Rule 607—Customer Account Statements.

SEA Rule 611—Order Protection Rule.

SEA Rule 612—Minimum Pricing Increment.

SEA Rule 613(g)(2)—Consolidated Audit Trail.*

* Covered Regulation NMS Rules with asterisks (*) pertain to NMS securities. Covered Regulation NMS Rules without asterisks pertain to NMS stocks.

SRO Covered CAT Rules

Cboe BZX—Rules 4.5–4.16

Cboe BYX [BATS-Y]—Rules 4.5–4.16

BOX—Rules 16020–16095

Cboe Options—Rules 7.20–7.31

Cboe C2—Chapter 7, Section B (only with respect to incorporation of Cboe Rules 7.20–7.31)

Cboe EDGA—Rules 4.5–4.16

Cboe EDGX—Rules 4.5–4.16

FINRA—Rules 6810–6895

IEX—Rules 11.610–11.695

MEMX Rules 4.5–4.16

MIAX—Rules 1701–1712

MIAX PEARL—Rules 1701–1712

MIAX Emerald—Rules 1701–1712

MIAX Sapphire—Rules 1701–1712

Nasdaq—General 7, Sections 1–13

BX Equities Rules—General 7

PHLX—General 7

ISE—General 7 GEMX—General 7

MRX—General 7

NYSE—Rules 6810–6895

NYSE Arca—Rules—11.6810–11.6895

NYSE American—Rules 6810–6895

NYSE Chicago—Rules 6810–6895

NYSE National—Rules 6.6810–6.6895

LTSE—Rules 11.610–11.695

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. 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 4–618 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 4–618. 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 plan that are filed with the Commission, and all written communications relating to the proposed plan 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 plan also will be available for inspection and copying at the principal offices of the Participating Organizations. 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 4–618 and should be submitted on or before August 28, 2024.

V. Discussion

The Commission finds that the Plan, as amended, is consistent with the factors set forth in Section 17(d) of the Act²² and Rule 17d-2(c) thereunder²³ in that the proposed amended Plan is necessary or appropriate in the public interest and for the protection of investors, fosters cooperation and coordination among SROs, and removes impediments to and fosters the development of the national market system. In particular, the Commission believes that the proposed amended Plan should reduce unnecessary regulatory duplication by allocating to the applicable DREA certain examination and enforcement responsibilities, and to the applicable DCSA certain surveillance, investigation, and enforcement

²² 15 U.S.C. 78q(d).

²³ 17 CFR 240.17d-2(c).

responsibilities, for Common Members that would otherwise be performed by multiple Parties. Accordingly, the proposed amended Plan promotes efficiency by reducing costs to Common Members. Furthermore, because the Parties will coordinate their regulatory functions in accordance with the proposed amended Plan, the amended Plan should promote investor protection.

The Commission is hereby declaring effective a plan that allocates regulatory responsibility for certain provisions of the federal securities laws, rules, and regulations as set forth in Exhibit A to the Plan. The Commission notes that any amendment to the Plan must be approved by the relevant Parties as set forth in Paragraph 24 of the Plan and must be filed with and approved by the Commission before it may become effective.²⁴

Under paragraph (c) of Rule 17d-2, the Commission may, after appropriate notice and comment, declare a plan, or any part of a plan, effective. In this instance, the Commission believes that appropriate notice and comment can take place after the proposed amendment is effective. In particular, the purpose of the amendment is to add MIAX Sapphire as a Participating Organization. The Commission notes that the most recent prior amendment to the Plan was published for comment and the Commission did not receive any comments thereon.²⁵ The Commission believes that the current amendment to the Plan does not raise any new regulatory issues that the Commission has not previously considered, and therefore believes that the amended Plan should become effective without any undue delay.

VI. Conclusion

This Order gives effect to the Plan filed with the Commission in File No. 4-618. The Parties shall notify all members affected by the Plan of their rights and obligations under the Plan.

It is therefore ordered, pursuant to Section 17(d) of the Act, that the Plan in File No. 4-618 is hereby approved and declared effective.

It is further ordered that the Parties who are not the DREA or DCSA as to a particular Common Member are relieved of those regulatory responsibilities allocated to the Common Member's

DREA or DCSA under the Plan to the extent of such allocation.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁶

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-17388 Filed 8-6-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100633; File No. SR-NYSENAT-2024-22]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify Rule 7.31

August 1, 2024.

Pursuant to Section 19(b)(1) ¹ of the Securities Exchange Act of 1934 ("Act") ² and Rule 19b-4 thereunder,³ notice is hereby given that on July 25, 2024, NYSE National, Inc. ("NYSE National" or the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I 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 modify Rule 7.31 regarding MPL-ALO Orders. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31 regarding MPL-ALO Orders.

Rule 7.31(d)(3) defines a Mid-Point Liquidity Order ("MPL Order") as a Limit Order to buy (sell) that is not displayed and does not route, with a working price at the lower (higher) of the midpoint of the PBBO or its limit price. An MPL Order is ranked Priority 3—Non-Display Orders and is valid for any session.

Rule 7.31(d)(3)(A) provides that an MPL Order to buy (sell) must be designated with a limit price in the MPV for the security and will be eligible to trade at the working price of the order.

Rule 7.31(d)(3)(B) provides that if there is no PBB, PBO, or the PBBO is locked or crossed, both an arriving and resting MPL Order will wait for a PBBO that is not locked or crossed before being eligible to trade. If a resting MPL Order to buy (sell) trades with an MPL Order to sell (buy) after there is an unlocked or uncrossed PBBO, the MPL Order with the later working time will be the liquidity-removing order.

Rule 7.31(d)(3)(C) provides that an Aggressing MPL Order to buy (sell) will trade at the working price of resting orders to sell (buy) when such resting orders have a working price at or below (above) the working price of the MPL Order. Resting MPL Orders to buy (sell) will trade against all Aggressing Orders to sell (buy) priced at or below (above) the working price of the MPL Order.

Rule 7.31(d)(3)(D) provides that an MPL Order may be designated IOC ("MPL-IOC Order"). Subject to such IOC instructions, an MPL-IOC Order will follow the same trading and priority rules as an MPL Order, expect that an MPL-IOC Order will be rejected if there is no PBBO or the PBBO is locked or crossed. An MPL-IOC Order cannot be designated ALO or with a Non-Display Remove Modifier.

Rule 7.31(d)(3)(E) and the subparagraphs thereunder define the MPL-ALO Order, which is an MPL Order designated with an ALO Modifier.⁴ An Aggressing⁵ MPL-ALO

⁴ An ALO Order is a Non-Routable Limit Order that, unless it receives price improvement, will not remove liquidity from the Exchange Book. See NYSE National Rule 7.31(e)(2).

⁵ An "Aggressing Order" is a buy (sell) order that is or becomes marketable against sell (buy) interest on the Exchange Book. A resting order may become an Aggressing Order if its working price changes,

Continued

²⁴ See Paragraph 24 of the Plan. The Commission notes, however, that changes to Exhibit B to the Plan (the allocation of Common Members to DREAs) are not required to be filed with, and approved by, the Commission before they become effective.

²⁵ See Securities Exchange Act Release No. 89042 (June 10, 2020), 85 FR 36450 (June 16, 2020).

²⁶ 17 CFR 200.30-3(a)(34).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

Order to buy (sell) will trade at the working price of resting orders to sell (buy) when such resting orders have a working price below (above) the less aggressive of the midpoint of the PBBO or the limit price of the MPL-ALO Order, but will not trade with resting orders to sell (buy) priced equal to the less aggressive of the midpoint of the PBBO or the limit price of the MPL-ALO Order (Rule 7.31(d)(3)(E)(i)). If an MPL-ALO Order to buy (sell) cannot trade with a same-priced resting order to sell (buy), a subsequently arriving order to sell (buy) eligible to trade at the working price of the MPL-ALO Order will trade ahead of a resting order to sell (buy) that is not displayed at that price; if such resting order to sell (buy) is displayed, the MPL-ALO Order to buy (sell) will not be eligible to trade at that price (Rule 7.31(d)(3)(E)(ii)). An MPL-ALO Order may not be designated with a Non-Display Remove Modifier (Rule 7.31(d)(3)(E)(iii)).

Proposed Rule Change

Currently, Aggressing MPL-ALO Orders to buy (sell) may trade with resting orders priced below (above) the less aggressive of the midpoint of the PBBO or the limit price of the MPL-ALO Order (*i.e.*, priced below (above) the MPL-ALO Order's working price), regardless of the amount of price improvement the Aggressing MPL-ALO Order would receive. The Exchange proposes to amend Rule 7.31(d)(3)(E)(i) to provide that an Aggressing MPL-ALO Order would only be eligible to trade with resting orders when it would receive price improvement over the MPL-ALO Order's working price of at least one MPV. This proposed change would not impact non-Aggressing MPL-ALO Orders (*e.g.*, MPL-ALO Orders resting on the Exchange Book). A non-Aggressing MPL-ALO Order would continue to provide liquidity at its working price unless it would not be eligible to trade as outlined in Rules 7.31(d)(3)(E)(ii)(a) and (b), as amended below.

The Exchange next proposes to amend Rule 7.31(d)(3)(E)(ii) to provide that an MPL-ALO Order not eligible to trade as described in proposed Rule 7.31(d)(3)(E)(i) would be ranked in the Exchange Book at its working price and would not trade at that price if it would lock or cross displayed interest or cross non-displayed interest on the Exchange Book. Specifically, the Exchange proposes to add new Rules

7.31(d)(3)(E)(ii)(a) and (b) to provide that resting MPL-ALO Orders would not be eligible to trade (a) at a price equal to or above (below) any sell (buy) orders that are displayed and that have a working price equal to or below (above) the working price of the MPL-ALO Order, or (b) at a price above (below) any sell (buy) orders that are not displayed and that have a working price below (above) the working price of the MPL-ALO Order. The Exchange notes that the circumstances under which such orders would not be able to trade are consistent with the Exchange's existing priority and ranking rules.

The Exchange further proposes to renumber current Rule 7.31(d)(3)(E)(ii) as Rule 7.31(d)(3)(E)(iii) and to amend the text of the rule to provide that if an MPL-ALO Order to buy (sell) cannot trade with a same-priced resting order to sell (buy) that is not displayed, a subsequently arriving order to sell (buy) eligible to trade at the working price of the MPL-ALO Order will trade ahead of such resting order to sell (buy). This proposed change is not intended to change the meaning of the rule, but rather to clarify that, if an MPL-ALO Order is resting at the same price as resting non-displayed interest, a subsequently arriving order that is eligible to trade with that MPL-ALO Order would, as currently, be permitted to trade ahead of such interest. The Exchange further proposes to delete the last sentence of current Rule 7.31(d)(3)(E)(ii), which provides that an MPL-ALO Order would not be eligible to trade at the price of a displayed resting order to buy (sell), as duplicative of proposed Rule 7.31(d)(3)(E)(ii)(a) described above.

The following example demonstrates how an arriving Aggressing MPL-ALO Order would trade or be ranked on the Exchange Book, as proposed:

- Assume the PBBO⁶ is \$10.00 × \$10.05 (midpoint is \$10.025). On the Exchange Book, there is a Limit Order to sell 90 shares at \$10.02 ("Order 1") and an MPL Order to sell 100 shares at \$10.00 ("Order 2"). Order 1 is displayed at its working price of \$10.02. Order 2 is non-displayed and has a working price at the midpoint, \$10.025.
- Order 3 is an incoming MPL-ALO Order to buy 100 shares at \$10.05. Order 3, as an Aggressing MPL-ALO Order, would not trade with either Order 1 or Order 2 because it would receive less

than \$0.01 price improvement over the midpoint. Pursuant to proposed Rule 7.31(d)(3)(E)(ii), Order 3 would be ranked on the Exchange Book at its working price, \$10.025 (which is the midpoint, as the working price of an MPL-ALO Order to buy is the lower of the midpoint or the order's limit price).

- Order 4 is an incoming MPL-IOC Order to sell 100 shares at \$10.00. Order 4 would not trade with Order 3 (which is now ranked on the Exchange Book at its working price) at \$10.025 per proposed Rule 7.31(d)(3)(E)(ii)(a) because an execution at that price would be at a price above displayed interest on the Exchange Book (Order 1 at \$10.02). Order 4, as an IOC Order, would be cancelled because it does not execute.

- Assume Order 1 is cancelled, and Order 5 is an incoming MPL-IOC Order to sell 100 shares at \$10.00. Order 5 would trade with Order 3 (where Order 3 is the liquidity provider) at \$10.025, consistent with proposed Rule 7.31(d)(3)(E)(iii), because the trade would execute at a price that is not above the price of any displayed or non-displayed interest on the Exchange Book, although it would be at the same price as Order 2 (non-displayed interest on the Exchange Book).⁷

The following example demonstrates how an MPL-ALO Order that is resting on the Exchange Book and subsequently becomes an Aggressing MPL-ALO Order (in this example, when the PBBO is updated) would trade, as proposed:

- Assume the PBBO is \$10.00 × \$10.05 (midpoint is \$10.025). Order 1 is a non-displayed Limit Order to sell 100 shares at \$10.03, resting on the Exchange Book at its working price of \$10.03. Order 2 is an MPL-ALO Order to buy 100 shares at \$10.05. Order 2 is resting non-displayed on the Exchange Book at its working price of \$10.025 (which is the midpoint, as the working price of an MPL-ALO Order to buy is the lower of the midpoint or the order's limit price).
- Assume the PBBO updates to \$10.03 × \$10.05 (midpoint is \$10.04). Order 2 reprices to the new midpoint, \$10.04, and becomes an Aggressing Order because its working price has changed and the PBBO has updated. Order 2 will trade as an Aggressing Order (as the liquidity taker) with Order 1 at \$10.03 because it would receive

if the PBBO or NBBO is updated, because of changes to other orders on the Exchange Book, or when processing inbound messages. See Rule 7.36(a)(5).

⁶ "Best Protected Bid" or "PBB" means the highest Protected Bid, "Best Protected Offer" or "PBO" means the lowest Protected Offer, and "Protected Best Bid and Offer" or "PBBO" means the Best Protected Bid and the Best Protected Offer, as those terms are defined in Rule 600(b)(57) of Regulation NMS. See Rule 1.1(t).

⁷ As noted above, Rule 7.31(d)(3)(E)(iii), as amended, reflects current Rule 7.31(d)(3)(E)(ii), which provides that an MPL-ALO Order that is resting at the same price as resting non-displayed interest would be permitted to trade with a subsequently arriving order that is eligible to trade with that MPL-ALO Order, ahead of the non-displayed interest.

\$0.01 price improvement over its working price.

Finally, the Exchange proposes to renumber current Rule 7.31(d)(3)(E)(iii) as Rule 7.31(d)(3)(E)(iv) to reflect the addition of the new rule text described above, without any changes to the text of the rule.

The Exchange believes that the proposed change, which would allow an Aggressing MPL–ALO Order to trade only when it would receive price improvement over its working price of at least one MPV, would promote higher-quality executions for ETP Holders and provide ETP Holders with greater certainty regarding the amount of price improvement such executions would receive, thereby encouraging increased order flow to the Exchange and enhanced opportunities for order execution for all market participants. The Exchange notes that evaluating the economic benefit of an execution is not a novel concept on equity exchanges.⁸ Accordingly, the Exchange believes that this proposed change, which would consider the amount of price improvement that an Aggressing MPL–ALO Order would receive upon execution, would offer ETP Holders a similar benefit to that available on at least one other equity exchange for an order type similar to the MPL–ALO Order and could thus promote competition among equity exchanges.

Because of the technology changes associated with this proposed rule change, the Exchange will announce the implementation date by Trader Update, which, subject to effectiveness of this proposed rule change, will be no later than in the fourth quarter of 2024.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,⁹ in general, and furthers the objectives of Section 6(b)(5),¹⁰ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in 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.

⁸ See, e.g., Nasdaq Stock Market LLC, Equity 4, Rule 4702(b)(5)(A) (defining the Midpoint Peg Post-Only Order, which is priced at the midpoint between the NBBO and will execute upon entry only in circumstances where economically beneficial to the party entering such order).

⁹ 15 U.S.C. 78f(b).

¹⁰ 15 U.S.C. 78f(b)(5).

The Exchange believes that the proposed change would promote just and equitable principles of trade, remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and protect investors and the public interest because allowing an Aggressing MPL–ALO Order to trade only when it would receive price improvement over its working price of at least one MPV would promote higher-quality executions for ETP Holders, thereby encouraging increased order flow to the Exchange and enhanced trading opportunities for all market participants. The Exchange also believes that the proposed conforming changes to Rule 7.31(d)(3)(E) would remove impediments to, and perfect the mechanism of, a free and open market and a national market system, and protect investors and the public interest by clarifying how Aggressing MPL–ALO Orders that would not be eligible to trade based on the amount of price improvement would be ranked and would trade once resting, in accordance with the Exchange's priority and ranking rules. Finally, the Exchange notes that considering the economic benefit of an execution is not a novel concept and believes that this proposed change would remove impediments to, and perfect the mechanism of, a free and open market and a national market system by providing ETP Holders with greater certainty as to the amount of price improvement they would receive when an Aggressing MPL–ALO Order executes, as well as by promoting competition among equity exchanges.¹¹

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 proposed rule change would amend Exchange rules to permit Aggressing MPL–ALO Orders to trade only when they would receive price improvement of at least one MPV over their working price, thereby providing a minimum amount of price improvement for ETP Holders entering such orders. To the extent the proposed rule change promotes higher-quality executions on the Exchange, the proposed change could encourage increased order flow to the Exchange and facilitate additional trading opportunities for all market participants. In addition, at least one other equity exchange considers the economic benefit to the entering party

when evaluating whether a similar order type may trade, and the Exchange's proposal would thus promote competition among exchanges by providing a minimum amount of price improvement to Aggressing MPL–ALO Orders.¹² The Exchange also believes that, to the extent the proposed change would increase opportunities for order execution, the proposed change would promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

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 after the date of the filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, it has become effective pursuant to Section 19(b)(3)(A) of the Act¹³ and Rule 19b–4(f)(6)¹⁴ thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)¹⁵ normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),¹⁶ the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange is requesting the waiver because it will allow the Exchange to implement the proposed change as soon as the associated technology is available, which is anticipated to be less than 30 days from

¹² See note 8, *supra*.

¹³ 15 U.S.C. 78s(b)(3)(A).

¹⁴ 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.

¹⁵ 17 CFR 240.19b–4(f)(6).

¹⁶ 17 CFR 240.19b–4(f)(6)(iii).

¹¹ See note 8, *supra*.

the date of this filing. The Exchange believes the proposed change would provide member organizations with greater certainty regarding the amount of price improvement their Aggressing MPL-ALO Orders would receive, thereby promoting higher-quality executions and encouraging increased order flow to the Exchange for the benefit of all market participants. For these reasons, and because the proposed rule change does not raise any novel legal or 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 30-day operative delay and designates the proposal operative upon filing.¹⁷

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSENAT-2024-22 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSENAT-2024-22. 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-NYSENAT-2024-22 and should be submitted on or before August 28, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁸

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2024-17385 Filed 8-6-24; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-100638; File No. SBSDR-2023-01]

Security-Based Swap Data Repositories; KOR Reporting, Inc.; Notice of Filing of Application for Registration as a Security-Based Swap Data Repository

August 2, 2024.

I. Introduction

On January 26, 2023, KOR Reporting, Inc. ("KOR") filed with the Securities and Exchange Commission ("Commission") an application on Form SDR to register as a security-based swap data repository ("SDR") pursuant to section 13(n)(1) of the Securities Exchange Act of 1934 ("Exchange Act") and 17 CFR 240.13n-1 ("Rule 13n-1") thereunder,¹ and as a securities

information processor ("SIP") under section 11A(b) of the Exchange Act.² KOR intends to operate as a registered SDR for security-based swap ("SBS") transactions in the equity, credit, and interest rate derivatives asset classes. KOR subsequently filed amendments to its application on the following dates: August 11, 2023, and February 23, 2024.³ The Commission is publishing this notice to solicit comments from interested persons regarding KOR's application,⁴ and the Commission will consider any comments it receives in making its determination whether to approve KOR's application for registration as an SDR and as a SIP.

II. Background

A. SDR Registration, Duties, and Core Principles

Section 13(n) of the Exchange Act makes it unlawful for any person, unless registered with the Commission, directly or indirectly, to make use of the mails or any means or instrumentality of interstate commerce to perform the functions of an SDR.⁵ To be registered and maintain registration, an SDR must comply with certain requirements and core principles described in section 13(n), as well as any requirements that the Commission may impose by rule or regulation.⁶ In 2015, the Commission adopted 17 CFR 240.13n-1 to 13n-12 under the Exchange Act to establish Form SDR, the procedures for registration as an SDR, and the duties and core principles applicable to an SDR ("SDR Rules").⁷ The Commission provided a temporary exemption from compliance with the SDR Rules and also extended exemptions from the provisions of the Dodd-Frank Act set forth in a Commission order providing temporary exemptions and other temporary relief from compliance with certain provisions of the Exchange Act concerning security-based swaps, and

confidential exhibits thereto are available for public viewing on the Commission's website.

² 15 U.S.C. 78k-1(b).

³ The amendments to KOR's application were filed to update certain exhibits, including those addressing the disclosure document, financial statements, and fee schedule.

⁴ The descriptions set forth in this notice regarding the structure and operations of KOR have been derived, excerpted, or summarized from KOR's application on Form SDR.

⁵ 15 U.S.C. 78m(n).

⁶ See *id.*

⁷ See Release No. 34-74246 (Feb. 11, 2015), 80 FR 14438, 14438 (Mar. 19, 2015) ("SDR Adopting Release"). In 2016, the Commission subsequently amended 17 CFR 240.13n-4 to address third-party regulatory access to SBS data obtained by an SDR. See Release No. 34-78716 (Aug. 29, 2016), 81 FR 60585 (Sept. 2, 2016).

¹⁷ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

¹⁸ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78m(n)(1); 17 CFR 240.13n-1. A copy of KOR's application on Form SDR and non-

these temporary exemptions expired in 2017.⁸

The Commission also has adopted 17 CFR 242.900 to 909 under the Exchange Act (collectively, “Regulation SBSR”), which governs regulatory reporting and public dissemination of security-based swap transactions.⁹ Among other things, Regulation SBSR requires each registered SDR to register with the Commission as a SIP,¹⁰ and the Form SDR constitutes an application for registration as a SIP, as well as an SDR.¹¹

In 2019, the Commission stated that implementation of the SBS Reporting Rules can and should be done in a manner that carries out the fundamental policy goals of the SBS Reporting Rules while minimizing burdens as much as practicable.¹² Noting ongoing concerns among market participants about incurring unnecessary burdens and the Commission’s efforts to promote harmonization between the SBS Reporting Rules and swap reporting rules, the Commission took the position that, for four years following Regulation SBSR’s Compliance Date 1 in each asset class,¹³ certain actions with respect to the SBS Reporting Rules would not provide a basis for a Commission enforcement action.¹⁴ The no-action statement’s relevance to KOR’s application for registration as an SDR and SIP is discussed further below.

B. Standard for Registration

As noted above, to be registered with the Commission as an SDR and maintain such registration, an SDR is required to comply with the requirements and core principles described in section 13(n) of the Exchange Act, as well as with any requirement that the Commission may

impose by rule or regulation.¹⁵ In addition, Rule 13n–1(c)(3) under the Exchange Act provides that the Commission shall grant the registration of an SDR if it finds that the SDR is so organized, and has the capacity, to be able to: (i) assure the prompt, accurate, and reliable performance of its functions as an SDR; (ii) comply with any applicable provisions of the securities laws and the rules and regulations thereunder; and (iii) carry out its functions in a manner consistent with the purposes of section 13(n) of the Exchange Act and the rules and regulations thereunder.¹⁶ The Commission shall deny the registration of an SDR if it does not make any such finding.¹⁷ Similarly, to be registered with the Commission as a SIP, the Commission must find that such applicant is so organized, and has the capacity, to be able to assure the prompt, accurate, and reliable performance of its functions as a SIP, comply with the provisions of the Exchange Act and the rules and regulations thereunder, carry out its functions in a manner consistent with the purposes of the Exchange Act, and, insofar as it is acting as an exclusive processor, operate fairly and efficiently.¹⁸

In determining whether an applicant meets the criteria set forth in Rule 13n–1(c), the Commission will consider the information reflected by the applicant on its Form SDR, as well as any additional information obtained from the applicant. For example, Form SDR requires an applicant to provide a list of the asset classes for which the applicant is collecting and maintaining data or for which it proposes to collect and maintain data, a description of the functions that it performs or proposes to perform, general information regarding its business organization, and contact information.¹⁹ Obtaining this information and other information reflected on Form SDR and the exhibits thereto—including the applicant’s overall business structure, financial condition, track record in providing access to its services and data, technological reliability, and policies and procedures to comply with its statutory and regulatory obligations—will enable the Commission to determine whether to grant or deny an application for registration.²⁰

Furthermore, the information requested in Form SDR will enable the Commission to assess whether the applicant is so organized and has the capacity to comply and carry out its functions in a manner consistent with the Federal securities laws and the rules and regulations thereunder, including the SBS Reporting Rules.²¹

Consistent with the Commission’s no-action statement in the ANE Adopting Release,²² an entity wishing to register with the Commission as an SDR must still submit an application on Form SDR but can address the rule provisions included in the no-action statement by discussing how the SDR complies with comparable Commodity Futures Trading Commission (“CFTC”) requirements.²³ Accordingly, in such instances the Commission will not assess an SDR application for consistency or compliance with the rule provisions included in the Commission’s no-action statement. Specifically, the Commission identified the following provisions as not providing a basis for an enforcement action against a registered SDR for the duration of the relief provided in the Commission statement: under Regulation SBSR, aspects of 17 CFR 242.901(a), 901(c)(2) through (7), 901(d), 901(e), 902, 903(b), 906(a) and (b), and 907(a)(1), (a)(3), and (a)(4) through (6); under the SDR Rules, aspects of section 13(n)(5)(B) of the Exchange Act and 17 CFR 240.13n–4(b)(3) thereunder, and aspects of 17 CFR 240.13n–5(b)(1)(iii); and under section 11A(b) of the Exchange Act, any provision pertaining to SIPs.²⁴ Thus, an SDR applicant will not need to include materials in its application explaining how it would comply with the provisions noted above, and could instead rely on its discussion about how it complies with comparable CFTC requirements.²⁵ The applicant may instead represent in its application that it: (i) is registered with the CFTC as a swap data repository; (ii) is in compliance with applicable requirements under the swap reporting rules; (iii) satisfies the standard for Commission registration of an SDR under Rule 13n–1(c); and (iv) intends to rely on the no-action statement included in the ANE Adopting Release for the period set forth in the ANE Adopting Release with respect to any SBS asset

⁸ See Release No. 34–80359 (Mar. 31, 2017), 82 FR 16867 (Apr. 6, 2017).

⁹ Release No. 34–74244 (Feb. 11, 2015), 80 FR 14563 (Mar. 19, 2015); Release No. 34–78321 (July 14, 2016), 81 FR 53546 (Aug. 12, 2016). Regulation SBSR and the SDR Rules are referred to collectively as the “SBS Reporting Rules.”

¹⁰ See 17 CFR 242.909.

¹¹ See Form SDR, Instruction 2.

¹² Release No. 34–87780 (Dec. 18, 2019), 85 FR 6270, 6347 (Feb. 4, 2020) (“ANE Adopting Release”).

¹³ See *id.* Under Regulation SBSR, the first compliance date (“Compliance Date 1”) for affected persons with respect to an SBS asset class is the first Monday that is the later of: (i) six months after the date on which the first SDR that can accept transaction reports in that asset class registers with the Commission; or (ii) one month after the compliance date for registration of SBS dealers and major SBS participants (“SBS entities”). *Id.* at 6346. The compliance date for registration of SBS entities is Oct. 6, 2021. See *id.* at 6270, 6345.

¹⁴ See *id.* The specific rule provisions of the SBS Reporting Rules affected by the no-action statement are discussed in Part II.B.

¹⁵ See 15 U.S.C. 78m(n)(3).

¹⁶ 17 CFR 240.13n–1(c)(3).

¹⁷ See *id.*

¹⁸ See 15 U.S.C. 78k–1(b)(3).

¹⁹ See SDR Adopting Release, *supra* note 7, at 14459.

²⁰ See *id.* at 14458.

²¹ See *id.* at 14458–59.

²² See *supra* notes 12–14 and accompanying text.

²³ See *supra* note 14.

²⁴ The ANE Adopting Release provides additional discussion of the particular aspects of the affected rules that would not provide a basis for an enforcement action. See ANE Adopting Release, *supra* note 12, at 6347–48.

²⁵ See *id.* at 6348.

class or classes for which it intends to accept transaction reports.²⁶

III. Summary of KOR's Application on Form SDR

As noted above, KOR intends to operate as a registered SDR for the equity, credit, and interest rate derivatives asset classes.²⁷ In its application, KOR represents that it is provisionally registered with the CFTC as a swap data repository,²⁸ is in compliance with applicable requirements under the CFTC reporting rules applicable to a registered swap data repository, and intends to rely on the Commission's position outlined in the ANE Adopting Release for applicable reporting rules and SDR duties for the period set forth therein.²⁹ Below is an overview of the representations made in the application materials regarding the KOR security-based swap data repository ("KOR SBSDR").

A. Organization and Governance

KOR is a Delaware corporation and along with its affiliate, KOR Financial Inc. ("KOR Financial"), is a wholly owned subsidiary of KOR US Holdings, Inc. ("KOR Holdings").³⁰ KOR is governed by a board of directors ("KOR Board").³¹ The KOR Board is comprised of at least three Directors with a majority being independent Directors and at least one director being a "Public Director" as defined in applicable CFTC regulations.³² According to the KOR Rulebook, KOR board members should have the characteristics essential for effectiveness as a member of the Board, including but not limited to: (a) integrity, objectivity, sound judgment and leadership; (b) the relevant expertise and experience required to offer advice and guidance to the Chief Executive Officer and other members of senior management; (c) the ability to

make independent analytical inquiries; (d) the ability to collaborate effectively and contribute productively to the Board's discussions and deliberations; (e) an understanding of the company's business, strategy and challenges; (f) the willingness and ability to devote adequate time and effort to Board responsibilities and to serve on Committees at the request of the Board; and (g) not being a disqualified person.³³ The KOR Board is composed of individuals selected from the following groups: employees of KOR, clients with derivatives industry experience, independents, and members of senior management.³⁴ The KOR Board will review annually the relationships that each Director has with KOR (either directly or as a partner, equity holder or officer of an organization that has a relationship with KOR).³⁵ According to KOR, following such annual review, only those Directors who the KOR Board affirmatively determines have no material relationship with KOR (either directly or as a partner, equity holder or officer of an organization that has a relationship with KOR) will be considered Independent Directors, subject to additional qualifications prescribed by applicable law.³⁶

According to KOR, the KOR Board's principal oversight functions are to: (a) review, approve, and monitor KOR's major strategic financial business activities and opportunities, including declarations of dividends and major transactions; (b) review, approve and monitor the KOR's annual budget; (c) review, monitor and take reasonable actions with respect to KOR's financial performance; (d) review, assess, and provide oversight of KOR's risk management practices, the integrity and adequacy of its enterprise risk management program, which is designed to identify, manage, and plan for its Security-based Swap Data Repository, compliance, financial, operational, reputational, and strategic and commercial risks; (e) select, evaluate and compensate the Chief Compliance Officer and, if necessary,

appoint a replacement; and (f) review and monitor plans for the succession of the Chief Executive Officer and other members of senior management.³⁷

In addition, the application provides that the KOR Board is responsible for the appointment and removal of the chief compliance officer ("CCO") and approval of CCO compensation, which is at the discretion of the Board and effected by a majority vote.³⁸ The CCO is responsible for overseeing the KOR SBSDR Compliance Department and ensuring compliance with the applicable rules.³⁹ The CCO consults with the CEO on the adequacy of resources and makes recommendations where needed.⁴⁰ The CCO has supervisory authority to inspect books and records and interview KOR SBSDR employees. Upon identification of a potential violation of any regulatory requirement or internal policy or procedure, the CCO is responsible for taking steps to investigate and remediate any such matter.⁴¹

According to KOR, the KOR Board has adopted a Conflict of Interest Policy that incorporates various provisions of applicable corporate law and other standards adopted by KOR to ensure that KOR Board and committee decisions are not impacted by conflicts of interests.⁴² With regard to director conflicts of interest, the application provides that a director conflict is present whenever the interests of KOR compete with the interests of a director or any party associated with a director and interfere with the director's ability to impartially vote on the matter pending before the KOR Board.⁴³ A director's interest may be direct or indirect through business investment or on "immediate family member" (defined as a person's spouse, domestic partner, parents, stepparents, children, stepchildren, siblings, mothers and fathers-in-law, sons and daughter-in-law and brothers and sisters-in-law and anyone residing in such person's home

²⁶ See *id.* For example, an applicant need not describe in Exhibit S its functions as a SIP.

²⁷ See Rulebook, Ex. HH, sec. 0.1; see also Form SDR.

²⁸ See 17 CFR 49.3(b) (providing that the CFTC may grant provisional registration of a swap data repository if such applicant is in substantial compliance with the standards set forth in 17 CFR 49.3(a)(4) and is able to demonstrate operational capability, real-time processing, multiple redundancy and robust security controls); 17 CFR 49.3(a)(4) (setting forth the standard for approval for granting registration to a swap data repository).

²⁹ See Form SDR, cover letter from Tara Collier Manuel, Chief Compliance Officer and Head of Regulatory Products, KOR Reporting, Inc.

³⁰ See Rulebook, Ex. HH, sec. 0.1; see also Form SDR; KOR Reporting Inc Certificate of Incorporation, Ex. E-1, sec. 1.0.

³¹ See KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 9.0.

³² See Rulebook, Ex. HH, sec. 3.2.2; see also Bylaws for KOR Reporting, Inc., Ex. E-2, sec. 1.6.

³³ See Rulebook, Ex. HH, sec. 3.2.3; see also Governance Principles, Ex. D-1, sec. 3.4.1; KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 9.1.2.3.

³⁴ See Rulebook, Ex. HH, sec. 3.2.2; see also Governance Principles, Ex. D-1, sec. 3.2.

³⁵ See Rulebook, Ex. HH, sec. 3.2.4; see also Governance Principles, Ex. D-1, sec. 3.5; KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 9.1.2.4.

³⁶ See Rulebook, Ex. HH, sec. 3.2.4; see also Governance Principles, Ex. D-1, sec. 3.5; Narrative explaining fitness standards of the Board, Ex. D-3, sec. 3.0; KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 9.1.2.4.

³⁷ See Rulebook, Ex. HH, sec. 3.1.1; see also Governance Principles, Ex. D-1, sec. 2.0; KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 9.1.1.1.

³⁸ See Rulebook, Ex. HH, sec. 12.1; see also Governance Principles, Ex. D-1, sec. 14.2.

³⁹ See Rulebook, Ex. HH, sec. 12.2; see also Personnel Qualification, Ex. P, sec. 2.2.

⁴⁰ See Rulebook, Ex. HH, sec. 12.2.

⁴¹ See Rulebook, Ex. HH, sec. 12.2.

⁴² See Rulebook, Ex. HH, sec. 3.2.5; see also Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 1.0; Governance Principles, Ex. D-1, sec. 4.0; KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 9.1.2.5.

⁴³ See Rulebook, Ex. HH, sec. 11.2; see also Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 2.0.

(other than a tenant or employee)).⁴⁴ The application also provides that any director who believes he or she may have a conflict of interest relating to a matter pending before the KOR Board or any Committee must provide written notification to the CCO, General Counsel, the Board Chairman, and the CEO prior to consideration of the matter by the KOR Board or Committee.⁴⁵ The notice should include all relevant material facts to enable the KOR Board or Board Committee, in consultation with the CCO, General Counsel and outside legal counsel, if necessary, to determine whether a conflict of interest exists.⁴⁶

The application further provides that in the event the KOR Board or Committee determines the director has a conflict of interest or the appearance of a conflict of interest, the KOR Board or Committee, after consultation with the General Counsel and outside legal counsel, if necessary, shall determine the appropriate action to be taken.⁴⁷ As a general matter, KOR believes it is appropriate for a director to abstain from voting on a matter in which he or she has an actual conflict of interest or the appearance of a conflict of interest.⁴⁸ The recusal from voting shall be mandatory when it is deemed appropriate.⁴⁹ In the event a director abstains because of a conflict of interest, the abstention shall be noted in the minutes of the meeting.⁵⁰ In addition to this policy, directors who serve on any committee established under KOR's rules must also follow the procedure set forth in the applicable Rulebook.⁵¹

B. Access and Information Security

According to KOR, access to and usage of its SDR service will be available to all market participants on a fair, open, and equal basis.⁵² The application provides that KOR does not and will not bundle or tie the offering of mandated regulatory services with ancillary services offered by KOR or a

KOR affiliate.⁵³ Further, KOR imposes the following qualification on clients of its services: (i) a valid Legal Entity Identifier ("LEI"), (ii) execution of membership documents, such as the KOR Universal Services Agreement ("KOR SA")⁵⁴ and applicable Addendums, (iii) compliance with the KOR SBSDR Rulebook and KOR Technical Specifications as published by KOR, and (iv) successful passing of KOR Know Your Customer (KYC) procedures, which include compliance with Applicable Law, specifically those related to sanctions administered and enforced by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("OFAC").⁵⁵

To be granted access to the KOR system, receive trade information, confirm or verify transactions, submit messages, or receive reports, a market participant must be an onboarded user.⁵⁶ Users are required to maintain at least two Administrative Users on the KOR System; Administrative Users are responsible for creating, managing, and removing access to their company's Users and to other Clients who are eligible to access the KOR System on behalf of the Client including firms that have Third-party Client access.⁵⁷

To participate in the SDR services offered by KOR, each client will be required to enter into a KOR SA; by entering into the KOR SA each client agrees to be bound by the terms of the KOR SA, the KOR Rulebook, and any published policies and guides.⁵⁸ In addition, the KOR Rulebook provides that where a client has authorized (i) a Delegated Reporter (a Third-Party Reporter or Related Entity Client under the same Parent) to submit on its behalf and access its data or (ii) a Third-Party Client to access its data, but not submit on its behalf, KOR will provide access to the Delegated Reporter or Third-Party Client so long as it has executed the appropriate KOR SA and applicable addendums and the client has granted

permission through the Client Portal.⁵⁹ Any market participant that has executed a Client Agreement may access SBSDR Data to which they are a party or for which they have been granted access on behalf of a client.⁶⁰ Access to the KOR System is strictly limited to active Users with valid permissions created by their Client's Administrative User.⁶¹ Once set up, Users will be provided logins and the ability to access data in the KOR System.⁶² Access is driven off the Client's LEIs for which the User has been associated.⁶³ Users may be granted access to multiple LEIs under the same Parent as related entities.⁶⁴ Client's designated Administrative Users are expected to maintain correct User access at all times.⁶⁵ In addition, following the end of each calendar quarter, all Clients will have access to a report on current User access levels and a list of all Clients to which they have granted access to their data.⁶⁶ At least one of the designated Administrative Users assigned to each Client must review the listing of Users and other party access and confirm whether access should be maintained, removed or changed and make the appropriate updates.⁶⁷ The KOR Rulebook also states that records of all User access are maintained and available for review by the Client and KOR Compliance at all time.⁶⁸

With respect to prohibiting or limiting a person's access to SDR services, the KOR Rulebook outlines the process required for KOR to decline, revoke, or suspend a user of SDR services.⁶⁹ For example, KOR's CCO may deny a client's access to the KOR system if required pursuant to applicable law (e.g., OFAC or the direction of a regulator), violation of KOR SBSDR Rules, or improper use of the system.⁷⁰ The KOR Rulebook provides that KOR

⁴⁴ See Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 3.0.

⁴⁵ See Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 3.0.

⁴⁶ See Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 3.0.

⁴⁷ See Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 3.0.

⁴⁸ See Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 3.0.

⁴⁹ See Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 3.0.

⁵⁰ See Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 3.0.

⁵¹ See Board of Directors Conflicts of Interest Policy, Ex. J-2, sec. 3.0.

⁵² See Rulebook, Ex. HH, sec. 4.1; *see also* Access Limiting Criteria, Ex. V, sec. 1.0; Client Access Requirements, Ex. W, sec. 2.1; Client Onboarding and Access Guide, Ex. X, sec. 1.0.

⁵³ See Rulebook, Ex. HH, sec. 4.1; *see also* Access Limiting Criteria, Ex. V, sec. 1.0; Client Access Requirements, Ex. W, sec. 2.1; Client Onboarding and Access Guide, Ex. X, sec. 1.0.

⁵⁴ See KOR Universal Services Agreement, Ex. I-2.

⁵⁵ See Rulebook, Ex. HH, sec. 4.1; *see also* Access Limiting Criteria, Ex. V, sec. 1.0; Client Access Requirements, Ex. W, sec. 2.1; Client Onboarding and Access Guide, Ex. X, sec. 1.0; KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 1.1.

⁵⁶ See Rulebook, Ex. HH, sec. 4.0; *see also* Client Onboarding and Access Guide, Ex. X, sec. 2.0.

⁵⁷ See Rulebook, Ex. HH, sec. 4.5.1; *see also* Client Onboarding and Access Guide, Ex. X, sec. 3.1; KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 1.5.1.

⁵⁸ See Rulebook, Ex. HH, sec. 4.2; *see also* Client Access Requirements, Ex. W, sec. 2.2; Client Onboarding and Access Guide, Ex. X, sec. 3.0.

⁵⁹ See Rulebook, Ex. HH, sec. 4.3, 4.4; *see also* Client Access Requirements, Ex. W, sec. 2.3, 2.4.

⁶⁰ See Rulebook, Ex. HH, sec. 4.5.2; *see also* Access Limiting Criteria, Ex. V, sec. 1.0.

⁶¹ See Rulebook, Ex. HH, sec. 4.5.2; *see also* Access Limiting Criteria, Ex. V, sec. 1.0.

⁶² See Rulebook, Ex. HH, sec. 4.5.2; *see also* Access Limiting Criteria, Ex. V, sec. 1.0.

⁶³ See Rulebook, Ex. HH, sec. 4.5.2; *see also* Access Limiting Criteria, Ex. V, sec. 1.0.

⁶⁴ See Rulebook, Ex. HH, sec. 4.5.2; *see also* Access Limiting Criteria, Ex. V, sec. 1.0.

⁶⁵ See Rulebook, Ex. HH, sec. 4.5.4; *see also* Client Onboarding and Access Guide, Ex. X, sec. 3.1.

⁶⁶ See Rulebook, Ex. HH, sec. 4.5.4.

⁶⁷ See Rulebook, Ex. HH, sec. 4.5.4.

⁶⁸ See Rulebook, Ex. HH, sec. 4.5.4.

⁶⁹ See Rulebook, Ex. HH, sec. 14.2; *see also* Denial, Revocation, or Suspension of Client Access Policy, Ex. Y, sec. 2.2.

⁷⁰ See Rulebook, Ex. HH, sec. 14.2; *see also* Denial, Revocation, or Suspension of Client Access Policy, Ex. Y, sec. 2.2.

will notify the applicable regulator of such action.⁷¹ In addition, any such clients would receive written notice containing the grounds for determination and an opportunity to appeal the decision to the CCO and KOR Board by written request.⁷² KOR may restore access to a Client following approval from the CCO and/or KOR Board.⁷³ The CCO will consider the applicable law, regulatory requirements, and the Market Participant's response to the cause of denial, revocation, or suspension.⁷⁴ In addition, all decisions will be documented when determining whether to restore Client's access.⁷⁵

The KOR Rulebook provides that KOR SBSDR will conduct regular, periodic, objective testing and review of its automated systems to ensure that they are reliable, secure, and have adequate scalable capacity.⁷⁶ It also provides that KOR will conduct regular, periodic testing and review of its business continuity-disaster recovery capabilities.⁷⁷ It also provides that KOR will, to the extent practicable: (a) coordinate with Clients and service providers to participate in synchronized testing in a manner adequate to enable effective resumption of KOR SBSDR's fulfillment of its duties and obligations following a disruption causing activation of KOR SBSDR's Business Continuity and Disaster Recovery (BCDR) plan; (b) participate in periodic, synchronized testing of its BCDR Plan and the BCDR plans of its Clients, and the BCDR plans required, as applicable, by each appropriate prudential regulator, the Financial Stability Oversight Council, the Securities and Exchange Commission, the Department of Justice or any other person deemed appropriate by the SEC; and (c) ensure that its BCDR plan take into account the BCDR plans of its telecommunications, power, water, and other essential service providers.⁷⁸

C. Acceptance and Use of SBS Data

According to KOR, data accepted and maintained by the SBSDR may not be used for commercial or business purposes by the SBSDR or any of its

affiliated entities.⁷⁹ KOR SBSDR has implemented adequate "firewalls" or controls to protect the reported SBSDR data required to be maintained under SEC regulations from any improper commercial use.⁸⁰ The application provides that a Client that submits SBSDR data maintained by the SBSDR may permit the commercial use by providing express written consent. Such consent will not be a requirement to report to the SBSDR.⁸¹ If such Client consent is given, KOR may not make such consented data available for commercial use prior to its public dissemination.⁸² KOR states that, in accordance with Exchange Act Rule 13n-5(b)(5), it has established systems and User access restrictions reasonably designed to prevent any provision in a valid swap from being invalidated or modified through its verification or recording process.⁸³

KOR SBSDR uses the LEI and the Unique Trade Identifier ("UTI").⁸⁴ Pursuant to KOR's rulebook, individuals not eligible for an LEI should be reported using a Natural Person Identifier.⁸⁵ KOR states that if a security-based swap counterparty is not eligible to receive an LEI as determined by the Global Legal Entity Identifier System, such counterparty will be identified in all recordkeeping and all Security-Based Swap Data reporting with a Natural Person Identifier.⁸⁶ KOR further provides that it is the duty of the Reporting Side to always submit a unique and consistent Natural Person Identifier.⁸⁷ Pursuant to KOR's rulebook, to ensure that the Reporting Side consistently submits a unique value for the identifier, the Reporting Side must combine the LEI of the Reporting Side with the natural person's email address associated with the National Person Identifier.⁸⁸ Each Client must maintain and renew its legal identity identifier in accordance with the standards set by the Global Legal Entity Identifier System.⁸⁹

The application provides that each swap will be identified in all recordkeeping and all Security-Based

Swap Data reporting by the use of a UTI, which will be created, transmitted, and used for each swap.⁹⁰ Each registered entity and swap counterparty will include the UTI for a swap in all of its records and all of its Security-Based Swap Data reporting concerning that swap, from the time it creates or receives the UTI throughout the existence of the security-based swap and for as long as any records are required by applicable law or regulation.⁹¹ Every submission to KOR SBSDR must contain the appropriate UTI, otherwise the submission will be rejected. KOR SBSDR will validate the format and uniqueness of every UTI.⁹² If a party submits the incorrect UTI, pursuant to KOR's rulebook, they must "error" that UTI and resubmit the swap as a new message with the correct UTI.⁹³ When the correct UTI is submitted it will be considered a new trade and, if it is submitted after the required reporting timelines, it will be classified as a late report.⁹⁴

The application provides that KOR has established procedures and provides facilities for effectively resolving disputes over the accuracy of the SBSDR Transaction Data and positions that are recorded in the KOR SBSDR.⁹⁵ When the Reporting Side does not agree with the accuracy of the reporting of a swap in KOR Trade Repository, but is prevented from amending the swap to what they believe to be accurate, the Client must (a) enter a ticket with KOR SBSDR support with the details of the issue and (b) submit an allowed value per the KOR Technical Specifications for the KOR SBSDR field that reflects the dispute.⁹⁶

D. Fees

The application includes KOR's fee schedules.⁹⁷ According to KOR, fees are assessed in a consistent, non-preferential manner and are not permitted to be used as a barrier to entry.⁹⁸ KOR offers a subscription model fee schedule which treats all submissions equally regardless of reporting counterparty, asset class,

⁷¹ See Rulebook, Ex. HH, sec. 14.2; *see also* Denial, Revocation, or Suspension of Client Access Policy, Ex. Y, sec. 2.2.

⁷² See Rulebook, Ex. HH, sec. 14.2; *see also* Denial, Revocation, or Suspension of Client Access Policy, Ex. Y, sec. 2.2.

⁷³ See Denial, Revocation, or Suspension of Client Access Policy, Ex. Y, sec. 2.3.

⁷⁴ See Denial, Revocation, or Suspension of Client Access Policy, Ex. Y, sec. 2.3.

⁷⁵ See Denial, Revocation, or Suspension of Client Access Policy, Ex. Y, sec. 2.3.

⁷⁶ See Rulebook, Ex. HH, sec. 13.3.1.

⁷⁷ See Rulebook, Ex. HH, sec. 13.3.1.

⁷⁸ See Rulebook, Ex. HH, sec. 13.3.2.

⁷⁹ See KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 5.0.

⁸⁰ See KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 5.0.

⁸¹ See KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 5.0.

⁸² See KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 5.0.

⁸³ See Rulebook, Ex. HH, sec. 9.2; *see also* Data Invalidation Policy, Ex. EE, sec. 1.0.

⁸⁴ See Rulebook, Ex. HH, sec. 5.1.1, 5.1.2.

⁸⁵ See Rulebook, Ex. HH, sec. 5.1.1.

⁸⁶ See Rulebook, Ex. HH, sec. 5.3.1.

⁸⁷ See Rulebook, Ex. HH, sec. 5.3.1.

⁸⁸ See Rulebook, Ex. HH, sec. 5.3.1.

⁸⁹ See Rulebook, Ex. HH, sec. 5.3.1.

⁹⁰ See Rulebook, Ex. HH, sec. 5.2.

⁹¹ See Rulebook, Ex. HH, sec. 5.2.

⁹² See Rulebook, Ex. HH, sec. 5.2.

⁹³ See Rulebook, Ex. HH, sec. 5.2.

⁹⁴ See Rulebook, Ex. HH, sec. 5.2.

⁹⁵ See Rulebook, Ex. HH, sec. 11.0; *see also* Dispute Policy, Ex. CC, sec. 2.0.

⁹⁶ See Rulebook, Ex. HH, sec. 11.0; *see also* Dispute Policy, Ex. CC, sec. 2.0.

⁹⁷ See KOR SEC SBSDR Fee Schedule, Ex. M-1. Additionally, KOR provides a fee schedule for KOR Users on its website at <https://www.korfinancial.com/pricing>.

⁹⁸ See Rulebook, Ex. HH, sec. 13.4; *see also* KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 8.0.

clearing status or execution.⁹⁹ The application provides that KOR will not offer preferential pricing arrangements to any Client on any basis, including volume discounts or reductions unless such discounts or reductions apply to all Clients uniformly and are not otherwise established in a manner that would effectively limit the application of such discount or reduction to a select number of Clients.¹⁰⁰ In addition, KOR represents in its rulebook that it ensures any dues, fees, or other charges imposed by, and any discounts or rebates offered by, its SBSDR are fair and reasonable and not unreasonably discriminatory.¹⁰¹ KOR states that such dues, fees, other charges, discounts, or rebates will be applied consistently across all similarly-situated users of such SBSDR services, including, but not limited to, market participants, market infrastructures (including central counterparties), venues from which data can be submitted to the SBSDR (including exchanges, security-based swap execution facilities, electronic trading venues, and matching and confirmation platforms), and third party service providers.¹⁰² All fees are fully disclosed and available on the KOR SBSDR website.¹⁰³ The fee schedule applies until such time as the KOR Board determines otherwise and provides clients at least one (1) month's notice for significant changes to existing pricing or policy.¹⁰⁴

In the application, KOR states that, as a real-time messaging-based service, KOR assesses fees on a per message basis to align SBSDR services and the expense to offer.¹⁰⁵ All Reporting Clients are assessed the same fee structure regardless of their pathway to KOR SBSDR to ensure a competitive and level playing field.¹⁰⁶ A "Reporting Client" means the reporting counterparty that has in place a fully executed agreement and is liable for the fees incurred for the use of KOR

Services.¹⁰⁷ The Reporting Client may delegate billing and payments to another Client by authorizing either a Related Entity or their Third-Party Reporter.¹⁰⁸ The "Related Entity" refers to other clients of KOR (*i.e.*, KOR Counterparty Clients) within the same corporate structure as the Reporting Client, creating a Client Group.¹⁰⁹ KOR will aggregate the fee liable activity for Related Entities under a Client Group and provide a single invoice.¹¹⁰ A "Third-Party Reporter" refers to an entity that has a fully executed Agreement with KOR and is facilitating reporting for a KOR Counterparty Client.¹¹¹ A Third-Party Reporter is not charged fees for the activity of their customers, who are also KOR Counterparty Clients, but may be assigned billing (receipt of invoices and payment responsibilities) by KOR Counterparty Clients.¹¹² When a Counterparty Client makes a billing assignment to a Third-Party Reporter it is for all billable activity related to use of KOR Services of that Counterparty Client (including activity beyond what is associated to the Third-Party Reporter) and Counterparty Clients may only assign billing to a single Third-Party Reporter.¹¹³ The application provides that reporting by Platforms which are Security-Based Swap Execution Facilities or National Securities Exchanges are treated as messages under a Third-Party Reporter whereby the Reporting Counterparty is assessed KOR reporting fees and the Platform, by default, is not.¹¹⁴ A Platform may elect to assume direct billing responsibility for any Reporting Counterparty that is a KOR Counterparty Client.¹¹⁵ If the Reporting Counterparty on a Platform reported transaction is not a KOR Counterparty Client, the Platform reporter will be billed for the message activity which will be aggregated with all other Platform billable message activity.¹¹⁶

KOR SBSDR offers simplified subscription plans where each tier plan limits the maximum number of messages a Reporting Client may report per month.¹¹⁷ To calculate the calendar monthly fee, KOR totals all eligible messages submitted in the prior month for each Counterparty Client or Client Group. KOR provides a 10% monthly overage allowance across all tiers for any given month per Counterparty Client or Client Group.¹¹⁸ KOR's subscription plan is organized into ten (10) tiers. Tier 1 allows for 100 monthly messages produced with a monthly fee of \$100; Tier 2 allows for 1,000 monthly messages produced with a monthly fee of \$500; Tier 3 allows for 10,000 monthly messages produced with a monthly fee of \$2,000; Tier 4 allows for 100,000 monthly messages produced with a monthly fee of \$6,000; Tier 5 allows for 1,000,000 monthly messages produced with a monthly fee of \$15,000; Tier 6 allows for 4,000,000 monthly messages produced with a monthly fee of \$36,000; Tier 7 allows for 9,000,000 monthly messages produced with a monthly fee of \$60,000; Tier 8 allows for 14,000,000 monthly messages produced with a monthly fee of \$95,000; Tier 9 allows for 19,000,000 monthly messages produced with a monthly fee of \$150,000; and Tier 10 allows for 24,000,000 monthly messages produced with a monthly fee of \$220,000.¹¹⁹

KOR SBSDR is a 100% cloud service leveraging the performance and scale available through the cloud infrastructure.¹²⁰ KOR incurs costs through the accessing of its Clients' data hosted and used to generate trade reports requested by Clients.¹²¹ The application states that the KOR SBSDR Fee Schedule is designed for simplicity and flexibility, modeling an expected mix of scheduled access to standard reports in addition to reasonable use of ad-hoc reporting.¹²² KOR will monitor the generation of reports across each Client and KOR will provide advice when it observes use that exceeds standard fair allowances.¹²³ KOR states that should a Client need continued reports at a sustained activity level higher than expected, a move to a higher

⁹⁹ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 1.0; *see also* Fee Schedule Rational and Differentiation, Ex. M-2, sec. 1.3.

¹⁰⁰ See Rulebook, Ex. HH, sec. 13.4; *see also* KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 8.0.

¹⁰¹ See Rulebook, Ex. HH, sec. 13.4; *see also* KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 8.0.

¹⁰² See Rulebook, Ex. HH, sec. 13.4.

¹⁰³ See Rulebook, Ex. HH, sec. 13.4; *see also* KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 8.0.

¹⁰⁴ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 1.0.

¹⁰⁵ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 1.0.

¹⁰⁶ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 1.0.

¹⁰⁷ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.1.

¹⁰⁸ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.1, 2.2.

¹⁰⁹ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.1, 2.2.

¹¹⁰ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.1, 2.2.

¹¹¹ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.3.

¹¹² See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.3.

¹¹³ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.3.

¹¹⁴ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.4.

¹¹⁵ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.4.

¹¹⁶ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 2.4.

¹¹⁷ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 3.0.

¹¹⁸ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 3.0.

¹¹⁹ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 3.0.

¹²⁰ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 3.2.

¹²¹ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 3.2.

¹²² See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 3.2.

¹²³ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 3.2.

fee tier may be deemed appropriate.¹²⁴ KOR will generate invoices by the fifth (5th) day of every calendar month for the prior month's activity.¹²⁵ The billing currency is USD (\$) and invoices must be paid in USD.¹²⁶ Invoices are payable within 45 days upon receipt.¹²⁷

Accounts not paid within terms are subject to a 1.5% monthly finance charge.¹²⁸ KOR SBSDR will accept and process billing adjustments up to 45 days after the invoice date.¹²⁹

Adjustment requests received after the 45-day period will not be accepted by KOR SBSDR.¹³⁰ Approved adjustments will be applied as credits and appear on the next billing cycle as a separate line item.¹³¹

E. Recordkeeping

The KOR Rulebook provides that KOR will maintain transaction data and related identifying information for not less than five years after the applicable security-based swap expires and historical positions for not less than five years: (a) in a place and format that is readily accessible and usable to the Commission and other persons with authority to access or view such information, and (b) in an electronic format that is non-rewriteable and non-erasable.¹³²

F. Disclosure

KOR publishes a disclosure document to provide a summary of information regarding its service offerings and the SBS data it maintains.¹³³ Specifically, the disclosure document sets forth a description of the following: (i) criteria for providing access to KOR SBSBR; (ii) criteria for market participants seeking to connect to the SBSDR; (iii) policies and procedures regarding the SBSDR's safeguarding of SBSDR data and operational reliability to protect the confidentiality and security of SBSDR data; (iv) policies and procedures to protect the privacy of SBSDR data; (v)

policies and procedures regarding the SBSDR's non-commercial and/or commercial use of SBSDR data; (vi) dispute resolution procedures; (vii) description of SBSDR services; (viii) the SBSDR fee schedule; and (ix) the SBSDR's governance arrangements.¹³⁴

G. Regulatory Reporting and Public Dissemination

As a registered SDR, KOR would carry out an important role in the regulatory reporting and public dissemination of SBS transactions. As noted above, KOR has stated that it intends to rely on the no-action statement included in the ANE Adopting Release for the period set forth in the ANE Adopting Release with respect to any SBS asset class or classes for which it intends to accept transaction reports.¹³⁵ Therefore, KOR does not need to include materials in its application explaining how it would comply with the provisions of the SBS Reporting Rules described in the no-action statement.¹³⁶ Instead, KOR may rely on its discussion about how it complies with comparable CFTC requirements pertaining to regulatory reporting and public dissemination of swap transactions.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning KOR's Form SDR, including whether KOR has satisfied the requirements for registration as an SDR and as a SIP. Commenters are requested, to the extent possible, to provide empirical data and other factual support for their views. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules-regulations/how-submit-comment>); or
- Send an email to rule-comments@sec.gov. Please include File Number SBSDR-2023-01 on the subject line.

Paper Comments

- Send paper comments to Secretary, Securities and Exchange Commission,

¹³⁴ See KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2.

¹³⁵ See *supra* notes 28–29 and accompanying text.

¹³⁶ However, the KOR application includes provisions explaining how KOR would require users to identify SBS, as required by Rule 901(c)(1) of Regulation SBSR. See Rulebook, Ex. HH, sec. 5.4 (regarding Unique Product Identifiers). The KOR application also includes provisions explaining how KOR would comply with the conditions to the no-action statement included in the ANE Adopting Release.

100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SBSDR-2023-01. To help the Commission process and review your comments more efficiently, please use only one method of submission. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/other.shtml>).

Copies of the Form SDR, all subsequent amendments, all written statements with respect to the Form SDR that are filed with the Commission, and all written communications relating to the Form SDR 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 Section, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m.

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 SBSDR-2023-01 and should be submitted on or before August 28, 2024.

By the Commission.

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2024-17423 Filed 8-6-24; 8:45 am]

BILLING CODE 8011-01-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2013-0109; FMCSA-2013-044; FMCSA-2022-0044]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

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

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for seven individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have “no established medical

¹²⁴ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 3.2.

¹²⁵ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 5.0.

¹²⁶ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 5.0.

¹²⁷ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 5.0.

¹²⁸ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 5.0.

¹²⁹ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 5.0.

¹³⁰ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 5.0.

¹³¹ See KOR SEC SBSDR Fee Schedule, Ex. M-1, sec. 5.0.

¹³² See Rulebook, Ex. HH, sec. 9.4; see also KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2, sec. 7.4.4.

¹³³ See KOR SEC SBSDR Disclosure Document v1.2, Ex. GG-2.

history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.” The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: The exemptions are applicable on August 31, 2024. The exemptions expire on August 31, 2026. Comments must be received on or before September 6, 2024.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA–2013–0109, Docket No. FMCSA–2013–044, or Docket No. FMCSA–2022–0044 using any of the following methods:

- *Federal eRulemaking Portal:* Go to www.regulations.gov/, insert the docket number (FMCSA–2013–0109, FMCSA–2013–044, or FMCSA–2022–0044) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click on the “Comment” button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the “Public Participation” portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, (202) 366–4001, fmcsamedical@dot.gov. Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2013–0109,

Docket No. FMCSA–2013–044, or Docket No. FMCSA–2022–0044), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to www.regulations.gov/, insert the docket number (FMCSA–2013–0109, FMCSA–2013–044, or FMCSA–2022–0044) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, click the “Comment” button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number (FMCSA–2013–0109, FMCSA–2013–044, or FMCSA–2022–0044) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov. As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at

<https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>, the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. However, FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver’s medical certification.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria¹ to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

The seven individuals listed in this notice have requested renewal of their exemptions from the epilepsy and seizure disorders prohibition in § 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA

¹ These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. *Epilepsy*: § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the seven applicants has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition. The seven drivers in this notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period. In addition, for commercial driver's license (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

As of August 31, 2024, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following seven individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Cody Baker (IN)
David P. Crowe (VA)
Michael Curtis Gibson (SC)
Raymond Lobo (NJ)
Alexis Roldan (IL)
William Smith (NC)
Yoon Song (CA)

The drivers were included in docket number FMCSA–2013–0109, FMCSA–2013–044, or FMCSA–2022–0044. Their exemptions are applicable as of August 31, 2024 and will expire on August 31, 2026.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as

defined by § 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based on its evaluation of the seven exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the epilepsy and seizure disorders prohibition in § 391.41(b)(8). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2024–17422 Filed 8–6–24; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT–OST–2024–0083]

Senior Executive Service Performance Review Board Membership

AGENCY: Office of the Secretary, Department of Transportation (DOT).

ACTION: Notice of Performance Review Board (PRB) appointments.

SUMMARY: DOT published the names of the persons selected to serve on Departmental PRBs.

FOR FURTHER INFORMATION CONTACT: Anne B. Audet, Director, Departmental Office of Human Resource Management (202) 366–2478.

SUPPLEMENTARY INFORMATION: The persons named below may be selected to serve on one or more Departmental PRBs.

(Authority: 5 U.S.C. 4314(c)(4))

Issued in Washington, DC, on August 1, 2024.

Anne B. Audet,

Director, Departmental Office of Human Resource Management.

DEPARTMENT OF TRANSPORTATION

FEDERAL HIGHWAY ADMINISTRATION

ALONZI, ACHILLE
ARNOLD, ROBERT E
BAKER, SHANA V
BENJAMIN, RANDALL KEITH II
BEZIO, BRIAN R
BIONDI, EMILY CHRISTINE
BRIGGS, VALERIE ANNETTE
BURROWS, SHAY K
BUTLER, JENNIFER AYANNA
CHIN, ARTHUR ANDREW
CHRISTIAN, JAMES C
CRONIN, BRIAN P
CURTIS, STEPHANIE
EVANS, MONIQUE REDWINE
FINFROCK, ARLAN E JR
FLEURY, NICOLLE M
FOUCH, BRIAN J
HARTMANN, JOSEPH L
HOGGE, BRIAN R.
HUGHES, CAITLIN GWYNNE
JENSEN, GARY ALAN
KALLA, HARI
KEHRLI, MARK R
KNOPP, MARTIN C
KONOVE, ELISSA K
LEWIS, DAVID A
MARQUIS, RICHARD J
MARSHALL, DANA R
MCLAURY, KEVIN L
NEHME, JEAN ANTOINE
NELSON, THOMAS L JR.
NESBITT, MICHAEL D
PETTY, KENNETH II
REGAL, GERALDINE K
RICHARDSON, CHRISTOPHER STEVEN
RICO, IRENE
RITTER, ROBERT G
RUSNAK, ALLISON B
SANTIAGO, DAMARIS
SCHAFTLEIN, SHARI M
SHAFFER, RHONDA C
SHEPHERD, GLORIA MORGAN
SIDDIQI, BASHARAT
SOSA, MAYELA
STEPHANOS, PETER J
THORNTON, NICHOLAS R
WHITE, KRISTIN RAE
WILNER, MARCUS D
WINTER, DAVID R
WRIGHT, LESLIE JANICE

FEDERAL MOTOR CARRIER SAFETY ADMINISTRATION

BECK, VALERIE S
FROMM, CHARLES J
HERNANDEZ, SCOTT

HUG, CARRIE A
KEANE, THOMAS P
KELLY, TAFT D
LAWLESS, SUE
LENFERT, WINSOME A
LIBERANTE, WENDY LOUISE
LIBERATORE, THOMAS JOSEPH
MINOR, LARRY W
NEMONS, PATRICK D
PIDUGU, PAVANKUMAR
RIDDLE, KENNETH H.
RUBAN, DARRELL L
STEELE, GEORGIA SHARLENE
THOMAS, PHILIP WALTER III
WHITE, VINCENT GERARD JR.

*FEDERAL RAILROAD
ADMINISTRATION*

ALEXY, JOHN KARL
ALLAHYAR, MARYAM
DAVIS, HAKIM R
DYER, WILLIAM PATRICK
FULTZ, ALLISON ISHIHARA
GARLAND, JAMES JASON
GLUCK, STUART MURRAY
HAYWARD-WILLIAMS, CAROLYN R
KOUL, NEERAJ
LESTINGI, MICHAEL W.
LONG, MICHAEL T
LONGLEY, MICHAEL M
MITCHELL, JENNIFER LOUISE
NISSENBAUM, PAUL
OSTERHUES, MARLYS A
PATTERSON, MARK A
RENNERT, JAMIE P.
REYES-ALICEA, REBECCA
RIGGS, TAMELA LYNN
VAN NOSTRAND, CHRISTOPHER S

FEDERAL TRANSIT ADMINISTRATION

ALLEN, REGINALD E
BROOKINS, KELLEY
BUTLER, PETER S
CULOTTA, MICHAEL L
DALTON-KUMINS, SELENE FAER
DELORENZO, JOSEPH P
FERRONI, MARK A
FLETCHER, SUSAN K
GARCIA CREWS, THERESA
IYER, SUBASH SUBRAMANIAN
KOHLE, THERESA JANE
LEARY, MARY A
LYSSY, GAIL C
NIFOSI, DANA C.
PFISTER, JAMIE DURHAM
ROBINSON, BRUCE A
TAYLOR, YVETTE G
TELLIS, RAYMOND S
TERWILLIGER, CINDY E
VAN TERPOOL, VERONICA MARIA
WELBES, MATTHEW J

MARITIME ADMINISTRATION

BECKETT, COREY ANDREW

DAVIS, DELIA P
DUNLAP, SUSAN LYNN
HARRINGTON, DOUGLAS M
HELLER, DAVID M
KAMMERER, GREGORY LOUIS
KUMAR, SHASHI N
LEWIS, JEFFREY HARDIN
NUNAN, JOANNA MARIE
PAAPE, WILLIAM
SIMMONS-HEALY, MELINDA B
WHERRY REESE FLACK, TAMEKIA
ADEL
WULF, DAVID MATTHEW

*NATIONAL HIGHWAY TRAFFIC
SAFETY ADMINISTRATION*

BAUMANN, ROLAND T III
BLINCOE, LAWRENCE J
CHEN, CHOU-LIN
CLAYTON, SEAN METRICE
DANIELSON, JACK H.
DOHERTY, JANE H
DOLAS, RAJEEV K
DONALDSON, K JOHN
GATTI, JONATHAN D
HATIPOGLU, CEM
HINES, DAVID M
JOHNSON, TIM J
KOLODZIEJ, KERRY E
KREEB, ROBERT M
MARSHALL, JOHN W
MATHEKE, OTTO G III
POSTEN, RAYMOND R
RAVIV, ADAM MICHAEL
SAUERS, BARBARA F
SHULMAN, SOPHIE MIKHAL
SOMMERS, TERRENCE
SRINIVASAN, NANDA N
SULLIVAN, EILEEN FALLON
SUMMERS, LORI K
TERRY, JANE SAMILLE
TOPKA, TANYA L
VALLESE, JULIETTE M.

*OFFICE OF THE SECRETARY OF
TRANSPORTATION*

ABRAHAM, JULIE
ALBRIGHT, JACK G
ALEXANDER, FELICIA LANISE
AUDET, ANNE H
AUGUSTINE, JOHN E
AYLWARD, ANNE D
BAKER, SARAH ELIZABETH
BARABAN, CINDY A
BERRY ROBERSON, ANGELA YVETTE
CALLENDER, DUANE A
CARLILE, SAESHA LYNN
CARLSON, TERENCE W
CASTRO, BRIAN MATTHEW
COGGINS, COLLEEN P
COHEN, DANIEL
DANE CAMDEN, ALLISON LEE
DOUGHERTY, BARBARA KAYE

FARAJIAN, MORTEZA
FISCHER, KARA LYNN
FLEMING, GREGG G
FUNK, JENNIFER S
GARRO, KERRY ELIZABETH
GEIER, PAUL M
GIORGIS, JOHN D
GOLDSTEIN, SCOTT ROSS
HALLE, MICHAEL MACKAY
HAMPSHIRE, ROBERT CORNELIUS
HOMAN, TODD M
HOWARD, JENNIFER MARGUERITE
HU, PATRICIA S.
HUBBARD, RHEA ANN
HUYNH, JULI C
IRVINE, PETER D
JACKSON, RONALD A
JARRIN, JOSEPH HUMPHREY
KALETA, JUDITH S
KING, DANIEL E.
LANG, JAMES M.
LAWRENCE, CHRISTINE A
LEFEVRE, MARIA S.
LOHRENZ, MAURA C
MARCHESE, APRIL LYNN
MARION, IRENE BIANCA
MARTIN, HAROLD W III
MCBETH, VERONICA PERRY
MCCARTNEY, ERIN P
MCNAMARA, PHILIP ADAM
MIDDLETON, GARY LEE
MORGAN, DANIEL S.
O'BERRY, DONNA
ORNDORFF, ANDREW R
PAIEWONSKY, LUISA M
POPKIN, STEPHEN M
REDUS, TYRA LATRICE
SCHACHTER, CORDELL
SCHMITT, ROLF R
SHEIKH IBRAHIM, FIRAS
SHEPARD, DESHAWN MONIQUE
SHIKANY, ANN MARIE
SIMPSON, JOAN
STANSBURY, BRIAN THOMAS
SUSSMAN, SABRINA SANAM
SWAFFORD, LISA ANN
SWITZER, MARCUS JEREMY
SYED, MOHSIN RAZA
SZAKAL, KEITH J
SZATMARY, RONALD ALLEN JR
TAYLOR, BENJAMIN J
TIMOTHY, DARREN P
URE, DEVIN L.
WADE, LUCINDA A.
WALKER, JONATHAN B
WASHINGTON, KEITH E
WORKIE, BLANE A
WRIGHT, KALA SADIQ
ZIFF, LAURA M
ZIMMERMAN, MARIIA VICARIUS

PIPELINE AND HAZARDOUS
MATERIALS SAFETY
ADMINISTRATION

BROWN, TRISTAN HILTON
CHAVEZ, RICHARD M.
DAUGHERTY, LINDA
DAVIS, CAREY THOMAS
FARLEY, AUDREY L.
HARR, TRICIA M

MAYBERRY, ALAN K
MCMILLAN, HOWARD W
QUADE, WILLIAM A III
SCHOONOVER, WILLIAM S
TAHAMTANI, MASSOUD
TSAGANOS, VASILIKI B

GREAT LAKES ST. LAWRENCE
SEAWAY DEVELOPMENT
CORPORATION

FISHER, ANTHONY JR
LAVIGNE, CARRIE LYNN
O'MALLEY, KEVIN P
SCHARF, JEFFREY W

[FR Doc. 2024-17391 Filed 8-6-24; 8:45 am]
BILLING CODE 4910-9X-P



FEDERAL REGISTER

Vol. 89

Wednesday,

No. 152

August 7, 2024

Part II

Department of the Treasury

Office of the Comptroller of the Currency

Federal Reserve System

Federal Deposit Insurance Corporation

National Credit Union Administration

Consumer Financial Protection Bureau

Federal Housing Finance Agency

12 CFR Parts 34, 225, 323, et al.

Quality Control Standards for Automated Valuation Models; Final Rule

DEPARTMENT OF THE TREASURY**Office of the Comptroller of the Currency****12 CFR Part 34**

[Docket No. OCC–2023–0002]

RIN 1557–AD87

FEDERAL RESERVE SYSTEM**12 CFR Part 225**

[Docket No. R–1807]

RIN 7100–AG60

FEDERAL DEPOSIT INSURANCE CORPORATION**12 CFR Part 323**

RIN 3064–AE68

NATIONAL CREDIT UNION ADMINISTRATION**12 CFR Parts 722 and 741**

[Docket No. NCUA–2023–0019]

RIN 3133–AE23

CONSUMER FINANCIAL PROTECTION BUREAU**12 CFR Part 1026**

[Docket No. CFPB–2023–0025]

RIN 3170–AA57

FEDERAL HOUSING FINANCE AGENCY**12 CFR Part 1222**

RIN 2590–AA62

Quality Control Standards for Automated Valuation Models

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury; Board of Governors of the Federal Reserve System (Board); Federal Deposit Insurance Corporation (FDIC); National Credit Union Administration (NCUA); Consumer Financial Protection Bureau (CFPB); and Federal Housing Finance Agency (FHFA).

ACTION: Final rule.

SUMMARY: The OCC, Board, FDIC, NCUA, CFPB, and FHFA (collectively, the agencies) are adopting a final rule to implement the quality control standards mandated by the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act) for the use of automated valuation models (AVMs) by mortgage originators and secondary

market issuers in determining the collateral worth of a mortgage secured by a consumer's principal dwelling. Under the final rule, institutions that engage in certain credit decisions or securitization determinations must adopt policies, practices, procedures, and control systems to ensure that AVMs used in these transactions to determine the value of mortgage collateral adhere to quality control standards designed to ensure a high level of confidence in the estimates produced by AVMs; protect against the manipulation of data; seek to avoid conflicts of interest; require random sample testing and reviews; and comply with applicable nondiscrimination laws. **DATES:** This final rule is effective October 1, 2025.

FOR FURTHER INFORMATION CONTACT:

OCC: G. Kevin Lawton, Appraiser (Real Estate Specialist), (202) 649–7152; Mitchell Plave, Special Counsel, Joanne Phillips, Counsel, or Marta Stewart-Bates, Counsel, Chief Counsel's Office, (202) 649–5490; Office of the Comptroller of the Currency, 400 7th Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

Board: Andrew Willis, Manager, Policy Development Section, (202) 912–4323; Matthew McQueeney, Senior Financial Institution Policy Analyst, (202) 452–2942; Devyn Jeffereis, Senior Financial Institution Policy Analyst, (202) 365–2467, Division of Supervision and Regulation; Jay Schwarz, Assistant General Counsel, (202) 452–2970; Matthew Suntag, Senior Counsel, (202) 452–3694; Derald Seid, Senior Counsel, (202) 452–2246; Trevor Feigleson, Senior Counsel, (202) 452–3274, David Imhoff, Senior Attorney (202) 452–2249, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW, Washington, DC 20551. For users of telephone systems via text telephone (TTY) or any TTY-based Telecommunications Relay Services, please call 711 from any telephone, anywhere in the United States.

FDIC: Patrick J. Mancoske, Senior Examination Specialist, Division of Risk Management Supervision, (202) 898–7032; Navid K. Choudhury, Counsel, Legal Division, (202) 898–6526; Mark Mellon, Counsel, Legal Division, (202) 898–3884; Lauren A. Whitaker, Counsel, Legal Division, (202) 898–3872; or Stuart Hoff, Senior Policy Analyst, Division of Depositor and Consumer Protection, (202) 898–3852; or supervision@fdic.gov, Federal Deposit Insurance Corporation, 550 17th Street

NW, Washington, DC 20429. For the hearing impaired only, TDD users may contact (202) 925–4618.

NCUA: *Policy and Accounting:* Victoria Nahrwold, Associate Director; Naghi H. Khaled, Director of Credit Markets; or Simon Hermann, Senior Credit Specialist; Office of Examination and Insurance at (703) 518–6360; *Legal:* Ian Marenga, Associate General Counsel for Regulations and Legislation; John H. Brodin, Senior Staff Attorney; or Ariel Pereira, Senior Staff Attorney; Office of General Counsel at (703) 518–6540, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314.

CFPB: George Karithanom, Regulatory Implementation & Guidance Program Analyst, Office of Regulations at (202) 435–7700 or at <https://reginquiries.consumerfinance.gov/>. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov.

FHFA: Julie Giesbrecht, Senior Policy Analyst, Office of Housing and Regulatory Policy, (202) 557–9866, Julie.Giesbrecht@fhfa.gov; or Karen Heidel, Assistant General Counsel, Office of General Counsel, (202) 738–7753, Karen.Heidel@fhfa.gov. For TTY/TRS users with hearing and speech disabilities, dial 711 and ask to be connected to any of the contact numbers above.

SUPPLEMENTARY INFORMATION:**I. Background**

Section 1473(q) of the Dodd-Frank Act amended title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA or title XI)¹ to add a new section 1125 relating to quality control standards for AVMs used in valuing real estate collateral securing mortgage loans (section 1125).² In June 2023, the agencies invited comment on a notice of proposed rulemaking (proposal or proposed rule) to implement these quality control standards.³ The agencies received approximately 50 comments concerning the proposed rule.

The term “automated valuation model” is commonly used to describe computer programs that estimate a property's value and are used for a variety of purposes, including loan underwriting and portfolio monitoring.⁴ Section 1125 defines an AVM as “any computerized model used by mortgage

¹ 12 U.S.C. 3331 *et seq.*

² Public Law 111–203, 124 Stat. 1376, 2198 (2010), *codified at* 12 U.S.C. 3354.

³ 88 FR 40638 (June 21, 2023).

⁴ See *Interagency Appraisal and Evaluation Guidelines*, 75 FR 77450, 77468 (Dec. 10, 2010).

originators and secondary market issuers to determine the collateral worth of a mortgage secured by a consumer's principal dwelling.”⁵

Section 1125 directs the agencies to promulgate regulations to implement quality control standards regarding AVMs.⁶ Section 1125 requires that AVMs, as defined in the statute, adhere to quality control standards designed to “(1) ensure a high level of confidence in the estimates produced by automated valuation models; (2) protect against the manipulation of data; (3) seek to avoid conflicts of interest; (4) require random sample testing and reviews; and (5) account for any other such factor that the agencies. . . determine to be appropriate.”⁷ As required by section 1125, the agencies consulted with the staff of the Appraisal Subcommittee and the Appraisal Standards Board of the Appraisal Foundation as part of promulgating this rule.⁸

Driven in part by advances in database and modeling technology and the availability of larger property datasets, the mortgage industry has begun to use AVMs with increasing frequency as part of the real estate valuation process. For example, the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac) (collectively, the Government Sponsored Enterprises or GSEs) use proprietary AVMs in their collateral valuation processes. While advances in AVM technology and data availability have the potential to contribute to lower costs and shorten turnaround times in the performance of property valuations, it is important that institutions using such tools take appropriate steps, as required by section 1125, to ensure the credibility and integrity of the valuations produced by AVMs.

Existing Guidance Relating to the Use of AVMs and Enforcement of the Final Rule

Since 2010, the OCC, Board, FDIC, and NCUA have provided supervisory guidance on the use of AVMs by the institutions they regulate in Appendix B to the Interagency Appraisal and Evaluation Guidelines (Appraisal Guidelines).⁹ The Appraisal Guidelines recognize that an institution may use a variety of analytical methods and technological tools in developing real

estate valuations, provided the institution can demonstrate that the valuation method is consistent with safe and sound banking practices. The Appraisal Guidelines recognize that the establishment of policies and procedures governing the selection, use, and validation of AVMs, including steps to ensure the accuracy, reliability, and independence of an AVM, is a sound banking practice.¹⁰

In addition to Appendix B of the Appraisal Guidelines, the OCC, Board, and FDIC have issued guidance on model risk management practices (Model Risk Management Guidance) that provides comprehensive supervisory guidance on validation and testing of models.¹¹ While the NCUA is not a party to the Model Risk Management Guidance, the NCUA monitors the model risk management efforts of federally insured credit unions through its supervisory approach by confirming that the governance and controls over AVMs are appropriate based on the size and complexity of the transactions, the risk the transactions pose to the credit union, and the capabilities and resources of the credit union.

The CFPB and FHFA are also not parties to the Appraisal Guidelines or the Model Risk Management Guidance. The FHFA has separately issued model risk management guidance that provides the FHFA's supervisory expectations for its regulated entities in the development, validation, and use of models.¹²

The OCC, Board, FDIC, NCUA, CFPB, and FHFA have also provided guidance on managing the risk inherent in the use of third-party service providers, such as outside entities that provide AVMs and AVM services.¹³ For example, under the

guidance issued by the Federal banking agencies, regardless of whether activities are performed internally or using a third party, banking organizations are required to operate in a safe and sound manner and in compliance with applicable laws and regulations. A banking organization's use of third parties does not diminish its responsibility to meet these requirements to the same extent as if its activities were performed by the banking organization in-house. To operate in a safe and sound manner, a banking organization establishes risk management practices to effectively manage the risks arising from its activities, including from third-party relationships. These guidance documents address the characteristics, governance, and operational effectiveness of a banking organization's risk management program for outsourced activities.

Institutions that are not regulated by the agency or agencies providing the guidance may still look to the guidance for assistance with compliance. The OCC, FDIC, Federal Reserve, NCUA, CFPB, FHFA, FTC, and State attorneys general each have an important role in enforcing this rule as to their respective regulated entities or covered market participants.¹⁴

II. Brief Summary of the Proposed Rule, Comments, and the Final Rule

The proposed rule would have required that mortgage originators and secondary market issuers adopt policies, practices, procedures, and control systems to ensure that AVMs used in certain credit decisions or covered securitization determinations (as defined below) adhere to quality control standards designed to (1) ensure a high level of confidence in the estimates produced; (2) protect against the manipulation of data; (3) avoid conflicts of interest; (4) require random sample testing and reviews; and (5) comply with applicable nondiscrimination laws. The proposed rule would not have set specific requirements for how institutions are to structure these policies, practices, procedures, and

01–CU–20 (Nov. 2001); *Oversight of Third-Party Provider Relationships*, FHFA Advisory Bulletin 2018–08 (Sept. 28, 2018); CFPB, *Compliance Bulletin and Policy Guidance; 2016–02, Service Providers* (Oct. 31, 2016); and CFPB, *Examination Procedures—Compliance Management Review* (Aug. 2017). See also, *Third-Party Relationships: A Guide for Community Banks*, OCC Bulletin 2024–11 (May 3, 2024); *Third-Party Risk Management: A Guide for Community Banks*, Federal Reserve Board SR Letter 24–2 (May 7, 2024); *Third-Party Risk Management, A Guide for Community Banks*, FDIC FIL–29–2024 (May 3, 2024).

¹⁴ See 12 U.S.C. 3354(c); 12 U.S.C. 4631(a)(1).

¹⁰ *Id.*

¹¹ See *Comptroller's Handbook, Model Risk Management*, OCC Bulletin 2021–39 (Aug. 18, 2021); *Supervisory Guidance on Model Risk Management*, OCC Bulletin 2011–12 (Apr. 4, 2011); *Guidance on Model Risk Management*, Federal Reserve Board SR Letter 11–7 (Apr. 4, 2011); and *Adoption of Supervisory Guidance on Model Risk Management*, FDIC FIL–22–2017 (June 7, 2017).

¹² See *Supplement Guidance to Advisory Bulletin 2013–07—Model Risk Management Guidance 2013–07*, FHFA Advisory Bulletin 2022–03 (Dec. 21, 2022) and *Model Risk Management Guidance*, FHFA Advisory Bulletin 2013–07 (Nov. 20, 2013).

¹³ See *Third-Party Relationships: Interagency Guidance on Risk Management*, OCC Bulletin 2023–17 (June 6, 2023); *Interagency Guidance on Third-Party Relationships: Risk Management*, Federal Reserve Board SR Letter 23–4 (June 7, 2023); *Interagency Guidance on Third-Party Relationships: Risk Management*, FDIC FIL 29–2023 (June 6, 2023); *Guidance on Managing Outsourcing Risk*, Federal Reserve Board SR Letter 13–9 (Dec. 3, 2013); *Evaluating Third Party Relationships*, NCUA Supervisory Letter 07–01 (Oct. 2007); *Due Diligence Over Third Party Service Providers*, NCUA Letter

⁵ 12 U.S.C. 3354(d). This preamble uses the terms “worth” and “value” interchangeably when discussing mortgage collateral.

⁶ 12 U.S.C. 3354(b).

⁷ 12 U.S.C. 3354(a).

⁸ See 12 U.S.C. 3354(b).

⁹ See *supra* note 4. The Appraisal Guidelines were adopted after notice and comment.

control systems. The proposed rule stated that this approach would provide institutions with the flexibility to set quality controls for AVMs as appropriate based on the size, complexity, and risk profile of the institution and the transactions for which they would use AVMs covered by the proposed rule. The proposed rule further stated that, as modeling technology continues to evolve, this flexible approach would allow institutions to refine their policies, practices, procedures, and control systems as appropriate and that the agencies' existing guidance related to AVMs would remain applicable.

The agencies received approximately 50 comments on the proposed rule to implement the quality control standards for AVMs in title XI, including comments from financial institutions, financial institution trade associations, real estate trade associations, mortgage insurance trade associations, appraiser trade associations, nonprofit advocacy organizations, AVM developers, and appraisers. Most commenters recognized that quality control standards for AVMs are required by title XI and are important to the safety and soundness of mortgage lending and securitizations involving mortgages. Most commenters also expressed support for the flexibility in the proposed rule for institutions to set quality controls for AVMs as appropriate based on the size, complexity, and risk profile of the institution and the transactions for which they would use AVMs covered by the proposed rule.

While most commenters recognized the importance of ensuring that AVMs used by mortgage originators and secondary market issuers do not violate fair lending laws, some commenters expressed concern about how to implement the proposed quality control standards, particularly the fifth quality control factor on nondiscrimination, and suggested that additional guidance from the agencies may be needed in the future. Some commenters suggested that the rule should apply to AVM developers and vendors, rather than lending institutions, given that mortgage originators have no control over how AVMs are created. A number of commenters recommended that the agencies work with the private sector to develop a standard setting organization (SSO) for AVMs and an independent third-party entity responsible for testing AVMs for compliance with the proposed quality control standards.

The agencies are finalizing the proposed rule largely as proposed. The agencies are also making clarifying edits

to the definition of the term "mortgage originator," adding a definition of "person" in response to comments received, and inserting the words "seek to" into the third quality control factor in order to match the language of section 1125, as discussed in the preamble to the proposed rule. The flexible approach to implementing the quality control standards provided by the final rule will allow the implementation of the standards to evolve along with changes in AVM technology and minimize compliance costs. Regarding the fifth quality control factor, the agencies note that existing nondiscrimination laws apply to appraisals and AVMs and that institutions have a preexisting obligation to comply with all Federal laws, including Federal nondiscrimination laws. Institutions will have flexibility to adopt approaches to implement this quality control factor in ways that reflect the risks and complexities of their individual business models. In addition, there is existing guidance on fair lending considerations to inform compliance with the nondiscrimination factor.¹⁵

Regarding commenters' suggestion to apply the rule to AVM developers and vendors, the agencies note that, while section 1125 applies to mortgage originators and secondary market issuers, financial institutions should be able to work with AVM developers and vendors to assist them with their compliance obligations under the rule, as they do with other third-party vendors in order to comply with relevant regulatory requirements. The agencies recognize that one or more SSOs and third-party AVM testing entities could be beneficial to effective compliance with the AVM rule. As long as financial institutions meet the obligations provided in the final rule, they are free to work with third parties to assist them with their compliance obligations.

III. Discussion of the Proposed Rule, Comments Received, and the Final Rule

The following is a detailed discussion of the proposed rule, the comments the

agencies received, the responses to the comments, and the final rule.

A. Scope of the Rule

1. AVMs Used in Connection With Making Credit Decisions

The proposed rule would have applied to AVMs used in connection with making a credit decision. The proposed rule would have defined "credit decision," in part, to include a decision regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage. The proposed rule would have expressly excluded the use of AVMs in monitoring the quality or performance of mortgages or mortgage-backed securities. The use of AVMs solely to monitor a creditor's mortgage portfolio would not have been a credit decision under the proposed rule because the lending institution has already made the credit decision. The scope of the proposed rule included, for example, decisions regarding originating a mortgage; modifying the terms of an existing loan; and renewing, increasing, or terminating a home equity line of credit (HELOC). The proposed rule used the term "credit decision" to help clarify that the proposed rule would have covered these various types of decisions.

The proposal to limit the scope of the rule to credit decisions (or, as discussed below, covered securitization determinations) reflected the statutory definition of AVM, which focuses on the use of an AVM "by mortgage originators and secondary market issuers to *determine* the collateral worth of a mortgage secured by a consumer's principal dwelling."¹⁶ The proposed rule distinguished between using AVMs to determine the value of collateral securing a mortgage and using AVMs to monitor, verify, or validate a previous determination of value (e.g., the proposed rule would not have covered a computerized tax assessment model used to verify the valuation made during the origination process).¹⁷ The proposed rule focused on those aspects of mortgage and securitization transactions where the value of collateral is typically determined.

Most commenters expressed support for limiting the scope of the rule to AVMs used in connection with making credit decisions (or, as discussed below,

¹⁶ 12 U.S.C. 3354(d) (emphasis added).

¹⁵ See, e.g., Interagency Task Force on Fair Lending, *Policy Statement on Discrimination in Lending*, 59 FR 18266 (Apr. 15, 1994), available at <https://www.govinfo.gov/content/pkg/FR-1994-04-15/html/94-9214.htm>; Interagency Fair Lending Examination Procedures (Aug. 2009), available at <https://www.ffiec.gov/PDF/fairlend.pdf>; CFPB, *Examination Procedures—ECOA* (Oct. 2015), available at https://files.consumerfinance.gov/f/documents/201510_cfpb_ecoa-narrative-and-procedures.pdf; Federal Housing Finance Agency, *Policy Statement on Fair Lending*, 86 FR 36199 (July 9, 2021), available at <https://www.govinfo.gov/content/pkg/FR-2021-07-09/pdf/2021-14438.pdf>.

¹⁷ Many secondary market transactions by regulated entities require an appraisal unless an appraisal consistent with regulatory standards was obtained at the time of origination. See 12 CFR 43.34(a)(8) (OCC); 12 CFR 225.63(a)(8) (Board); 12 CFR 323.3(a)(8) (FDIC); 12 CFR 722.3(a)(5) (NCUA).

covered securitization determinations) and excluding use of AVMs for portfolio monitoring, which does not involve credit decision-making. The commenters also stated that excluding portfolio monitoring would reduce some burdens and costs that may otherwise be passed on to borrowers. One commenter stated that these exclusions would permit lenders more certainty in using AVMs for purposes such as portfolio monitoring.

Some commenters argued that the rule should apply to the use of AVMs to value a consumer's principal dwelling for any purpose. For example, one commenter argued that the statutory definition of "automated valuation model" at section 1125 does not limit applicability only to AVMs used during underwriting.

The final rule limits the scope of the rule to credit decisions and, as discussed below, covered securitization determinations. This scope is consistent with the statutory language in section 1125, which focuses on determinations of value. The focus on determinations of value made in connection with credit decisions or covered securitization determinations, and the exclusion of AVM use for portfolio monitoring, will also reduce the compliance costs associated with a broader application of the quality control standards.

Loan modifications and other changes to existing loans. The proposed rule would have defined a credit decision broadly to include, among other things, a decision regarding whether and under what circumstances to modify or to make other changes to a mortgage. As a result, the proposed rule would have covered AVMs used to determine the value of an existing mortgage secured by a consumer's principal dwelling in conjunction with a decision to modify or change the terms of that mortgage when such decision is made by a "mortgage originator," "secondary market issuer," or servicer working on behalf of a mortgage originator or secondary market issuer. For example, the proposed rule would have covered AVMs used by a "mortgage originator" or "secondary market issuer," or servicer working on behalf of a mortgage originator or secondary market issuer to deny a loan modification or to confirm the value of collateral in response to a request to change or release collateral.

The agencies received several comments on this topic. Two commenters asked the agencies to clarify how the rule would apply to certain credit decisions. The first of these commenters expressed support for treating a decision to modify a loan as a credit decision because, like an initial

credit decision, when a mortgage originator assesses collateral value for a loan modification, the mortgage originator is assessing whether the value of the collateral is sufficient to support the decision to engage in the transaction. However, the commenter asked the agencies to strike the reference to "other changes" from the definition of "credit decision." The commenter believed that this change would reduce ambiguity regarding the type of conduct covered by the definition of credit decision. The other commenter suggested that the agencies make clear that assumptions are a credit event and would fall under the rule. This commenter added that the use of assumptions may rise in the future, so the market would benefit from that clarity.

As discussed further below, the agencies have considered these two comments, but do not find it necessary to provide any additional clarification regarding how the rule applies to credit decisions. Section 1125 of FIRREA defines an AVM as "any computerized model used by mortgage originators and secondary market issuers to determine the collateral worth of a mortgage secured by a consumer's principal dwelling."¹⁸ As explained in the proposed rule, the agencies interpret the scope of section 1125 as covering the use of an AVM to make a credit decision, but not the use of an AVM to monitor, to verify, or to validate a prior determination of value. The proposed rule further provided that a "credit decision" is "a decision regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage, including a decision on whether to extend new or additional credit or change the credit limit on a line of credit." Striking the reference to "other changes" from the definition of credit decision, as suggested by the first commenter, would be inconsistent with the agencies' interpretation of the scope of section 1125 because it would narrow the scope of the rule to apply only to origination, modification, and termination decisions. The agencies also find it unnecessary to clarify that assumptions are credit events that fall under the rule, as suggested by the second commenter, because the proposed definition of "credit decision" is broad enough to cover assumptions.

Several other commenters disagreed with applying the rule to AVMs used to modify or change the terms of an existing loan. One of these commenters suggested that covering loan

modifications would present operational challenges and is unsupported by an articulated benefit to consumers. Another commenter stated that covering modifications could discourage the use of AVMs and push lenders to use appraisals for modifications, which are more costly and time-consuming. Two other commenters expressed concern that covering loan modifications could increase costs for borrowers already facing financial distress. One of these commenters further noted that covering loan modifications also could make the loss mitigation process take longer. Finally, another commenter stated that the proposal to include loan modifications should have minimal, if any, impact on the market because the majority of loan modifications do not require a valuation of the property. However, the commenter recommended that the rule align with the traditional practice described in the Truth in lending Act (TILA) of distinguishing the role of servicers from that of originators in cases where there is no new extension of credit. The commenter argued that, unless this rule's definition of credit decision excludes loan modifications that are not a new extension of credit, the regulatory framework for this rule could be misapplied to other regulations.

The agencies have considered these comments and are adopting the final rule as proposed. AVMs are often used to determine the value of collateral in connection with loan modifications and other changes to mortgages. Further, the agencies continue to view quality control standards for AVMs used to make credit decisions relating to loan modifications and other changes to mortgages as important both to safety and soundness and to consumer protection. As discussed below, many institutions have already set up quality control systems for AVMs and have third-party risk management programs in place. For those institutions, existing quality control systems and third-party risk management programs should mitigate the burden of implementing additional quality control standards for AVMs used to modify or to change the terms of existing loans as well as any related costs passed on to consumers. In addition, the flexibility the rule provides to institutions to design policies, practices, procedures, and control systems to implement the quality control standards should reduce the burden of implementing additional quality control standards for AVMs used to modify or to change the terms of existing loans. This flexibility should

¹⁸ 12 U.S.C. 3354(d) (emphasis added).

reduce any related costs passed on to consumers.

Finally, the agencies considered the comment recommending that the rule align with the traditional practice described in TILA of distinguishing the role of servicers from that of mortgage originators in cases where there is no new extension of credit. However, the agencies decline to adopt changes to the proposed rule based on the comment. Although, as discussed in detail in part III.C.7 of this **SUPPLEMENTARY INFORMATION**, the rule defines mortgage originator by adopting the full text of the TILA definition of the term with technical revisions, this rulemaking is being conducted pursuant to FIRREA and it is consistent with FIRREA for valuation requirements to apply to both new and existing extensions of credit. For example, under the appraisal regulations of the Federal banking agencies and NCUA, loan modifications that are real estate-related financial transactions must, in general, comply with appraisal requirements or obtain an evaluation (for entities regulated by the banking agencies) or a written estimate of market value (for credit unions) that is consistent with safe and sound banking practices. Therefore, it is consistent with the regulatory framework of FIRREA for the agencies to apply AVM requirements to transactions involving both new and existing credit.

Home equity line of credit (HELOC) reductions or suspensions. The proposed rule would have covered AVMs used in deciding whether or to what extent to reduce or suspend a HELOC. In the proposal, the agencies considered mortgage originators and secondary market issuers to be using AVMs in connection with making a credit decision when they use AVMs to decide whether or to what extent to reduce or suspend a HELOC.

The agencies received several comments on this topic. Two commenters generally supported applying the rule to HELOCs, while two commenters opposed this application. These commenters expressed the concern that the burden and expense of compliance would outweigh the consumer protection and safety and soundness benefits. Another commenter requested further clarification regarding how the rule would apply when AVMs are used to make credit decisions relating to HELOC reductions and suspensions.

The agencies have considered these comments and are adopting the final rule as proposed. The agencies have determined that AVMs used to make credit decisions relating to HELOC reductions and suspensions are

important both to safety and soundness and to consumer protection. As discussed below, many institutions have already set up quality control systems for AVMs and have third-party risk management programs in place. These existing quality control systems and third-party risk management programs should mitigate the burden and expense of implementing additional quality control standards for AVMs used to make credit decisions relating to HELOC reductions and suspensions as well as any related costs passed on to consumers. In addition, the flexibility provided to institutions under the final rule to design policies, practices, procedures, and control systems to implement the quality control standards should also reduce both the burden of implementing additional quality controls standards for AVMs used to make credit decisions relating to HELOC reductions and suspensions and any related costs passed on to consumers.

2. AVMs Used by Secondary Market Issuers

The language of section 1125 includes not only mortgage originators, but also secondary market issuers.¹⁹ For this reason, the proposed rule would have extended to certain securitization activities, defined as “covered securitization determinations.”

Appraisal waivers by secondary market issuers. The proposed rule defined “covered securitization determination” to include determinations regarding, among other things, whether to waive an appraisal requirement for a mortgage origination (appraisal waiver decisions).²⁰ Under the proposed rule, a secondary market issuer that uses AVMs in connection with making appraisal waiver decisions would have been required to have policies, practices, procedures, and control systems in place to ensure that the AVM supporting those appraisal waiver decisions adheres to the rule’s quality control standards. In contrast, a mortgage originator that requests an appraisal waiver decision from a secondary market issuer would not have needed to ensure that the AVM used to support the waiver meets the rule’s quality control standards. This

treatment is because the secondary market issuer would be using the AVM to make the appraisal waiver decision in this context, not the mortgage originator. The proposal noted that when mortgage originators submit loans to GSEs for appraisal waiver decisions, the mortgage originators offer an estimated value of the property, but do not make a determination of value.

Both GSEs have appraisal waiver programs and are the predominant issuers of appraisal waivers in the current mortgage market.²¹ To determine whether a loan qualifies for an appraisal waiver under any GSE program, a mortgage originator submits the loan casefile to the GSE’s automated underwriting system with an estimated value of the property (for a refinancing transaction) or the contract price (for a purchase transaction). The GSE then processes this information through its internal model(s), which may include use of an AVM, to determine the acceptability of the estimated value or the contract price for the property. If the GSE’s analysis determines, among other eligibility parameters, that the estimated value or contract price meets its risk thresholds, the GSE offers the lender an appraisal waiver.²²

In this example, when the GSEs use AVMs to determine whether the mortgage originator’s estimated collateral value or the contract price meets acceptable thresholds for issuing an appraisal waiver offer, the GSEs would be making a “covered securitization determination” under the proposed rule. As a result, the proposed rule would have required the GSEs, as secondary market issuers, to maintain policies, practices, procedures, and control systems designed to ensure that their use of such AVMs adheres to the rule’s quality control standards. On the other hand, the mortgage originator in this context would not be making a “covered securitization determination” under the proposed rule because the GSE would be using its AVM to make the appraisal waiver decision. As a result, the mortgage originator would not be responsible for ensuring that the GSEs’ AVMs comply with the proposed rule’s quality control standards.

Most commenters agreed that the GSEs make the valuation decision in connection with appraisal waivers and should be covered by the quality control

¹⁹ 12 U.S.C. 3354(d).

²⁰ On March 1, 2023, Fannie Mae began a transition in terminology away from “appraisal waivers” and to “value acceptance.” As stated in the March 1 announcement, “value acceptance is being used in conjunction with the term ‘appraisal waiver’ to better reflect the actual process of using data and technology to accept the lender-provided value. We are moving away from implying that an appraisal is a default requirement.” See *Fannie Mae Provides Updates Regarding Valuation Modernization* | Fannie Mae.

²¹ See Fannie Mae, *Appraisal Waivers*, available at <https://singlefamily.fanniemae.com/originating-underwriting/appraisal-waivers>; Freddie Mac, *Automated Collateral Evaluation (ACE)*, available at <https://sf.freddie.com/tools-learning/loan-advisor/our-solutions/ace-automated-collateral-evaluation>.

²² *Id.*

standards in the appraisal waiver context. One commenter requested clarification in cases where AVMs are used to determine eligibility for appraisal waivers and recommended that the proposed regulatory text align with the description in the preamble. Another commenter supported an exception for AVMs used to determine whether a loan may be eligible for an appraisal waiver. Another commenter stated that the Equal Credit Opportunity Act (ECOA) requires creditors to provide consumers with a copy of any estimate of the value of a dwelling developed in connection with a creditor's decision to provide credit, including those values developed pursuant to a policy of a GSE or by an AVM, a broker price opinion, or other methodology or mechanism. The commenter further stated that the GSEs should be obligated to provide a consumer with any valuation on which the waiver is based.

Many commenters stated that it would be very difficult for lenders to conduct quality control of the GSEs' AVMs for reasons including that the GSEs have treated their data, analytics, and testing as proprietary and have not shared information with the industry. Commenters also suggested that requiring lenders to conduct quality control of secondary market issuers' AVMs would be redundant because the secondary market issuers are already covered by the proposed rule and are better positioned to implement quality controls on their AVMs.

The agencies have determined that secondary market issuers are best positioned to conduct quality control for the AVMs they use in appraisal waiver decisions. This is because the secondary market issuer would be using the AVM to make the appraisal waiver decision in this context, not the mortgage originator. For this reason and after considering the comments, the final rule adopts the proposal to require the secondary market issuers, rather than mortgage originators, to implement the final rule for such AVM use.

Regarding providing to consumers copies of valuations used in connection with appraisal waiver decisions, the comment is on a matter outside the scope of this rulemaking. The agencies also note that the CFPB's rules in Regulation B implementing ECOA generally require creditors to provide applicants for first-lien loans on a dwelling with copies of written valuations developed in connection with an application.²³ "While some

AVMs may use proprietary methods, the [2013 ECOA Valuations Final Rule] does not require the disclosure of these methods *per se*; rather, the [2013 ECOA Valuations Final Rule] requires disclosure of the written valuations developed by the AVMs which are provided to the creditors."²⁴

Other uses by secondary market issuers. As noted earlier, the language of section 1125 includes not only mortgage originators, but also secondary market issuers. Given that section 1125 refers to secondary market issuers and the primary business of secondary market issuers is to securitize mortgage loans and to sell those mortgage-backed securities to investors, the proposed rule would have covered AVMs used in securitization determinations. In the proposal, the agencies stated that covering AVMs used in securitizations could potentially protect the safety and soundness of institutions and could protect consumers and investors by reducing the risk that secondary market issuers would misvalue homes. For example, misvaluation by secondary market issuers could, in turn, incentivize mortgage originators to originate misvalued loans when making lending decisions.²⁵ Such misvaluations could pose a risk of insufficient collateral for financial institutions and secondary market participants and could limit consumers' refinancing and selling opportunities.²⁶

The proposed rule would have covered AVM usage when a secondary market issuer uses an AVM as part of a new or revised value determination in connection with a covered securitization determination. For example, the GSEs currently use the origination appraised value or the estimated value in appraisal waivers when issuing mortgage-backed securities (MBS). Hence, AVMs are not used by the GSEs to make a new or revised value determination in

connection with MBS issuances. However, because the GSEs provide guarantees of timely payment of principal and interest on loans that are included in an MBS, they are obligated to purchase loans that are in default from MBS loan pools. The GSEs may modify such loans and subsequently re-securitize them as new MBS offerings. In these instances, the GSEs may use an AVM to estimate collateral value for investor transparency and disclosure. AVMs used in this manner by the GSEs would have been considered covered securitization determinations because there are new or revised value determinations. As discussed below, the proposed rule would have distinguished between secondary market issuers using AVMs to determine the value of collateral securing a mortgage versus using AVMs solely to review completed value determinations. For example, AVMs used solely to review appraisals obtained during mortgage origination would not have been covered by the proposed rule.

Most commenters supported the proposal to cover AVMs used by secondary market issuers in connection with covered securitization determinations. One commenter expressed general support for covering securitizations, stating that transparency in how AVMs are tested, measured, and applied would allow for better valuations and more informed risk decision-making. Another commenter expressed support for consistent requirements across all activities by institutions, including secondary market issuers, stating that covering securitizations would alleviate the risk of an inconsistent approach to the development of quality control standards. Another commenter stated that it is important for the GSEs to be covered by the proposed rule because the GSEs (1) finance more than half of all purchase originations, and (2) the internalization of valuation risk by the GSEs poses a systemic threat to the housing finance system that could undermine investor confidence if questioned, especially if they exit conservatorship without an explicit Federal backstop.

One commenter echoed this point, stating that it is important to cover secondary market issuers because the issuers significantly influence how mortgage originators perform their underwriting. Similarly, another commenter stated it is important to cover the GSEs because they are two of the largest users and managers of AVMs in the market. The commenter stated further that there is additional potential for increased taxpayer risk if an AVM

²⁴ 78 FR at 7239. The 2013 ECOA Valuations Final Rule "does not apply to persons who are not creditors within the meaning of Regulation B, § 1002.2(l), and thus does not impose any obligation on a creditor to compel a third-party to provide a copy of such documentation to the applicant." *Id.* at 7239 n.89.

²⁵ For example, the 2008 financial crisis was precipitated in part by secondary market issuers that "lowered the credit quality standards of the mortgages they securitized" and mortgage originators that "took advantage of these lower credit quality securitization standards . . . to relax the underwriting discipline in the loans they issued" because, "[a]s long as they could resell a mortgage to the secondary market, they didn't care about its quality." Financial Crisis Inquiry Commission, *The Financial Crisis Inquiry Report*, at 425 (2011), available at <https://www.gpo.gov/fdsys/pkg/GPO-FCIC/pdf/GPO-FCIC.pdf>.

²⁶ See, e.g., *Appraisals for Higher-Priced Mortgage Loans*, 78 FR 10367, 10418 (Feb. 13, 2013).

²³ See 12 CFR 1002.14; 78 FR 7216 (Jan. 31, 2013) (2013 ECOA Valuations Final Rule).

produces a property valuation that misprices or eliminates loan-level private mortgage insurance credit protection.

One commenter also suggested that, because AVMs are developed using data and models that reflect past and ongoing discrimination, the agencies should seek broad coverage of AVMs, including those used by the GSEs. Another commenter suggested that covering AVMs used by secondary market issuers also would promote financial stability. A number of commenters stated that Federal governmental support for the GSEs and the Government National Mortgage Association provides an additional reason to apply quality control standards to AVMs used by these entities.

As stated in the proposal, covering secondary market issuers is consistent with the plain language of the statute and provides quality control for AVMs used in an expansive and crucial segment of the mortgage lending market. For these reasons and after considering the comments, the agencies are adopting the proposal to cover secondary market issuers' use of AVMs in covered securitization determinations.

3. AVM Uses Not Covered by the Rule

Use of AVMs by appraisers. The proposed rule would not have covered the use of an AVM by a certified or licensed appraiser in developing an appraisal.²⁷ This approach reflects the fact that, while appraisers may use AVMs in preparing appraisals, they must achieve credible results in preparing an appraisal under USPAP and its interpreting opinions.²⁸ As such, an appraiser must make a valuation

conclusion that is supportable independently and does not rely on an AVM to determine the value of the underlying collateral. The proposal stated that it also may be impractical for mortgage originators and secondary market issuers to adopt policies, procedures, practices, and control systems to ensure quality controls for AVMs used by the numerous independent appraisers with whom they work.

Under the appraisal regulations issued by the OCC, Board, FDIC, and NCUA, lenders regulated by those agencies are required to obtain "evaluations," or "written estimates of market value" under the NCUA's regulations, for certain transactions that fall within exceptions specified in the appraisal regulations.²⁹ Such evaluations must be consistent with safe and sound banking practices.

The proposed rule would have covered AVMs used in the process of preparing evaluations. This distinction between application of the rule to appraisals versus evaluations reflects the fact that USPAP standards and appraiser credentialing are not required for individuals who prepare evaluations. The proposed rule's coverage of AVMs used in the process of preparing evaluations also reflected the more extensive use of, and reliance on, AVMs within the evaluation function.

Most commenters agreed with the proposed exclusion of appraisals performed by licensed or certified appraisers from the scope of the rule. The commenters noted that appraisers are already subject to quality control standards and that exempting appraisers would avoid duplicative and burdensome regulation in an area where banks are already encountering shortages of appraisers. One commenter stated that the proposal's excluded uses do not involve credit decision making and suggested that excluding these uses will reduce burden and costs that may otherwise be passed on to consumers.

One commenter stated that, while appraisers often use an AVM or other tools to provide support and understanding for their opinions, appraisers are experts designated by Congress to protect public trust and they dedicate their lives to studying real

estate data. Another commenter observed that appraisers do not use "lending grade" AVMs to develop full, traditional appraisals. The commenter stated that some appraisers may use AVMs to gauge a starting point for appraisals, but that appraisers have limited access to lending-grade AVMs. Another commenter noted that under USPAP, an AVM is a tool that appraisers may use for their work (such as for internal checks and balances), but not for the completion of an appraisal in determining the appraiser's opinion of value. The commenter expressed agreement with the statement in the preamble that an appraiser must make a valuation conclusion that is supportable independently and does not rely on an AVM to determine the value of the underlying collateral. One commenter stated that AVM use by appraisers is low and infrequent and noted that higher quality AVMs are often cost prohibitive for appraisers to use. The commenter suggested that imposing compliance costs on use of AVMs by appraisers would discourage the use of AVMs as a check for obvious errors.

A small number of commenters argued that the quality control standards should be broadly applicable and advocated for removing the exclusions for development of appraisals by appraisers. For example, one commenter suggested that allowing appraisers to use AVMs that are not subject to quality control would create institutional and consumer confusion and a heightened risk of misapplication of AVM results. The commenter noted that USPAP provides that an appraiser may only use an AVM as part of the valuation process if the appraiser has a basic understanding of how the AVM works.

As discussed earlier, while appraisers may use AVMs in preparing appraisals, they must achieve credible results in preparing an appraisal under USPAP and its interpreting opinions. As such, an appraiser must make a valuation conclusion that is supportable independently and does not rely on an AVM to determine the value of the underlying collateral. In addition, it may be impractical for mortgage originators and secondary market issuers to adopt policies, practices, procedures, and control systems to ensure quality controls for AVMs used by the numerous independent appraisers with whom they work. For these reasons and after considering the comments, the final rule excludes from coverage the use of AVMs by a certified or licensed appraiser in developing an appraisal, consistent with the proposal. The agencies did not receive specific comments on covering evaluations. For

²⁷ The appraisal regulations issued by the OCC, Board, FDIC, and NCUA set forth, among other requirements, minimum standards for the performance of real estate appraisals in connection with federally related transactions. See 12 CFR part 34, subpart C (OCC); 12 CFR part 208, subpart E, and 12 CFR part 225, subpart G (Board); 12 CFR part 323 (FDIC); and 12 CFR part 722 (NCUA). The CFPB proposed to codify the AVM requirements in Regulation Z, 12 CFR part 1026, and to cross-reference Regulation Z § 1026.35(c)(1)(i), which defines "certified or licensed appraiser" as a person who is certified or licensed by the State agency in the State in which the property that secures the transaction is located, and who performs the appraisal in conformity with the Uniform Standards of Professional Appraisal Practice (USPAP) and the requirements applicable to appraisers in title XI, and any implementing regulations in effect at the time the appraiser signs the appraiser's certification.

²⁸ See USPAP STANDARDS RULE 1-1, GENERAL DEVELOPMENT REQUIREMENTS ("In developing a real property appraisal, an appraiser must . . . be aware of, understand, and correctly employ those recognized methods and techniques that are necessary to produce a credible appraisal"); see also Advisory Opinion 37 (AO-37) on Computer Assisted Valuation Tools.

²⁹ See 12 CFR 34.43(b) (OCC); 12 CFR 225.62(c) (Board); 12 CFR 323.3(b) (FDIC); and 12 CFR 722.3(d) (NCUA) (requiring that written estimates of market value be performed for transactions not requiring an appraisal and providing differing requirements for such estimates). See also *Appraisal Guidelines*, 75 FR at 77460 (discussing transactions that require evaluations under the appraisal rules and providing recommendations for evaluation development).

the reasons stated above, the final rule covers AVMs used in preparation of evaluations.

Reviews of completed collateral valuation determinations. The proposed rule would not have covered AVMs used in reviews of completed collateral value determinations (completed determinations), given that the underlying appraisal or evaluation determines the value of the collateral, rather than the review of the appraisal or evaluation. The appraisal or evaluation review, including those where an AVM is used in the review, serves as a separate and independent quality control function.³⁰

Many commenters expressed support for not covering the use of AVMs for reviews of completed determinations in the rule. The commenters stated such exclusion would reduce some burdens and costs that may otherwise be passed on to borrowers. One commenter stated that an institution may, but is not required to, use an AVM to test the reasonableness of an appraisal or evaluation. The commenter recommended that the rule cover such AVM use. Other commenters suggested that AVMs used for appraisal review should be covered to avoid inconsistent standards, to ensure that discriminatory valuations are identified, or because all AVMs used in housing finance should be subject to quality control standards.

As discussed earlier, the agencies continue to view the focus on value determinations as consistent with section 1125. For this reason and those stated above, after considering the comments, the agencies are adopting the proposal to exclude reviews of completed determinations from the scope of the rule. The agencies note that the rule does not make distinctions based on the amount of time between the completed determination and the subsequent review; if an AVM is being used solely to review the completed determination, the AVM use is not covered by the rule regardless of when the AVM is used after that determination.

A. Quality Control Standards

1. Proposed Requirements for the First Four Quality Control Factors

The proposed rule would have required mortgage originators and secondary market issuers that engage in

credit decisions or covered securitization determinations themselves, or through or in cooperation with a third party or affiliate, to adopt and maintain policies, practices, procedures, and control systems to ensure that AVMs used in these transactions adhere to certain quality control standards. The proposed rule would have required those quality control standards be designed to ensure a high level of confidence in the estimates produced; protect against the manipulation of data; avoid conflicts of interest; and require random sample testing and reviews. These four quality control factors would have implemented the minimum standards required by the statute. The proposal would have allowed mortgage originators and secondary market issuers covered by the proposal the flexibility to set their quality control standards for covered AVMs as appropriate based on the size, complexity, and risk profile of the institution and the transactions for which they would use AVMs covered by the proposed rule.

Most commenters supported the proposed flexibility for implementing the statutory quality control standards. These commenters agreed that mortgage originators and secondary market issuers should have the flexibility to adopt policies, practices, procedures, and control systems to implement the quality control standards based on size, complexity, and risk profile of the institution and the transactions for which they would use AVMs covered by the rule. One commenter stated that AVM models will continue to grow and evolve, making the flexible approach appropriate in order to allow institutions to make refinements as technology changes. The commenter also stated that the flexible approach would reduce regulatory burden and that a prescriptive approach could constrain meaningful use of AVMs. Another commenter stated that a more prescriptive rule might not adjust to changing industry developments.

One commenter stated that the principles-based approach of the rule would give credit unions flexibility to narrowly tailor their quality control standards to their unique circumstances. Another commenter stated that a prescriptive rule could present an undue burden on small institutions. Another commenter indicated that a principles-based option could mitigate compliance costs and foster innovation in the AVM space but suggested that there is a need for uniformity and consistency when determinations of relevancy and confidence levels are required. The commenter suggested that

the rule specifically cite those determinations of relevance and confidence levels.

One commenter who supported the flexible approach stated that banks already adhere to supervisory guidance on model risk management, appraisals, and third-party risk management, making prescriptive regulation unnecessary. This commenter also suggested that a “one size fits all” approach would not work well, given the variety of mortgage originators and their business models. The commenter also argued that prescriptive AVM standards would impede technical innovation but suggested that it would be helpful for the agencies to provide guidance on the types of issues the agencies have identified with AVMs, as well as potential remedies of those issues, with narratives, analytical and quantitative examples, and case studies to inform stakeholders. Another commenter stated that flexible, transparent, principles-based approaches to AVM standards are relatively inexpensive and not time-consuming to incorporate and apply and that AVM testing and individual AVM model performance detail may be readily available through a firm’s internal testing group or numerous third-party, independent testing organizations.

One commenter stated that principles-based quality control standards would help foster innovation that will ultimately benefit consumers and the housing market. The commenter stated that as AVM technology continues to develop, a prescriptive approach to regulation would likely become outdated and ineffective quickly, impeding innovation and limiting regulators’ ability to protect consumers as technology evolves. The commenter suggested, however, that focused guidance is warranted to address issues such as testing of AVMs and consideration of whether the use of pricing information in AVM models is appropriate.

One commenter stated that the proposed quality control standards would not hinder competition among AVM developers, AVM users, or future innovation. The commenter stated further that the standards would empower AVM users to utilize risk management practices consistent with the Appraisal Guidelines.

Another commenter who expressed support for the nonprescriptive approach suggested that the wide variety of AVMs and the vast diversity in lender, investor, guarantor, and related stakeholder uses of AVMs would make a prescriptive approach difficult

³⁰ Appraisals are subject to appropriate review under the appraisal regulations. See 12 CFR 34.44(c) (OCC); 12 CFR 225.64(c) (Board); 12 CFR 323.4(c) (FDIC); 12 CFR 722.4(c) (NCUA). While these reviews are independent of, and subsequent to, the underlying appraisals and evaluations, the reviews generally take place before the final approval of a mortgage loan.

to fashion. This commenter expressed concerns about the unintended consequences of a prescriptive approach. Further, this commenter stated that different stakeholders across the U.S. housing finance industry will (and should) have different strategies, processes, and risk tolerances for the use of AVMs. The commenter also argued that a prescriptive approach would be ill-advised as technology is continuously evolving at an increasing pace, citing artificial intelligence as an example.

Another commenter stated that the proposed principles-based approach is appropriate because AVMs are constantly evolving and model development techniques, model deployment processes, data types, and data sources will change, AVMs will evolve, and risk mitigation, testing, and quality control will have to adapt.

Another commenter stated that the techniques used to train models, including AVMs, that rely on artificial intelligence and machine learning are developing rapidly, and that it would be imprudent to take an overly specific approach that may be incompatible with—or even deter the adoption of—advancements in AVM techniques that are likely to be forthcoming. The commenter stated further that a flexible and principles-based approach, on the other hand, will remain applicable regardless of changes in AVM methodologies, quality control best practices, and data availability. The commenter stated that this is especially true for the proposed nondiscrimination quality control factor, given that techniques for mitigating disparate impact, debiasing models, and searching for less discriminatory alternatives continue to develop. The commenter argued that a flexible, principles-based approach will encourage and enable entities to adopt the latest, most effective techniques for mitigating discrimination risk.

A minority of commenters preferred a more prescriptive approach to implementing the quality control standards. One commenter argued that the flexible approach would not likely help community banks that may prefer or require clear and simple instructions on how to comply with the quality control standards. Another commenter suggested that a prescriptive approach would create uniformity in the use of AVMs in the marketplace, provide broader consumer protection, and create a consistent level of safety and soundness when institutions rely on AVM conclusions.

One commenter suggested that the final rule include prescriptive standards

for AVM testing, validation, and confidence needed to assess whether an AVM was appropriate to use for a particular transaction. Two commenters suggested that the agencies use a blended approach to quality control measures for AVMs, with some standardized reporting and testing requirements, while also allowing covered entities to develop tailored policies, practices, procedures, and control systems. One commenter suggested that AVMs need standardized confidence scores and standardized reporting formats to enable broader use and basic statistics on the temporality, proximity, and homogeneity of the data.

Another commenter stated that the rule should provide specific guidelines to explain how institutions are to structure policies, practices, procedures, and control systems, and should add specific minimum standards for the quality control standards in the final rule. The commenter stated that consumers deserve the same level of protection whether they are obtaining a loan from a larger or smaller originator and recommended that the agencies adopt the Appraisal Guidelines as a rule to make the Appraisal Guidelines stronger and more effective.

Two commenters noted that there was an inconsistency in the proposed rule concerning the third quality control factor relating to avoiding conflicts of interest. The commenters noted that the preamble referred to the third factor as “seek to avoid conflicts of interest” while the regulatory text used “avoid conflicts of interest.” These commenters stated that the use of “seek” would be consistent with the statutory language in section 1125. As discussed in more detail below, some commenters also suggested that AVMs should be tested or certified by a third-party tester instead of, or as a supplement to, the approach taken in the proposed rule.

After considering the comments, the agencies have determined that the proposed method was appropriate, and that a flexible approach to implementing the quality control standards would allow the implementation of the standards to evolve along with AVM technology and reduce compliance costs. Different policies, practices, procedures, and control systems may be appropriate for institutions of different sizes with different business models and risk profiles, and a more prescriptive rule could unduly restrict institutions’ efforts to set their risk management practices accordingly. As modeling technology continues to evolve, this flexible approach will allow institutions to refine their implementation of the

rule as appropriate. The proposed and now adopted approach will allow mortgage originators and secondary market issuers the flexibility to set their quality control standards for covered AVMs as appropriate based on the size, complexity, and risk profile of their institution and the transactions for which they would use AVMs covered by the rule.

In regard to the suggestion by some commenters that fostering uniformity in the AVM market would benefit consumers and stakeholders, such uniformity could interfere with the appropriate current and future use of AVMs. In addition, the agencies determined that prescriptive rules would pose a challenge due to the inherent complexity of AVMs and their use cases and the differing size and activities of the institutions that use AVMs. The quality control standards adopted are clear and simple and a more prescriptive rule would become unmanageable over time due to rapidly evolving technology.

Moreover, the quality control standards are also consistent with practices that many participants in the mortgage lending market already follow and with the guidance described above that applies to many regulated institutions that will be subject to the final rule. For example, the Model Risk Management Guidance provides comprehensive suggestions for assessing and monitoring model risk, including on appropriate governance, policies, and procedures for model risk management. In addition, Appendix B of the Appraisal Guidelines contains detailed guidance for institutions seeking to establish policies, practices, procedures, and control systems to ensure the accuracy, reliability, and independence of AVMs. The requirement for quality control standards is also consistent with third-party risk guidance, as discussed earlier. Furthermore, in line with the agencies’ service provider guidance, regardless of whether mortgage originators and secondary market issuers use their own AVMs or third-party AVMs, the final rule requires mortgage originators and secondary market issuers to adopt and maintain policies, practices, procedures, and control systems to ensure that AVMs adhere to the rule’s requisite quality control standards.

Regarding one commenter’s suggestion that existing agency guidance be adopted as part of the rule, the agencies determined that doing so is not necessary at this time and could make it more difficult to adapt the guidance as new issues arise. As previously discussed, many of the institutions that

will be covered by the final rule already consider existing guidance for assistance in structuring their quality control standards for AVM use. Furthermore, the agencies note that institutions that are not regulated by the agency or agencies providing the guidance may still look to the guidance for assistance with compliance. In addition, the statute does not require the agencies to set prescriptive standards for AVMs. For these reasons and those explained above, and after considering the comments, the agencies have concluded that a rule requiring institutions to develop policies, practices, procedures, and control systems designed to satisfy the requirement for quality control standards will more effectively carry out the purposes of section 1125 than a more prescriptive rule.³¹ Therefore, the agencies are adopting the four quality control factors from the statute. The agencies are also making a technical correction to the regulatory text to match the factors with those in section 1125. The omission of “seek to” in regulatory text, as pointed out by two

commenters, was inadvertent and has been added to the final text.

2. Specifying a Nondiscrimination Quality Control Factor

Section 1125 provides the agencies with the authority to “account for any other such factor” that the agencies “determine to be appropriate.”³² Based on this authority, the agencies proposed to include a fifth quality control factor that would require mortgage originators and secondary market issuers to adopt policies, practices, procedures, and control systems to ensure that AVMs used in connection with making credit decisions or covered securitization determinations adhere to quality control standards designed to comply with applicable nondiscrimination laws. The agencies proposed that institutions would have the flexibility to design policies, procedures, practices, and control systems for AVMs that are in compliance with fair lending laws and take into account their business models, as discussed above regarding the first four quality control factors.

Many commenters expressed support for the fifth factor, agreeing that it is important to assess whether AVMs are consistent with fair lending laws and that existing law requires this step. Many commenters endorsed the proposal to add this fifth factor on nondiscrimination to highlight this element of existing laws and create an independent legal requirement for institutions to adopt policies, practices, procedures, and control systems for AVMs that comply with applicable nondiscrimination laws.

Many commenters stated that discrimination is an issue in valuations, including in AVMs, and that specifying a nondiscrimination factor would be useful for reinforcing the applicability of nondiscrimination laws to AVMs. Several commenters asserted that AVMs risk reproducing bias and perpetuating discrimination if they are not adequately examined and tested. These commenters stated that the information used to develop and train AVMs is often drawn from existing data sets that may reflect human biases and historical prejudices. One commenter stated that inclusion of the nondiscrimination factor for AVM models serves as an important reminder to AVM developers and users about the necessity of fair lending and fair housing to a functional marketplace, while another commenter stated that it would help ensure a level playing field. Some commenters asserted that the nondiscrimination factor would work in parallel and

reinforce the other quality control factors. One commenter noted that nondiscrimination is implicitly included in the first four factors. This commenter stated further that the nondiscrimination quality control factor does not introduce a new requirement, but rather emphasizes the applicability of nondiscrimination laws to AVMs and is consistent with current law and existing fair lending guidance.

One commenter stated that nondiscrimination should be understood as a dimension of model performance and a required aspect of quality control. The commenter further asserted that discrimination should be understood as a safety and soundness risk. One commenter stated that banks fully support fair lending laws and currently implement fair lending requirements. The commenter stated further that they are aware of the unique considerations that AVMs present and that banks in their State rely on current fair lending requirements and underwriting and appraisal management guidance to guide their use of AVMs, for example through current model risk management guidance. Another commenter stated that the advantages of specifying the fifth factor are that it will emphasize the safe and effective use of AVMs and encourage expanded use of AVMs as a valuation tool in the industry, both on a stand-alone and independent basis where appropriate, as well as in concert with, and as additional support for, traditional, hybrid, and alternative approaches to value.

A number of commenters suggested that AVM use has the potential to reduce bias in valuations, given that AVMs do not take into account the race of the participants to a particular transaction. One commenter suggested that use of nondiscriminatory AVMs has the potential to provide significant benefits to industry and consumers. The commenter stated that, since AVMs do not know the racial composition of the borrower or neighborhood, an AVM may help provide a fair and unbiased estimate of value. The commenter stated further that the fifth quality control factor would encourage expanded use of AVMs as a valuation tool in the industry. The commenter also stated that specifying a nondiscrimination quality control factor in the rule would be useful in emphasizing the importance of providing support for nondiscrimination or analysis of the potential disparate impact in the use of AVMs.

Similar to the first four quality control factors, most commenters supported a nonprescriptive approach to the

³¹ The agencies have, in other contexts, allowed institutions to adjust their compliance programs in a way that reflects institution-specific factors, such as an institution's size and complexity and the nature and scope of its lending activities. See, e.g., *Interagency Guidelines Establishing Standards for Safety and Soundness*, 12 CFR part 30, Appendix A (OCC); 12 CFR part 208, Appendix D–1 (Board); 12 CFR part 364, Appendix A (FDIC) (requiring institutions to have internal controls and information systems for implementing operational and managerial standards that are appropriate to their size and the nature, scope and risk of their activities); 12 CFR 34.62 (OCC); 12 CFR 208.51 (Board); 12 CFR 365.2 (FDIC) (requiring institutions to adopt policies that establish appropriate limits and standards for extensions of credit that are secured by liens on or interests in real estate); *Interagency Guidelines Establishing Information Security Standards*, 12 CFR part 30, Appendix B (OCC); 12 CFR part 208, Appendix D–2 (Board); 12 CFR part 364, Appendix B (FDIC); 12 CFR part 748, Appendix A (NCUA) (providing guidelines on federally insured credit unions' requirement to implement a comprehensive written information security program that is appropriate to the size and complexity of the institution and the nature and scope of its activities); and 12 CFR 41.90 (OCC); 12 CFR 222.90 (Board); 12 CFR 334.90 (FDIC) (requiring that banks establish policies and procedures for the detection, prevention, and mitigation of identity theft). See also *Guidelines Establishing Standards for Residential Mortgage Lending Practices*, 12 CFR part 30, Appendix C (OCC) (providing that residential mortgage lending activities should reflect standards and practices appropriate for the size and complexity of the bank and the nature and scope of its lending activities); 12 CFR 1007.104 (CFPB) (requiring policies and procedures regarding the registration of mortgage loan originators that are appropriate to the nature, size, complexity, and scope of the financial institution's mortgage lending activities); and 12 CFR 1026.36(j) (CFPB) (requiring policies and procedures regarding mortgage loan origination that are appropriate to the nature, size, complexity, and scope of the mortgage lending activities of the depository institution and its subsidiaries).

³² 12 U.S.C. 3354(a)(5).

nondiscrimination factor. One commenter explained that a flexible approach would assist in the process of adapting existing policies into the framework of quality control standards. One commenter suggested that a principles-based approach would enable innovation while building a sustainable framework to reduce discrimination, advance fair lending and fair housing, and ensure accuracy in home valuation processes by requiring entities to align their policies and procedures with promulgated principles. Another commenter stated that a nonprescriptive approach would prevent interference with the industry developing innovative solutions to address discrimination. A few commenters stated that the principles-based approach would allow lenders to take into account changes in AVM technology. One commenter noted that there is a lack of consensus among stakeholders concerning how AVMs should be evaluated with respect to fair lending and suggested that the proposed flexible approach is best because it would account for the current level of uncertainty.

One commenter stated that agency guidance would be the appropriate venue to address the more nuanced issues of compliance, such as how to conduct particular types of testing, including outcomes-based testing for disparate impact, and how to evaluate potential less discriminatory alternatives to an AVM that results in disparate outcomes. The commenter suggested that the final rule should articulate baseline standards for nondiscrimination from applicable statutes and regulations, specifically the ECOA and Fair Housing Act's prohibitions on disparate treatment and disparate impact. The commenter also suggested that compliance with applicable antidiscrimination laws calls for more than simply avoiding the use of prohibited bases as predictive variables in an AVM and that a proper compliance program involves other forms of antidiscrimination testing, such as disparate impact and bias testing.

One commenter stated that existing compliance management systems and fair lending monitoring programs should be able to assess whether an AVM applies different standards or produces disparate valuations on a prohibited basis. A few commenters supported a more prescriptive approach and expressed a need for bias testing standards.

Commenters made additional recommendations, including that the agencies release loan-level data from the Uniform Appraisal Dataset to provide a robust data set to evaluate AVMs and

identify less discriminatory alternatives. One commenter also suggested that the agencies organize and encourage private sector activities, such as conferences and research, to inform ongoing guidance on compliance with the quality controls standards. Other commenters suggested that the agencies issue guidance on how to implement the fifth quality control factor.

In contrast, several commenters opposed including the fifth factor. Commenters expressed various concerns, including that the factor would impose a significant compliance burden, lender systems are not able to assess whether an AVM discriminates, the factor is not required by statute, and the addition of the factor is unnecessary and duplicates existing law and the other quality control factors. Two commenters suggested that documented instances of bias in AVMs are not prevalent, and one of these commenters stated that it would be a mistake to attempt to eradicate through regulation the speculative possibility of bias in AVMs, which could reduce AVM use, when the use of this technology can remove the type of subjective, personal bias that traditional appraisals bring to the valuation process. In addition, some commenters stated that the agencies should use other tools to address AVM bias concerns and the onus should be on AVM vendors to ensure models comply with nondiscrimination laws. A few commenters stated that adding this factor may have unintended effects, such as increased loan costs for consumers and small institutions deciding to stop using AVMs altogether in mortgage origination due to uncertainty and the cost of compliance.

One commenter stated that banks support fair lending laws, dedicate considerable resources to comply with them, and are regularly examined for compliance with those laws. The commenter stated, however, that adding a fifth factor on nondiscrimination is not necessary. This commenter noted that long-standing fair lending laws have and will continue to apply to mortgage transactions and the agencies regularly assess banks' compliance management systems. According to this commenter, the agencies can ensure through their examinations that policies, procedures, and controls are in place to address fair lending risk in AVM use. The commenter stated that the agencies can heighten the awareness of fair lending risks without regulation through bulletins and policy guidance. The commenter also expressed concern that codifying the rule in Regulation Z could result in plaintiffs challenging originators with the private right of

action and statutory damages set forth in the TILA, which could increase costs for banks and their customers. The commenter stated that Congress clearly did not intend such a result, given that it added the quality control requirements in FIRREA, not TILA.

Several commenters expressed concerns about the ability of lenders to apply quality control standards for fair lending to AVM models. Some commenters expressed concern about how small entities can assess fair lending issues in AVMs or know that they are violating the law. They asserted that existing compliance management systems and fair lending monitoring programs are not able to assess whether an AVM applies different standards or produces disparate valuations on a prohibited basis. They argued that small entities do not have access to an AVM's data or methodology, are unable to validate the algorithms that AVM providers use, and lack the staff to assess the AVM models results.

One commenter stated that most community banks lack in-house expertise needed to test for disparate impact and will lack the volume to yield the number of observations required for testing. The commenter stated that even many larger institutions lack sufficient mortgage lending activity to engage in testing and to justify the cost of disparate impact testing. Another commenter stated that the quality control factor for nondiscrimination may force community banks to shift to using appraisals because of the compliance challenges and uncertainty relating to implementation of the factor. The commenter stated that this will likely disincentivize mortgage lending in rural areas where AVMs can be utilized as a more cost-effective, efficient, and accurate option. The commenter stated that requiring community banks to assess and evaluate models for potential fair lending concerns would be unreasonable, redundant, and extremely costly. The commenter stated further that a community bank is unlikely to retain staff with sufficient expertise to determine valuation accuracy and reverse engineer the algorithms to assess any fair lending red flags.

One commenter stated that credit unions' existing systems are not able to assess whether AVMs discriminate and that the data and resources needed to undertake an analysis of AVMs, including analysis for discriminatory bias, would be significant. Another commenter argued that the inclusion of the factor may make it difficult for credit unions to use AVMs in originating loans. The commenter stated

further that to the extent the quality control standards require fair lending testing of AVM values, small credit unions may not have large enough data sets to be able to do meaningful, statistically significant testing of their AVM results. The commenter stated that credit unions lack control over the proprietary inputs and data that feed into AVMs and lack bargaining power and resources to examine third-party proprietary algorithms that power AVMs.

Other commenters stated that the agencies should use other tools to address AVM bias concerns, including asserting supervisory authority over AVM vendors as service providers and utilizing Dodd-Frank Act authority to supervise nonbank companies that pose risks to consumers. Another commenter argued that fair lending guidelines and mandates should remain within the purview of the Interagency Fair Lending Examination Procedures, thereby creating clarity for compliance management systems and a consistent examiner approach.

Several commenters stated that the burden of compliance with the fifth factor should be placed on the AVM provider. Commenters argued that lenders do not have access to proprietary models used by third parties to be able to assess fair lending performance. One commenter argued that to place the burden on financial institutions would be excessive as financial institutions are obligated to comply with existing regulatory regimes under the ECOA and the Fair Housing Act. One commenter expressed concern regarding lender liability for violating nondiscrimination law when relying on third-party AVMs.

Several commenters requested additional guidance regarding compliance with the nondiscrimination factor. One commenter stated that the agencies have not provided a clear performance indicator by which a lender could discern any inherent bias within a data set. The commenter urged the agencies to provide clear guidance on discriminatory red flags in AVMs. The commenter stated that different industry players have access to varying quality of data, that the agencies should account for this in their guidance and recommendations, and that little legal clarity exists around practices in the AVM industry that may violate the Fair Housing Act.

As the agencies noted in the proposal, existing nondiscrimination laws apply to appraisals and AVMs, and institutions have a preexisting obligation to comply with all Federal laws, including Federal

nondiscrimination laws. For example, the ECOA and its implementing Regulation B bar discrimination on a prohibited basis in any aspect of a credit transaction.³³ The agencies have long recognized that this prohibition extends to using different standards to evaluate collateral,³⁴ which includes the design or use of an AVM in any aspect of a credit transaction in a way that would treat an applicant differently on a prohibited basis or result in unlawful discrimination against an applicant on a prohibited basis. Similarly, the Fair Housing Act prohibits unlawful discrimination in all aspects of residential real estate-related transactions, including appraisals of residential real estate.³⁵

As with models more generally, there are increasing concerns about the potential for AVMs to produce property estimates that reflect discriminatory bias, such as by replicating systemic inaccuracies and historical patterns of discrimination. Models could discriminate because of the data used or other aspects of a model's development, design, implementation, or use.³⁶

³³ 15 U.S.C. 1691(a) (prohibiting discrimination on the basis of race, color, religion, national origin, sex (including sexual orientation and gender identity) or marital status, age (provided the applicant has the capacity to contract), because all or part of the applicant's income derives from any public assistance program, or because the applicant has in good faith exercised any right under the Consumer Credit Protection Act); see also 12 CFR part 1002. This prohibition includes discrimination on the prohibited basis characteristics of "the neighborhood where the property offered as collateral is located." 12 CFR part 1002, supp. I, para. 2(z)-1.

³⁴ See Interagency Task Force on Fair Lending, *Policy Statement on Discrimination in Lending*, 59 FR 18266, 18268 (Apr. 15, 1994) (noting that under both ECOA and the Fair Housing Act, a lender may not, because of a prohibited factor, use different standards to evaluate collateral).

³⁵ 42 U.S.C. 3605 (prohibiting discrimination because of race, color, religion, national origin, sex, handicap, or familial status in residential real estate-related transactions); 42 U.S.C. 3605(b)(2) (defining "real estate-related transactions" to include the "selling, brokering, or appraising of residential real property."); see also 24 CFR part 100.

³⁶ In other contexts, models and data have the potential to be a source of bias and may cause consumer harm if not designed, implemented, and used properly. See generally, Federal Trade Commission, *Big Data: A Tool for Inclusion or Exclusion? Understanding the Issues* (Jan. 2016), available at <https://www.ftc.gov/system/files/documents/reports/big-data-tool-inclusion-or-exclusion-understanding-issues/160106big-data-rpt.pdf>; Reva Schwartz et al., *A Proposal for Identifying and Managing Bias in Artificial Intelligence*, Nat'l Inst. of Standards & Tech., U.S. Department of Commerce (June 2021), available at <https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.1270-draft.pdf>. See also Andreas Fuster et al., *Predictably Unequal? The Effects of Machine Learning on Credit Markets*, 77 J. of Fin. 5 (Feb. 2022), available at <https://doi.org/10.1111/jofi.13090>; Emily Bembeneck, et al., *To Stop Algorithmic Bias, We First Have to Define It*,

Attention to data is particularly important to ensure that AVMs do not rely on data that incorporate potential bias and create discrimination risks. Because AVMs arguably involve less human discretion than appraisals, AVMs have the potential to reduce human biases. Yet without adequate attention to ensuring compliance with Federal nondiscrimination laws, AVMs also have the potential to introduce discrimination risks. Moreover, if models such as AVMs are biased, the resulting harm could be widespread because of the high volume of valuations that even a single AVM can process. These concerns have led to an increased focus by the public and the agencies on the connection between nondiscrimination laws and AVMs.

While existing nondiscrimination law applies to an institution's use of AVMs, the agencies proposed to include a fifth quality control factor relating to nondiscrimination to heighten awareness among lenders of the applicability of nondiscrimination laws to AVMs. Specifying a fifth factor on nondiscrimination would create an independent requirement for institutions to establish policies, practices, procedures, and control systems to specifically ensure compliance with applicable nondiscrimination laws, thereby further mitigating discrimination risk in their use of AVMs. Specifying a nondiscrimination factor will increase confidence in AVM estimates and support well-functioning AVMs. In addition, specifying a nondiscrimination factor will help protect against potential safety and soundness risks, such as operational, legal, and compliance risks, associated with failure to comply with nondiscrimination laws.

In proposing to add a fifth quality control factor on nondiscrimination, the agencies noted that compliance with applicable nondiscrimination laws with respect to AVMs may be indirectly reflected within and related to three of the first four statutory quality control factors. For example, the first factor requires quality control standards designed to ensure a high level of confidence in the estimates produced by AVMs. AVMs that reflect discriminatory bias in the data or discriminatory assumptions could affect confidence in AVM outputs and may also result in a form of data manipulation, particularly with respect to model assumptions and in the interactions among variables in a

Brookings Inst. (Oct. 21, 2021), available at <http://brookings.edu/research/to-stop-algorithmic-bias-we-first-have-to-define-it/>.

model, which bears on the second quality control factor in section 1125. The fourth quality control factor requires random sample testing and reviews of AVMs. The proposed fifth factor on nondiscrimination may include an array of tests and reviews, including fair lending reviews, which would support the general requirement for random sample testing, and review in section 1125. The first four factors do not, however, expressly address quality control measures relating to compliance with nondiscrimination laws.

The fifth quality control factor is consistent not only with current law, but also with well-established fair lending guidance. The OCC, Board, FDIC, NCUA, CFPB, and FHFA have issued statements and other materials setting forth principles they will consider to identify discrimination.³⁷ The OCC, Board, FDIC, NCUA, and CFPB have further underscored the importance of robust consumer compliance management to prevent consumer harm in the Interagency Policy Statement on the Use of Alternative Data in Credit Underwriting (Alternative Data Policy Statement). In the Alternative Data Policy Statement, the agencies emphasized that “[r]obust compliance management includes appropriate testing, monitoring and controls to ensure consumer protection risks are understood and addressed.”³⁸

³⁷ See, e.g., Interagency Task Force on Fair Lending, *Policy Statement on Discrimination in Lending*, 59 FR 18266 (Apr. 15, 1994), available at <https://www.govinfo.gov/content/pkg/FR-1994-04-15/html/94-9214.htm>; Interagency Fair Lending Examination Procedures (Aug. 2009), available at <https://www.ffiec.gov/PDF/fairlend.pdf>; CFPB, *Examination Procedures—ECOA* (Oct. 2015), available at https://files.consumerfinance.gov/f/documents/201510_cfpb_ecoa-narrative-and-procedures.pdf; Federal Housing Finance Agency, *Policy Statement on Fair Lending*, 86 FR 36199 (July 9, 2021), available at <https://www.govinfo.gov/content/pkg/FR-2021-07-09/pdf/2021-14438.pdf>.

³⁸ *Id.* Interagency Statement on the Use of Alternative Data in Credit Underwriting, OCC Bulletin 2019–62 (Dec. 3, 2019); Federal Reserve CA Letter 19–11 (Dec. 12, 2019); FDIC FIL–82–2019 (Dec. 13, 2019); NCUA Letter 19–CU–04 (December 2019); CFPB, Federal Regulators Issue Joint Statement on the Use of Alternative Data in Credit Underwriting (Dec. 3, 2019) available at <https://www.consumerfinance.gov/about-us/newsroom/federal-regulators-issue-joint-statement-use-alternative-data-credit-underwriting/> and https://files.consumerfinance.gov/f/documents/cfpb_interagency-statement_alternative-data.pdf; CFPB, *Supervisory Highlights: Summer 2013*, 5–11 (Aug. 2013), available at https://files.consumerfinance.gov/f/201308_cfpb_supervisory-highlights-august.pdf (discussing the pillars of a well-functioning CMS). See also Federal Financial Institutions Examination Council (FFIEC), *Notice and Final Guidance, Uniform Interagency Consumer Compliance Rating System*, 81 FR 79473 (Nov. 14, 2016), available at https://www.ffiec.gov/press/PDF/FFIEC_CCR_SystemFR_Notice.pdf (“in developing the revised CC Rating System, the Agencies believed it was also important for the new

In addition, the CFPB has published procedures for CFPB examiners to assess an institution’s fair lending related risks and controls related to the use of models—including, potentially, AVMs—in the credit decision process.³⁹

The agencies have determined that the fifth factor is important to the quality control of AVMs and to fair lending. As with the four statutory quality control factors, the agencies are aware of the concerns expressed by some commenters that implementation hurdles, such as access to AVM data and design, could complicate compliance, especially for small entities. However, the existing guidance, as discussed earlier, already addresses many of the elements of quality control for AVMs, including fair lending considerations. In addition, institutions will have the flexibility to adopt approaches to implement the fifth factor in ways that reflect the risks and complexities of institutions’ business models.

Regarding a commenter’s concern about lender liability for third-party AVMs, the agencies remind institutions that make use of third-party providers that they remain responsible for ensuring that the third parties comply with applicable laws and regulations in performing their activities, including nondiscrimination laws and the safety and soundness requirements established by the OCC, Board, FDIC, and NCUA. As discussed earlier, the agencies have already provided guidance on implementing policies, practices, procedures, and control systems relating to model risk, third-party risk, AVMs, and nondiscrimination. Institutions should refer to relevant rules and statutes for the specific requirements which may apply. Regarding a commenter’s concern that the CFPB codifying this rule in Regulation Z could result in plaintiffs challenging originators with a private right of action and statutory damages for some violations set forth in TILA, the CFPB notes that the statutory authority for this AVM rulemaking is FIRREA rather than TILA.

For these reasons and after considering the comments, the agencies are adopting the proposed quality control factor on nondiscrimination.

rating system to establish incentives for institutions to promote consumer protection by preventing, self-identifying, and addressing compliance issues in a proactive manner. Therefore, the revised rating system recognizes institutions that consistently adopt these compliance strategies.”).

³⁹ CFPB, *ECOA Baseline Review Module 2*, 6 (Apr. 2019), available at https://files.consumerfinance.gov/f/documents/cfpb_supervision-and-examination-manual_ecoa-baseline-exam-procedures_2019-04.pdf.

C. Definitions

1. Automated Valuation Model

Section 1125 of title XI defines “automated valuation model” as “any computerized model used by mortgage originators and secondary market issuers to determine the collateral worth of a mortgage secured by a consumer’s principal dwelling.”⁴⁰ The agencies proposed that the rule define an AVM as “any computerized model used by mortgage originators and secondary market issuers to determine the value of a consumer’s principal dwelling collateralizing a mortgage.” The proposed definition was substantively identical to the definition in section 1125 but reflects common terminology and clarifies that the determination of value relates to the dwelling.

Most comments supported using the statutory definition of AVM as the basis for the definition in the proposed rule. A few commenters questioned the need to revise the statutory language for “plain English” purposes and to reflect current practice. Other commenters offered proposals to expand the definition. One commenter stated that the agencies should amend the definition to add the components of an AVM, such as comparable sales values. Another commenter suggested that the proposed definition be modified to clarify that an AVM means a model used without alteration of valuation results by a person and that the final rule should include the components of an AVM. Some commenters suggested that the definition should be drafted more broadly to include all market participants using AVMs in mortgage lending and securitization determinations, rather than limiting the scope to mortgage originators and secondary market issuers. One commenter stated that a consumer-facing definition of AVM is needed that discloses the significant uncertainty that exists when using AVMs.

The agencies have concluded that the nonsubstantive changes to the statutory definition of AVM make the definition set forth in regulatory text clearer and more understandable. Changes suggested by commenters (to identify components of an AVM, add usages by other market participants, and serve as a consumer-facing disclosure) would represent a significant departure from the statutory language. For these reasons, and after considering the comments, the agencies are adopting the proposed definition of automated valuation model.

⁴⁰ 12 U.S.C. 3354(d).

2. Control Systems

The proposal defined “control systems” as the functions (such as internal and external audits, risk review, quality control, and quality assurance) and information systems that institutions use to measure performance, make decisions about risk, and assess the effectiveness of processes and personnel, including with respect to compliance with statutes and regulations. Under the proposal, the agencies intended for institutions to use control systems that are appropriate for the size, complexity, and risk profile of the institution and the transactions for which they would use AVMs covered by the proposed rule.

Most commenters expressed support for the proposed definition of “control systems.” One commenter suggested that adding further detail to the “control systems” definition could contribute to a misalignment of controls and complexity, given that the proposed rule allows entities to align control systems to the size, complexity, and risk profile of the institution and the transactions for which they would use covered AVMs. Another commenter stated that the definition should address the analytical and statistical nature of control systems designed for an AVM. The commenter suggested that the agencies provide more guidance to ensure a clear understanding of control expectations. Similarly, another commenter asked that the agencies provide more information on how the proposed rule relates to existing guidance about control systems and model usage. The commenter suggested that the agencies issue a compliance guide and frequently asked questions to facilitate implementation for small entities. One commenter stated that, while a “policies and procedures” requirement is the established, well-understood compliance implementation framework for this type of regulation, the proposed definition of control systems is nonstandard and overly defined. The commenter further stated that the rule’s related but undefined term “practices” is nonstandard. Other commenters suggested that the final rule include specific control standards.

As discussed earlier, guidance is already in place to assist regulated institutions in implementing policies, practices, procedures, and control systems relating to model risk, third-party risk, AVMs, and nondiscrimination. Institutions that are not regulated by the agency or agencies providing the guidance may still look to the guidance for assistance with compliance. Regarding the comments

concerning the inclusion of control systems, the agencies note that policies, practices, procedures, and control systems are all part of ensuring that AVMs adhere to the rule’s requisite quality control standards. In addition, many institutions already employ control systems with respect to AVM use. These factors, in addition to the rule’s flexible approach to implementing the statute, should allow institutions to implement appropriate control systems and mitigate compliance costs, particularly for smaller institutions. For these reasons, and after considering the comments, the agencies are adopting the proposed definition of “control systems.”

3. Covered Securitization Determination

The proposed rule defined “covered securitization determination” to mean a determination regarding (1) whether to waive an appraisal requirement for a mortgage origination in connection with its potential sale or transfer to a secondary market issuer, or (2) structuring, preparing disclosures for, or marketing initial offerings of mortgage-backed securitizations. Monitoring collateral value in mortgage-backed securitizations after they have already been issued would not have been a covered securitization determination under the proposed rule. One commenter, however, stated that small entities do not securitize loans and remarked that the rule could create a cost burden and hinder access to the secondary market, particularly for small mortgage originators.

The agencies received few comments on the proposed definition of “covered securitization determination.” As discussed earlier, commenters supported the application of the quality control standards to secondary market issuers and in the appraisal waiver context. The agencies did not receive comments asking for changes to the proposed definition of “covered securitization determination.”

As discussed above, covering secondary market issuers’ use of AVMs in covered securitization determinations—including determinations regarding appraisal waivers and structuring, preparing disclosures for, or marketing initial offerings of mortgage-backed securitizations—is consistent with protecting the safety and soundness of institutions and protecting consumers and investors by reducing the risk that secondary market issuers would misvalue homes. For these reasons and after considering the comments, the agencies are adopting the proposed

definition of covered securitization determination.

4. Credit Decision

The proposed rule would have defined the term credit decision to mean a decision regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage, including a decision on whether to extend new or additional credit or change the limit on a line of credit. Monitoring the value of the underlying real estate collateral in loan portfolios would not have been a credit decision for the purposes of the proposed rule. This point reflects the fact that the collateral worth of a mortgage is generally determined in connection with credit decisions or covered securitization determinations, rather than when the value of the collateral supporting a mortgage is monitored or verified.

The commenters generally did not offer any suggestions for making the proposed definition of “credit decision” clearer, but one commenter stated that the phrase “make other changes to a mortgage” is ambiguous and should be excluded from the definition. The phrase “make other changes to a mortgage” in the definition is clarified by the context of other words in the definition (*i.e.*, “modify,” “terminate,” and “extend new or additional credit or change the credit limit”). Moreover, the phrase “make other changes to a mortgage” ensures that other types of credit decisions are appropriately encompassed within the rule’s definition of credit decision. For example, one commenter stated that decisions regarding assumptions should be covered, and another commenter stated that decisions regarding private mortgage insurance and shared equity should also be covered. To the extent those are decisions regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage, such decisions are credit decisions under the rule. Therefore, mortgage originators and secondary market issuers that engage in such decisions themselves, or through or in cooperation with a third-party or affiliate, must adopt and maintain policies, practices, procedures, and control systems to ensure that AVMs used in these credit decisions adhere to the rule’s requisite quality control standards.

For these reasons, and for the reasons stated earlier with respect to the scope of the rule and after considering the comments, the agencies are adopting the proposed definition of “credit decision.”

5. Dwelling

The definition of AVM in section 1125 refers to a mortgage secured by a “consumer’s principal dwelling.”⁴¹ The OCC, Board, FDIC, NCUA, and FHFA proposed to define “dwelling” to mean a residential structure that contains one to four units, whether or not that structure is attached to real property. The term would include, if used as a residence, any individual condominium unit, cooperative unit, factory-built housing, or manufactured home. The proposed definition of “dwelling” provided that a consumer can have only one principal dwelling at a time. Thus, a vacation or other second home would not be a principal dwelling. However, if a consumer buys or builds a new dwelling that will become the consumer’s principal dwelling within a year or upon the completion of construction, the new dwelling would be considered a principal dwelling for purposes of this rule.⁴²

The CFPB proposed to codify its AVM requirements in Regulation Z, 12 CFR part 1026, which generally implements TILA. The definition of “dwelling” proposed by the other agencies was consistent with the CFPB’s existing Regulation Z.⁴³ Unlike TILA, however, title XI does not limit its coverage generally to credit transactions that are primarily for personal, family, or household purposes.⁴⁴ Because this rulemaking is conducted pursuant to title XI rather than TILA, the CFPB proposed to revise Regulation Z §§ 1026.1, 1026.2, 1026.3, and 1026.42,

and related commentary, to clarify that the final AVM rule would apply when a mortgage is secured by a consumer’s principal dwelling, even if the mortgage is primarily for business, commercial, agricultural, or organizational purposes.⁴⁵

Several commenters suggested that the definition of “dwelling” should cover real property only and exclude AVMs used in lending for manufactured homes and recreational vehicles (RVs), trailers, and other structures that retain their mobility. These commenters similarly suggested that the final rule should exclude from coverage cost estimate guides and other valuation tools used to value such collateral that may be a consumer’s principal dwelling but is not real estate. One commenter asked that the final rule confirm that the rule does not apply to cost estimates like those used in complying with the higher-priced mortgage loan appraisal requirements of Regulation Z § 1026.35. In explaining its suggestion, the commenter stated that a cost estimate is derived from closed sales data and that the designation as a cost approach is significant as it does not rely on comparable sales and is simply the cost to make less depreciation.

The commenter stated further that cost estimates are not location (address or neighborhood) specific; they are region specific. The commenter noted that, for example, one cost estimate guide was developed exclusively for the factory built, manufactured housing industry and that manufactured homeowners, consumers, retailers, and lenders all rely on such independent cost estimates to confirm home values. The commenter further stated that the burden of attempting to comply with the AVM rule, should it be read to cover these cost estimates, would be significant and nearly impossible, especially when compared with any negligible risk to consumers. Another commenter expressed similar concerns relating to valuation tools for non-real estate related loans. This commenter noted that lenders in some markets make non-real estate loans to meet the credit and housing needs of their customers, and, in making these loans, use different tools that might be considered AVMs under the proposed definition of dwelling. The commenter stated that the increased burden associated with complying with the rule could lead some lenders to exit this market.

One commenter expressed concern about the rule covering loans that are used for business purposes, but are secured by principal residences, suggesting that Congress intended to limit the statute to consumer-purpose credit given that the statute refers to a “consumer’s principal dwelling.”

In contrast, several other commenters recommended that the agencies adopt a broad definition of dwelling. One stated that coverage should extend to all mortgages involving loans for dwellings, including manufactured housing classified as personal property and accessory dwelling units. Two commenters suggested the agencies define dwelling in a way consistent with uses in the Fair Housing Act and in other relevant statutes. Another commenter suggested that it would be consistent with safe and sound practices to expand the scope of the rule to cover all dwellings, not only those that are principal dwellings. One commenter stated that the agencies should consider how the principal dwelling requirement may apply to active military personnel who are purchasing a home for their future permanent residence but who are assigned temporarily to a different duty station.

In response to these comments, the agencies note that section 1125 does not limit the definition of AVM to collateral that is deemed to be real property, nor does it limit coverage by the AVM requirements to credit transactions that are primarily for personal, family, or household purposes. Instead, the statute focuses on the valuation of a consumer’s principal dwelling that secures a mortgage. In response to the comments on limiting the rule to a principal dwelling, the agencies note that the statute expressly defines an AVM as one used to value a consumer’s principal dwelling. The final rule is consistent with the plain language of the statute and the agencies decline to expand the scope of the requirements beyond principal dwellings.

With respect to the commenters’ argument that valuation tools used for manufactured homes, RVs, and boats are not AVMs, the definition of AVM in the statute covers “any computerized model” used to determine the value of a consumer’s principal dwelling.⁴⁶ The agencies do not opine on whether any specific product, including a cost estimate and other valuation tool, is an AVM that would be covered under this rule. As noted by commenters, AVMs that rely on artificial intelligence, machine learning, and other technologies are developing rapidly.

⁴¹ 12 U.S.C. 3354(d).

⁴² The NCUA notes that under its regulations, a Federal credit union may make a mortgage loan to a member for a maturity of up to 40 years if the loan is secured by a one-to-four family dwelling that is or will be the principal residence of the member-borrower, among other requirements. 12 CFR 701.21(g). The use of the term “principal residence” in § 701.21(g) of the NCUA’s regulations is distinct from the term “principal dwelling” used in this final rule. The definition of “dwelling” and the condition that the dwelling is or will be a principal dwelling within one year for purposes of this AVM final rule would not change what type of dwelling is considered to be a principal residence under the NCUA’s regulation, § 701.21(g), the parameters of which are drawn directly from the Federal Credit Union Act. 12 U.S.C. 1757(5)(A)(i).

⁴³ See 12 CFR 1026.2(a)(19) (definition of “dwelling”) and 1026.2(a)(24) (definition of “residential mortgage transaction”). The phrase “consumer’s principal dwelling” is used in the Regulation Z provisions on valuation independence. 12 CFR 1026.42. Regulation Z generally defines “consumer” as a natural person to whom consumer credit is offered or extended. 12 CFR 1026.2(a)(11). The CFPB notes that pursuant to Regulation Z comments 2(a)(11)–3 and 3(a)–10, consumer credit includes credit extended to trusts for tax or estate planning purposes and to land trusts.

⁴⁴ See 12 CFR 1026.2(a)(12) (definition of “consumer credit”).

⁴⁵ Therefore, the exemptions in 12 CFR 1026.3 would not apply to the requirements established by the CFPB under this rule.

⁴⁶ 12 U.S.C. 3354(d) (emphasis added).

Since AVM modeling technology will continue to evolve, valuation products that do not currently meet the definition of an AVM may meet that definition in the future. As such, the agencies have determined that a flexible and principles-based approach to this rule would be more appropriate than a prescriptive approach. Under this principles-based approach, mortgage originators and secondary market issuers will need to consider whether the valuation products that they are using are (1) automated (*i.e.*, computerized); (2) a model;⁴⁷ and (3) designed to estimate the value of a consumer's principal dwelling collateralizing a mortgage.

With respect to the comment that the agencies consider the effect of the rule on servicemembers who are purchasing a home for their future permanent residence, but are assigned to temporary duty stations, the final rule will not have an effect on the place servicemembers designate as their principal dwelling.

For these reasons and after considering the comments, the agencies are adopting the proposed definition of "dwelling." Under the final rule, a dwelling is defined as a residential structure that contains one to four units, whether or not that structure is attached to real property. Mortgages secured by non-real estate property are covered by this rule if the property is used as the borrower's principal dwelling and the

mortgage originator or secondary market issuer uses an AVM to determine the value of the collateral securing the loan.

6. Mortgage

Section 1125(d) defines an AVM with reference to determining "the collateral worth of a mortgage secured by a consumer's principal dwelling."⁴⁸ Section 1125 does not define "mortgage." Because the statute does not refer to "mortgage loans" or "mortgage credit," but rather uses the word "mortgage," the proposal defined "mortgage" to broadly cover the mortgage market as fully as the statute appears to envision in the language of section 1125(d) and throughout section 1125. Consequently, for this purpose, the agencies proposed to adopt, in part, the Regulation Z definition of "residential mortgage transaction,"⁴⁹ which existed at the time the statute was passed. The proposal would define the term "mortgage" to mean a transaction in which a mortgage, deed of trust, purchase money security interest arising under an installment sales contract, or equivalent consensual security interest is created or retained in a consumer's principal dwelling.

Most commenters who addressed the definition of "mortgage" in the proposal expressed support for the proposed language. Several commenters supported including purchase money security interests arising under installment sales contracts in the definition of "mortgage." One commenter stated that consumers should have the same protection in these contracts as in other types of mortgage financing. The commenter also stated that TILA, the Real Estate Settlement Procedures Act, and the S.A.F.E. Act apply to installment sales contracts to the same extent as to traditional mortgage loans (depending on whether the originating lender makes a certain volume of transactions), so including installment contracts in the rule would be consistent with other current laws. The commenter stated further that including sales contracts in the AVM rule would ensure appropriate protections for these transactions that disproportionately impact homebuyers of color. The commenter also stated that sales contracts are typically made for smaller amounts and used to purchase less expensive homes, and thus AVMs are more likely to be used in these transactions.

Another commenter in support of covering installment contracts stated that a narrower definition would have a

disparate impact on protected classes by excluding broad swaths of the market from the quality control standards. Similarly, a different commenter stated that applying quality controls for AVMs used in these contracts would provide consumer protection in a space where consumers are often vulnerable to coercive agreements.

Conversely, one commenter stated that, when combined with the proposed definitions of "consumer" and "dwelling," the definition of "mortgage" is not clear. The commenter stated that the rule proposes to adjust the definition of "primary use," removing the exception for business-purpose lending, among other exceptions, from Regulation Z § 1026.3. The commenter suggested that the proposed definitions and changes to the TILA rules will cause a disconnect in how organizations apply the rest of the TILA standards, which take the exceptions into consideration when applying the rule to mortgage transactions. The commenter stated further that the definitions would not align with the current Federal credit union definitions of mortgage. For those reasons, the commenter suggested that definitions of "consumer," "dwelling," and "mortgage" should only be applicable to AVM use, and not cause universal changes to Regulation Z. In addition, a different commenter suggested that the inclusion of sales contracts in the definition of "mortgage" should be decided separately from a consideration of AVM standards and requested that the agencies clarify whether the rule would include HELOCs and closed-end home equity loans.

The agencies have determined that the comprehensive coverage of the mortgage market that the proposed definition would bring about is the best way to implement the statutory language. The agencies agree with those commenters who stated that this definition will provide appropriate consumer protection for the often-vulnerable consumers in the installment sales contracts market. The agencies do not agree that this definition, and the others adopted in this rule, will interfere with the current interpretation of Regulation Z. The agencies note that these definitions apply to AVM compliance alone, and are not meant to alter the current definitions in Regulation Z. Furthermore, the definition of "mortgage" does not exclude HELOCs and closed-end home equity loans that are secured by a consumer's principal dwelling. For these reasons and after considering the

⁴⁷ For example, the *Supervisory Guidance on Model Risk Management*, issued by the OCC, Board, and FDIC describes a "model" as follows:

[T]he term *model* refers to a quantitative method, system, or approach that applies statistical, economic, financial, or mathematical theories, techniques, and assumptions to process input data into quantitative estimates. A *model* consists of three components: an information input component, which delivers assumptions and data to the model; a processing component, which transforms inputs into estimates; and a reporting component, which translates the estimates into useful business information. Models meeting this definition might be used for analyzing business strategies, informing business decisions, identifying and measuring risks, valuing exposures, instruments or positions, conducting stress testing, assessing adequacy of capital, managing client assets, measuring compliance with internal limits, maintaining the formal control apparatus of the bank, or meeting financial or regulatory reporting requirements and issuing public disclosures. The definition of *model* also covers quantitative approaches whose inputs are partially or wholly qualitative or based on expert judgment, provided that the output is quantitative in nature.

Supervisory Guidance on Model Risk Management, OCC Bulletin 2011–12 at 3 (Apr. 4, 2011) (emphasis in original); *Guidance on Model Risk Management*, Federal Reserve SR Letter 11–7 (Apr. 4, 2011); *Adoption of Supervisory Guidance on Model Risk Management*, FDIC FIL–22–2017 (June 7, 2017). Institutions that are not regulated by the agency or agencies providing this guidance may still look to the guidance for assistance with compliance.

⁴⁸ 12 U.S.C. 3354(d).

⁴⁹ 12 CFR 1026.2(a)(24).

comments, the agencies are adopting the proposed definition of “mortgage.”

7. Mortgage Originator

The proposal would have defined the term “mortgage originator” in the rule by cross reference to the TILA definition of “mortgage originator”.⁵⁰ Thus, under the proposal, the term “mortgage originator” generally would have included creditors as defined by 15 U.S.C. 1602(g), notwithstanding that the definition of “mortgage originator” at 15 U.S.C. 1602(dd)(2) excludes creditors for certain other purposes.⁵¹ The CFPB’s proposal also would have added proposed Regulation Z comment 42(i)(2)(vi)–1 to its rule reflecting this clarification. Additionally, based on the exception provided at 15 U.S.C. 1602(dd)(2)(G), the term “mortgage originator” generally would have excluded servicers as defined by 15 U.S.C. 1602(dd)(7) as well as their employees, agents, and contractors. However, consistent with the interpretation published in the CFPB’s 2013 Loan Originator Compensation Rule, the proposed rule would have applied to servicers as defined by 15 U.S.C. 1602(dd)(7) as well as their employees, agents, and contractors if, in connection with new extensions of credit, they both use covered AVMs to engage in credit decisions and to perform any of the activities listed in 15 U.S.C. 1602(dd)(2)(A). The CFPB’s proposal also would have added proposed Regulation Z comment 42(i)(2)(vi)–2 reflecting this clarification.

Although commenters generally supported this proposed definition, two commenters asked the agencies to consider making substantive changes to the definition. One of these commenters asked the agencies to amend the definition of “mortgage originator” in the final rule so that it would include servicing-only servicers in addition to the persons covered as mortgage originators under TILA § 103(dd)(2), 15 U.S.C. 1602(dd)(2). As explained in the proposal, the agencies proposed to define the term “mortgage originator” by cross reference to the TILA definition of “mortgage originator” because doing so “would maintain consistency in the usage of this term with other sections of title XI and the agencies’ appraisal regulations.”⁵² Specifically, Congress adopted the TILA definition of “mortgage originator” by cross reference

in a 2018 amendment to title XI (section 1127 on appraisals in rural areas)⁵³ and that the OCC, Board, and FDIC implemented the same definition in the appraisal exception for certain rural areas in their appraisal regulations.⁵⁴

TILA § 103(dd)(2)(G), 15 U.S.C. 1602(dd)(2)(G), generally excludes servicers as well as their employees, agents, and contractors from TILA’s definition of “mortgage originator” as long as they do not perform any of the activities listed in 15 U.S.C. 1602(dd)(2)(A) for a transaction that constitutes a new extension of credit, including a refinancing or an assumption. Accordingly, the final rule does not expand the definition of “mortgage originator” to cover servicing-only servicers in the final rule. Relatedly, the CFPB adopts proposed Regulation Z comment 42(i)(2)(vi)–2, which clarifies the activities that can make a mortgage servicer a mortgage originator for purposes of the rule, as proposed but redesignates it as Regulation Z comment 42(i)(2)(vi)–1.

Another commenter noted that the proposed definition of “mortgage originator” does not align with the proposed changes to the term “principal dwelling” and the inclusion of business purpose loans. To address this issue, the final rule no longer cross references the TILA definition of “mortgage originator,” but instead defines the term “mortgage originator” by incorporating the full text of the TILA definition of “mortgage originator” with several revisions as discussed herein.

The TILA definition of “mortgage originator” applies to persons performing activities relating to residential mortgage loans.⁵⁵ In relevant part, TILA defines the term “residential mortgage loan” as “any **consumer credit transaction** that is secured by a mortgage, deed of trust, or other equivalent consensual security interest

on a dwelling or on residential real property that includes a dwelling, other than a consumer credit transaction under an open end credit plan. . . .”⁵⁶ A consumer credit transaction is “one in which the party to whom credit is offered or extended is a natural person, and the money, property, or services which are the subject of the transaction are primarily for personal, family, or household purposes.”⁵⁷

Title XI generally does not limit its coverage to consumer credit transactions.⁵⁸ As a result, the agencies intended the proposal to cover a mortgage, including a HELOC, secured by a consumer’s principal dwelling, even if the mortgage were primarily for business, commercial, agricultural, or organizational purposes.⁵⁹ This intent is reflected in the proposal’s discussion of the definition of the term “mortgage.” In that discussion, the agencies explained that, although they based the proposal’s definition of the term “mortgage” in part on TILA’s definition of residential mortgage transaction, they proposed “to broadly cover the mortgage market as fully as the statute appears to envision.”⁶⁰ As a result, the agencies proposed to define the term “mortgage” to cover not only consumer credit transactions but any transaction in which a mortgage, deed of trust, purchase money security interest arising under an installment sales contract, or equivalent consensual security interest is created or retained in a consumer’s principal dwelling.⁶¹

The agencies’ proposal intended the term “mortgage originator” to apply with breadth equal to that of the term “mortgage” and its application only to persons performing activities relating to residential mortgage loans was an oversight.

In defining “mortgage originator” by incorporating the full text of the TILA definition of “mortgage originator”, the final rule replaces the term “residential mortgage transaction” with the term “mortgage” wherever it appears in the TILA definition. As discussed in the next section, the term “mortgage” retains its meaning from the proposal and means “a transaction in which a mortgage, deed of trust, purchase money security interest arising under an installment sales contract, or equivalent consensual security interest is created or retained in a consumer’s principal dwelling.” In line with the intent of the

⁵³ 12 U.S.C. 3356.

⁵⁴ *Id.*

⁵⁵ The term “mortgage originator”:

(A) means any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain—

(i) takes a **residential mortgage loan** application;

(ii) assists a consumer in obtaining or applying to obtain a **residential mortgage loan**; or

(iii) offers or negotiates terms of a **residential mortgage loan**;

(B) includes any person who represents to the public, through advertising or other means of communicating or providing information (including the use of business cards, stationery, brochures, signs, rate lists, or other promotional items), that such person can or will provide any of the services or perform any of the activities described in subparagraph (A). . . .

See 15 U.S.C. 1602(dd)(2)(A) and (B) (emphasis added).

⁵⁶ 15 U.S.C. 1602(dd)(5) (emphasis added).

⁵⁷ 15 U.S.C. 1602(i).

⁵⁸ 88 FR 40638 at 40645.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁵⁰ 15 U.S.C. 1602(dd)(2).

⁵¹ *Id.*

⁵² See 12 CFR 34.43(a)(14) (OCC), 12 CFR 225.63(a)(15) (Board), and 12 CFR 323.3(a)(14) (FDIC).

proposal, this change applies the term “mortgage originator” to any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain, takes a mortgage application, assists a consumer in obtaining or applying to obtain a mortgage, or offers or negotiates terms of a mortgage.

The final rule includes three additional conforming changes to the text of the TILA definition of “mortgage originator” as incorporated in the final rule’s definition of “mortgage originator.” First, the final rule removes the exclusion for seller financiers provided at TILA § 103(dd)(2)(E), 15 U.S.C. 1602(dd)(2)(E), and replaces it with the seller financier exclusions contained in Regulation Z § 1026.36(a)(4) and (5). This change reflects that the seller financier exclusion in TILA § 103(dd)(2)(E) contains five elements, the last of which is that the transaction “meets any other criteria the Board may prescribe.” These additional criteria are incorporated into Regulation Z § 1026.36(a)(4) and (5),⁶² and, therefore, the agencies, with the exception of the CFPB, are replacing the text from TILA § 103(dd)(2)(E) with the text from Regulation Z § 1026.36(a)(4) and (5) with minor, non-substantive changes, as necessary, to conform the text from Regulation Z § 1026.36(a)(4) and (5) with the paragraph structure of each agency’s final rule. Instead of replacing the text from TILA § 103(dd)(2)(E) with the text from Regulation Z § 1026.36(a)(4) and (5), the CFPB will provide a cross reference to Regulation Z § 1026.36(a)(4) and (5) in its version of the final rule.

Second, the final rule removes the exclusion provided at TILA § 103(dd)(2)(F), 15 U.S.C. 1602(dd)(2)(F). That exclusion provides that the term “mortgage originator” is inapplicable to creditors for purposes of TILA § 129B(c)(1), (2), and (4), 15 U.S.C. 1639b(c)(1), (2), and (4) (which relate to TILA’s prohibition on the payment of steering incentives).⁶³ Since the exclusion applies only with respect to TILA § 129B(c)(1), (2), and (4), it is inapplicable in the context of the AVM rule and has been deleted in the final rule. Because the definition of “mortgage originator” in the final rule does not contain the exclusion at TILA § 103(dd)(2)(F), proposed Regulation Z comment 42(i)(2)(vi)–1, which clarified that “[t]he term mortgage originator includes creditors, notwithstanding that the definition of mortgage originator at 15 U.S.C. 1602(dd)(2) excludes creditors

for certain other purposes,” is no longer necessary. As a result, the CFPB does not adopt proposed Regulation Z comment 42(i)(2)(vi)–1. Third, the final rule makes minor, nonsubstantive regulatory text changes and adjusts paragraph designations and cross-references incorporated from the full text of the TILA definition of “mortgage originator” as necessary to align the text with the paragraph structure of each agency’s final rule.

One commenter that noted that the proposed definition of “mortgage originator” does not align with the proposed changes to the term “principal dwelling” and the inclusion of business purpose loans also noted that some entities that make business purpose loans may not make consumer purpose loans and that, consequently, those entities may face uncertainty about their compliance obligations if, as proposed, they were mortgage originators for purposes of the rule. The agencies have considered this comment. However, because, as previously noted, title XI generally does not limit its coverage to consumer credit transactions, the agencies have determined that the final rule should broadly cover the mortgage market. Accordingly, the final rule applies the definition of “mortgage originator” to any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain, takes a mortgage application, assists a consumer in obtaining or applying to obtain a mortgage, or offers or negotiates terms of a mortgage secured by a consumer’s principal dwelling, even if the mortgage is primarily for business, commercial, agricultural, or organizational purposes.⁶⁴

The final rule includes another technical change relating to the definition of “mortgage originator.” This technical change is the addition of a definition of person by cross reference to the definition of person in TILA. The addition of a stand-alone definition of “person” is needed because the final rule, unlike the proposed rule, does not define “mortgage originator” by incorporating by reference the definition of “mortgage originator” in TILA. As a result, the definition of “person,” which is defined by cross reference within the TILA definition of “mortgage originator,” is no longer part of the final rule’s revised definition of “mortgage originator.” The adoption of a stand-

alone definition of “person” does not change the incorporated definition of person and is a technical change only. The agencies other than the CFPB provide this clarification to ensure that the definition of “mortgage originator” in the final rule covers both natural persons and organizations. The CFPB’s final rule does not require this clarification because Regulation Z already defines the term “person” at § 1026.2(a)(22) in a manner that is consistent with the meaning provided in TILA § 103(e), 15 U.S.C. 1602(e).

8. Secondary Market Issuer

The agencies proposed to define a “secondary market issuer” as any party that creates, structures, or organizes a mortgage-backed securities transaction. The agencies proposed the definition in this manner due to the statutory focus in section 1125 on “issuers” and “determin[ing] the collateral worth” of a mortgage. This type of determination, as opposed to verification or monitoring of such determination, would typically take place in the secondary market in connection with the creation, structuring, and organization of a mortgage-backed security. A number of parties may be involved in the securitization process. The proposed definition was designed to ensure coverage of entities responsible for the core decisions required for the issuance of mortgage-backed securities, including making determinations of the value of collateral securing the loans in the securitization transaction.

The agencies received two comments on the proposed definition of “secondary market issuer.” One commenter expressed support for the definition as proposed. Another commenter stated that the rule should cover not only the GSEs, but also other secondary market issuers that structure and market residential mortgage-backed securities, such as in private-label securitization. The commenter asked that the agencies clarify that the final rule will apply beyond the GSEs to these other entities.

The agencies have determined that the proposed definition will ensure coverage of entities responsible for the core decisions required for the issuance of mortgage-backed securities. For this reason and after considering the comments, the agencies are adopting the proposed definition of “secondary market issuer,” which includes not only the GSEs, but any other party that creates, structures, or organizes a mortgage-backed securities transaction.

⁶⁴ 88 FR 40638 at 40645; see also, *Frequently Asked Questions on the Appraisal Regulations and the Interagency Appraisal and Evaluation Guidelines* 4, OCC Bulletin 2018–39 (Oct. 16, 2018); Federal Reserve Board SR Letter 18–9 (Oct. 16, 2018); FDIC FIL–62–2018 (Oct. 16, 2018).

⁶² 78 FR 11280, 11309–11311 (Feb. 15, 2013).

⁶³ 15 U.S.C. 1639b(c)(1), (2), and (4).

9. Comments Regarding Undefined Terms

One commenter stated that the terms “mortgage-backed securities transaction,” “securitizations,” and “mortgage-backed securitizations” should be defined. In response, the agencies note that related terms (e.g., “mortgage-backed securities” and “securitization”) are currently used without definition in other sections of title XI and throughout the agencies’ appraisal regulations. Based on the agencies’ experience, these terms have commonly understood meanings and have not caused confusion. For these reasons and after considering the comment, the final rule does not include definitions of these terms.

D. Implementation Period

The agencies proposed an effective date of the first day of a calendar quarter following the 12 months after publication in the **Federal Register** of any final rule based on this proposal. The proposed extended effective date would have given institutions time to come into compliance with the rule. Most commenters expressed support for the proposed 12-month implementation period for the final rule. One commenter asked the agencies to consider an 18-month implementation period. Another commenter recommended a tiered implementation model with at least 24 months for credit unions to work with vendors, test systems, and train staff.

The agencies have determined that a 12-month effective date is appropriate, given that many institutions already have in place measures to assess AVMs for quality control and that the final rule provides flexibility to tailor policies, practices, procedures, and control systems as appropriate. For these reasons and after considering the comments, the final rule will be effective on the first day of the calendar quarter following the 12 months after publication in the **Federal Register**.

E. Other Comments

1. Uniform Standards and Independent Testing

A number of commenters suggested that the agencies work with the public to foster the development of an SSO for AVMs to create a level playing field for AVM users and to reduce regulatory burden. One commenter requested that the agencies engage in a full notice and comment rulemaking process if the use of an SSO is contemplated. Another commenter recommended that SSO members be comprised of AVM providers, consumer advocates, investors, mortgage guarantors,

mortgage insurers, mortgage originators, underwriters, and servicers. The commenter also suggested that regulators participate in the SSO. A number of commenters called for the establishment of a separate, fully independent third-party nonprofit organization to test AVM systems for both accuracy and racial bias. Some commenters stated that SSOs and third-party testing would save lenders considerable time and effort and bolster quality control for AVMs. One commenter, for example, suggested that it would be useful to have a set of standards similar to USPAP for AVMs that includes key definitions, minimum reporting requirements, and required certifications.

One commenter stated that it would be beneficial to have some level of standardization of metrics used to measure an AVM’s success or failure. The commenter suggested that the industry is best suited to continue working with developers and users of AVMs to promote consistency in AVM measurement and testing, such as by developing a consistent approach to confidence scores.

Another commenter suggested that regulated parties would greatly benefit from more transparency and access to data from the FHFA, the Uniform Collateral Data Portal, and the Uniform Mortgage Data Program. This commenter further suggested that Federal regulators should evaluate real estate data availability at the State and local level, as these data are essential for ensuring AVM credibility.

In contrast, one commenter stated that industry stakeholders, including originators, secondary market participants, and property valuation vendors have already established straightforward, transparent, and fair AVM testing and ranking (i.e., cascading rule sets allowing for comparing predictions from different AVMs). The commenter stated further that flexible, transparent, principles-based approaches to AVM guidelines are relatively inexpensive and not time-consuming to incorporate and apply and that AVM testing and individual AVM model performance detail may be readily available through a firm’s internal testing group or numerous third-party, independent testing organizations. In responding to the question in the proposal about the impact on small entities, that commenter stated that AVM testing is inexpensive and can be done easily by large or small entities. In addition, the commenter stated that cascading rule sets and platforms using multiple lending grade AVMs from quality

providers are readily available. For these reasons, the commenter argued that quality control standards for AVMs would not disadvantage small entities.

Another commenter stated that AVM vendors already provide comprehensive information to financial institutions to demonstrate the quality control of their AVMs. The commenter further stated that financial institutions currently require AVM vendors to fill out numerous questionnaires (usually once to twice per year) to address large numbers of compliance issues and best practices, in addition to AVM developer, lender, and third-party testing. The commenter also stated that financial institutions require explanations and testing detail that documents how AVMs work, their accuracy, their multiple models, and the models’ infrastructure. The commenter stated that the predominant purpose of the questionnaires is to address concerns that the financial institution has, and that the financial institution is following a process to protect its customers and its safety and soundness. In addition, another commenter recommended that there be education and training for users of AVMs.

The agencies recognize that SSOs and third-party AVM testing entities could be beneficial to effective compliance with the AVM rule. As long as financial institutions meet the obligations stated in the final rule, they are free to work with third parties to assist them with their compliance obligations. In regard to comments suggesting other methods to promote uniformity in metrics and policies, the agencies note that existing standards and guidance on model risk management and on testing of AVMs remain applicable, and can be used by institutions to assist with compliance.

2. Potential for Additional Guidance

A number of commenters suggested that the agencies issue guidance focused specifically on AVM quality control to help institutions, especially small institutions, implement the quality control standards. Many of these commenters acknowledged that existing guidance, such as model risk guidance and the Appraisal Guidelines, already address elements of how to implement the AVM rule, but a number of commenters requested additional guidance on how to evaluate AVMs, particularly with respect to how to assess AVMs for potential discrimination under the fifth factor. One commenter stated that the agencies should provide some structure or examples of policies, practices, procedures, or control systems. The commenter also stated that it should be

made clear that lenders can rely on data and external reviews produced by the AVM provider to comply with this rule. In addition, one commenter suggested that the agencies facilitate further efforts to develop fair lending and fair housing testing for AVMs by making additional GSE data available to industry stakeholders, organizing hackathons and conferences, and encouraging academic research and similar engagements that leverage private sector expertise to inform ongoing guidance around AVM guidelines.

One commenter stated that additional guidance is not necessary, highlighting the current guidance on third-party and model risk management. However, the commenter suggested that commentary on how existing guidance applies to third-party oversight of the AVM quality control standards may be beneficial at some point in the future.

Another commenter stated that the Appraisal Guidelines and NCUA's third-party risk management expectations already advise credit unions that they need to understand the AVMs they use, including the AVM's limitations; have controls in place to mitigate risks (including with regard to non-discrimination laws); and monitor the relationship and results to ensure that the AVM is working and being used as designed.

As discussed earlier, many of the agencies have already provided guidance on implementing policies, practices, procedures, and control systems relating to model risk, third-party risk, AVMs, and nondiscrimination. As explained above, institutions that are not regulated by the agency or agencies providing the guidance may still look to the guidance for assistance with compliance. In addition, institutions should be able to work with AVM providers to assist them with their compliance obligations under the rule.

Under safety and soundness standards, and as reflected in related guidance, while institutions should not rely solely on testing and validation representations provided by an AVM vendor, an institution does not necessarily need to conduct its own testing and validation, provided that the institution's policies, practices, procedures, and control systems for evaluating the sufficiency of the vendor's testing and validation are appropriate based on the size, complexity, and risk profile of the institution and the transactions for which they would use AVMs covered by the rule.

As described above, the agencies have determined that a flexible approach to

implementing the quality control standards would allow the implementation of the standards to evolve along with AVM technology and reduce compliance costs. Different policies, practices, procedures, and control systems may be appropriate for institutions of different sizes with different business models and risk profiles, and a more prescriptive rule could unduly restrict institutions' efforts to set their risk management practices accordingly. For these reasons and after considering the comments, the agencies are not issuing additional guidance at this time and recommend that institutions review and consider existing guidance when establishing and implementing appropriate policies, practices, procedures, and control systems for AVM quality control.

3. Small Entity Compliance

Several commenters asked the agencies to adopt a transaction threshold for application of the AVM quality control standards. For example, one commenter suggested that the agencies revise the proposed rule to exempt loans at or below \$400,000 held in portfolio from the quality control requirements for AVMs, allow reliance on third-party certifications of AVM providers, or provide a safe harbor for small lenders. One commenter cited the appraisal thresholds as an example of how the agencies could reduce burden for smaller lenders.

Another commenter stated that small entities do not control the data that is used in the AVM and, therefore, do not have the ability to quality control the data or the algorithms used by AVM vendors. This commenter also argued that small businesses do not have the bargaining power that a large company may have to demand information from an AVM vendor and do not have the resources to assess the algorithms that are used by AVMs. The commenter suggested that it is unreasonable to hold small entities responsible for the actions of AVM vendors. The commenter stated further that if an exemption is not possible, the agencies should consider some type of safe harbor or a certification program where a third party reviews the AVM and provides an approval to assure small entities that the AVM complies with the regulatory requirements.

As discussed earlier, the flexibility in the rule will limit the burden of complying with the rule for institutions, particularly smaller entities. As explained above, the policies, practices, procedures, and control systems used to ensure compliance may vary based on the size, complexity, and risk profile of

the institution and the transactions for which they would use AVMs covered by the rule. The agencies also note that section 1125 does not include safe harbors or exemptions, including for smaller entities. For these reasons and after considering the comments, the final rule does not include an exemption threshold, or other specific provision for smaller institutions.

IV. Paperwork Reduction Act

Certain provisions of the final rule contain "collection of information" requirements within the meaning of the Paperwork Reduction Act (PRA) of 1995.⁶⁵ In accordance with the requirements of the PRA, the agencies may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a current Office of Management and Budget (OMB) control number.

The agencies received three comments on estimated labor hours and costs for the information collection requirements of the proposed rule. One commenter stated that the agencies' estimate of the labor hours associated with recordkeeping by covered entities in years following implementation may be appropriate for documentation of policies and procedures, but suggested that the proposed rule underestimated other regulatory burdens associated with ongoing compliance. Another commenter stated that the agencies' estimate of labor hours associated with recordkeeping by covered entities seemed relatively low given the effort needed to establish control systems. Finally, one commenter stated that incorporating principles-based guidelines regarding AVMs is not costly or time consuming.

The agencies have carefully reviewed burdens associated with recordkeeping, reporting, and disclosure for each section of the rule in consideration of the comments received. The agencies note that, consistent with the PRA, the PRA burden estimates reflect only the burden related to recordkeeping, reporting, and disclosure requirements in the final rule. PRA burdens, like compliance costs, may vary across institutions, and the agencies' PRA burden estimates are meant to be overall averages. The agencies believe the estimates of burden hours are reasonable considering the recordkeeping requirements of the final rule. For further discussion of response to commenters, particularly related to other regulatory costs incurred by covered entities, please refer to the part titled "Discussion of the Proposed Rule,

⁶⁵ 44 U.S.C. 3501–3521.

Comments Received, and the Final Rule” within the **SUPPLEMENTARY INFORMATION** section of this document.

The final rule establishes quality control standards mandated by the Dodd-Frank Act for the use of AVMs by mortgage originators and secondary market issuers in determining the collateral worth of a mortgage secured by a consumer’s principal dwelling. Section 1473(q) of the Dodd-Frank Act amended title XI to add section 1125 relating to the use of AVMs in valuing real estate collateral securing mortgage loans. Section 1125 directs the agencies to promulgate regulations to implement quality control standards regarding AVMs.

The final rule requires supervised mortgage originators and secondary market issuers that engage in credit decisions or covered securitization determinations themselves, or through or in cooperation with a third-party or affiliate, to adopt and maintain policies, practices, procedures, and control systems to ensure that AVMs used in these transactions adhere to quality control standards designed to:

- (a) Ensure a high level of confidence in the estimates produced;
- (b) Protect against the manipulation of data;
- (c) Seek to avoid conflicts of interest;
- (d) Require random sample testing and reviews; and
- (e) Comply with applicable nondiscrimination laws.

The quality control standards in the final rule are applicable only to covered AVMs, which are AVMs as defined in the final rule. The final rule requires the regulated mortgage originators and secondary market issuers to adopt policies, practices, procedures, and control systems to ensure that AVMs adhere to the specified quality control standards whenever they use covered AVMs while engaging in certain credit decisions or covered securitization determinations.

As a result, the final rule creates new recordkeeping requirements. The agencies therefore revised their current information collections related to real estate appraisals and evaluations. The OMB control numbers are for the OCC, 1557–0190; for the Board, 7100–0250; for the FDIC, 3064–0103; and for the NCUA, 3133–0125. These information collections will be extended for three years, with revision. In addition to accounting for the PRA burden incurred, as a result of this final rule, the agencies are also updating and aligning their information collections with respect to the estimated burden hours associated with the Appraisal Guidelines.

The information collection requirements contained in this final rule have been submitted by the OCC, the FDIC, and the NCUA to the OMB for review and approval under section 3507(d) of the PRA⁶⁶ and section 1320.11 of the OMB’s implementing regulations.⁶⁷ The Board reviewed the final rule under the authority delegated to the Board by OMB.

Comments are invited on:

(a) Whether the collections of information are necessary for the proper performance of the agencies’ functions, including whether the information has practical utility;

(b) The accuracy of the estimate of the burden of the information collections, including the validity of the methodology and assumptions used;

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

(d) Ways to minimize the burden of the information collections 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.

All comments will become a matter of public record. Comments on the collections of information should be sent to the address listed in the **ADDRESSES** section of this document. 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 information collection by selecting “Currently under 30-day Review—Open for Public Comments” or using the search function.

Title of Information Collection: Recordkeeping and Disclosure Requirements and Provisions Associated with Real Estate Appraisals and Evaluations.

Frequency of Response: Annual and event generated.

Affected Public: Businesses, other for-profit institutions, and other not-for-profit institutions.

Respondents:

OCC: National banks, Federal savings associations.

Board: State member banks (SMBs), bank holding companies (BHCs), nonbank subsidiaries of BHCs, savings and loan holding companies (SLHCs), nondepository subsidiaries of SLHCs,

Edge and agreement corporations, U.S. branches and agencies of foreign banks, and any nonbank financial company designated by FSOC to be supervised by the Board.

FDIC: Insured state nonmember banks and state savings associations, insured state branches of foreign banks.

NCUA: Private Sector: Not-for-profit institutions.

General Description of Information Collection:

For federally related transactions, title XI requires regulated institutions⁶⁸ to obtain appraisals prepared in accordance with USPAP as promulgated by the Appraisal Standards Board of the Appraisal Foundation. Generally, these standards include the methods and techniques used to estimate the market value of a property as well as the requirements for reporting such analysis and a market value conclusion in the appraisal. Regulated institutions are expected to maintain records that demonstrate that appraisals used in their real estate-related lending activities comply with these regulatory requirements.

The final rule requires supervised mortgage originators and secondary market issuers that engage in credit decisions or covered securitization determinations themselves, or through or in cooperation with a third-party or affiliate, to adopt and maintain policies, practices, procedures, and control systems to ensure that AVMs used in these transactions adhere to quality control standards designed to:

- (a) Ensure a high level of confidence in the estimates produced;
- (b) Protect against the manipulation of data;
- (c) Seek to avoid conflicts of interest;
- (d) Require random sample testing and reviews; and
- (e) Comply with applicable nondiscrimination laws.

Current Action: The final rule creates new recordkeeping requirements in connection with adopting and maintaining policies, practices, procedures, and control systems. The agencies estimate that the new recordkeeping burden associated with the final rule will result in an implementation burden of 40 hours and .33 responses per respondent and an annual ongoing burden of 5 hours and one response per respondent. In addition to accounting for the PRA burden incurred, as a result of this final rule, the agencies are also updating and

⁶⁸ National banks, Federal savings associations, SMBs and nonbank subsidiaries of BHCs, insured state nonmember banks and state savings associations, and insured state branches of foreign banks.

⁶⁶ 44 U.S.C. 3507(d).

⁶⁷ 5 CFR 1320.

aligning their information collections (IC) with respect to the estimated burden hours associated with the

Appraisal Guidelines. This will result in an annual ongoing burden of 10 hours per respondent for recordkeeping and

an annual ongoing burden of 5 hours per respondent for disclosure.
OCC Burden

TABLE 1—SUMMARY OF ESTIMATED ANNUAL BURDEN
[OMB No. 1557–0190]

Requirement	Citations	Number of respondents	Burden hours per respondent	Total number of hours annually
<i>Recordkeeping</i> : Resolution stating plans for use of property.	§ 7.1024(d)	6	5	30
<i>Recordkeeping</i> : ARM loan documentation must specify indices to which changes in the interest rate will be linked.	§ 34.22(a), § 160.35(b)	164	6	984
<i>Recordkeeping</i> : Appraisals must be written and contain sufficient information and analysis to support engaging in the transaction.	§ 34.44	976	1,465 responses per respondent @5 minutes per response.	119,072
<i>Recordkeeping</i> : Written policies (reviewed annually) for extensions of credit secured by or used to improve real estate.	§ 34.62; appendix A to subpart D to part 34; § 160.101; appendix A to § 160.101.	1,413	30	42,390
<i>Recordkeeping</i> : Real estate evaluation policy to monitor OREO.	§ 34.85	9	5	45
<i>Recordkeeping</i> : New IC 1—AVM Rule—Policies and Procedures (Implementation).	Proposed § 34.222	342	13.33 hours (40 hours divided by 3 years).	4,560
<i>Recordkeeping</i> : New IC 2—AVM Rule—Policies and Procedures (Ongoing).	Proposed § 34.222	342	5	1,710
<i>Recordkeeping</i> : New IC 3—Interagency Appraisal and Evaluation Guidelines—Policies and Procedures.	N/A	976	10	9,760
<i>Reporting</i> : Procedure to be followed when seeking to use an alternative index.	§ 34.22(b); § 160.35(d)(3)	249	6	1,494
<i>Reporting</i> : Prior notification of making advances under development or improvement plan for OREO.	§ 34.86	6	5	30
<i>Disclosure</i> : Default notice to debtor at least 30 days before repossession, foreclosure, or acceleration of payments.	§ 190.4(h)	42	2	84
<i>Disclosure</i> : New IC 4—Interagency Appraisal and Evaluation Guidelines.	N/A	976	5	4,880
Total Annual Burden Hours				185,039

Board Burden

TABLE 2—SUMMARY OF ESTIMATED ANNUAL BURDEN
[FR Y-30; OMB No. 7100-0250]

FR Y-30	Estimated number of respondents	Estimated annual frequency	Estimated average hours per response	Estimated annual burden hours
Recordkeeping				
Sections 225.61—225.67 for SMBs	706	498	5 minutes	29,299
Sections 225.61—225.67 for BHCs and nonbank subsidiaries of BHCs	4,516	409	5 minutes	153,920
Guidelines	5,222	1	10	52,220
Policies and Procedures AVM rule (Initial setup)	2,036	1	13.3	27,147
Policies and Procedures AVM rule (Ongoing)	2,036	1	5	10,180
Disclosure				
Guidelines	5,222	1	5	26,110
Total Annual Burden Hours				298,876

FDIC Burden

TABLE 3—SUMMARY OF ESTIMATED ANNUAL BURDEN
[OMB No. 3064–0103]

Information collection (obligation to respond)	Type of burden (frequency of response)	Average annual number of respondents	Number of responses per respondent	Time per response (hours/minutes)	Annual burden (hours)
Recordkeeping Requirements Associated with Real Estate Appraisals and Evaluations (Mandatory).	Recordkeeping (On Occasion).	2,936	259	5 minutes (0.083)	63,369
New IC 1—AVM Rule—Policies and Procedures—Implementation (Mandatory).	Recordkeeping (Annual).	1,010	.33	40 hours	13,320
New IC 2—AVM Rule—Policies and Procedures—Ongoing (Mandatory).	Recordkeeping (Annual).	1,010	1	5 hours	5,050
New IC 3—2010 Guidelines—Policies and Procedures—Ongoing (Mandatory).	Recordkeeping (Annual).	2,936	1	10 hours	29,360
New IC 4—2010 Guidelines—Disclosure—Ongoing (Mandatory).	Disclosure (Annual).	2,936	1	5 hours	14,680
Total Annual Burden Hours					125,779

NCUA Burden

TABLE 4—SUMMARY OF ESTIMATED ANNUAL BURDEN
[OMB No. 3133–0125]

Information collection	Type of burden	Average annual number of respondents	Number of responses per respondent	Time per response (hours)	Annual burden (hours)
Recordkeeping Requirements Associated with Real Estate Appraisals and Evaluations.	Recordkeeping (On Occasion).	3,555	514	0.083	152,272
New IC 1—AVM Rule—Policies and Procedures—Implementation.	Recordkeeping (Annual)	356	1	13.33	4,745
New IC 2—AVM Rule—Policies and Procedures—Ongoing.	Recordkeeping (Annual)	356	1	5	1,780
New IC 3—2010 Guidelines—Policies and Procedures—Ongoing.	Recordkeeping (Annual)	3,555	1	10	35,550
New IC 4—2010 Guidelines—Disclosure—Ongoing.	Disclosure (Annual)	3,555	1	5	17,775
Total Annual Burden Hours					212,122

The CFPB, in consultation with OMB, and the FHFA do not believe that they have any supervised entities that will incur burden as a result of this final rule and therefore will not be making a submission to OMB. Comments are invited on this determination by the CFPB and the FHFA.

V. Regulatory Flexibility Act Analysis

A. OCC

The Regulatory Flexibility Act (RFA) requires an agency to prepare a regulatory flexibility analysis describing the impact of the final rule on small entities (defined by the Small Business Administration (SBA) for purposes of the RFA to include commercial banks and savings institutions with total assets of \$850 million or less and trust companies with total revenue of \$47.5 million or less) or certify that the rule will not have a significant economic

impact on a substantial number of small entities.

The OCC has assessed the burden of the final rule and has determined that the costs associated with the rule will be limited to reviewing the rule; ensuring that existing policies, practices, procedures, and control systems adequately address the four statutory quality control standards; and adopting policies, practices, procedures, and control systems to ensure that AVMs adhere to quality control standards designed to comply with applicable nondiscrimination laws. To estimate expenditures, the OCC reviews the costs associated with the activities necessary to comply with the final rule. These include an estimate of the total time required to implement the final rule and the estimated hourly wage of bank employees who may be responsible for the tasks associated with achieving compliance with the rule. The OCC uses

a bank employee compensation rate of \$128 per hour.⁶⁹

The OCC currently supervises approximately 636 small entities.⁷⁰ The

⁶⁹ To estimate wages, the OCC reviewed May 2022 data for wages (by industry and occupation) from the U.S. Bureau of Labor Statistics (BLS) for credit intermediation and related activities (NAICS 5220A1). To estimate compensation costs associated with the rule, the OCC uses \$128.05 per hour, which is based on the average of the 90th percentile for six occupations adjusted for inflation (5.1 percent as of Q1 2023), plus an additional 34.3 percent for benefits (based on the percent of total compensation allocated to benefits as of Q4 2022 for NAICS 522: credit intermediation and related activities).

⁷⁰ The OCC bases its estimate of the number of small entities on the SBA's size thresholds, which are \$850 million or less in total assets for commercial banks and savings institutions, and \$47 million or less in total assets for trust companies. Consistent with the General Principles of Affiliation in 13 CFR 121.103(a), the OCC counts the assets of affiliated financial institutions when determining whether to classify an OCC-supervised institution as a small entity. The OCC uses December 31, 2023, to determine size because a "financial institution's assets are determined by averaging the assets

final rule will impact approximately 590 of these small entities. The OCC estimates the annual cost for small entities to comply with the final rule will be approximately \$23,040 per bank (180 hours × \$128 per hour). In general, the OCC classifies the economic impact on a small entity as significant if the total estimated impact in one year is greater than 5 percent of the small entity's total annual salaries and benefits or greater than 2.5 percent of the small entity's total non-interest expense. The OCC considers 5 percent or more of OCC-supervised small entities to be a substantial number. Thus, at present, 32 OCC-supervised small entities would constitute a substantial number. Based on these thresholds, the OCC estimates that the final rule will have a significant economic impact on 24 small entities, which is below our substantial number threshold. Therefore, the OCC certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

B. Board

An initial regulatory flexibility analysis (IRFA) was included in the proposal in accordance with section 603(a) of the RFA.⁷¹ In the IRFA, the Board requested comment on the effect of the proposed rule on small entities. The Board did not receive any comments on the IRFA. One commenter suggested that the Board's initial regulatory flexibility analysis failed to recognize the web of overlapping and duplicative laws and rules that apply to mortgage valuations.

The RFA requires an agency to prepare a final regulatory flexibility analysis (FRFA) unless the agency certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities. Based on its analysis and for the reasons stated below, the Board certifies that the rule will not have a significant economic impact on a substantial number of small entities.

1. Reasons action is being taken by the Board.

As discussed above, the Dodd-Frank Act amended title XI to add a new section governing the use of AVMs in mortgage lending and directing the agencies to promulgate regulations to implement specified quality control standards. The final rule serves to implement this statutory mandate.

reported on its four quarterly financial statements for the preceding year." See footnote 8 of the U.S. Small Business Administration's *Table of Size Standards*.

⁷¹ 5 U.S.C. 601 *et seq.*

2. The objectives of, and legal basis for, the rule.

The final rule implements statutorily mandated quality control standards for the use of AVMs. The Board is adopting this rule pursuant to section 1125 of title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989.⁷²

3. Estimate of the number of small entities.

The final rule applies to Board-regulated small entities that are mortgage originators or secondary market issuers. There are approximately 462 state member banks and approximately 3,281 bank holding companies and savings and loan holding companies that qualify as small entities for purposes of the RFA.⁷³

4. Description of the compliance requirements of the rule.

The final rule requires Board-regulated small entities that are mortgage originators or secondary market issuers to adopt and maintain policies, practices, procedures, and control systems to ensure that AVMs used in credit decisions or covered securitization determinations adhere to specified quality control standards. These quality control standards must ensure a high level of confidence in the estimates produced, protect against the manipulation of data, seek to avoid conflicts of interest, and require random sample testing and reviews and comply with applicable nondiscrimination laws. To the extent that small entities do not already maintain adequate policies, practices, procedures, and control systems, they could incur administrative costs to do so. It is likely that the majority of Board-regulated small entities that are mortgage originators or secondary market issuers either do not use AVMs in credit decisions or covered securitization determinations or would already be in compliance with the specified standards or could become compliant with

⁷² 12 U.S.C. 3354.

⁷³ Under regulations issued by the SBA, a small entity includes a depository institution, bank holding company, or savings and loan holding company with total assets of \$850 million or less. See *Small Business Size Standards: Adjustment of Monetary-Based Size Standards, Disadvantage Thresholds, and 8(a) Eligibility Thresholds for Inflation*, 87 FR 69118 (Nov. 17, 2022). Consistent with the General Principles of Affiliation in 13 CFR 121.103, the Board counts the assets of all domestic and foreign affiliates when determining if the Board should classify a Board-supervised institution as a small entity. Small entity information for bank holding companies and savings holding companies is based on average assets reflected in December 31, 2023 *Parent Company Only Financial Statements for Small Holding Companies* (FR Y-9SP) data.

relatively minor modifications to their current practices.⁷⁴

Board staff estimates that impacted Board-supervised small entities would spend 160 hours establishing or modifying policies, practices, procedures, and control systems, at an hourly cost of \$116.86.⁷⁵ The estimated aggregate initial administrative costs of the proposal to Board-supervised small entities amount to \$8,638,291 or \$18,697.60 per bank⁷⁶ and ongoing costs are expected to be small when measured by small entities' annual expenses. The Board also notes that, while section 1125 explicitly applies to mortgage originators and secondary market issuers, not third-party AVM vendors, financial institutions should be able to work with AVM developers and vendors to assist them with their compliance obligations under the rule, as they do with other third-party vendors in order to comply with relevant regulatory requirements.

5. Consideration of duplicative, overlapping, or conflicting rules and significant alternatives to the proposal.

Although there are multiple statutes and regulations that apply to various aspects of real estate lending, the Board has not identified any Federal statutes or regulations that would duplicate, overlap, or conflict with the final rule's quality control standards for AVMs. The Board is required by statute to promulgate regulations to implement the quality control standards required under section 1125 of title XI, and thus no significant alternatives are available.⁷⁷

Therefore, the Board concludes that the final rule will not have a significant

⁷⁴ For example, the Board has provided guidance to most such entities on use of AVMs. See *Appraisal Guidelines*, 75 FR 77450, 77468.

⁷⁵ To estimate wages, the Federal Reserve reviewed May 2023 estimates for wages (by industry and occupation) from the BLS for credit intermediation and related activities (NAICS 5220A1). To estimate compensation costs associated with the rule, the Federal Reserve uses \$116.86 per hour, which is based on the average of the 90th percentile for five occupations adjusted for inflation (2 percent as of Q1 2021), plus an additional 34.6 percent for benefits (based on the percent of total compensation allocated to benefits as of Q4 2023 for NAICS 522: credit intermediation and related activities). The number of hours, 160, to establish policies, procedures and control systems is an estimate based on supervisory experience.

⁷⁶ This analysis assumes that the majority of credit decision and securitization determinations are performed at depository institutions. Therefore, only the number of State member depository institutions that are small entities, 462, are included in the calculation of administrative costs. The impact on the majority of small bank holding companies and savings and loan holding companies is expected to be minimal.

⁷⁷ 12 U.S.C. 3354.

economic impact on a substantial number of small entities.

C. FDIC

The RFA generally requires an agency, in connection with a final rule, to prepare and make available for public comment a FRFA that describes the impact of the final rule on small entities.⁷⁸ However, a FRFA is not required if the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. The SBA has defined “small entities” to include banking organizations with total assets of less than or equal to \$850 million.⁷⁹ Generally, the FDIC considers a significant economic impact to be a quantified effect in excess of 5 percent of total annual salaries and benefits or 2.5 percent of total noninterest expenses. The FDIC believes that effects in excess of one or more of these thresholds typically represent significant economic impacts for FDIC-supervised institutions. For the reasons described below and under section 605(b) of the RFA, the FDIC certifies that this rule will not have a significant economic impact on a substantial number of small entities.

The final rule applies to all FDIC-supervised insured depository institutions (IDIs) that are mortgage originators or secondary market issuers. As of the quarter ending December 31, 2023, the FDIC supervised 2,936 insured depository institutions, of which 2,221 are considered small entities for the purposes of the RFA. Of these, 2,183 FDIC-supervised small institutions reported a non-zero value for mortgages on their books.⁸⁰ Therefore, the FDIC estimates that 2,183 small institutions could be subject to the final rule.

The FDIC lacks data on the number of small FDIC-supervised institutions that use AVMs for their mortgage originations. FDIC subject matter experts believe that up to approximately

10 percent of all FDIC-supervised institutions currently use an AVM for mortgage origination decisions, loan modification decisions, and securitization decisions covered by the rule. However, based on supervisory experience, these experts believe a smaller percentage of small, FDIC-supervised institutions use AVMs because they believe AVM use is strongly positively correlated with institution size.

The final rule generally reflects existing Guidelines, supervisory expectations, and statutory obligations regarding the use of AVMs by supervised institutions. As mentioned, since 2010, the FDIC has provided supervisory Guidelines on the use of AVMs by its regulated institutions.⁸¹ The FDIC believes that institutions covered by the rule⁸² using AVMs, including small institutions, have considered the Guidelines in developing policies, procedures, practices, and control systems, and therefore should also be consistent with the final rule’s quality control standards 1 through 4. This belief is supported by a review of ten years of FDIC bank examination reports, which revealed that just 0.2 percent of the examinations flagged shortcomings in AVM management practices.⁸³ This suggests that the labor hours required to implement the four quality control standards would be relatively modest for small, FDIC-supervised institutions.

The final rule’s fifth quality control standard is consistent with existing applicable nondiscrimination laws. For example, the ECOA and its implementing Regulation B, bar discrimination on a prohibited basis in any aspect of a credit transaction.⁸⁴

⁸¹ The FDIC provides guidance on the use of AVMs by their regulated institutions in Appendix B to the Appraisal Guidelines. The Guidelines advise that institutions should establish policies, practices, and procedures governing the selection, use, and validation of AVMs, including steps to ensure the accuracy, reliability, and independence of an AVM. In addition, the FDIC has issued guidance on model risk management practices (Model Risk Guidance) that provides supervisory guidance on validation and testing of computer-based financial models (FDIC FIL–22–2017, dated June 7, 2017). See generally part I.A. of the SUPPLEMENTARY INFORMATION in this document.

⁸² The term “covered institutions” refers to financial institutions that would be subject to the proposed rule.

⁸³ The search of nearly 22,000 FDIC Reports of Examination from June 2011 to June 2021 revealed just 44 instances of a flag indicating an institution’s AVM use or management practices needed to improve. Therefore, 99.8 percent of the examination reports do not mention AVM practices and imply satisfactory practices (or no AVM use).

⁸⁴ 15 U.S.C. 1691(a) (prohibiting discrimination on the basis of race, color, religion, national origin, sex or marital status, age (provided the applicant has the capacity to contract), because all or part of

Similarly, the Fair Housing Act⁸⁵ prohibits unlawful discrimination in all aspects of residential real estate-related transactions, including valuations of residential real estate. However, the FDIC has not previously issued guidance or regulations that directly address nondiscrimination laws as it relates to expected or required AVM policies, procedures, practices, and controls. As a result, some small, FDIC-supervised institutions may not have fully integrated nondiscrimination laws directly into their AVM policies and risk management practices.

The FDIC lacks information on the labor hours and costs that will be incurred by covered institutions to comply with the final rule. Therefore, it assumes that small, FDIC-supervised institutions will expend 120 labor hours, on average, to comply with the final rule during the first year of implementation, and 40 labor hours, on average, in each successive year. In the first year, the FDIC’s estimates include the review of the newly enacted rule, conducting a review of existing policies, practices, procedures, and controls for their consistency with the rule; identifying any deficiencies; and implementing corrective action as needed. In the second year, the FDIC believes that institutions’ expected costs would be lower on average, as they limit their actions to primarily reviewing and maintaining their compliance.

This analysis subdivides the assumed compliance-related average labor hours spent by small FDIC-supervised IDIs into two types: (1) compliance with recordkeeping, reporting, and disclosure requirements under the PRA; and (2) hours for non-PRA compliance activities. According to supervisory experience, covered, small, FDIC-supervised IDIs using AVMs for originations or modifications would spend 40 hours in the first year and 5 hours in each subsequent year, on average for recordkeeping.

The FDIC believes small, FDIC-supervised IDIs affected by the final rule will incur additional labor hours and costs associated with compliance activities other than recordkeeping. For the first four quality control standards, these requirements may include, for

the applicant’s income derives from any public assistance program, or because the applicant has in good faith exercised any right under the Consumer Credit Protection Act); see also 12 CFR part 1002.

⁸⁵ 42 U.S.C. 3605 (prohibiting discrimination because of race, color, religion, national origin, sex, handicap, or familial status in residential real estate-related transactions); 42 U.S.C. 3605(b)(2) (defining “real estate-related transactions” to include the “selling, brokering, or appraising of residential real property”); see also 24 CFR part 100.

⁷⁸ 5 U.S.C. 601 *et seq.*

⁷⁹ The SBA defines a small banking organization as having \$850 million or less in assets, where an organization’s “assets are determined by averaging the assets reported on its four quarterly financial statements for the preceding year.” See 13 CFR 121.201 (as amended by 87 FR 69118, effective December 19, 2022). In its determination, the “SBA counts the receipts, employees, or other measure of size of the concern whose size is at issue and all of its domestic and foreign affiliates.” See 13 CFR 121.103. Following these regulations, the FDIC uses an insured depository institution’s affiliated and acquired assets, averaged over the preceding four quarters, to determine whether the insured depository institution is “small” for the purposes of RFA.

⁸⁰ Based on Call Reports data as of December 31, 2023. The variable LNRERES represents balances for 1–4 family residential real estate loans.

example, back-testing of AVM outputs relative to property sale prices to understand the degree of confidence they merit, and the development and implementation of safeguards against data manipulation. The FDIC believes that compliance activities other than recordkeeping associated with the first four quality control standards in the final rule will be relatively modest for small, FDIC-supervised IDIs. As previously discussed, the 2010 Appraisal Guidelines already encourage small, FDIC-supervised IDIs to conduct such activities. The FDIC believes that small, FDIC-supervised IDIs may incur relatively greater labor hours and costs to comply with the fifth quality control standard initially. The FDIC lacks data on the time required by the institutions to develop and implement the nondiscrimination quality control standard. Based on supervisory experience and subject matter expertise, the FDIC assumes that all compliance activities other than recordkeeping would average 80 hours per institution in the first year of the final rule's adoption and 35 hours in subsequent years.

This analysis estimates the total labor hours and costs incurred by small, FDIC-supervised IDIs associated with the final rule by adding compliance estimates associated with recordkeeping with activities other than recordkeeping. The FDIC estimates first year compliance labor hours per covered institution to be 120 on average,⁸⁶ and compliance labor hours to be 40 on average⁸⁷ for each subsequent year. As previously discussed, and for the purposes of this analysis, the FDIC assumes that 10 percent of small, FDIC-supervised IDIs that report non-zero value for mortgages on their books will incur costs to comply with the rule. Therefore, the FDIC estimates that small, FDIC-supervised IDIs will incur 26,196 labor hours in the first year⁸⁸ after the final rule becomes effective, and 8,732 labor hours in each subsequent year.⁸⁹ Employing a total hourly compensation estimate of \$99.65⁹⁰ for the first year and an

estimate of \$92.07⁹¹ for subsequent years, the FDIC estimates that small, FDIC-supervised IDIs will incur \$2,610,431 compliance costs in the first year⁹² after the final rule becomes effective, and \$803,955 in compliance costs in each subsequent year.⁹³

Further analysis shows that the estimated costs of the final rule would not impose a significant economic impact on a substantial number of small institutions. The analysis estimates that small, FDIC-supervised IDIs will incur approximately \$11,960 in compliance costs on average in the first year⁹⁴ after the final rule becomes effective and approximately \$3,680 in each subsequent year.⁹⁵ In the first year after the final rule becomes effective, estimated average costs exceed the 5 percent threshold of annual salaries and benefits for 6 (0.27 percent) small, FDIC-supervised IDIs, and 94 (4.23 percent) exceed the 2.5 percent threshold of total non-interest expense.⁹⁶ A combined total of 99 (4.46 percent) small, FDIC-supervised IDIs exceed either or both thresholds in the first year. In subsequent years, estimated average costs do not exceed the 5 percent threshold of annual salaries and benefits for any small, FDIC-supervised IDIs, and 13 (0.59 percent) exceed the 2.5 percent threshold of total non-interest expense. A combined total of 13 (0.59 percent) small, FDIC-supervised IDIs exceed either or both thresholds in subsequent years.

The compliance costs incurred by any one covered institution is likely to vary with the volume of covered AVM activity, the degree to which current AVM compliance activities differ from the robust quality control standards in the proposed rule, or the usage of in-house or third-party AVM service providers.

\$99.65. This average rate is derived from the BLS' Specific Occupational Employment and Wage Estimates, and BLS' Cost of Employee Compensation data.

⁹¹ In year 2 and beyond, the assumed distribution is Financial Analysts (50 percent of hours), Compliance Officers (40 percent), Lawyers (5 percent), and Executives and Managers (5 percent). This combination of occupations results in an overall estimated hourly total compensation rate of \$92.07. This average rate is derived from the BLS' Specific Occupational Employment and Wage Estimates, and BLS' Cost of Employee Compensation data.

⁹² $(2,183 * 10 \text{ percent AVM use rate}) * 120 \text{ labor hours} * \$99.65 \text{ per hour} = \$2,610,431$.

⁹³ $(2,183 * 10 \text{ percent AVM use rate}) * 40 \text{ labor hours} * \$92.07 \text{ per hour} = \$803,955$.

⁹⁴ $120 \text{ labor hours} * \$99.65 \text{ per hour} = \$11,958.00$.

⁹⁵ $40 \text{ labor hours} * \$92.07 \text{ per hour} = \$3,682.80$.

⁹⁶ Based on Call Report data as of December 31, 2023. The variable ESALA represents annualized salaries and employee benefits and the variable CHBALNI represents non-interest bearing cash balances.

Some commenters expressed concerns that the proposed rule would be costly and burdensome, especially for small entities and their ability to ensure that their policies and procedures meet the quality control standards. Some commenters cautioned that the proposed rule would create an uneven playing field between large and small companies and that some small entities would be at risk of going out of business. For additional discussion of the comments received on the proposed rule, please refer to part III (Discussion of the Proposed Rule, Comments Received, and the Final Rule) within the **SUPPLEMENTARY INFORMATION** of this document. The FDIC carefully considered the comments it received. The FDIC notes that compliance costs may vary across institutions but believes that they are unlikely to have a significant effect on a substantial number of small, FDIC-supervised IDIs. Finally, the FDIC notes that section 1125 does not provide for exemption authority and the FDIC does not believe that an exemption is necessary or appropriate.

In light of the foregoing, the FDIC certifies that the final rule will not have a significant economic impact on a substantial number of small, supervised entities.

D. NCUA

The RFA generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment, unless the agency certifies it will not have a *significant* economic impact on a *substantial* number of small entities.⁹⁷

The RFA establishes terms for various subgroups that potentially qualify as a "small entity"—including "small business," "small organization," and "small governmental jurisdiction."⁹⁸ Federally-insured credit unions (FICUs), as not-for-profit enterprises, are "small organizations," within the broader meaning of "small entity." Moreover, the RFA permits a regulator (such as the NCUA) to sharpen the definition of "small organization" as appropriate for agency activities—provided that definition is subjected to public comment and published in the **Federal Register**.⁹⁹ The NCUA's Interpretive Ruling and Policy Statement (IRPS) 15–1 defined "small entity" as any FICU with less than \$100 million in assets.¹⁰⁰ IRPS 15–1 (with this definition) was published in the **Federal Register**, and

⁹⁷ 5 U.S.C. 601 *et seq.*

⁹⁸ 5 U.S.C. 601.

⁹⁹ 5 U.S.C. 601(4).

¹⁰⁰ 80 FR 57512 (Sept. 24, 2015).

⁸⁶ 40 labor hours + 80 labor hours = 120 labor hours.

⁸⁷ 5 labor hours + 35 labor hours = 40 labor hours.
⁸⁸ $(2,183 * 10 \text{ percent AVM use rate}) * 120 \text{ labor hours} = 26,196 \text{ labor hours}$.

⁸⁹ $(2,183 * 10 \text{ percent AVM use rate}) * 40 \text{ labor hours} = 8,732 \text{ labor hours}$.

⁹⁰ The assumed distribution of occupation groups involved in the actions taken by institutions in response to the proposed rule in year 1 include Financial Analysts (40 percent of hours), Compliance Officers (40 percent), Lawyers (15 percent), and Executives and Managers (5 percent). This combination of occupations results in an overall estimated hourly total compensation rate of

the NCUA solicited and reviewed public comments on this definition.¹⁰¹

FICUs tend to be much smaller than commercial banks. Indeed, at year-end 2023, median asset size was \$55.9 million—less than one-sixth the median for U.S. commercial banks. As of December 31, 2023, there were 4,604 FICUs, of which 2,831 (61.5 percent) qualified as “small entities” by holding fewer than \$100 million in assets.¹⁰² Only 699 commercial banks (15.2 percent) fall beneath this threshold. For reasons noted below, the NCUA does not believe the regulatory amendments will have a *significant* economic impact on a *substantial* number of small entities.

1. Why *action is being considered*.

The final rule fulfills the statutory mandate in the Dodd-Frank Act requiring agencies to promulgate quality control standards for AVMs used by mortgage originators and secondary market issuers to value principal dwellings used as collateral. As noted, this final rule follows publication of a June 23, 2023, proposed rule and takes into consideration the public comments received in response to the proposal. Interested readers are referred to the discussion elsewhere in this preamble of the significant issues raised by the public comments, the assessment of the agencies of such issues, and changes made in the proposed rule as a result of such comments. Further, the RFA analysis provided by the CFPB elsewhere in this preamble responds to the comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule and provide a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.

2. *Policy objectives of, and legal basis for, the final rule.*

The NCUA is issuing this final rule to: (1) promote credit union safety and soundness by enhancing the integrity of collateral valuation for residential mortgage lending; and (2) help ensure credit unions comply with all applicable nondiscrimination laws. The legal basis for this rule is section 1125

of title XI of the FIRREA, as added by the Dodd-Frank Act—which directs covered agencies (in consultation with the staff of the Appraisal Subcommittee and Appraisal Standards Board of the Appraisal Foundation) to promulgate regulations with AVM quality-control standards.¹⁰³ The statute charges the NCUA with enforcing the regulations with respect to financial institutions, defined in title XI to include FICUs, for which the NCUA is the primary Federal supervisor.¹⁰⁴

3. *Description and estimate of the number of small institutions subject to final rule.*

The final rule will apply to FICUs relying on AVMs in their residential mortgage-lending decisions. Year-end 2023 data indicate 1,789 small-entity FICUs held residential real-estate loans (1st or junior liens). This represents 63.2 percent of small credit unions.

The NCUA does not currently require supervised credit unions to note in their quarterly data submissions whether AVMs are used in mortgage originations/modifications for owner-occupied residential real estate. In prior AVM analysis, the FDIC estimated that as many as 10 percent of their supervised institutions currently use an AVM for mortgage origination decisions, loan modification decisions, and securitization decisions covered by the final rule.¹⁰⁵ Applying this 10 percent estimate suggests the final rule could apply to up to 178 “small entity” credit unions. The FDIC notes AVM use is likely strongly positively correlated with institution size. Given the small size of most FICUs, it is likely far fewer than 10 percent use AVMs in residential-mortgage underwriting.¹⁰⁶ To be conservative, the 10 percent is used as an upper bound in the following analysis.

4. *Projected reporting, recordkeeping, and other compliance requirements of the final rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for preparation of the report or record.*

As noted, since 2010, the OCC, Board, FDIC, and NCUA have provided supervisory guidance on AVM use to regulated institutions in Appendix B to the Appraisal Guidelines.¹⁰⁷ The Appraisal Guidelines recommend that institutions establish policies, practices,

and procedures governing the selection, use, and validation of AVMs—including steps to ensure accuracy, reliability, and independence.¹⁰⁸ The quality-control standards in the final rule are consistent with those in the Appraisal Guidelines, existing supervisory expectations, and statutory nondiscrimination requirements. The NCUA believes the final rule will largely serve to make explicit standards that have been communicated through less formal, more varied means for over ten years. Accordingly, the NCUA anticipates compliance costs for “small” credit unions are likely be minimal.

Based on interviews with examiners and supervisors (about experience with rules largely codifying existing practice as well as the specifics of the AVM rule), the NCUA estimates the upper-bound for compliance burden is 33 labor hours annually. The upper-bound estimate for AVM usage of 178 credit unions implies the aggregate compliance burden should not exceed 5,874 hours. To put this figure in context, the 1,789 credit unions under \$100 million with residential mortgages on their books paid their employees an average of \$33.13 per hour in salary and benefits.¹⁰⁹ The upper-bound compliance estimate of 5,874 hours, therefore, implies an upper bound on aggregate cost of \$194,606.¹¹⁰ Viewed another way, this aggregate cost is only 0.008 percent of total 2023 non-interest expense for “small” credit unions. These figures suggest the compliance cost of the final rule will not impose a significant burden on a substantial number of “small entities.”¹¹¹

¹⁰⁸ Because such a small percentage of credit unions actively relied on AVMs at the time, written NCUA guidance was not as detailed as that provided by the banking agencies. Nonetheless, expectations for safe-and-sound use have been conveyed through the supervisory process to FICUs employing AVMs in residential mortgage lending.

¹⁰⁹ This figure was obtained by dividing 2023 total compensation expense for the 1,789 credit unions by the product of full-time equivalent employees, 52 weeks per year, and 40 hours per week.

¹¹⁰ There are other good reasons to believe 5,874 hours is an upper bound. The final rule should, for example, ease compliance with existing supervisory guidance/expectations by making the exact “rules of the game” more explicit. In theory, this applies to all covered institutions. But, given the small size of credit unions—the median number full-time equivalent employees for the 1,789 “small entities” with residential mortgages at year-end 2023 was eight—time savings from any reduction in supervisory ambiguity are particularly valuable. Moreover, following the now explicit guidance should result in fewer safety-and-soundness and fair-lending issues for small credit unions to address).

¹¹¹ Of course, estimates of an extremely modest impact based on central tendency do not exclude the possibility the compliance costs will prove meaningful for *some* small credit unions.

¹⁰¹ IRPS 15–1 was preceded by IRPS 81–4, which defined “small entity” as any FICU with fewer than \$1 million in assets (46 FR 29248 (June 1, 1981)). The NCUA Board updated the definition in 2003 to include FICUs holding fewer than \$10 million in assets with IRPS 03–2 (68 FR 31949 (May 29, 2003)). In 2013, IRPS 13–1 increased the threshold to under \$50 million in assets (78 FR 4032 (Jan. 18, 2013)). In addition, the NCUA’s Board pledged to review the RFA threshold after two years and thereafter on a three-year cycle, as part of its routine cycle of regulatory review.

¹⁰² These figures are based on data submitted by FICUs quarterly on their 5300 forms (call report).

¹⁰³ 12 U.S.C. 3354.

¹⁰⁴ See 12 U.S.C. 3350(7).

¹⁰⁵ 88 FR 40638 at 40659 (June 23, 2023).

¹⁰⁶ Discussions with NCUA examiners and supervisors supported the notion 10 percent is a high upper bound.

¹⁰⁷ See *supra* note 4. The Appraisal Guidelines were adopted after notice and comment.

5. *An identification, to the extent practicable, of all relevant federal rules which may duplicate, overlap with, or conflict with the final rule.*

The NCUA has not identified any likely duplication, overlap, or potential conflict with this final rule and any other federal rule.

6. *Any significant alternatives to the final rule that accomplish its stated objectives.*

As noted, the final rule implements a statutory mandate, thereby limiting the ability of covered agencies to consider alternatives. That said, agencies did exercise authority provided by section 1125 to include the nondiscrimination quality-control factor (given continued evidence of disparities in residential property lending terms along racial and ethnic lines). Further, covered agencies determined this factor should impose little additional burden since institutions have a preexisting obligation to comply with all federal law, including federal nondiscrimination laws. For the above reasons, the NCUA certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

E. CFPB

The RFA¹¹² generally requires an agency to conduct an IRFA and a FRFA of any rule subject to notice-and-comment rulemaking requirements. These analyses must “describe the impact of the proposed rule on small entities.”¹¹³ An IRFA or FRFA is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.¹¹⁴ If it will have such an impact, the CFPB is subject to certain additional procedures under the RFA, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA)¹¹⁵ and the Dodd-Frank Act, involving the convening of a panel (SBREFA Panel) to

consult with small entity representatives (SERs) prior to proposing a rule for which an IRFA is required.¹¹⁶

The CFPB has not certified that the proposed rule would not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. Accordingly, the CFPB convened and chaired a SBREFA Panel to consider the impact of the proposed rule on small entities that would be subject to that rule and to obtain feedback from representatives of such small entities. On May 13, 2022, the CFPB released the Final Report of the Panel on the CFPB’s Proposals and Alternatives Under Consideration for the AVM Rulemaking (SBREFA Panel Report).¹¹⁷ The proposal preamble included a discussion of the SBREFA Panel for this rulemaking.¹¹⁸ The CFPB also published an IRFA in the proposal. Comments addressing individual provisions of the proposed rule are addressed in part III of the **SUPPLEMENTARY INFORMATION** of this document. Comments addressing the impact on small entities are discussed below. Many of these comments implicated individual provisions of the final rule and are also addressed in those parts.

The FRFA for this rulemaking follows this discussion. Section 604(a) of the RFA sets forth the required elements of the FRFA. Section 604(a)(1) requires the FRFA to contain a statement of the need for, and objectives of, the rule. Section 604(a)(2) requires the FRFA to contain a statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made in the proposed rule as a result of such comments. Section 604(a)(3) requires the CFPB to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (Advocacy)¹¹⁹ in response to the proposed rule and provide a detailed statement of any change made to the

proposed rule in the final rule as a result of the comments.

The FRFA further must contain a description of and an estimate of the number of small entities to which the rule will apply or an explanation of why no such estimate is available.¹²⁰ Section 604(b)(5) requires a description of the projected reporting, recordkeeping, and other compliance requirements of the rule, including an estimate of the classes of small entities that will be subject to the requirement and the type of professional skills necessary for the preparation of the report or record. In addition, the CFPB must describe any steps it has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency which affect the impact on small entities was rejected.¹²¹ Finally, as amended by the Dodd-Frank Act, RFA section 604(a)(6) requires that the FRFA include a description of the steps the agency has taken to minimize any additional cost of credit for small entities.

1. *Statement of the need for, and objectives of, the rule.*

As discussed in part I of the **SUPPLEMENTARY INFORMATION** section of this document, section 1473(q) of the Dodd-Frank Act amended title XI of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 to add a new section 1125. Section 1125 directs the agencies to promulgate regulations for quality control standards for AVMs, which are “any computerized model used by mortgage originators and secondary market issuers to determine the collateral worth of a mortgage secured by a consumer’s principal dwelling.”¹²² Specifically, section 1125 requires that AVMs meet quality control standards designed to ensure a high level of confidence in the estimates produced by AVMs; protect against the manipulation of data; seek to avoid conflicts of interest; require random sample testing and reviews; and account for any other such factor that the agencies determine to be appropriate. The final rule effectuates Congress’s mandate to the agencies to adopt rules to implement quality control standards for AVMs.

¹¹² 5 U.S.C. 601 *et seq.*

¹¹³ 5 U.S.C. 603(a). For purposes of assessing the impacts of the proposed rule on small entities, “small entities” is defined in the RFA to include small businesses, small not-for-profit organizations, and small government jurisdictions. 5 U.S.C. 601(6). A “small business” is determined by application of SBA regulations and reference to the NAICS classifications and size standards. 5 U.S.C. 601(3). A “small organization” is any “not-for-profit enterprise which is independently owned and operated and is not dominant in its field.” 5 U.S.C. 601(4). A “small governmental jurisdiction” is the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. 5 U.S.C. 601(5).

¹¹⁴ 5 U.S.C. 605(b).

¹¹⁵ Public Law 104–121, 110 Stat. 857 (1996) (5 U.S.C. 609) (amended by Dodd-Frank Act section 1100G).

¹¹⁶ 5 U.S.C. 609.

¹¹⁷ CFPB, *Final Report of the Small Business Review Panel on the CFPB’s Proposals and Alternatives Under Consideration for the Automated Valuation Model (AVM) Rulemaking* (May 13, 2022), available at https://files.consumerfinance.gov/f/documents/cfpb_avm_final-report_2022-05.pdf.

¹¹⁸ 88 FR 40638 at 40649. The CFPB’s documents and content from its SBREFA process for this rulemaking should not be construed to represent the views or recommendations of the Board, OCC, FDIC, NCUA, or FHFA.

¹¹⁹ Advocacy is an independent office within SBA, so the views expressed by Advocacy do not necessarily reflect the views of the SBA.

¹²⁰ 5 U.S.C. 604(a)(4).

¹²¹ 5 U.S.C. 604(a)(6). (So in original. Two paragraphs (6) were enacted.)

¹²² 12 U.S.C. 3354(d).

The objectives of the final rule include protecting consumers and protecting Federal financial and public policy interests in real estate related transactions. To achieve these objectives, the final rule will require mortgage originators and secondary market issuers to adopt policies, practices, procedures, and control systems to ensure that covered AVMs adhere to quality control standards designed to meet specific quality control factors. The objectives of the final rule are further discussed in parts I and III of the **SUPPLEMENTARY INFORMATION** of this document.

2. Statement of the significant issues raised by the public comments in response to the initial regulatory flexibility analysis, a statement of the assessment of the agency of such issues, and a statement of any changes made to the proposed rule in the final rule as a result of such comments.

In the IRFA, the CFPB estimated the possible compliance cost for small entities with respect to a pre-statute baseline. Additionally, the IRFA discussed possible impacts on small entities.

Very few commenters specifically addressed the IRFA included in the proposal. Comments made by Advocacy related to the estimates included in the IRFA are addressed below in part V.E.3 of this document. This section addresses specific significant comments that affect the FRFA analysis.

Many industry commenters expressed concerns that the proposed rule would be costly and burdensome, especially for small entities and their ability to ensure that their policies and procedures meet the quality control standards. Some commenters even cautioned that the proposed rule would create an uneven playing field between large and small companies and that some small entities would be at risk of going out of business. These commenters did not provide specifics about the costs or burdens on small entities. The CFPB reviewed these comments and recognizes that small entities will experience some new compliance costs in the final rule. The CFPB accounted for these costs in the IRFA and therefore is not making any changes related to these concerns in the FRFA.

Some industry commenters provided feedback on the magnitude of the estimated burden hours, which form a core part of the IRFA analysis. Two commenters provided estimates for what they believe the burden hours will be. One of these commenters stated that a statistically-based, rigorous analytical approach would require between 100

and 400 hours a year and that, in particular, testing AVMs for compliance with nondiscrimination laws requires building a database, cleaning data, carefully building samples, and running regression tests. The commenter noted that if a company were to outsource their validation of AVMs, then the agencies' estimated burden hours might be adequate, but that there would be a cost to outsourcing. Another commenter stated that covered institutions would need to create some controls that would be based on statistical analysis and provided a rough estimate of 320 to 480 hours. The CFPB outlined the estimated burden hours that it uses in the IRFA analysis more explicitly in the SBREFA Panel Report: 69 hours for verifying compliance, 65 hours for drafting and developing policies, practices, procedures, and control systems, and 60 hours for training. Therefore, the total number of estimated hours in the first year is 194 and primarily includes costs for "Legal Services." In both the SBREFA Panel Report and the IRFA, the CFPB did not assume costs for statistician services. If a small entity needs statistician services, the SBREFA analysis "anticipates that most third parties would be able to provide institution-specific . . . service that accompanies an AVM." As discussed in part III.E.2 of the **SUPPLEMENTARY INFORMATION** of this document, as long as institutions adopt and maintain policies, practices, procedures, and control systems to ensure that AVMs adhere to the rule's requisite quality control standards—and consistent with the flexibility to set their quality control standards as appropriate based on the size of their institution and the risk and complexity of transactions for which they will use covered AVMs—institutions should be able to work with AVM providers to assist them with their compliance obligations under the rule.

Furthermore, the SBREFA analysis states that "Whether small entities' costs increase depends ultimately on whether third-party service providers [such as AVM providers] pass along costs. For example, costs may increase if each third-party service provider has . . . to customiz[e] . . . for each small entity. Costs may not increase if third-party service providers can sell the same general set . . . to many small entities with little modification." The CFPB has considered the estimates provided by the commenters and either considers them consistent with the CFPB's estimates or deficient in showing that more burden hours are necessary. Therefore, the CFPB is not making any

changes related to the estimated burden hours in the FRFA.

3. Response of the agency to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration in response to the proposed rule, and a detailed statement of any change made to the proposed rule in the final rule as a result of the comments.

Advocacy provided a formal comment letter to the agencies in response to the proposed rule. This letter stated that small entities should not be responsible for the actions of AVM providers, that the agencies should reduce the burden of the rule so that harm to small entities and consumers would be minimized, and that the nondiscrimination quality control factor should not be included in the final rule. Additionally, Advocacy suggested that small entities be exempt from the rule and, if that was not possible, that they should be allowed to rely on third-party certification of AVM providers or be provided a safe harbor for compliance. Finally, Advocacy asked that the agencies provide clear guidance to small entities to aid in compliance with the rule.

Small entities and AVM providers. Advocacy stated that small entities should not be responsible for the activities of AVM providers because they do not control those providers, and therefore cannot quality control the data or the algorithms used. In addition, Advocacy stated that small entities do not have the bargaining power to require AVM providers to take actions to be in compliance with the rule. As discussed above, the agencies believe that financial institutions, including small financial institutions, will be able to work with AVM providers to assist them with their compliance obligations under the rule, as they do with other third-party vendors in order to comply with relevant regulatory requirements.

Burden on small entities. Advocacy stated that the agencies should work to reduce the burden of the rule on small entities. Advocacy explained that it believed that the rule's costs would harm small entities and potentially reduce the use of AVMs, causing consumers to pay for more costly appraisals. As discussed above and below, in an effort to minimize the economic impact on small entities, the agencies considered and rejected a number of alternatives while drafting the final rule that otherwise would have resulted in greater costs to small entities than would the final rule. The CFPB recognizes that small entities will experience some new costs to comply with the final rule, but the CFPB does not believe that the burden of the rule

is excessive. Furthermore, the CFPB believes that the rule will not reduce the availability of AVMs, and that it will benefit consumers by ensuring the quality and accuracy of the valuations provided.

Nondiscrimination quality control factor. Advocacy stated that the agencies should exclude the nondiscrimination quality control factor from the regulation. Advocacy stated that the statute does not specifically state that quality control standards for AVMs must address the issue of discrimination. In addition, Advocacy noted that at the SBREFA Panel outreach meeting, the SERs uniformly raised concerns regarding how they could assess fair lending issues in AVMs or know that they are violating the law. Moreover, Advocacy stated that there are other mechanisms to address the issue of discrimination. Advocacy explained that small entities are already required to comply with nondiscrimination and fair lending laws, and making small entities responsible for assessing fair lending issues in AVMs adds an extra layer of burden. As explained above, the agencies have the authority to account for any other such factor that the agencies determine to be appropriate. Moreover, while existing nondiscrimination law applies to an institution's use of AVMs, the CFPB believes that it is important to specify a fifth factor relating to nondiscrimination to heighten awareness among lenders of the applicability of nondiscrimination laws to AVMs. Given the existing obligation, the CFPB does not believe

that the burden of the rule is excessive. Furthermore, as discussed above, the agencies believe that financial institutions, including small financial institutions, will be able to work with AVM providers to assist them with their compliance obligations under the rule, including compliance with the nondiscrimination factor, as they do with other third-party vendors in order to comply with relevant regulatory requirements.

Exemption, certification or safe harbor. Advocacy suggested that small entities be exempt from the rule and, if that was not possible, that they should be allowed to rely on third-party certification of AVM providers or be provided a safe harbor for compliance. The CFPB notes that section 1125 does not provide for exemption authority and the CFPB does not believe that an exemption is necessary or appropriate. Section 1125 requires quality controls for AVMs, and the CFPB believes that consumers who patronize small entities should benefit from the consumer protections that the rule provides, and the CFPB does not believe that the burden of the rule is excessive. In regard to the request for third-party certification, as explained above, the CFPB recognizes that third-party certification could be beneficial to effective implementation of the AVM rule and, as long as financial institutions meet the obligations stated in the rule, they are free to work with third parties to assist them with their compliance obligations. Finally, the CFPB does not believe that a safe harbor is warranted, as the burden on small

entities will not be such that a simplified compliance method, which might be less protective of consumers, would be needed.

Clear guidance. Finally, Advocacy asked that the agencies provide clear guidance to small entities to aid in compliance with the rule. As explained above, the rule's quality control standards are consistent with the existing guidance described in part I of this **SUPPLEMENTARY INFORMATION** and institutions that are not regulated by the agency or agencies providing the guidance may still look to the guidance for assistance with complying with this final rule. In addition, the CFPB will consider issuing further guidance in the future, as implementation of the rule is carried out, depending on the need.

4. Description of and an estimate of the number of small entities to which the final rule will apply.

A "small business" is determined by application of SBA regulations in reference to the North American Industry Classification System (NAICS) classification and size standards.¹²³ Under such standards, the CFPB identified three categories of small nondepository entities that may be subject to the proposed provisions: (1) real estate credit companies; (2) secondary market financing companies; and (3) other activities related to credit intermediation (which includes mortgage loan servicers).

The following table summarizes the CFPB's estimate of the number and industry of entities that may be affected by the final rule:

TABLE A—ESTIMATED NUMBER OF SMALL ENTITIES BY INDUSTRY

NAICS	Industry	SBA small entity threshold (m)	Est. total entities in 2017	Est. number of small entities in 2017	Est. number of small entities in 2023
522292	Real Estate Credit	\$470	3,289	2,904	3,881
522294	Secondary Market Financing	470	115	106	142
522390	Other Activities Related to Credit Intermediation	28.5	566	566	756
Column Total			3,970	3,576	4,779

Note: See footnote 124 for methodology to extrapolate 2017 numbers to 2023.

Source: 2017 County Business Patterns and Economic Census (Release Date: 5/28/2021).

In developing these estimates, the CFPB chose assumptions that would likely overcount the number of small entities and explains this reasoning in detail herein. Thus, the true number of small entities is likely to be less than the estimates reported. The following

paragraphs describe the categories of entities that the CFPB expects will be affected by the final rule.

Real Estate Credit companies (NAICS 522292). This industry encompasses establishments primarily engaged in lending funds with real estate as

collateral, including mortgage companies and real estate credit lenders. Economic Census data states that there were 3,289 nondepository institutions (nondepositories) in 2017 that engaged in real estate credit and whose use of AVMs may be covered by

¹²³ The current SBA size standards are found on SBA's website, Small Bus. Admin., *Table of size*

standards (March 17, 2023), <https://www.sba.gov/document/support-table-size-standards>.

the final rule. The SBA established a revenue threshold for small entities of average annual receipts of less than \$47 million. The Economic Census provides data for the number of small entities with less than \$40 million and less than \$50 million in revenue, but not less than \$47 million in revenue. Using the conservative threshold of \$50 million, the CFPB estimates that about 2,904 of these 3,289 institutions were small entities in 2017. This estimate is most likely an overcount because this NAICS industry also includes firms involved in construction lending, farm mortgages, and Federal land banks, which will not be covered by the final rule if such credit is not secured by a consumer's principal dwelling. Lastly, due to a lack of more recent data in the Economic Census, the CFPB scales up the 2017 estimate by a factor of 1.3363 to obtain a 2023 estimate of 3,881 small entities.¹²⁴

Secondary market financing companies (NAICS 522294). This industry encompasses establishments primarily engaged in buying, pooling, and repackaging loans for sale to others on the secondary market, including collateralized mortgage obligation issuers and real estate mortgage investment conduits. Economic Census data states that there were 115 nondepository secondary market financing companies in 2017 whose use of AVMs may be covered by the final rule. This industry has a size standard threshold of less than \$47 million in average annual receipts. However, the Economic Census only reports breakdowns in number of firms with less than \$15 million and less than \$100

million in revenue. Using the more conservative threshold of less than \$100 million, the CFPB estimates that 106 secondary market financing companies were small entities in 2017. This estimate is most likely an overcount because this NAICS industry also includes firms involved in secondary market financing of student loans and other debt products, which will not be covered by the AVM rule. Lastly, due to a lack of more recent data in the Economic Census, the CFPB scales up the 2017 estimate by a factor of 1.3363 (same as before) to obtain a 2023 estimate of 142 small entities.

Other Activities Related to Credit Intermediation (NAICS 522390). This industry encompasses establishments primarily engaged in facilitating credit intermediation (except mortgage and loan brokerage; and financial transactions processing, reserve, and clearinghouse activities), and includes loan servicing firms. NAICS 522390 is a broader category than the previous two categories discussed in this section. Some examples of business activity in this NAICS industry are check cashing services, loan servicing, money transmission services, payday lending services, and traveler's check issuance services, but only loan servicing will fall under the final rule. To account for this broader categorization, using Economic Census data on number of establishments in this NAICS industry broken down by the North American Product Classification System (NAPCS), the CFPB filtered NAICS 522390 by the relevant NAPCS collection codes: (1) Residential Mortgage Loans, and (2) Other Secured or Guaranteed Home

Loans to Consumers. The filtered count of the number of establishments is 566. However, these data do not provide the number of firms, each of which may consist of one or more establishments. Thus, the CFPB uses the most conservative assumption—that each firm has only one establishment—to estimate the number of firms covered by the final rule to be (at most) 566 in 2017. Furthermore, data broken down by firm/establishment size are unavailable, so the CFPB assumes the most conservative extreme that all 566 of these firms are small entities. Lastly, due to a lack of more recent data in the Economic Census, the CFPB scales up the 2017 estimate by a factor of 1.3363 (same as before) to obtain a 2023 estimate of 756 small entities.

Finally, only small entities that themselves, or through or in cooperation with a third-party or affiliate, utilize AVMs in credit decisions or covered securitization determinations will be covered by the final rule. The remaining small entities may opt for alternative valuation methods not involving AVMs. Due to the lack of data on the usage of AVMs by small entities in credit decisions or covered securitization determinations, the CFPB follows the FDIC and makes the following assumption: the range of AVM usage lies between 10 percent (lower bound) and 100 percent (upper bound). Applying this assumption to the estimated total number of small entities results in the estimated range of covered small entities shown in the following table:

TABLE B—ESTIMATED LOWER AND UPPER BOUNDS OF COVERED SMALL ENTITIES IN 2023

	Lower bound	Upper bound
Est. Number of Covered Small Entities	478	4,779
Assumed Proportion of Small Entities Using AVMs	10%	100%

In summary, the CFPB estimates that between 478 and 4,779 small entities will be covered by the final rule.

In this analysis, the CFPB also considered including other NAICS categories, most notably “Mortgage and Nonmortgage Loan Brokers” (NAICS 522310). This industry includes establishments primarily engaged in arranging loans by bringing borrowers and lenders together on a commission or fee basis. Based on this definition, the

CFPB believes that this industry is generally not involved in credit decisions or covered securitization determinations and, thus, typically will not be covered by the final rule.

5. Projected reporting, recordkeeping, and other compliance requirements of the final rule, including an estimate of the classes of small entities which will be subject to the requirement and the type of professional skills necessary for the preparation of the report or record.

The final rule will not impose new reporting or recordkeeping requirements for CFPB respondents but will impose new compliance requirements on small entities subject to the rule. The final rule requirements and the costs associated with them are discussed herein.

Entities will likely have to spend time and resources reading and understanding the regulation and developing the required policies,

¹²⁴ According to U.S. Bureau of Economic Analysis, “Gross Output by Industry” (<https://apps.bea.gov/iTable/?reqid=150&step=2&isuri=1&categories=gdpind>, accessed March 28, 2024), from

2017 to 2023 (the latest available data at the time of writing), the finance sector (NAICS 52) gross output expanded from \$2,807.7 billion to \$ 3,752.0 billion, a 33.63 percent increase. Thus, the CFPB

scales up the number of entities in 2017 by a factor of 1.3363 and rounds to the nearest whole number.

practices, procedures, and control systems for their employees to follow to ensure compliance, in addition to engaging a legal team to review their draft policies, practices, procedures, and control systems. Costs associated with drafting compliance policies, practices, procedures, and control systems are likely to be higher for institutions who use AVMs for a more diverse set of circumstances. Such entities will likely need to tailor guidance for each specific use case. Small entities will also likely have to implement training of staff that utilize AVM output for covered purposes.

Costs to small entities. The CFPB expects that the final rule may impose one-time and ongoing costs on small nondepository entities who use AVMs in valuing real estate collateral securing mortgage loans. The CFPB has identified three categories of costs that make up the components necessary for a nondepository institution to comply with the final rule. Those categories are drafting and developing policies, practices, procedures, and control systems; verifying compliance; and training staff and third parties. Nondepositories will incur the bulk of these costs in the first year. However, the CFPB anticipates that nondepositories will incur some ongoing costs in subsequent years, such as updating policies, practices, procedures, and control systems, continuing review for compliance, and training new staff. Following the FDIC, the CFPB assumes that the ongoing annual costs will be one-third of the one-time first-year costs.

Using the cost methodology outlined in the SBREFA Panel Report, the CFPB estimates that the one-time costs in the first year for each covered small nondepository entity will be the following: \$7,000 for drafting and developing policies, practices, procedures, and control systems, \$10,000 for verifying compliance, and \$6,000 for training. Thus, the total costs per entity will be \$23,000 in the first year and \$7,667 for each subsequent year.

The CFPB calculates the overall market impact of the final rule on small entities by multiplying the costs per entity by the estimated number of covered small entities. The CFPB estimates that the overall market impact of one-time costs in the first year for covered small nondepositories will be between \$10,994,000 and \$109,917,000. The CFPB estimates that the overall market impact of ongoing costs in each subsequent year for covered small nondepositories will be between \$3,664,826 and \$36,640,593 per year.

The ranges in estimated impact are wide due to uncertainty surrounding the percentage of small entities using AVMs in credit decisions or covered securitization determinations.

6. Description of the steps the agency has taken to minimize the significant economic impact on small entities consistent with the stated objectives of applicable statutes, including a statement of the factual, policy, and legal reasons for selecting the alternative adopted in the final rule and why each one of the other significant alternatives to the rule considered by the agency that affect the impact on small entities was rejected.

In an effort to minimize the significant economic impact on small entities, the CFPB considered a number of alternatives while drafting the final rule, including those considered as part of the SBREFA process. Many of the alternatives considered would have resulted in greater costs to small entities than would the final rule. For example, the CFPB considered proposing a prescriptive rule with more detailed and specific requirements, and the CFPB considered a rule that would also cover the use of AVMs solely to review completed value determinations (e.g., to review appraisals). Since such alternatives would result in a greater economic impact on small entities than the final rule, they are not discussed here.

The CFPB also considered alternatives that might have resulted in a smaller economic impact on small entities than would the final rule. Some of these alternatives are briefly described and their impacts relative to the final provisions are discussed herein.

Coverage of loan modifications and other changes to existing loans. The CFPB considered a rule that would exclude AVMs used in loan modifications not resulting in new mortgage originations. As discussed in the proposal preamble and the SBREFA Panel Report, during the SBREFA process SERs generally favored that approach. The CFPB understands that the final rule's coverage of loan modifications and other changes to existing loans will introduce additional burden to small entities. However, the CFPB has determined that this coverage will aid in fulfilling the consumer protection objective of section 1125. For consumers seeking loss mitigation, obtaining an AVM valuation that adheres to the quality control standards in the final rule during the loan modification process will be particularly important for their financial decision-making and outcomes, given they are already in financial distress.

During the proposed rule stage, the CFPB requested comments on the likely impact of this coverage aspect of the rule on the compliance costs of small entities and did not receive specific feedback to warrant excluding AVMs used in loan modifications that do not result in new mortgage originations.

Coverage of credit line reductions or suspensions. The CFPB considered a rule that would not cover AVMs used solely in deciding whether or to what extent to reduce or suspend a home equity line of credit. As discussed in the proposal preamble and the SBREFA Panel Report, during the SBREFA process SERs discussed balancing the consumer protections of covering credit line reductions or suspensions against the burdens of such regulation. The CFPB understands that the final rule's coverage of credit line reductions and suspensions will introduce additional burden to small entities. However, the CFPB has determined that this coverage will aid in fulfilling the consumer protection objective of section 1125. Credit line reductions and suspensions impose hardship on consumers, who now face greater credit constraints and reduced financial options. Obtaining an AVM valuation that adheres to the quality control standards in the final rule during the credit decision process is particularly important for these consumers, given the potential for improving consumer financial outcomes. During the proposed rule stage, the CFPB requested comments on the likely impact of this coverage aspect of the rule on the compliance costs of small entities and did not receive specific feedback to warrant excluding AVMs used in deciding whether or to what extent to reduce or suspend a home equity line of credit.

Nondiscrimination quality control factor. The CFPB considered a rule that would not specify a nondiscrimination quality control factor. As discussed in the proposal preamble and the SBREFA Panel Report, during the SBREFA process, SERs expressed concern regarding the nondiscrimination quality control factor. In particular, SERs noted the impracticality of having small entities assess fair lending performance of AVMs provided by third parties, as well as noting concerns that this nondiscrimination quality control factor potentially duplicates other fair lending regulatory infrastructure. The CFPB understands that the final rule's nondiscrimination quality control factor will introduce additional burden to small entities. However, the CFPB has determined that this factor will aid in fulfilling the consumer protection objective of section 1125. There is a long

history of housing market discrimination in the United States, including misvaluation of property owned by minority consumers, as observed in biases in the appraisal process.¹²⁵ Misvaluations limit credit access for minority consumers, potentially leading to worse financial outcomes by hampering home ownership and wealth accumulation among minority consumers.

The CFPB acknowledges that for small entities with a limited volume of AVM valuation observations, detecting discrimination in AVMs may not be feasible. Nevertheless, there are other steps small entities could take towards satisfying the nondiscrimination quality control factor. For example, the SBREFA process described various points in the valuation process where humans interact with AVMs and make decisions regarding AVM usage and application of AVM outputs; having policies, practices, procedures, and control systems in place that ensure such human interactions and decision-making comply with applicable nondiscrimination laws would be feasible for small entities. As another example, in choosing third-party AVM providers, small entities can do research into how providers assess and account for discrimination in their AVMs and opt for providers who have taken such factors into consideration.

During the proposed rule stage, the CFPB requested comments on the likely impact of the nondiscrimination quality control factor of the rule on the compliance costs of small entities and did not receive specific feedback to warrant not specifying a nondiscrimination quality control factor.

7. Description of the steps the agency has taken to minimize any additional cost of credit for small entities.

The CFPB believes that there will be little to no impact on the cost of credit incurred by small entities covered by the final rule. Should a covered small entity apply for a business loan, the lender is unlikely to consider that covered small entity's use of AVMs or their compliance with the final rule in their credit pricing or credit extension decisions.

During the SBREFA process, the CFPB asked SERs (including community banks, credit unions, and non-

depository mortgage lenders) about this possible impact, but they did not provide feedback on how their credit would be affected by the rule. This lack of feedback is consistent with the above assertions.

F. FHFA

The RFA requires that a regulation that has a significant economic impact on a substantial number of small entities, small businesses, or small organizations must include an analysis describing the regulation's impact on small entities.¹²⁶ FHFA need not undertake such an analysis if the Agency has certified that the regulation will not have a significant economic impact on a substantial number of small entities.¹²⁷ FHFA has considered the impact of the final rule under the RFA and FHFA certifies that the final rule will not have a significant economic impact on a substantial number of small entities because the regulation only applies to Fannie Mae and Freddie Mac, which are not small entities for purposes of the RFA.

VI. Use of Plain Language

Section 722 of the Gramm-Leach-Bliley Act¹²⁸ requires the agencies to use plain language in all proposed and final rules published after January 1, 2000. The agencies invited comment on how to make the rule easier to understand, but no such comments were received.

VII. Riegle Community Development and Regulatory Improvement Act of 1994

Pursuant to section 302(a) of the Riegle Community Development and Regulatory Improvement Act (RCDRIA),¹²⁹ in determining the effective date and administrative compliance requirements for new regulations that impose additional reporting, disclosure, or other requirements on insured depository institutions (IDIs), each Federal banking agency must consider, consistent with principles of safety and soundness and the public interest, any administrative burdens that such regulations would place on depository institutions, including small depository institutions, and customers of depository institutions, as well as the benefits of such regulations. In addition, section 302(b) of RCDRIA requires new regulations and amendments to regulations that impose additional

reporting, disclosures, or other new requirements on IDIs generally to take effect on the first day of a calendar quarter that begins on or after the date on which the regulations are published in final form.¹³⁰

The agencies have considered the administrative burdens and the benefits of the proposed rule in preparing this final rule and have adopted a 12-month delayed effective date. The final rule will be effective on the first day of the calendar quarter following the 12 months after publication in the **Federal Register**.

VIII. OCC Unfunded Mandates Reform Act of 1995 Determination

The OCC has analyzed the final rule under the factors set forth in the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1532. Under this analysis, the OCC considered whether the final rule includes a federal mandate that may result in the expenditure by state, local, and tribal governments, in the aggregate, or by the private sector, of \$183 million or more in any one year.¹³¹

The burden associated with the final rule will be limited to reviewing the rule, ensuring that existing practices, procedures, and control systems adequately address the four statutory quality control standards, and adopting policies, practices, procedures, and control systems to ensure that AVMs adhere to quality control standards designed to comply with applicable nondiscrimination laws. To estimate expenditures, the OCC reviews the costs associated with the activities necessary to comply with the final rule. These include an estimate of the total time required to implement the final rule and the estimated hourly wage of bank employees who may be responsible for the tasks associated with achieving compliance with the final rule. For the cost estimates, the OCC uses a compensation rate of \$128 per hour.¹³² Based on this approach, the OCC estimates that expenditures to comply with the final rule's mandates will be approximately \$21 million (180 hours × \$128 per hour × 909 banks = \$20.94 million). Therefore, the OCC concludes that the final rule will not result in the expenditure of \$183 million or more annually by state, local, and tribal governments, or by the private sector.

¹²⁵ Interagency Task Force on Property Appraisal and Valuation Equity (PAVE), *Action Plan to Advance Property Appraisal and Valuation Equity: Closing the Racial Wealth Gap by Addressing Misvaluations for Families and Communities of Color* 2–4 (Mar. 2022), available at <https://pave.hud.gov/sites/pave.hud.gov/files/documents/PAVEActionPlan.pdf>.

¹²⁶ 12 U.S.C. 601 *et seq.*

¹²⁷ 12 U.S.C. 605(b).

¹²⁸ Public Law 106–102, section 722, 113 Stat. 1338 1471 (1999).

¹²⁹ 12 U.S.C. 4802(a).

¹³⁰ 12 U.S.C. 4802.

¹³¹ *Id.*

¹³² See *supra* note 69 (providing information on how the OCC estimates wages and compensation costs associated with the rule).

IX. NCUA Executive Order 13132 Federalism

Executive Order 13132 encourages independent regulatory agencies to consider the impact of their actions on State and local interests. The NCUA, an independent regulatory agency as defined in 44 U.S.C. 3502(5), voluntarily complies with the executive order to adhere to fundamental federalism principles. This final rule will not have substantial direct effects on the states, on the relationship between the National Government and the states, or on the distribution of power and responsibilities among the various levels of government. Although the AVM statute and the final rule apply to federally insured, state-chartered credit unions, the NCUA does not believe that the rule will change the relationship between the NCUA and state regulatory agencies. The NCUA anticipates coordinating with state regulatory agencies to implement and enforce the rule as part of its ongoing coordination with these agencies. Accordingly, the NCUA believes that the effect of this change on the states will be limited. The NCUA has therefore determined that this rule does not constitute a policy that has federalism implications for purposes of the executive order.

X. NCUA Assessment of Federal Regulations and Policies on Families

The NCUA Board has determined that this final rule will not affect family well-being within the meaning of section 654 of the Treasury and General Government Appropriations Act, 1999.¹³³ As discussed, the final rule implements the quality control standards mandated by section 1125 for the use of AVMs by mortgage originators and secondary market issuers in determining the collateral worth of a mortgage secured by a consumer's principal dwelling. Accordingly, the rule could potentially affect mortgage financing options regarding principal dwelling units purchased by a family. However, the potential effect on family well-being of these mortgage financing decisions is, at most, indirect.

XI. Severability

Each of the agencies intend that, if any provision of the final rule, or any application of a provision, is stayed or determined to be invalid, the remaining provisions or applications are severable and shall continue in effect.

List of Subjects

12 CFR Part 34

Appraisal, Appraiser, Banks, banking, Consumer protection, Credit, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

12 CFR Part 225

Administrative practice and procedure, Banks, banking, Federal Reserve System, Holding companies, Investments, Reporting and recordkeeping requirements, Securities.

12 CFR Part 323

Banks, banking, Mortgages, Reporting and recordkeeping requirements, Savings associations.

12 CFR Part 722

Appraisal, Appraiser, Credit unions, Mortgages, Reporting and recordkeeping requirements, Truth in lending.

12 CFR Part 741

Credit, Credit unions.

12 CFR Part 1026

Advertising, Banks, banking, Consumer protection, Credit, Credit unions, Mortgages, National banks, Reporting and recordkeeping requirements, Savings associations, Truth in lending.

12 CFR Part 1222

Appraisals, Government-sponsored enterprises, Mortgages.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Chapter I

Authority and Issuance

For reasons set out in the joint preamble, the Office of the Comptroller of the Currency amends part 34 of chapter I of title 12 of the Code of Federal Regulations to read as follows:

PART 34—REAL ESTATE LENDING AND APPRAISALS

- 1. The authority citation for part 34 is revised to read as follows:

Authority: 12 U.S.C. 1 *et seq.*, 25b, 29, 93a, 371, 1465, 1701j–3, 1828(o), 3331 *et seq.*, 5101 *et seq.*, and 5412(b)(2)(B).

- 2. Add subpart I, consisting of §§ 34.220 through 34.222, to part 34 to read as follows:

Subpart I—Quality Control Standards for Automated Valuation Models Used for Mortgage Lending Purposes

Sec.

34.220 Authority, purpose, and scope.

34.221 Definitions.

34.222 Quality control standards.

§ 34.220 Authority, purpose, and scope.

(a) *Authority.* This subpart is issued pursuant to section 1125 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, 12 U.S.C. 3354, as added by section 1473(q) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203, 124 Stat. 1376, 2198 (2010)).

(b) *Purpose and scope.* (1) The purpose of this subpart is to implement the quality control standards in section 3354 of title 12 for the use of automated valuation models in determining the value of collateral in connection with making a credit decision or covered securitization determination regarding a mortgage or mortgage-backed security. This subpart applies to entities regulated by the OCC that are mortgage originators or secondary market issuers.

(2) This subpart does not apply to the use of automated valuation models in:

- (i) Monitoring of the quality or performance of mortgages or mortgage-backed securities;
- (ii) Reviews of the quality of already completed determinations of the value of collateral; or
- (iii) The development of an appraisal by a certified or licensed appraiser.

§ 34.221 Definitions.

As used in this subpart:

Automated valuation model means any computerized model used by mortgage originators and secondary market issuers to determine the value of a consumer's principal dwelling collateralizing a mortgage.

Control systems means the functions (such as internal and external audits, risk review, quality control, and quality assurance) and information systems that are used to measure performance, make decisions about risk, and assess the effectiveness of processes and personnel, including with respect to compliance with statutes and regulations.

Covered securitization determination means a determination regarding:

- (1) Whether to waive an appraisal requirement for a mortgage origination in connection with its potential sale or transfer to a secondary market issuer; or
- (2) Structuring, preparing disclosures for, or marketing initial offerings of mortgage-backed securitizations.

Credit decision means a decision regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage, including a decision whether to extend new or additional credit or change the credit limit on a line of credit.

¹³³ Public Law 105–277, 112 Stat. 2681 (1998).

Dwelling means a residential structure that contains one to four units, whether or not that structure is attached to real property. The term includes an individual condominium unit, cooperative unit, factory-built housing, or manufactured home, if it is used as a residence. A consumer can have only one "principal" dwelling at a time. Thus, a vacation or other second home would not be a principal dwelling. However, if a consumer buys or builds a new dwelling that will become the consumer's principal dwelling within a year or upon the completion of construction, the new dwelling is considered the principal dwelling for purposes of this subpart.

Mortgage means a transaction in which a mortgage, deed of trust, purchase money security interest arising under an installment sales contract, or equivalent consensual security interest is created or retained in a consumer's principal dwelling.

Mortgage originator means:

(1) Any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain—

- (i) Takes a mortgage application;
- (ii) Assists a consumer in obtaining or applying to obtain a mortgage; or
- (iii) Offers or negotiates terms of a mortgage;

(2) Includes any person who represents to the public, through advertising or other means of communicating or providing information (including the use of business cards, stationery, brochures, signs, rate lists, or other promotional items), that such person can or will provide any of the services or perform any of the activities described in paragraph (1) of this definition;

(3) Does not include any person who is—

(i) Not otherwise described in paragraph (1) or (2) of this definition and who performs purely administrative or clerical tasks on behalf of a person who is described in any such paragraph; or

(ii) A retailer of manufactured or modular homes or an employee of the retailer if the retailer or employee, as applicable—

(A) Does not receive compensation or gain for engaging in activities described in paragraph (1) of this definition that is in excess of any compensation or gain received in a comparable cash transaction;

(B) Discloses to the consumer—

(1) In writing any corporate affiliation with any creditor; and

(2) If the retailer has a corporate affiliation with any creditor, at least 1 unaffiliated creditor; and

(C) Does not directly negotiate with the consumer or lender on loan terms (including rates, fees, and other costs);

(4) Does not include a person or entity that only performs real estate brokerage activities and is licensed or registered in accordance with applicable State law, unless such person or entity is compensated by a lender, a mortgage broker, or other mortgage originator or by any agent of such lender, mortgage broker, or other mortgage originator;

(5) Does not include a person that meets all of the following criteria:

(i) The person provides seller financing for the sale of three or fewer properties in any 12-month period to purchasers of such properties, each of which is owned by the person and serves as security for the financing;

(ii) The person has not constructed, or acted as a contractor for the construction of, a residence on the property in the ordinary course of business of the person;

(iii) The person provides seller financing that meets the following requirements:

(A) The financing is fully amortizing;

(B) The financing is one that the person determines in good faith the consumer has a reasonable ability to repay;

(C) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(6) Does not include a natural person, estate, or trust that meets all of the following criteria:

(i) The natural person, estate, or trust provides seller financing for the sale of only one property in any 12-month period to purchasers of such property, which is owned by the natural person, estate, or trust and serves as security for the financing;

(ii) The natural person, estate, or trust has not constructed, or acted as a contractor for the construction of, a residence on the property in the ordinary course of business of the person;

(iii) The natural person, estate, or trust provides seller financing that meets the following requirements:

(A) The financing has a repayment schedule that does not result in negative amortization;

(B) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(7) Does not include a servicer or servicer employees, agents and contractors, including but not limited to those who offer or negotiate terms of a mortgage for purposes of renegotiating, modifying, replacing and subordinating principal of existing mortgages where borrowers are behind in their payments, in default or have a reasonable likelihood of being in default or falling behind.

Person has the meaning given in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

Secondary market issuer means any party that creates, structures, or organizes a mortgage-backed securities transaction.

§ 34.222 Quality control standards.

Mortgage originators and secondary market issuers that engage in credit decisions or covered securitization determinations themselves, or through or in cooperation with a third-party or affiliate, must adopt and maintain policies, practices, procedures, and control systems to ensure that automated valuation models used in these transactions adhere to quality control standards designed to:

(a) Ensure a high level of confidence in the estimates produced;

(b) Protect against the manipulation of data;

(c) Seek to avoid conflicts of interest;

(d) Require random sample testing and reviews; and

(e) Comply with applicable nondiscrimination laws.

FEDERAL RESERVE SYSTEM

12 CFR Chapter II

Authority and Issuance

For the reasons set forth in the joint preamble, the Board amends part 225 of chapter II of title 12 of the Code of Federal Regulations, as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

■ 3. The authority citation for part 225 is revised to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3354, 3906, 3907, and 3909; 15 U.S.C. 1681s, 1681w, 6801 and 6805.

■ 4. Add subpart O, consisting of §§ 225.350 through 225.352, to part 225 to read as follows:

Subpart O—Quality Control Standards for Automated Valuation Models Used for Mortgage Lending Purposes

Sec.

225.350 Authority, purpose and scope.

225.351 Definitions.

225.352 Quality control standards.

Subpart O—Quality Control Standards for Automated Valuation Models Used for Mortgage Lending Purposes

§ 225.350 Authority, purpose and scope.

(a) *Authority.* (1) *In general.* This subpart is issued pursuant to section 1125 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, 12 U.S.C. 3354, as added by section 1473(q) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203, 124 Stat. 1376, 2198 (2010)), as well as under the Federal Reserve Act, as amended (12 U.S.C. 221 *et seq.*); the Bank Holding Company Act of 1956, as amended (12 U.S.C. 1841 *et seq.*); the Home Owners' Loan Act of 1933 (12 U.S.C. 1461 *et seq.*); section 165 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (12 U.S.C. 5365); and the International Banking Act of 1978, as amended (12 U.S.C. 3101 *et seq.*).

(2) Nothing in this part shall be read to limit the authority of the Board to take action under provisions of law other than 12 U.S.C. 3354, including but not limited to action to address unsafe or unsound practices or conditions, or violations of law or regulation, under section 8 of the Federal Deposit Insurance Act, as amended (12 U.S.C. 1818).

(b) *Purpose and scope.* (1) The purpose of this subpart is to implement the quality control standards in section 3354 of title 12 for the use of automated valuation models in determining the value of collateral in connection with making a credit decision or covered securitization determination regarding a mortgage or a mortgage-backed security. This subpart applies to entities and institutions regulated by the Board (Board-regulated institutions) that are

mortgage originators or secondary market issuers.

(2) This subpart does not apply to the use of automated valuation models in:

(i) Monitoring of the quality or performance of mortgages or mortgage-backed securities;

(ii) Reviews of the quality of already completed determinations of the value of collateral; or

(iii) The development of an appraisal by a certified or licensed appraiser.

§ 225.351 Definitions.

As used in this subpart:

Automated valuation model means any computerized model used by mortgage originators and secondary market issuers to determine the value of a consumer's principal dwelling collateralizing a mortgage.

Control systems means the functions (such as internal and external audits, risk review, quality control, and quality assurance) and information systems that are used to measure performance, make decisions about risk, and assess the effectiveness of processes and personnel, including with respect to compliance with statutes and regulations.

Covered securitization determination means a determination regarding:

(1) Whether to waive an appraisal requirement for a mortgage origination in connection with its potential sale or transfer to a secondary market issuer; or

(2) Structuring, preparing disclosures for, or marketing initial offerings of mortgage-backed securitizations.

Credit decision means a decision regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage, including a decision whether to extend new or additional credit or change the credit limit on a line of credit.

Dwelling means a residential structure that contains one to four units, whether or not that structure is attached to real property. The term includes an individual condominium unit, cooperative unit, factory-built housing, or manufactured home, if it is used as a residence. A consumer can have only one "principal" dwelling at a time. Thus, a vacation or other second home would not be a principal dwelling. However, if a consumer buys or builds a new dwelling that will become the consumer's principal dwelling within a year or upon the completion of construction, the new dwelling is considered the principal dwelling for purposes of this subpart.

Mortgage means a transaction in which a mortgage, deed of trust, purchase money security interest arising under an installment sales contract, or

equivalent consensual security interest is created or retained in a consumer's principal dwelling.

Mortgage originator means:

(1) Any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain—

(i) Takes a mortgage application;

(ii) Assists a consumer in obtaining or applying to obtain a mortgage; or

(iii) Offers or negotiates terms of a mortgage;

(2) Includes any person who represents to the public, through advertising or other means of communicating or providing information (including the use of business cards, stationery, brochures, signs, rate lists, or other promotional items), that such person can or will provide any of the services or perform any of the activities described in paragraph (1) of this definition;

(3) Does not include any person who is—

(i) Not otherwise described in paragraph (1) or (2) of this definition and who performs purely administrative or clerical tasks on behalf of a person who is described in any such paragraph; or

(ii) A retailer of manufactured or modular homes or an employee of the retailer if the retailer or employee, as applicable—

(A) Does not receive compensation or gain for engaging in activities described in paragraph (1) of this definition that is in excess of any compensation or gain received in a comparable cash transaction;

(B) Discloses to the consumer—

(1) In writing any corporate affiliation with any creditor; and

(2) If the retailer has a corporate affiliation with any creditor, at least 1 unaffiliated creditor; and

(C) Does not directly negotiate with the consumer or lender on loan terms (including rates, fees, and other costs);

(4) Does not include a person or entity that only performs real estate brokerage activities and is licensed or registered in accordance with applicable State law, unless such person or entity is compensated by a lender, a mortgage broker, or other mortgage originator or by any agent of such lender, mortgage broker, or other mortgage originator;

(5) Does not include a person that meets all of the following criteria:

(i) The person provides seller financing for the sale of three or fewer properties in any 12-month period to purchasers of such properties, each of which is owned by the person and serves as security for the financing;

(ii) The person has not constructed, or acted as a contractor for the

construction of, a residence on the property in the ordinary course of business of the person;

(iii) The person provides seller financing that meets the following requirements:

(A) The financing is fully amortizing;

(B) The financing is one that the person determines in good faith the consumer has a reasonable ability to repay;

(C) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(6) Does not include a natural person, estate, or trust that meets all of the following criteria:

(i) The natural person, estate, or trust provides seller financing for the sale of only one property in any 12-month period to purchasers of such property, which is owned by the natural person, estate, or trust and serves as security for the financing;

(ii) The natural person, estate, or trust has not constructed, or acted as a contractor for the construction of, a residence on the property in the ordinary course of business of the person;

(iii) The natural person, estate, or trust provides seller financing that meets the following requirements:

(A) The financing has a repayment schedule that does not result in negative amortization;

(B) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(7) Does not include a servicer or servicer employees, agents and contractors, including but not limited to those who offer or negotiate terms of a mortgage for purposes of renegotiating, modifying, replacing and subordinating principal of existing mortgages where borrowers are behind in their payments, in default or have a reasonable

likelihood of being in default or falling behind.

Person has the meaning given in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

Secondary market issuer means any party that creates, structures, or organizes a mortgage-backed securities transaction.

§ 225.352 Quality control standards.

Mortgage originators and secondary market issuers that engage in credit decisions or covered securitization determinations themselves, or through or in cooperation with a third-party or affiliate, must adopt and maintain policies, practices, procedures, and control systems to ensure that automated valuation models used in these transactions adhere to quality control standards designed to:

(a) Ensure a high level of confidence in the estimates produced;

(b) Protect against the manipulation of data;

(c) Seek to avoid conflicts of interest;

(d) Require random sample testing and reviews; and

(e) Comply with applicable nondiscrimination laws.

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Chapter III

Authority and Issuance

For the reasons set forth in the joint preamble, the FDIC amends 12 CFR part 323 as follows:

PART 323—APPRAISALS

■ 5. The authority citation for part 323 continues to read as follows:

Authority: 12 U.S.C. 1818, 1819(a) (“Seventh” and “Tenth”), 1831p–1 and 3331 *et seq.*

■ 6. Add subpart C, consisting of §§ 323.15 through 323.17, to part 323 to read as follows:

Subpart C—Quality Control Standards for Automated Valuation Models Used for Mortgage Lending Purposes

Sec.

323.15 Authority, purpose, and scope.

323.16 Definitions.

323.17 Quality control standards.

§ 323.15 Authority, purpose, and scope.

(a) *Authority.* This subpart is issued pursuant to section 1125 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, 12 U.S.C. 3354, as added by section 1473(q) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203, 124 Stat. 1376, 2198 (2010)).

(b) *Purpose and scope.* (1) The purpose of this subpart is to implement the quality control standards in section 3354 of title 12 for the use of automated valuation models in determining the value of collateral in connection with making a credit decision or covered securitization determination regarding a mortgage or mortgage-backed security. This subpart applies to entities regulated by the FDIC that are mortgage originators or secondary market issuers.

(2) This subpart does not apply to the use of automated valuation models in:

(i) Monitoring of the quality or performance of mortgages or mortgage-backed securities;

(ii) Reviews of the quality of already completed determinations of the value of collateral; or

(iii) The development of an appraisal by a certified or licensed appraiser.

§ 323.16 Definitions.

As used in this subpart:

Automated valuation model means any computerized model used by mortgage originators and secondary market issuers to determine the value of a consumer’s principal dwelling collateralizing a mortgage.

Control systems means the functions (such as internal and external audits, risk review, quality control, and quality assurance) and information systems that are used to measure performance, make decisions about risk, and assess the effectiveness of processes and personnel, including with respect to compliance with statutes and regulations.

Covered securitization determination means a determination regarding:

(1) Whether to waive an appraisal requirement for a mortgage origination in connection with its potential sale or transfer to a secondary market issuer; or

(2) Structuring, preparing disclosures for, or marketing initial offerings of mortgage-backed securitizations.

Credit decision means a decision regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage, including a decision whether to extend new or additional credit or change the credit limit on a line of credit.

Dwelling means a residential structure that contains one to four units, whether or not that structure is attached to real property. The term includes an individual condominium unit, cooperative unit, factory-built housing, or manufactured home, if it is used as a residence. A consumer can have only one “principal” dwelling at a time. Thus, a vacation or other second home would not be a principal dwelling. However, if a consumer buys or builds

a new dwelling that will become the consumer's principal dwelling within a year or upon the completion of construction, the new dwelling is considered the principal dwelling for purposes of this subpart.

Mortgage means a transaction in which a mortgage, deed of trust, purchase money security interest arising under an installment sales contract, or equivalent consensual security interest is created or retained in a consumer's principal dwelling.

Mortgage originator means:

(1) Any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain—

(i) Takes a mortgage application;
(ii) Assists a consumer in obtaining or applying to obtain a mortgage; or
(iii) Offers or negotiates terms of a mortgage;

(2) Includes any person who represents to the public, through advertising or other means of communicating or providing information (including the use of business cards, stationery, brochures, signs, rate lists, or other promotional items), that such person can or will provide any of the services or perform any of the activities described in paragraph (1) of this definition;

(3) Does not include any person who is—

(i) Not otherwise described in paragraph (1) or (2) of this definition and who performs purely administrative or clerical tasks on behalf of a person who is described in any such paragraph; or

(ii) A retailer of manufactured or modular homes or an employee of the retailer if the retailer or employee, as applicable—

(A) Does not receive compensation or gain for engaging in activities described in paragraph (1) of this definition that is in excess of any compensation or gain received in a comparable cash transaction;

(B) Discloses to the consumer—

(1) In writing any corporate affiliation with any creditor; and

(2) If the retailer has a corporate affiliation with any creditor, at least 1 unaffiliated creditor; and

(C) Does not directly negotiate with the consumer or lender on loan terms (including rates, fees, and other costs);

(4) Does not include a person or entity that only performs real estate brokerage activities and is licensed or registered in accordance with applicable State law, unless such person or entity is compensated by a lender, a mortgage broker, or other mortgage originator or by any agent of such lender, mortgage broker, or other mortgage originator;

(5) Does not include a person that meets all of the following criteria:

(i) The person provides seller financing for the sale of three or fewer properties in any 12-month period to purchasers of such properties, each of which is owned by the person and serves as security for the financing;

(ii) The person has not constructed, or acted as a contractor for the construction of, a residence on the property in the ordinary course of business of the person;

(iii) The person provides seller financing that meets the following requirements:

(A) The financing is fully amortizing;

(B) The financing is one that the person determines in good faith the consumer has a reasonable ability to repay;

(C) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(6) Does not include a natural person, estate, or trust that meets all of the following criteria:

(i) The natural person, estate, or trust provides seller financing for the sale of only one property in any 12-month period to purchasers of such property, which is owned by the natural person, estate, or trust and serves as security for the financing;

(ii) The natural person, estate, or trust has not constructed, or acted as a contractor for the construction of, a residence on the property in the ordinary course of business of the person;

(iii) The natural person, estate, or trust provides seller financing that meets the following requirements:

(A) The financing has a repayment schedule that does not result in negative amortization;

(B) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(7) Does not include a servicer or servicer employees, agents and contractors, including but not limited to those who offer or negotiate terms of a mortgage for purposes of renegotiating, modifying, replacing and subordinating principal of existing mortgages where borrowers are behind in their payments, in default or have a reasonable likelihood of being in default or falling behind.

Person has the meaning given in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

Secondary market issuer means any party that creates, structures, or organizes a mortgage-backed securities transaction.

§ 323.17 Quality control standards.

Mortgage originators and secondary market issuers that engage in credit decisions or covered securitization determinations themselves, or through or in cooperation with a third-party or affiliate, must adopt and maintain policies, practices, procedures, and control systems to ensure that automated valuation models used in these transactions adhere to quality control standards designed to:

- (a) Ensure a high level of confidence in the estimates produced;
- (b) Protect against the manipulation of data;
- (c) Seek to avoid conflicts of interest;
- (d) Require random sample testing and reviews; and
- (e) Comply with applicable nondiscrimination laws.

NATIONAL CREDIT UNION ADMINISTRATION

12 CFR Part 722 and Part 741

Authority and Issuance

For the reasons set forth in the joint preamble, the NCUA Board amends 12 CFR parts 722 and 741 as follows:

PART 722—APPRAISALS

■ 7. The authority citation for part 722 continues to read as follows:

Authority: 12 U.S.C. 1766, 1789, and 3331 *et seq.* Section 722.3(a) is also issued under 15 U.S.C. 1639h.

§§ 722.1 through 722.7 [Redesignated as §§ 722.101 through 722.107]

■ 8. Redesignate §§ 722.1 through 722.7 as §§ 722.101 through 722.107.

§§ 722.101 through 722.107 [Designated as Subpart A]

■ 9. Designate newly redesignated §§ 722.101 through 722.107 as subpart A.

■ 10. Add a heading for newly designated subpart A to read as follows:

Subpart A—Appraisals Generally

■ 11. Add subpart B, consisting of §§ 722.201 through 722.203, to read as follows:

Subpart B—Quality Control Standards for Automated Valuation Models Used for Mortgage Lending Purposes

Sec.

722.201 Authority, purpose, and scope.

722.202 Definitions.

722.203 Quality control standards.

Subpart B—Quality Control Standards for Automated Valuation Models Used for Mortgage Lending Purposes**§ 722.201 Authority, purpose, and scope.**

(a) *Authority.* This subpart is issued pursuant to section 1125 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989, 12 U.S.C. 3354, as added by section 1473(q) of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Pub. L. 111–203, 124 Stat. 1375, 2198 (2010)).

(b) *Purpose and scope.* (1) The purpose of this subpart is to implement the quality control standards in section 3354 of title 12 for the use of automated valuation models in determining the value of collateral in connection with making a credit decision or covered securitization determination regarding a mortgage or mortgage-backed security. This subpart applies to credit unions insured by the NCUA that are mortgage originators or secondary market issuers.

(2) This subpart does not apply to the use of automated valuation models in:

(i) Monitoring of the quality or performance of mortgages or mortgage-backed securities;

(ii) Reviews of the quality of already completed determinations of the value of collateral; or

(iii) The development of an appraisal by a certified or licensed appraiser.

§ 722.202 Definitions.

As used in this subpart:

Automated valuation model means any computerized model used by mortgage originators and secondary market issuers to determine the value of a consumer's principal dwelling collateralizing a mortgage.

Control systems means the functions (such as internal and external audits, risk review, quality control, and quality assurance) and information systems that are used to measure performance, make decisions about risk, and assess the effectiveness of processes and personnel, including with respect to compliance with statutes and regulations.

Covered securitization determination means a determination regarding:

(1) Whether to waive an appraisal requirement for a mortgage origination in connection with its potential sale or transfer to a secondary market issuer; or

(2) Structuring, preparing disclosures for, or marketing initial offerings of mortgage-backed securitizations.

Credit decision means a decision regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage, including a decision whether to extend new or additional credit or change the credit limit on a line of credit.

Dwelling means a residential structure that contains one to four units, whether or not that structure is attached to real property. The term includes an individual condominium unit, cooperative unit, factory-built housing, or manufactured home, if it is used as a residence. A consumer can have only one “principal” dwelling at a time. Thus, a vacation or other second home would not be a principal dwelling. However, if a consumer buys or builds a new dwelling that will become the consumer's principal dwelling within a year or upon the completion of construction, the new dwelling is considered the principal dwelling for purposes of this subpart.

Mortgage means a transaction in which a mortgage, deed of trust, purchase money security interest arising under an installment sales contract, or equivalent consensual security interest is created or retained in a consumer's principal dwelling.

Mortgage originator means:

(1) Any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain—

(i) Takes a mortgage application;

(ii) Assists a consumer in obtaining or applying to obtain a mortgage; or

(iii) Offers or negotiates terms of a mortgage;

(2) Includes any person who represents to the public, through advertising or other means of communicating or providing information (including the use of business cards, stationery, brochures, signs, rate lists, or other promotional items), that such person can or will provide any of the services or perform any of the activities described in paragraph (1) of this definition;

(3) Does not include any person who is—

(i) Not otherwise described in paragraph (1) or (2) of this definition and who performs purely administrative or clerical tasks on behalf of a person who is described in any such paragraph; or

(ii) A retailer of manufactured or modular homes or an employee of the retailer if the retailer or employee, as applicable—

(A) Does not receive compensation or gain for engaging in activities described in paragraph (1) of this definition that is in excess of any compensation or gain received in a comparable cash transaction;

(B) Discloses to the consumer—

(1) In writing any corporate affiliation with any creditor; and

(2) If the retailer has a corporate affiliation with any creditor, at least 1 unaffiliated creditor; and

(C) Does not directly negotiate with the consumer or lender on loan terms (including rates, fees, and other costs);

(4) Does not include a person or entity that only performs real estate brokerage activities and is licensed or registered in accordance with applicable State law, unless such person or entity is compensated by a lender, a mortgage broker, or other mortgage originator or by any agent of such lender, mortgage broker, or other mortgage originator;

(5) Does not include a person that meets all of the following criteria:

(i) The person provides seller financing for the sale of three or fewer properties in any 12-month period to purchasers of such properties, each of which is owned by the person and serves as security for the financing;

(ii) The person has not constructed, or acted as a contractor for the construction of, a residence on the property in the ordinary course of business of the person;

(iii) The person provides seller financing that meets the following requirements:

(A) The financing is fully amortizing;

(B) The financing is one that the person determines in good faith the consumer has a reasonable ability to repay;

(C) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(6) Does not include a natural person, estate, or trust that meets all of the following criteria:

(i) The natural person, estate, or trust provides seller financing for the sale of only one property in any 12-month period to purchasers of such property,

which is owned by the natural person, estate, or trust and serves as security for the financing;

(ii) The natural person, estate, or trust has not constructed, or acted as a contractor for the construction of, a residence on the property in the ordinary course of business of the person;

(iii) The natural person, estate, or trust provides seller financing that meets the following requirements:

(A) The financing has a repayment schedule that does not result in negative amortization;

(B) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(7) Does not include a servicer or servicer employees, agents and contractors, including but not limited to those who offer or negotiate terms of a mortgage for purposes of renegotiating, modifying, replacing and subordinating principal of existing mortgages where borrowers are behind in their payments, in default or have a reasonable likelihood of being in default or falling behind.

Person has the meaning given in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

Secondary market issuer means any party that creates, structures, or organizes a mortgage-backed securities transaction.

§ 722.203 Quality control standards.

Mortgage originators and secondary market issuers that engage in credit decisions or covered securitization determinations themselves, or through or in cooperation with a third-party or affiliate, must adopt and maintain policies, practices, procedures, and control systems to ensure that automated valuation models used in these transactions adhere to quality control standards designed to:

- (a) Ensure a high level of confidence in the estimates produced;
- (b) Protect against the manipulation of data;
- (c) Seek to avoid conflicts of interest;
- (d) Require random sample testing and reviews; and
- (e) Comply with applicable nondiscrimination laws.

PART 741—REQUIREMENTS FOR INSURANCE

■ 12. The authority citation for part 741 is revised to read as follows:

Authority: 12 U.S.C. 1757, 1766(a), 1781–1790, 1790d, 3331 *et seq.*; 31 U.S.C. 3717.

■ 13. Revise § 741.203(b) to read as follows:

§ 741.203 Minimum loan policy requirements.

* * * * *

(b) Adhere to the requirements stated in part 722 of this chapter.

* * * * *

CONSUMER FINANCIAL PROTECTION BUREAU

Authority and Issuance

For reasons set out in the joint preamble, the CFPB amends Regulation Z, 12 CFR part 1026, as follows:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 14. The authority citation for part 1026 is revised to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 3353, 3354, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

Subpart A—General

■ 15. Section 1026.1 is amended by adding paragraph (c)(6) to read as follows:

§ 1026.1 Authority, purpose, coverage, organization, enforcement, and liability.

* * * * *

(c) * * *

(6) The requirements of § 1026.42(i) apply to certain persons regardless of whether they are creditors and even if the mortgage, as defined in § 1026.42(i)(2)(v), is primarily for business, commercial, agricultural, or organizational purposes.

* * * * *

■ 16. Section 1026.2 is amended by revising paragraph (a)(11) to read as follows:

§ 1026.2 Definitions and rules of construction.

(a) * * *

(11) *Consumer* means a cardholder or natural person to whom consumer credit is offered or extended. However, for purposes of rescission under §§ 1026.15 and 1026.23, the term also includes a natural person in whose principal dwelling a security interest is or will be retained or acquired, if that person's ownership interest in the dwelling is or will be subject to the security interest. For purposes of

§ 1026.42(i), the term means a natural person to whom credit is offered or extended, even if the credit is primarily for business, commercial, agricultural, or organizational purposes. For purposes of §§ 1026.20(c) through (e), 1026.36(c), 1026.39, and 1026.41, the term includes a confirmed successor in interest.

* * * * *

■ 17. Section 1026.3 is amended by adding paragraph (i) to read as follows:

§ 1026.3 Exempt transactions.

* * * * *

(i) The exemptions in this section are not applicable to § 1026.42(i) (Quality Control Standards for Automated Valuation Models).

Subpart E—Special Rules for Certain Home Mortgage Transactions

■ 18. Section 1026.42 is amended by revising paragraph (a) and adding paragraph (i) to read as follows:

§ 1026.42 Valuation independence.

(a) *Scope.* Except for paragraph (i) of this section, this section applies to any consumer credit transaction secured by the consumer's principal dwelling. Paragraph (i) of this section applies to any mortgage, as defined in paragraph (i)(2)(v) of this section, secured by the consumer's principal dwelling, even if the mortgage is primarily for business, commercial, agricultural, or organizational purposes.

* * * * *

(i) *Quality Control Standards for Automated Valuation Models—(1) Scope.* The purpose of this paragraph (i) is to implement quality control standards for the use of automated valuation models in determining the value of collateral in connection with making a credit decision or covered securitization determination regarding a mortgage or mortgage-backed security. This paragraph (i) applies to the use of automated valuation models by any mortgage originator or secondary market issuer, other than either a financial institution as defined in 12 U.S.C. 3350(7), or a subsidiary owned and controlled by such a financial institution and regulated by one of the Federal financial institutions regulatory agencies as defined in 12 U.S.C. 3350(6). This paragraph (i) does not apply to the use of automated valuation models in:

- (i) Monitoring of the quality or performance of mortgages or mortgage-backed securities;
- (ii) Reviews of the quality of already completed determinations of the value of collateral; or

(iii) The development of an appraisal by a certified or licensed appraiser as defined in § 1026.35(c)(1)(i).

(2) *Definitions*. As used in this paragraph (i):

(i) *Automated valuation model* means any computerized model used by mortgage originators and secondary market issuers to determine the value of a consumer's principal dwelling collateralizing a mortgage.

(ii) *Control systems* means the functions (such as internal and external audits, risk review, quality control, and quality assurance) and information systems that are used to measure performance, make decisions about risk, and assess the effectiveness of processes and personnel, including with respect to compliance with statutes and regulations.

(iii) *Covered securitization determination* means a determination regarding:

(A) Whether to waive an appraisal requirement for a mortgage origination in connection with its potential sale or transfer to a secondary market issuer; or

(B) Structuring, preparing disclosures for, or marketing initial offerings of mortgage-backed securitizations.

(iv) *Credit decision* means a decision regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage, including a decision whether to extend new or additional credit or change the credit limit on a line of credit.

(v) *Mortgage* means a transaction in which a mortgage, deed of trust, purchase money security interest arising under an installment sales contract, or equivalent consensual security interest is created or retained in a consumer's principal dwelling.

(vi) *Mortgage originator* means:

(A) Any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain—

(1) Takes a mortgage application;

(2) Assists a consumer in obtaining or applying to obtain a mortgage; or

(3) Offers or negotiates terms of a mortgage;

(B) Includes any person who represents to the public, through advertising or other means of communicating or providing information (including the use of business cards, stationery, brochures, signs, rate lists, or other promotional items), that such person can or will provide any of the services or perform any of the activities described in paragraph (A) of this definition;

(C) Does not include any person who is not otherwise described in paragraph (A) or (B) of this definition and who

performs purely administrative or clerical tasks on behalf of a person who is described in any such paragraph;

(D) Does not include a retailer of manufactured or modular homes or an employee of the retailer if the retailer or employee, as applicable—

(1) Does not receive compensation or gain for engaging in activities described in paragraph (A) of this definition that is in excess of any compensation or gain received in a comparable cash transaction;

(2) Discloses to the consumer in writing any corporate affiliation with any creditor and, if the retailer has a corporate affiliation with any creditor, at least 1 unaffiliated creditor; and

(3) Does not directly negotiate with the consumer or lender on loan terms (including rates, fees, and other costs);

(E) Does not include a person or entity that only performs real estate brokerage activities and is licensed or registered in accordance with applicable State law, unless such person or entity is compensated by a lender, a mortgage broker, or other mortgage originator or by any agent of such lender, mortgage broker, or other mortgage originator;

(F) Does not include a person that meets the criteria for seller financiers provided in § 1026.36(a)(4) and (5); and

(G) Does not include a servicer or servicer employees, agents and contractors, including but not limited to those who offer or negotiate terms of a mortgage for purposes of renegotiating, modifying, replacing and subordinating principal of existing mortgages where borrowers are behind in their payments, in default or have a reasonable likelihood of being in default or falling behind.

(vii) *Secondary market issuer* means any party that creates, structures, or organizes a mortgage-backed securities transaction.

(3) *Quality control standards*. Mortgage originators and secondary market issuers that engage in credit decisions or covered securitization determinations themselves, or through or in cooperation with a third-party or affiliate, must adopt and maintain policies, practices, procedures, and control systems to ensure that automated valuation models used in these transactions adhere to quality control standards designed to:

(i) Ensure a high level of confidence in the estimates produced;

(ii) Protect against the manipulation of data;

(iii) Seek to avoid conflicts of interest;

(iv) Require random sample testing and reviews; and

(v) Comply with applicable nondiscrimination laws.

■ 19. In *Supplement I to Part 1026—Official Interpretations*:

■ a. Under *Section 1026.2—Definitions and Rules of Construction*, revise and republish 2(a)(19)—*Dwelling*;

■ b. Under *Section 1026.3—Exempt Transactions*, paragraph 1 is republished and paragraph 2 is added.

■ c. Under *Section 1026.42—Valuation Independence*:

■ i. Revise and republish section 42(a)—*Scope*;

■ ii. Revise section *Paragraph 42(b)(2)*;

■ iii. Add, in alphabetical order, a heading for 42(i) *Quality Control Standards for Automated Valuation Models*;

■ iv. Under heading 42(i) *Quality Control Standards for Automated Valuation Models* add section *Paragraph 42(i)(2)(vi)*.

The revisions and additions read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Section 1026.2—Definitions and Rules of Construction

* * * * *

2(a)(19) Dwelling

1. *Scope*. A dwelling need not be the consumer's principal residence to fit the definition, and thus a vacation or second home could be a dwelling. However, for purposes of the definition of residential mortgage transaction, the right to rescind, and the application of automated valuation model requirements, a dwelling must be the principal residence of the consumer. (See the commentary to §§ 1026.2(a)(24), 1026.15, 1026.23, and 1026.42.)

2. *Use as a residence*. Mobile homes, boats, and trailers are dwellings if they are in fact used as residences, just as are condominium and cooperative units. Recreational vehicles, campers, and the like not used as residences are not dwellings.

3. *Relation to exemptions*. Any transaction involving a security interest in a consumer's principal dwelling (as well as in any real property) remains subject to the regulation despite the general exemption in § 1026.3(b).

4. *Automated valuation models*. For purposes of the application of the automated valuation model requirements in § 1026.42(i), a consumer can have only one principal dwelling at a time. Thus, a vacation or other second home would not be a principal dwelling. However, if a consumer buys or builds a new dwelling that will become the consumer's principal dwelling within a year or upon the completion of construction, the new dwelling is considered the principal dwelling for purposes of applying this definition to a particular transaction. (See the commentary to § 1026.2(a)(24).)

* * * * *

Section 1026.3—Exempt Transactions

1. *Relationship to § 1026.12*. The provisions in § 1026.12(a) and (b) governing

the issuance of credit cards and the limitations on liability for their unauthorized use apply to all credit cards, even if the credit cards are issued for use in connection with extensions of credit that otherwise are exempt under this section.

2. *Relationship to § 1026.42(i)*. As provided in § 1026.3(i), the provisions in § 1026.42(i) governing the use of automated valuation models apply even if the transactions in which automated valuation models are used would otherwise be exempt under this section.

* * * *

Section 1026.42—Valuation Independence

42(a) Scope

1. *Open- and closed-end credit*. Section 1026.42 applies to both open-end and closed-end transactions secured by the consumer's principal dwelling.

2. *Consumer's principal dwelling*. Except for section 1026.42(i), section 1026.42 applies only if the dwelling that will secure a consumer credit transaction is the principal dwelling of the consumer who obtains credit. Section 1026.42(i) applies if the dwelling that will secure a mortgage, as defined in § 1026.42(i)(2)(v), is the principal dwelling of the consumer who obtains credit, even if the mortgage is primarily for business, commercial, agricultural, or organizational purposes. The term “dwelling” is defined in § 1026.2(a)(19). Comments 2(a)(19)–4 and 42(b)(2)–1 discuss the term “principal dwelling.”

42(b) Definitions

* * * *

Paragraph 42(b)(2)

1. *Principal dwelling*. The term “principal dwelling” has the same meaning under § 1026.42(b) and (i) as under §§ 1026.2(a)(24), 1026.15(a), and 1026.23(a). See comments 2(a)(19)–4, 2(a)(24)–3, 15(a)(1)–5, and 23(a)–3. The term “dwelling” is defined in § 1026.2(a)(19).

* * * *

42(i) Quality Control Standards for Automated Valuation Models

Paragraph 42(i)(2)(vi)

1. *Servicers*. The term mortgage originator generally excludes servicers and their employees, agents, and contractors. However, a person is a servicer with respect to a particular transaction only after it is consummated, and that person retains or obtains its servicing rights. Therefore, the term mortgage originator includes a servicer and its employees, agents, or contractors when they perform mortgage originator activities for purposes of 15 U.S.C. 1602(dd)(2) with respect to any transaction that constitutes a new extension of credit, including a refinancing or a transaction that obligates a different consumer on an existing debt.

* * * *

CHAPTER XII—FEDERAL HOUSING FINANCE AGENCY

Authority and Issuance

For the reasons stated in the joint preamble, the Federal Housing Finance Agency amends 12 CFR part 1222, of chapter 12 of title 12 of the Code of Federal Regulations as follows:

PART 1222—APPRAISALS

■ 20. The authority citation for part 1222 is revised to read as follows:

Authority: 12 U.S.C. 3354(b); 12 U.S.C. 4501 *et seq.*; 12 U.S.C. 4526; and 15 U.S.C. 1639h.

■ 21. Add subpart C, consisting of §§ 1222.27 through 1222.29, to part 1222 to read as follows:

Subpart C—Quality Control Standards for Automated Valuation Models

Sec.

1222.27 Authority, purpose, and scope.

1222.28 Definitions.

1222.29 Quality control standards.

§ 1222.27 Authority, purpose, and scope.

(a) *Authority*. This subpart is issued by the Federal Housing Finance Agency pursuant to 12 U.S.C. 4501 *et seq.*, 12 U.S.C. 4526, section 1125 of FIRREA, 12 U.S.C. 3354, as added by section 1473(q) of the Dodd-Frank Act.

(b) *Purpose and scope*. (1) The purpose of this subpart is to implement the quality control standards in section 3354 of title 12 for the use of automated valuation models in determining the value of collateral in connection with making a credit decision or covered securitization determination regarding a mortgage or mortgage-backed security. This subpart applies to entities regulated by the Federal Housing Finance Agency.

(2) This subpart does not apply to the use of automated valuation models in:

(i) Monitoring of the quality or performance of mortgages or mortgage-backed securities;

(ii) Reviews of the quality of already completed determinations of the value of collateral; or

(iii) The development of an appraisal by a certified or licensed appraiser.

§ 1222.28 Definitions.

As used in this subpart:

Automated valuation model means any computerized model used by mortgage originators and secondary market issuers to determine the value of a consumer's principal dwelling collateralizing a mortgage.

Control systems means the functions (such as internal and external audits, risk review, quality control, and quality

assurance) and information systems that are used to measure performance, make decisions about risk, and assess the effectiveness of processes and personnel, including with respect to compliance with statutes and regulations.

Covered securitization determination means a determination regarding:

(1) Whether to waive an appraisal requirement for a mortgage origination in connection with its potential sale or transfer to a secondary market issuer; or

(2) Structuring, preparing disclosures for, or marketing initial offerings of mortgage-backed securitizations.

Credit decision means a decision regarding whether and under what terms to originate, modify, terminate, or make other changes to a mortgage, including a decision whether to extend new or additional credit or change the credit limit on a line of credit.

Dwelling means a residential structure that contains one to four units, whether or not that structure is attached to real property. The term includes an individual condominium unit, cooperative unit, factory-built housing, or manufactured home, if it is used as a residence. A consumer can have only one “principal” dwelling at a time. Thus, a vacation or other second home would not be a principal dwelling. However, if a consumer buys or builds a new dwelling that will become the consumer's principal dwelling within a year or upon the completion of construction, the new dwelling is considered the principal dwelling for purposes of this subpart.

Mortgage means a transaction in which a mortgage, deed of trust, purchase money security interest arising under an installment sales contract, or equivalent consensual security interest is created or retained in a consumer's principal dwelling.

Mortgage originator means:

(1) Any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain—

(i) Takes a mortgage application;

(ii) Assists a consumer in obtaining or applying to obtain a mortgage; or

(iii) Offers or negotiates terms of a mortgage;

(2) Includes any person who represents to the public, through advertising or other means of communicating or providing information (including the use of business cards, stationery, brochures, signs, rate lists, or other promotional items), that such person can or will provide any of the services or perform any of the activities described in paragraph (1) of this definition;

(3) Does not include any person who is—

(i) Not otherwise described in paragraph (1) or (2) of this definition and who performs purely administrative or clerical tasks on behalf of a person who is described in any such paragraph; or

(ii) A retailer of manufactured or modular homes or an employee of the retailer if the retailer or employee, as applicable—

(A) Does not receive compensation or gain for engaging in activities described in paragraph (1) of this definition that is in excess of any compensation or gain received in a comparable cash transaction;

(B) Discloses to the consumer—

(1) In writing any corporate affiliation with any creditor; and

(2) If the retailer has a corporate affiliation with any creditor, at least one unaffiliated creditor; and

(C) Does not directly negotiate with the consumer or lender on loan terms (including rates, fees, and other costs);

(4) Does not include a person or entity that only performs real estate brokerage activities and is licensed or registered in accordance with applicable State law, unless such person or entity is compensated by a lender, a mortgage broker, or other mortgage originator or by any agent of such lender, mortgage broker, or other mortgage originator;

(5) Does not include a person that meets all of the following criteria:

(i) The person provides seller financing for the sale of three or fewer properties in any 12-month period to purchasers of such properties, each of which is owned by the person and serves as security for the financing;

(ii) The person has not constructed, or acted as a contractor for the construction of, a residence on the property in the ordinary course of business of the person;

(iii) The person provides seller financing that meets the following requirements:

(A) The financing is fully amortizing;

(B) The financing is one that the person determines in good faith the consumer has a reasonable ability to repay;

(C) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(6) Does not include a natural person, estate, or trust that meets all of the following criteria:

(i) The natural person, estate, or trust provides seller financing for the sale of only one property in any 12-month period to purchasers of such property, which is owned by the natural person, estate, or trust and serves as security for the financing;

(ii) The natural person, estate, or trust has not constructed, or acted as a contractor for the construction of, a residence on the property in the ordinary course of business of the person;

(iii) The natural person, estate, or trust provides seller financing that meets the following requirements:

(A) The financing has a repayment schedule that does not result in negative amortization;

(B) The financing has a fixed rate or an adjustable rate that is adjustable after five or more years, subject to reasonable annual and lifetime limitations on interest rate increases. If the financing agreement has an adjustable rate, the rate is determined by the addition of a margin to an index rate and is subject to reasonable rate adjustment limitations. The index the adjustable rate is based on is a widely available index such as indices for U.S. Treasury securities or SOFR.

(7) Does not include a servicer or servicer employees, agents and contractors, including but not limited to those who offer or negotiate terms of a mortgage for purposes of renegotiating, modifying, replacing and subordinating principal of existing mortgages where borrowers are behind in their payments, in default or have a reasonable

likelihood of being in default or falling behind.

Person has the meaning given in section 103 of the Truth in Lending Act (15 U.S.C. 1602).

Secondary market issuer means any party that creates, structures, or organizes a mortgage-backed securities transaction.

§ 1222.29 Quality control standards.

Mortgage originators and secondary market issuers that engage in credit decisions or covered securitization determinations themselves, or through or in cooperation with a third-party or affiliate, must adopt and maintain policies, practices, procedures, and control systems to ensure that automated valuation models used in these transactions adhere to quality control standards designed to:

(a) Ensure a high level of confidence in the estimates produced;

(b) Protect against the manipulation of data;

(c) Seek to avoid conflicts of interest;

(d) Require random sample testing and reviews; and

(e) Comply with applicable nondiscrimination laws.

Michael J. Hsu,

Acting Comptroller of the Currency.

By order of the Board Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

Federal Deposit Insurance Corporation.

By order of the Board of Directors.

Dated at Washington, DC, on June 20, 2024.

James P. Sheesley,

Assistant Executive Secretary.

Melane Conyers-Ausbrooks,

Secretary of the Board, National Credit Union Administration.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

Sandra L. Thompson,

Director, Federal Housing Finance Agency.

[FR Doc. 2024-16197 Filed 8-6-24; 8:45 am]

BILLING CODE 4810-33-P; 6210-01-P; 6714-01-P; 7535-01-P; 4810-AM-P; 8070-01-P



FEDERAL REGISTER

Vol. 89

Wednesday,

No. 152

August 7, 2024

Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 412

Medicare Program; FY 2025 Inpatient Psychiatric Facilities Prospective
Payment System—Rate Update; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services****42 CFR Part 412****[CMS–1806–F]****RIN 0938–AV32****Medicare Program; FY 2025 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update****AGENCY:** Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).**ACTION:** Final action.

SUMMARY: This final action updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPF), which include psychiatric hospitals and excluded psychiatric units of an acute care hospital or critical access hospital. This final action also revises the patient-level adjustment factors, the Emergency Department adjustment, and the payment amount for electroconvulsive therapy. These changes will be effective for IPF discharges occurring during the fiscal year (FY) beginning October 1, 2024 through September 30, 2025 (FY 2025). In addition, this final action finalizes the adoption of a new quality measure. It does not finalize modifications to the reporting requirements under the IPF Quality Reporting Program beginning with the FY 2027 payment determination. Furthermore, this final action summarizes comments received through Requests for Information regarding potential future revisions to the IPF PPS facility-level adjustments and regarding the development of a standardized IPF Patient Assessment Instrument.

DATES: This final action is effective on October 1, 2024.

FOR FURTHER INFORMATION CONTACT: The IPF Payment Policy mailbox at IPFPaymentPolicy@cms.hhs.gov for general information.

Nick Brock (410) 786–5148, for information regarding the inpatient psychiatric facilities prospective payment system (IPF PPS) and regulatory impact analysis.

Kaleigh Emerson (470) 890–4141, for information regarding the inpatient psychiatric facilities quality reporting program (IPFQR).

SUPPLEMENTARY INFORMATION:

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a

plain language summary of this rule may be found at <https://www.regulations.gov/>.

Availability of Certain Tables Exclusively Through the Internet on the CMS Website

Addendum A to this final rule summarizes the fiscal year (FY) 2025 IPF PPS payment rates, outlier threshold, cost of living adjustment factors (COLA) for Alaska and Hawaii, national and upper limit cost-to-charge ratios, and adjustment factors. In addition, Addendum B to this final rule shows the complete listing of ICD–10 Clinical Modification (CM) and Procedure Coding System (PCS) codes, the FY 2025 IPF PPS comorbidity adjustment, and electroconvulsive therapy (ECT) procedure codes. Addenda A and B to this final rule are available on the CMS website at: <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>. Tables setting forth the FY 2025 Wage Index for Urban Areas Based on Core Based Statistical Area (CBSA) Labor Market Areas, the FY 2025 Wage Index Based on CBSA Labor Market Areas for Rural Areas, and a county-level crosswalk of the FY 2024 CBSA Labor Market Areas to the FY 2025 CBSA Labor Market Areas are available exclusively through the internet, on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/IPFPPS/WageIndex.html>.

I. Executive Summary**A. Purpose**

This final rule updates the prospective payment rates, the outlier threshold, and the wage index for Medicare inpatient hospital services provided by Inpatient Psychiatric Facilities (IPFs) for discharges occurring during fiscal year (FY) 2025 (beginning October 1, 2024, through September 30, 2025). This rule also adopts the Core-Based Statistical Area (CBSA) Labor Market Areas for the IPF PPS wage index as defined in the Office of Management and Budget (OMB) Bulletin 23–01. In addition, this rule refines the patient-level adjustment factors and increases the payment amount for electroconvulsive therapy (ECT) treatments. This final rule also clarifies the eligibility criteria for an IPF to be approved to file all-inclusive cost reports. This rule includes a summary of the public comments received to inform revisions to the payment adjustments for rural location and teaching status, along with a potential payment adjustment for safety net population. In

addition, this final rule includes a summary of the public comments received in response to our request for information (RFI) regarding the creation of a patient assessment instrument (PAI), as mandated by section 4125 of the Consolidated Appropriations Act (CAA), 2023 (hereafter referred to as CAA, 2023) (Pub. L. 117–328). Lastly, this final rule updates quality measures and discusses reporting requirements under the Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program.

B. Summary of the Major Provisions**1. Inpatient Psychiatric Facilities Prospective Payment System (IPF PPS)**

For the IPF PPS, we are finalizing our proposals to:

- Revise the patient-level IPF PPS adjustment factors and increase the ECT per treatment payment amount.
- Update the IPF PPS wage index to use the CBSAs defined within OMB Bulletin 23–01.
- Clarify the eligibility criteria for an IPF to be approved to file all-inclusive cost reports. Only a government-owned or tribally owned facility satisfies these criteria and is eligible to file its cost report using an all-inclusive rate or no charge structure.
- Make technical rate setting updates: The IPF PPS payment rates will be adjusted annually for input price inflation, as well as statutory and other policy factors.

This rule updates:

- ++ The IPF PPS Federal per diem base rate from \$895.63 to \$876.53.
- ++ The IPF PPS Federal per diem base rate for providers who failed to report quality data to \$859.48.
- ++ The ECT payment per treatment from \$385.58 to \$661.52.
- ++ The ECT payment per treatment for providers who failed to report quality data to \$648.65.
- ++ The labor-related share from 78.7 percent to 78.8 percent.
- ++ The wage index budget neutrality factor to 0.9996. This rule applies a refinement standardization factor of 0.9524.
- ++ The fixed dollar loss threshold amount from \$33,470 to \$38,110, to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF PPS payments.

2. Inpatient Psychiatric Facilities Quality Reporting (IPFQR) Program

For the IPFQR Program, we are finalizing our proposal to adopt the 30-Day Risk-Standardized All-Cause Emergency Department (ED) Visit Following an IPF Discharge measure

beginning with the FY 2027 payment determination. We are not finalizing our proposal to modify reporting requirements to require IPFs to submit patient-level data on a quarterly basis.

We also refer readers to the summary of the comments to our RFI in which we solicited comments to inform elements to be included in the IPF PAI, which the CAA, 2023 requires the Centers for

Medicare & Medicaid Services (CMS) to develop and implement for Rate Year (RY) 2028.

C. Summary of Impacts

Provision Description	Total Transfers & Cost Reductions
FY 2025 IPF PPS payment update	The overall economic impact of this final rule is an estimated \$65 million in increased payments to IPFs during FY 2025.
FY 2025 IPFQR Program update	We estimate no economic impact for the policies we are finalizing for the IPFQR Program.

II. Background

A. Overview of the Legislative Requirements of the IPF PPS

Section 124 of the Medicare, Medicaid, and State Children's Health Insurance Program Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) required the establishment and implementation of an IPF PPS. Specifically, section 124 of the BBRA mandated that the Secretary of the Department of Health and Human Services (the Secretary) develop a per diem payment perspective system (PPS) for inpatient hospital services furnished in psychiatric hospitals and excluded psychiatric units including an adequate patient classification system that reflects the differences in patient resource use and costs among psychiatric hospitals and excluded psychiatric units. “Excluded psychiatric unit” means a psychiatric unit of an acute care hospital or of a Critical Access Hospital (CAH), which is excluded from payment under the Inpatient Prospective Payment System (IPPS) or CAH payment system, respectively. These excluded psychiatric units will be paid under the IPF PPS.

Section 405(g)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–17–3) extended the IPF PPS to psychiatric distinct part units of CAHs.

Sections 3401(f) and 10322 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) as amended by section 10319(e) of that Act and by section 1105(d) of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (hereafter referred to jointly as “the Affordable Care Act”) added subsection (s) to section 1886 of the Act.

Section 1886(s)(1) of the Act titled “Reference to Establishment and Implementation of System,” refers to

section 124 of the BBRA, which relates to the establishment of the IPF PPS.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the rate year (RY) beginning in 2012 (that is, a RY that coincides with a FY) and each subsequent RY.

Section 1886(s)(2)(A)(ii) of the Act required the application of an “other adjustment” that reduced any update to an IPF PPS base rate by a percentage point amount specified in section 1886(s)(3) of the Act for the RY beginning in 2010 through the RY beginning in 2019. As noted in the FY 2020 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for fiscal year Beginning October 1, 2019 final rule, for the RY beginning in 2019, section 1886(s)(3)(E) of the Act required that the other adjustment reduction be equal to 0.75 percentage point; that was the final year the statute required the application of this adjustment. Because FY 2021 was a RY beginning in 2020, FY 2021 was the first year section 1886(s)(2)(A)(ii) of the Act did not apply since its enactment.

Sections 1886(s)(4)(A) through (D) of the Act require that for RY 2014 and each subsequent RY, IPFs that fail to report required quality data with respect to such a RY will have their annual update to a standard Federal rate for discharges reduced by 2.0 percentage points. This may result in an annual update being less than 0.0 for a RY, and may result in payment rates for the upcoming RY being less than such payment rates for the preceding RY. Any reduction for failure to report required quality data will apply only to the RY involved, and the Secretary will not consider such reduction in computing the payment amount for a subsequent RY. Additional information

about the specifics of the current IPFQR Program is available in the FY 2020 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates for fiscal year beginning October 1, 2019 (FY 2020) final rule (84 FR 38459 through 38468).

Section 4125 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328), which amended section 1886(s) of the Act, requires CMS to revise the Medicare prospective payment system for psychiatric hospitals and psychiatric units. Specifically, section 4125(a) of the CAA, 2023 added section 1886(s)(5)(A) of the Act to require the Secretary to collect data and information, as the Secretary determines appropriate, to revise payments under the IPF PPS. CMS discussed this data collection last year in the FY 2024 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update (FY 2024 IPF PPS) final rule, as CMS was required to begin collecting this data and information not later than October 1, 2024. As discussed in that rule, the Agency has already been collecting data and information consistent with the types set forth in the CAA, 2023 as part of our extensive and years-long analyses and consideration of potential payment system refinements. We refer readers to the FY 2024 IPF PPS final rule (88 FR 51095 through 51098) where we discussed existing data collection and requested information to inform future IPF PPS revisions.

In addition, section 1886(s)(5)(D) of the Act, as added by section 4125(a) of the CAA, 2023 requires that the Secretary implement revisions to the methodology for determining the payment rates under the IPF PPS for psychiatric hospitals and psychiatric units, effective for RY 2025 (FY 2025). The revisions may be based on a review of the data and information collected under section 1886(s)(5)(A) of the Act.

Sections IV.B, IV.C, and IV.D of this FY 2025 IPF PPS final rule discuss final decisions about our proposed revisions under section 1886(s)(5)(D) of the Act for FY 2025.

Section 4125(b) of the CAA, 2023 amended section 1886(s)(4) of the Act by inserting a new subparagraph (E), which requires IPFs participating in the IPFQR Program to collect and submit to the Secretary standardized patient assessment data, using a standardized patient assessment instrument, for RY 2028 (FY 2028) and each subsequent rate year. IPFs must submit such data with respect to at least the admission and discharge of an individual, or more frequently as the Secretary determines appropriate. For IPFs to meet this new data collection and reporting requirement for RY 2028 and each subsequent rate year, the Secretary must implement a standardized patient assessment instrument that collects data with respect to the following categories: functional status; cognitive function and mental status; special services, treatments, and interventions; medical conditions and comorbidities; impairments; and other categories as determined appropriate by the Secretary. This patient assessment instrument must enable comparison of such patient assessment data that IPFs submit across all such IPFs to which such data are applicable.

Section 4125(b) of the CAA, 2023 further amended section 1886(s) of the Act by adding a new subparagraph (6) that requires the Secretary to implement revisions to the methodology for determining the payment rates for psychiatric hospitals and psychiatric units (that is, payment rates under the IPF PPS), effective for RY 2031 (FY 2031), as the Secretary determines to be appropriate, to take into account the patient assessment data described in paragraph (4)(E)(ii).

To implement and periodically update the IPF PPS, we have published various proposed and final rules and notices in the **Federal Register**. For more information regarding these documents, we refer readers to the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html?redirect=/InpatientPsychFacilPPS/>.

B. Overview of the IPF PPS

We issued the RY 2005 IPF PPS final rule which appeared in the November 15, 2004 **Federal Register** (69 FR 66922). The RY 2005 IPF PPS final rule established the IPF PPS, as required by section 124 of the BBRA and codified at 42 CFR part 412, subpart N. The RY

2005 IPF PPS final rule set forth the Federal per diem base rate for the implementation year (the 18-month period from January 1, 2005 through June 30, 2006) and provided payment for the inpatient operating and capital costs to IPFs for covered psychiatric services they furnish (that is, routine, ancillary, and capital costs, but not costs of approved educational activities, bad debts, and other services or items that are outside the scope of the IPF PPS). Covered psychiatric services include services for which benefits are provided under the fee-for-service Part A (Hospital Insurance Program) of the Medicare program.

The IPF PPS established the Federal per diem base rate for each patient day in an IPF derived from the national average daily routine operating, ancillary, and capital costs in IPFs in FY 2002. The average per diem cost was updated to the midpoint of the first year under the IPF PPS, standardized to account for the overall positive effects of the IPF PPS payment adjustments, and adjusted for budget neutrality.

The Federal per diem payment under the IPF PPS is comprised of the Federal per diem base rate described previously and certain patient- and facility-level payment adjustments for characteristics that were found in the regression analysis to be associated with statistically significant per diem cost differences, with statistical significance defined as p less than 0.05. A complete discussion of the regression analysis that established the IPF PPS adjustment factors can be found in the RY 2005 IPF PPS final rule (69 FR 66933 through 66936).

The patient-level adjustments include age, Diagnosis-Related Group (DRG) assignment, and comorbidities, as well as adjustments to reflect higher per diem costs at the beginning of a patient's IPF stay and lower costs for later days of the stay. Facility-level adjustments include adjustments for the IPF's wage index, rural location, teaching status, a cost-of-living adjustment for IPFs located in Alaska and Hawaii, and an adjustment for the presence of a qualifying emergency department (ED).

The IPF PPS provides additional payment policies for outlier cases, interrupted stays, and a per treatment payment for patients who undergo ECT. During the IPF PPS mandatory 3-year transition period, stop-loss payments were also provided; however, since the transition ended as of January 1, 2008, these payments are no longer available.

C. Annual Requirements for Updating the IPF PPS

Section 124 of the BBRA did not specify an annual rate update strategy for the IPF PPS and was broadly written to give the Secretary discretion in establishing an update methodology. Therefore, in the RY 2005 IPF PPS final rule, we implemented the IPF PPS using the following update strategy:

- Calculate the final Federal per diem base rate to be budget neutral for the 18-month period of January 1, 2005 through June 30, 2006.
- Use a July 1 through June 30 annual update cycle.
- Allow the IPF PPS first update to be effective for discharges on or after July 1, 2006 through June 30, 2007.

The RY 2005 final rule (69 FR 66922) implemented the IPF PPS. In developing the IPF PPS, and to ensure that the IPF PPS can account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and certain patient and facility characteristics to determine those characteristics associated with statistically significant cost differences on a per diem basis. That regression analysis is described in detail in our RY 2004 IPF proposed rule (68 FR 66923; 66928 through 66933) and our RY 2005 IPF final rule (69 FR 66933 through 66960). For characteristics with statistically significant cost differences, we used the regression coefficients of those variables to determine the size of the corresponding payment adjustments.

In the RY 2005 IPF final rule, we explained the reasons for delaying an update to the adjustment factors, derived from the regression analysis, including waiting until we have IPF PPS data that yields as much information as possible regarding the patient-level characteristics of the population that each IPF serves. We indicated that we did not intend to update the regression analysis and the patient-level and facility-level adjustments until we complete that analysis. Until that analysis is complete, we stated our intention to publish a notice in the **Federal Register** each spring to update the IPF PPS (69 FR 66966).

We issued a final rule which appeared in the May 6, 2011 **Federal Register** titled, "Inpatient Psychiatric Facilities Prospective Payment System—Update for Rate Year Beginning July 1, 2011 (RY 2012)" (76 FR 26432), which changed the payment rate update period to a RY that coincides with a FY update. Therefore, final rules are now published in the **Federal Register** in the summer

to be effective on October 1st. When proposing changes in IPF payment policy, a proposed rule is issued in the spring, and the final rule in the summer to be effective on October 1st. For a detailed list of updates to the IPF PPS, we refer readers to our regulations at 42 CFR 412.428. Beginning October 1, 2012, we finalized that we will refer to the 12-month period from October 1 through September 30 as a “fiscal year” (FY) rather than a RY (76 FR 26435). Therefore, in this final rule we refer to rules that took effect after RY 2012 by the FY, rather than the RY, in which they took effect.

CMS issued the most recent IPF PPS annual update, which appeared in a final rule on August 2, 2023, in the **Federal Register** titled, “Medicare Program; FY 2024 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update” (88 FR 51054), which updated the IPF PPS payment rates for FY 2024. That final rule updated the IPF PPS Federal per diem base rates that were published in the FY 2023 IPF PPS Rate Update final rule (87 FR 46846) in accordance with our established policies.

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances.

This final rule finalizes provisions set forth in the April 3, 2024 Medicare Program; FY 2025 Inpatient Psychiatric Facilities Prospective Payment System—Rate Update; Proposed Rule (89 FR 23145). In addition, this final rule has been published within the 3-year time limit imposed by section 902 of the MMA. Therefore, we believe that the final rule is in accordance with the Congress’ intent to ensure timely publication of final regulations.

III. Analysis of and Responses to Public Comments

We received 69 public comments that pertain to proposed IPF PPS payment policies, requests for information, and the proposed updates to the IPFQR Program. Comments were from inpatient psychiatric facilities, health systems,

national and state level provider and patient advocacy organizations, the Medicare Payment Advisory Commission (MedPAC), and individuals. We reviewed each comment and grouped related comments, after which we placed them in categories based on subject matter or section(s) of the regulation affected. Summaries of the public comments received and our responses to those comments are provided in the appropriate sections in the preamble of this final rule.

In addition, we received a few comments that were out of the scope of the FY 2025 IPF PPS proposed rule. We appreciate these comments but note that, because they fall outside the scope of this rulemaking, we do not address them in this rule. We will consider these comments as we continue to develop policies for future rulemaking.

IV. Provisions of the FY 2025 IPF PPS Final Rule and Responses to Comments

A. FY 2025 Market Basket Update and Productivity Adjustment for the IPF PPS

1. Background

Originally, the input price index used to develop the IPF PPS was the Excluded Hospital with Capital market basket. This market basket was based on 1997 Medicare cost reports for Medicare-participating inpatient rehabilitation facilities (IRFs), IPFs, long-term care hospitals (LTCHs), cancer hospitals, and children’s hospitals. Although “market basket” technically describes the mix of goods and services used in providing health care at a given point in time, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies) derived from that market basket. Accordingly, the term “market basket,” as used in this document, refers to an input price index.

Since the IPF PPS inception, the market basket used to update IPF PPS payments has been rebased and revised to reflect more recent data on IPF cost structures. We last rebased and revised the IPF market basket in the FY 2024 IPF PPS rule, where we adopted a 2021-based IPF market basket, using Medicare cost report data for both Medicare participating freestanding psychiatric hospitals and psychiatric units. We refer readers to the FY 2024 IPF PPS final rule for a detailed discussion of the 2021-based IPF PPS market basket and its development (88 FR 51057 through 51081). References to the historical market baskets used to update IPF PPS payments are listed in the FY 2016 IPF PPS final rule (80 FR 46656).

2. FY 2025 IPF Market Basket Update

For FY 2025 (beginning October 1, 2024 and ending September 30, 2025), we proposed to update the IPF PPS payments by a market basket increase factor with a productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act. Consistent with historical practice, we proposed to estimate the market basket update for the IPF PPS based on the most recent forecast available at the time of rulemaking from IHS Global Inc. (IGI). IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets and productivity adjustment. For the proposed rule, based on IGI’s fourth quarter 2023 forecast with historical data through the third quarter of 2023, the 2021-based IPF market basket increase factor for FY 2025 was 3.1 percent.

Section 1886(s)(2)(A)(i) of the Act requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, 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 sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the “productivity adjustment”). The United States Department of Labor’s Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States 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 MFP. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term “multifactor productivity” with “total factor productivity” (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business TFP. However, as mentioned previously, the data and methods are unchanged. We refer readers to 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/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>. In addition, in the FY 2022 IPF final rule (86 FR 42611), we noted that effective with FY 2022 and forward, CMS changed the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment.

Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act to the IPF PPS for the RY beginning in 2012 (a RY that coincides with a FY) and each subsequent RY. For the FY 2025 IPF PPS proposed rule, based on IGI's fourth quarter 2023 forecast, the proposed productivity adjustment for FY 2025 (the 10-year moving average of TFP for the period ending FY 2025) was projected to be 0.4 percent. Accordingly, we proposed to reduce the 3.1 percent IPF market basket increase by this 0.4 percentage point productivity adjustment, as mandated by the Act. This resulted in a proposed FY 2025 IPF PPS payment rate update of 2.7 percent ($3.1 - 0.4 = 2.7$). We also proposed that if more recent data became available, we would use such data, if appropriate, to determine the FY 2025 IPF market basket increase and productivity adjustment for the final rule.

We solicited comments on the proposed IPF market basket increase and productivity adjustment for FY 2025.

Comment: Several commenters expressed concerns about the proposed 2021-based IPF market basket increase factor for FY 2025 of 3.1 percent suggesting that the proposed rate increases might still be insufficient to meet the growing costs of healthcare provision. They stated that with the significant increase in the costs of labor, pharmaceuticals, and supplies, the payment update is inadequate. Commenters stated that labor-related inflation has been driven in large part by a severe workforce shortage. The commenters also stated that hospitals are turning to costlier contract labor to sustain operations; one commenter noted that they believed that contract labor costs increased 258 percent from 2019 through 2023. The commenters stated these increased costs are felt acutely by IPFs as they struggle to maintain highly skilled technicians, clinical social workers, psychologists, and therapists. They requested that CMS provide a more robust payment update for FY 2025 and in the future, until a more accurate PPS methodology can be

adopted. Commenters also stated that the cumulative effect of this inflationary pressure, coupled with the proposed Medicare payment increases for FY 2025, will continue to have negative effects on IPF operating margins. They cited the Medicare Payment Advisory Commission, which determined that Medicare has failed to cover the cost of caring for patients in hospital-based and freestanding nonprofit IPFs since at least 2016. They further stated that when looking at the 2022 Medicare cost reports for freestanding IPFs that included a full year of data, over half of the hospitals had a negative operating margin. The commenter requested that CMS reassess the data and methodology used to determine the annual market basket update in light of continued inflationary pressures for hospitals.

One commenter stated that the proposed 3.1 percent increase in the market basket is insufficient at this crucial time for many healthcare facilities, especially those in rural and underserved areas. One commenter recommended exploring all options to ensure that provider reimbursement is adequate to meet patient needs. They further stated that in the Medicare behavioral health arena, CMS has leverage to improve financial stability for providers and their patients because the IPF PPS authorizing statute did not specify an annual rate update, giving the Secretary discretion in establishing an update methodology. One commenter noted that in some instances, hospital beds go unused despite increasing demand due to the lack of sufficient staffing. The commenter suggested a 5-percent increase consistent with recently experienced inflation, which they stated would be compounded by the anticipated inflation during the coming year.

One commenter stated that from 2019 to 2023, costs per adjusted discharge rose 25 percent; however, base payment rates for Medicare have failed to keep pace with input price inflation. They recommended CMS use data that better reflects the input price inflation that IPFs have experienced and are projected to experience in 2025.

One commenter generally supported the proposed rate increase; however, they noted that this increase is likely still at a level insufficient to sustain capacity and improve access to high-quality care effectively. One commenter supported increasing the IPF PPS rate by 2.7 percent, noting that increased funding for IPFs would improve access to care and quality of services. One commenter suggested that CMS use more recent data, as proposed, that includes the recent inflationary

increases in costs. In absence of such data, they requested that CMS consider an alternative approach to better align the market basket increases with the rising cost of treating patients.

Response: We appreciate the commenters' concern regarding inflationary pressure facing IPFs and the proposed FY 2025 market basket update.

As stated in the FY 2024 IPF final rule (88 FR 51057), the 2021-based IPF market basket is a fixed-weight, Laspeyres-type index that measures price changes over time. Since the inception of the IPF PPS, the IPF payment rates (with the exception of statutorily mandated updates) have been updated by a projection of a market basket percentage increase, consistent with other CMS PPS updates (including for inpatient hospitals, skilled nursing facilities, and home health agencies). CMS established this practice in the RY 2004 IPF PPS final rule (69 FR 66928 through 66930), in accordance with section 1886(b)(3)(B)(ii) of the Act. Because the market basket is designed to measure price inflation for IPF providers, it would not reflect increases in costs associated with changes in the volume or intensity of input goods and services (such as the quantity of labor used) or Medicare allowable costs per risk-adjusted discharge.

As is our general practice, we proposed in the FY 2025 IPF proposed rule (89 FR 23150) that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2025 IPF market basket update for the final rule. As noted in that rule and above, the projection of the 2021-based IPF market basket is based on the most recent forecast from IGI, a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the price proxies of the market baskets. We also note that when developing its forecast for labor prices, IGI considers overall labor market conditions (including rise in contract labor employment due to tight labor market conditions), as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital. For this final rule, based on the more recent IGI second quarter 2024 forecast with historical data through the first quarter of 2024, the projected 2021-based IPF market basket increase factor for FY 2025 is 3.3 percent, which is 0.2 percentage point higher than the projected FY 2025 market basket increase factor in the proposed rule, and reflects an increase in compensation prices of 3.7 percent. We note that the 10-year historical average (2014 through

2023) growth rate of the 2021-based IPF market basket is 2.7 percent with compensation prices increasing 2.9 percent.

Comment: One commenter recommended that CMS consider reconfiguring how it projects its annual payment updates. They stated that most years, CMS offers modest increases to the payment rates, largely driven by its analysis of cost data from prior years. The commenter stated that CMS payment updates have continued to lag, further expanding the gap between the cost of providing care and the reimbursement received from the public payers. They suggested that CMS work with its Congressional partners to raise awareness and address the underfunding of health care services. One commenter did not understand why the proposed FY 2025 market basket increase is lower than the FY 2024 market basket increase or why the proposed FY 2025 productivity adjustment is higher than the FY 2024 productivity adjustment (88 FR 51076 through 51077).

Response: The projection of the 2021-based IPF market basket is based on the most recent forecast from IGI. The market basket percentage increase is a forecast of the price pressures that IPFs are expected to face in 2025. As projected by IGI and other independent forecasters, upward price pressures are expected to be less significant in 2025 relative to 2022 through 2024. IGI's latest forecast of prices facing hospitals in FY 2025 reflects overall economic and industry-specific influences. We note that these projections do not reflect analysis of cost data from prior years, as stated by the commenter.

Comment: One commenter requested that CMS ensure mechanisms are put in place to capture costs (that is, staffing, capital expense, pharmaceuticals, emerging evidence-based interventions) accurately now and in the future with as little administrative burden as possible.

Response: We appreciate the commenter's suggestion on the topic of data collection. As stated in the FY 2024 IPF final rule, (88 FR 51057 through 51081), the 2021-based IPF market basket major cost weights were derived using the 2021 Medicare cost reports (CMS Form 2552–10, OMB No. 0938–0050) for freestanding and hospital-based IPFs. The Medicare cost report data captures detailed expenses for IPFs (including but not limited to wages and salaries, employee benefits, contract labor, pharmaceuticals, and capital). We continue to encourage all providers to report complete and accurate cost data on the Medicare cost reports—

particularly on Worksheet S3, part V, which in prior years has had limited reporting as discussed in the FY 2024 IPF PPS final rule (88 FR 51060), but importantly captures detailed compensation costs.

Comment: One commenter opposed the proposal to reduce the federal per diem base rate from \$895.63 to \$874.93. They stated with the cost of labor, benefits, pharmacy, and other supplies increasing much greater than inflation, a 2.31 percent decrease is unacceptable. They stated that hospitals are already losing money at the current per diem rate, and anything less than a market basket increase of at least 3 percent, which is comparable to other market basket increases, is insufficient. They stated that there is a shortage of valuable IPF beds, and that cutting reimbursement will exacerbate the issue.

Response: We appreciate the commenter's concern, and we note that although we proposed a decrease to the federal per diem base rate, we estimated that payments under the IPF PPS would increase by approximately 2.6 percent overall after all payment adjustments are applied. As stated in the FY 2025 IPF PPS proposed rule (89 FR 23149), based on IGI's fourth quarter 2023 forecast with historical data through the third quarter of 2023, we proposed a 2021-based IPF market basket increase for FY 2025 of 3.1 percent. As mandated by the Act, we also proposed to reduce the 3.1 percent IPF market basket increase by the proposed 0.4 percentage point productivity adjustment, which was also based on IGI's fourth quarter 2023 forecast. As stated in the FY 2025 IPF PPS proposed rule (89 FR 23153), for the proposed FY 2025 Federal per diem base rate, we applied the payment rate update of 2.7 percent to the FY 2024 Federal per diem base rate of \$895.63. Then, we also applied the proposed wage index budget neutrality factor of 0.9998 and a proposed refinement standardization factor of 0.9514 to yield a proposed Federal per diem base rate of \$874.93 for FY 2025. As required by section 1886(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, proposed revisions to the IPF PPS adjustment factors must be budget neutral. Therefore, we proposed a refinement standardization factor to be applied to the FY 2024 IPF PPS payment rates to maintain budget neutrality for FY 2025. This proposed refinement standardization factor reduced the proposed Federal per diem base rate to account for the overall increase to payments (approximately 5.1 percent) that would otherwise occur under the revised IPF PPS adjustment

factors. As indicated in the proposed rule, we note that for this final rule, we are updating the refinement standardization factor to 0.9524 based on more recent data. As proposed (89 FR 23149), we are also updating the projected 2021-based IPF market basket increase for FY 2025 to reflect IGI's more recent second quarter 2024 forecast with historical data through the first quarter of 2024. For the final rule, the projected 2021-based IPF market basket increase for FY 2025 is 3.3 percent. We believe the 2021-based IPF market basket increase for FY 2025 adequately reflects the price increases IPFs are projected to face since the index reflects the mix of inputs used to provide IPF services.

Comment: Several commenters expressed concern about the application of the productivity adjustment stating that the COVID–19 public health emergency (PHE) has had unimaginable impacts on U.S. productivity and that most estimates of labor productivity highlight uncharacteristic reductions. They stated that even before the PHE, the CMS Office of the Actuary (OACT) indicated that hospital productivity will be less than the general economy-wide productivity, though they note the general economy-wide measure is required by law to be used to derive the productivity adjustment. They requested that CMS use its “special exceptions and adjustments” authority to eliminate the productivity adjustment for FY 2025.

One commenter stated that hospitals continue to encounter difficulties obtaining nurses and nursing assistants to care for patients, and these struggles could potentially be exacerbated by the recently finalized minimum staffing requirement at nursing facilities. They argued that these issues should be accounted for when determining a productivity factor. One commenter requested CMS lower the productivity adjustment factor to the rate used in FY 2024, which was 0.2 percentage point.

Response: Section 1886(s)(2)(A)(i) of the Act requires the application of the productivity adjustment described in section 1886(b)(3)(xi)(II) of the Act. As required by statute, the FY 2025 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending FY 2025. We acknowledge the concerns of the commenters regarding the appropriateness of the productivity adjustment and potential impacts of other rulemaking, including minimum nurse staffing requirements; however, we are required pursuant to section 1886(s)(2)(A)(i) of the Act to apply the

specific productivity adjustment. Because that provision specifically requires application of the productivity adjustment, we do not believe section 1886(s) of the Act permits the Secretary discretion to remove it from the calculation of the market basket update.

As stated in the FY 2025 IPF proposed rule (89 FR 23149), the United States Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of annual economy-wide, private nonfarm business total factor productivity (previously referred to as annual economy-wide, private nonfarm business multifactor productivity). IGI forecasts total factor productivity consistent with BLS methodology by forecasting the detailed components of TFP. A complete description of IGI's TFP projection methodology is available on the CMS website at <https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information>.

We believe our methodology for the productivity adjustment is consistent with the statute that states the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor 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).

The FY 2025 proposed productivity adjustment of 0.4 percent was based on IGI's forecast of the 10-year moving average of annual economy-wide private nonfarm business TFP, reflecting historical data through 2022 as published by BLS and forecasted TFP for 2023 through 2025. The higher productivity adjustment for FY 2025 (0.4 percent proposed and 0.5 percent for the final rule) compared to FY 2024 (0.2 percent) is primarily a result of incorporating BLS revised historical data through 2022 and preliminary historical growth in TFP for 2023, and an updated forecast for TFP growth for 2024 reflecting higher expected growth in economic output.

Finally, we note that CMS appreciates the concerns that the commenter raised about challenges related to staffing. We remain focused on improving the health and safety of patients seeking care at IPFs, and ensuring access to care.

Comment: Several commenters stated that in FYs 2022, 2023, and 2024, CMS provided market basket updates of 2.7 percent, 4.1 percent, and 3.5 percent, respectively. They claimed that CMS's actual figures have demonstrated the deficiency in these figures, with recent estimates showing the market basket for

these years to be 5.3 percent, 4.8 percent, and 3.7 percent, respectively. The commenters argued that the ongoing shortcomings of the market basket perpetuate underpayments to IPFs since future payment adjustments continue to be based on these updates. They stated that given ongoing inflationary pressure, cost increases, and the inadequacy of the prior year market basket updates, they believe CMS's proposed update for FY 2025 will be insufficient to cover costs. They stated that while they appreciate that CMS will update the market basket in the final rule based on more recent data, they are concerned that it will still be inadequate. They noted that when CMS underestimates the market basket update under the Skilled Nursing Facility Prospective Payment System (PPS) and the capital input price index used in the Inpatient Prospective Payment System (IPPS), CMS makes a forecast error adjustment when the error exceeds a threshold. The commenters requested a consistent policy between these payment systems and implementation of a forecast error adjustment. Commenters, anticipating that CMS may respond that rulemaking procedures under section 1871 of the Act would not permit adoption of a forecast error adjustment for the FY 2023 IPF PPS update because such a policy was not proposed, argued that, because the IPF market basket update for FY 2025 has been made subject to public comment in the FY 2025 IPF PPS proposed rule, CMS could finalize a forecast error adjustment.

Several commenters stated that they believed the persistent gap between the forecasted market basket percentage increase and the actual market basket percentage increase is indefensible on policy grounds, particularly when considering what the commenters described as an overwhelming urgency of the behavioral health service shortages facing the United States. The commenters requested that CMS apply a 0.7 percentage point increase to the per diem base rate for FY 2025 to account for the forecast error for FY 2023.

Several commenters requested that CMS make a one-time 3.5 percent adjustment to the IPF market basket in FY 2025 to account for what the commenters consider to be underpayments from FYs 2022 through FY 2024. One commenter requested that CMS adopt a one-time forecast error adjustment to the FY 2025 IPF PPS update based on the 3.9 percentage points difference in the IPF PPS market basket in FYs 2021, 2022, and 2023.

Response: We appreciate the concerns of commenters; however, we did not

propose and are not finalizing a forecast error adjustment for the IPF PPS for FY 2025. As we have noted in prior years, the IPF market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. For instance, the FY 2025 market basket update in this final rule reflects historical data through the first quarter of CY 2024 and forecasted data through the third quarter of CY 2025.

While there is no precedent for adjusting for market basket forecast error in the IPF payment update, a forecast error can be calculated for a prior year by comparing the actual market basket increase for a given year less the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. As of now, the cumulative forecast error since IPF PPS inception (rate year 2007 to FY 2023) is -0.2 percent, which reflects that forecasted market basket updates for each payment year for IPFs were higher than the actual market basket updates from 2012 through 2020 (with the exception of 2018); the opposite was true for 2021 through 2023. Only considering the forecast error for years when the IPF market basket update was lower than the actual market basket update does not consider the full experience and impact of forecast error.

Comment: One commenter stated that the increasing number of beneficiaries who are choosing Medicare Advantage (MA) over Medicare fee-for-service is causing additional strain on overall IPF margins. They stated that MA is increasing the overall cost to care for patients by unilaterally implementing overly restrictive medical necessity and prior authorization processes and increasing the administrative burden of obtaining payments. They stated that although MA plans are receiving higher increases in payment rates than providers, the rate increases paid to MA plans are not actually materializing in the form of higher payments to providers. The commenter recommended CMS adjust Medicare fee-for-service payments to compensate for MA losses incurred.

Response: We appreciate the concerns regarding payment adequacy under the IPF PPS; however, we do not agree that it would be appropriate to adjust IPF PPS payments to compensate providers for losses that IPFs may incur under other payors. Section 124 of the BBRA mandated that the Secretary develop a per diem PPS for inpatient hospital

services furnished in psychiatric hospitals and psychiatric units. As required by § 412.424(c)(6)(ii), the FY 2025 IPF PPS Federal per diem base rate is based on an increase factor to adjust for the most recent estimate of increases in the prices of an appropriate market basket of goods and services provided by inpatient psychiatric facilities. Specifically, we applied the 2021-based IPF market basket increase for FY 2025, reduced by the productivity adjustment, which as noted earlier in this final rule measures expected price inflation for IPF providers in FY 2025.

Final Decision: After consideration of the comments received, we are finalizing our proposal to update IPF PPS payment rates using the latest available productivity-adjusted market basket increase factor. Based on IGI's more recent second quarter 2024 forecast with historical data through the first quarter of 2024, the projected 2021-based IPF market basket increase for FY 2025 rule is 3.3 percent and the projected productivity adjustment is 0.5 percent.

3. FY 2025 IPF Labor-Related Share

Due to variations in geographic wage levels and other labor-related costs, we believe that payment rates under the IPF PPS should continue to be adjusted by a geographic wage index, which will apply to the labor-related portion of the Federal per diem base rate (hereafter referred to as the labor-related share). The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We proposed to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market.

Based on our definition of the labor-related share and the cost categories in the 2021-based IPF market basket, we proposed to continue to include in the labor-related share the sum of the relative importance of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services; and a portion of the Capital-Related relative importance from the 2021-based IPF market basket. For more details regarding the methodology for determining specific cost categories for inclusion in the labor-related share based on the 2021-based IPF market basket, we refer readers to the FY 2024 IPF PPS final rule (88 FR 51078 through 51081).

The relative importance reflects the different rates of price change for these

cost categories between the base year (FY 2021) and FY 2025. Based on IGI's fourth quarter 2023 forecast of the 2021-based IPF market basket, the sum of the FY 2025 relative importance moving average of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services was 75.7 percent. We proposed, consistent with prior rulemaking, that the portion of Capital-Related costs that are influenced by the local labor market is 46 percent. Since the relative importance for Capital-Related costs was 6.8 percent of the 2021-based IPF market basket for FY 2025, we proposed to take 46 percent of 6.8 percent to determine a labor-related share of Capital-Related costs for FY 2025 of 3.1 percent. Therefore, we proposed a total labor-related share for FY 2025 of 78.8 percent (the sum of 75.7 percent for the labor-related share of operating costs and 3.1 percent for the labor-related share of Capital-Related costs). We also proposed that if more recent data became available, we would use such data, if appropriate, to determine the FY 2025 labor-related share for the final rule. For more information on the labor-related share and its calculation, we refer readers to the FY 2024 IPF PPS final rule (88 FR 51078 through 51081). We solicited comments on the proposed labor-related share for FY 2025.

Comment: One commenter supported the proposed increase in the labor-related share of the IPF market basket for FY 2025. The commenter expected the increase in the labor-related share given their concerns about labor costs increasing at a higher rate than other hospital costs during the pandemic. They also requested that CMS consider a period less than 5 years for the next rebasing and revising of the IPF market basket, as they believe the current labor share based on FY 2021 cost reports may not fully reflect the increased weight for labor in the overall index that hospital experienced during the COVID-19 PHE.

Response: We appreciate the commenter's request for CMS to consider a shorter period than 5 years for the next rebasing. We generally rebase the IPF market basket every 5 years, in part because the cost weights obtained from the Medicare cost reports generally do not indicate a significant change in the weights over shorter intervals. However, we acknowledge the commenter's concern and the possible impact of the PHE on the cost weights. We regularly monitor the Medicare cost report data to assess whether a rebasing

is technically appropriate, and we will continue to do so in the future. Consistent with historical practice, a rebasing of the IPF market basket would be proposed in rulemaking and subject to public comments.

Comment: One commenter encouraged CMS to consider collecting information on staffing. The commenter noted that CMS calculates a labor share for IPFs of 78.8 percent for FY 2025, which they note is higher than other institutional settings (e.g., labor costs comprise less than 70 percent of IPPS hospital costs, 74 percent of inpatient rehabilitation facility costs, and 71 percent of skilled nursing facility costs). However, they noted there was little available information on the mix (and quantity) of staff employed by IPFs and how staff spend their time across various IPF tasks (such as inpatient assessment, counseling, drug management, nursing care, and behavioral monitoring). They further stated that IPF staffing data would provide essential insights into the variation in costs and quality of care across providers, enabling CMS (and Medicare beneficiaries, if data were publicly available) to better understand the services they are purchasing and using. The commenter stated there is a precedent in Medicare for regularly collecting staffing information, as SNFs are required to submit detailed staffing data through the Payroll Based Journal. The commenter stated payroll data are considered the gold standard for measuring staffing; the data are submitted electronically and can be audited by other data sources.

Response: We appreciate the commenter's suggestion to collect more information on staffing at IPFs. We will take these comments into consideration as we explore the possibility of collecting this information in the future.

Final Decision: After consideration of the comments, we are finalizing a FY 2025 labor-related share based on the latest available data. Based on IGI's second quarter 2024 forecast of the 2021-based IPF market basket, the sum of the FY 2025 relative importance moving average of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services is 75.7 percent. Since the relative importance for Capital-Related costs is 6.7 percent of the 2021-based IPF market basket for FY 2025, we take 46 percent of 6.7 percent to determine a labor-related share of Capital-Related costs for FY 2025 of 3.1 percent. Therefore, the total labor-related share for FY 2025 is 78.8

percent (the sum of 75.7 percent for the labor-related share of operating costs and 3.1 percent for the labor-related share of Capital-Related costs).
Table 1 shows the final FY 2025 labor-related share and the final FY

2024 labor-related share using the 2021-based IPF market basket relative importance.

TABLE 1: FY 2025 Final IPF Labor-Related Share and FY 2024 IPF Labor-Related Share

	Relative importance, final labor-related share FY 2025 ¹	Relative importance, labor-related share FY 2024 ²
Wages and Salaries	53.6	53.4
Employee Benefits	14.1	14.2
Professional Fees: Labor-Related	4.7	4.7
Administrative and Facilities Support Services	0.6	0.6
Installation, Maintenance and Repair Services	1.2	1.2
All Other Labor-Related Services	1.5	1.5
Subtotal	75.7	75.6
Labor-related portion of Capital-Related (.46)	3.1	3.1
Total Labor-Related Share	78.8	78.7

1. Based on the 2nd quarter 2024 IGI forecast of the 2021-based IPF market basket.
2. Based on the 2nd quarter 2023 IGI forecast of the 2021-based IPF market basket.

B. Revisions to the IPF PPS Rates for FY 2025

The IPF PPS is based on a standardized Federal per diem base rate calculated from the IPF average per diem costs and adjusted for budget neutrality in the implementation year. The Federal per diem base rate is used as the standard payment per day under the IPF PPS and is adjusted by the patient-level and facility-level adjustments that are applicable to the IPF stay. A detailed explanation of how we calculated the average per diem cost appears in the RY 2005 IPF PPS final rule (69 FR 66926).

1. Determining the Standardized Budget Neutral Federal per Diem Base Rate

Section 124(a)(1) of the BBRA requires that we implement the IPF PPS in a budget neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that will have been made if the IPF PPS were not implemented. Therefore, we calculated the budget neutrality factor by setting the total estimated IPF PPS payments to be equal to the total estimated payments that will have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) methodology

had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the RY 2005 IPF PPS final rule (69 FR 66926).

Under the IPF PPS methodology, we calculated the final Federal per diem base rate to be budget neutral during the IPF PPS implementation period (that is, the 18-month period from January 1, 2005, through June 30, 2006) using a July 1 update cycle. We updated the average cost per day to the midpoint of the IPF PPS implementation period (October 1, 2005), and this amount was used in the payment model to establish the budget neutrality adjustment.

Next, we standardized the IPF PPS Federal per diem base rate to account for the overall positive effects of the IPF PPS payment adjustment factors by dividing total estimated payments under the TEFRA payment system by estimated payments under the IPF PPS. The information concerning this standardization can be found in the RY 2005 IPF PPS final rule (69 FR 66932) and the RY 2006 IPF PPS final rule (71 FR 27045). We then reduced the standardized Federal per diem base rate to account for the outlier policy, the stop loss provision, and anticipated behavioral changes. A complete discussion of how we calculated each component of the budget neutrality

adjustment appears in the RY 2005 IPF PPS final rule (69 FR 66932 through 66933) and in the RY 2007 IPF PPS final rule (71 FR 27044 through 27046). The final standardized budget neutral Federal per diem base rate established for cost reporting periods beginning on or after January 1, 2005 was calculated to be \$575.95.

The Federal per diem base rate has been updated in accordance with applicable statutory requirements and 42 CFR 412.428 through publication of annual notices or proposed and final rules. A detailed discussion on the standardized budget neutral Federal per diem base rate and the Electroconvulsive Therapy (ECT) payment per treatment appears in the FY 2014 IPF PPS update notice (78 FR 46738 through 46740). These documents are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/index.html>.

As discussed in section IV.B.2 of this final rule, we proposed to revise the patient-level adjustment factors and increase the ECT payment amount for FY 2025. Section 1866(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, requires that revisions to the IPF PPS adjustment factors must be made budget-neutrally. Therefore, as discussed in section IV.F of this final rule, we proposed to apply a

standardization factor to the FY 2025 base rate that takes these refinements into account to keep total IPF PPS payments budget neutral.

2. Increase in the Electroconvulsive Therapy (ECT) Payment per Treatment

a. Background

In the RY 2005 IPF PPS final rule (69 FR 66951), we analyzed the costs of IPF stays that included ECT treatment using the FY 2002 MedPAR data based on comments we received on the RY 2005 IPF PPS proposed rule. Consistent with the comments we received about ECT, our analysis and review indicated that cases with ECT treatment are substantially more costly than cases without ECT treatment. Based on this analysis, in that final rule we finalized an additional payment for each ECT treatment furnished during the IPF stay. This ECT payment per treatment is made in addition to the per diem and outlier payments under the IPF PPS. To receive the payment per ECT treatment, IPFs must indicate on their claims the revenue code and procedure code for ECT (Rev Code 901; procedure code 90870) and the number of units of ECT, that is, the number of ECT treatments the patient received during the IPF stay.

To establish the ECT per treatment payment, we used the pre-scaled and pre-adjusted median cost for procedure code 90870 developed for the Hospital Outpatient Prospective Payment System (OPPS), based on hospital claims data. We explained in the RY 2005 IPF PPS final rule that we used OPPS data because after a careful review and analysis of IPF claims, we were unable to separate out the cost of a single ECT treatment (69 FR 66922). We used the unadjusted hospital claims data under the OPPS because we did not want the ECT payment under the IPF PPS to be affected by factors that are relevant to OPPS, but not specifically applicable to IPFs. The median cost was then standardized and adjusted for budget neutrality. We also adjusted the ECT rate for wage differences in the same manner that we adjust the per diem rate.

Since the ECT payment rate was established in the RY 2005 IPF PPS rule, it has been updated annually by application of each year's market basket, productivity adjustment, and wage index budget neutrality factor to the previous year's ECT payment rate (referred to as our "standard methodology" in this section). While the ECT payment rate has been updated each year by these factors, we have not recalculated the ECT payment per treatment based on more recent cost

data since the establishment of the IPF PPS.

b. Increase to the Electroconvulsive Therapy Payment per Treatment

For the FY 2025 IPF PPS proposed rule, we analyzed data in both the IPF PPS and the OPPS. In the IPF PPS setting, our analysis of recent IPF PPS data indicates that IPF costs have increased for stays that include ECT treatments. As discussed in the next paragraph, our analysis of these costs led us to consider whether the current payment per treatment for ECT is aligned with the additional costs associated with stays that include ECT treatments. We began by analyzing IPF stays with ECT treatment using the CY 2022 Medicare Provider and Analysis Review (MedPAR) data. IPF stays with ECT treatment comprised about 1.7 percent of all stays, which is a decrease from the FY 2002 MedPAR data discussed in the RY 2005 IPF PPS final rule, where stays with ECT treatment were 6.0 percent of all IPF stays. A total of 288 IPF facilities had stays with ECT treatment in 2022, with an average 6.7 units of ECT per stay. We compared the total cost for stays with and without ECT treatment, and found that IPF stays with ECT treatment were approximately three times more costly than IPF stays without ECT treatment (\$44,687.50 per stay vs. \$15,432.30 per stay). Most of the variance in cost was due to differences in the IPF length of stay (LOS) (28.00 days for stays with ECT treatment vs. 13.43 days for stays without ECT treatment). We note that the IPF PPS makes additional per diem payments for longer lengths of stay, which makes the total payment larger for a longer stay. However, we also observed that there are differences in the per-day cost for stays with and without ECT. We calculated the average cost per day for stays with and without ECT treatment and found that stays with ECT treatment have an average cost per day of \$1,595.76, while stays without ECT treatment have an average cost per day of \$1,149.51.

Furthermore, as we discuss in section IV.C.3.d.(2) of this final rule, our latest regression analysis includes a control variable to account for the presence of ECT during an IPF stay. That control variable indicates that, holding all other patient-level and facility-level factors constant, there is a statistically significant increase in cost per day for IPF stays that include ECT, further demonstrating that resource use is higher for IPF stays with ECT than those without ECT. As we previously noted in the RY 2005 IPF PPS final rule (69 FR 66922), IPF claims and cost data are not

sufficiently granular to identify the per-treatment cost of ECT. Therefore, we examined the difference in ancillary costs for IPF stays with and without ECT treatment. In the CY 2022 MedPAR data, the ancillary costs per IPF stay with ECT treatment were \$7,116.85 higher than ancillary costs per IPF stay without ECT treatment. The ancillary costs were calculated as follows: for each ancillary department (for example, drugs or labs), the charges were multiplied by the department-level CCR, and those department-level costs were summed across departments for each stay. The average ancillary costs per stay were calculated accordingly for stays with and without ECT treatment, revealing that average ancillary costs per day are three times higher for stays with ECT treatment: \$99.36 for stays without ECT treatment versus \$301.77 for stays with ECT treatment. Accounting for differences in length of stay between stays with and without ECT, the average additional ancillary cost per ECT unit was approximately \$849.72.

We noted that the application of our standard methodology for updating the ECT payment would have resulted in an FY 2025 payment of \$377.54. We note that for this final rule, that figure is \$378.23 per ECT treatment, based on the FY 2024 ECT payment amount of \$385.58, increased by the market basket update of 2.8 percent and reduced by the FY 2025 wage index budget neutrality factor of 0.9996 and a refinement standardization factor of 0.9546, which is the standardization factor that would account for all other proposed refinements without increasing the ECT per treatment. As we noted above, this ECT payment would be added to the per diem and any applicable outlier payments for the entire stay. CMS considered this rate in proposing to adjust the ECT per treatment rate. However, the analysis of ancillary costs for IPF stays with ECT treatment suggested that a further increase to the current ECT payment amount per treatment could better align IPF PPS payments with the increased costs of furnishing ECT. The ancillary cost data showed that costs for furnishing ECT have risen by a factor greater than the standard methodology for updating the rate will adjust for.

It continues to be the case that, as we discussed in the RY 2005 IPF PPS final rule, current IPF cost and claims data are not sufficiently granular to identify the per-treatment cost of ECT. We believe that using the costs in the OPPS setting are the most accurate for purposes of updating the ECT per treatment rate because we believe this treatment requires comparable resources

when performed in outpatient and inpatient settings. Thus, we analyzed the most recent OPPS cost information to consider changes to the ECT payment per treatment for FY 2025.

The original methodology for determining the ECT payment per treatment was based on the median cost for procedure code 90870 developed for the OPPS, as discussed in the RY 2005 IPF PPS final rule (69 FR 66951). Since that time, the OPPS has adopted certain changes to its methodology for calculating costs. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68270), CMS finalized a methodology for developing the relative payment weights for Ambulatory Payment Classifications using geometric mean costs instead of median costs. We explained that geometric means better capture the range of costs associated with providing services, including those cases where very efficient hospitals have provided services at much lower costs. While medians and geometric means both capture the impact of uniform changes, that is, those changes that influence all providers, only geometric means capture cost changes that are introduced slowly into the system on a case-by-case or hospital-by-hospital basis, allowing us to detect changes in the cost of services earlier.

We believe the rationale for using geometric mean cost in the OPPS setting as the underpinning methodology for establishing payments applies equally to the costs of providing ECT on a per treatment basis under the IPF PPS. Therefore, in considering changes for the IPF PPS ECT payment per treatment for FY 2025, we compared the costs observed in the IPF setting to the geometric mean cost for an ECT treatment posted as part of the CY 2024 OPPS/ASC update, which is based on CY 2022 outpatient hospital claims. Although we proposed to increase the ECT payment with reference to the CY 2024 OPPS ECT geometric mean cost for FY 2025, we did not propose to adopt the OPPS rate (which is distinct from the geometric mean cost) for the ECT payment per treatment for FY 2025 because the final OPPS rates include policy decisions and payment rate updates that are specific to the OPPS. We intend to continue to monitor the costs associated with ECT treatment and may propose adjustments in the future as needed.

The pre-scaled and pre-adjusted CY 2024 OPPS geometric mean cost for ECT is \$675.93. Comparatively, the FY 2024 IPF ECT payment rate was \$385.58 (88 FR 51054). As discussed in the prior paragraphs, our analysis of updated

ancillary cost data indicates that the IPF PPS ECT payment rate per treatment, when updated according to the standard methodology alone, has not kept pace with the cost of furnishing the treatment in the IPF setting. As we stated previously, we believe this treatment requires comparable resources when performed in outpatient and inpatient settings. Therefore, we proposed to use the pre-scaled and pre-adjusted CY 2024 OPPS geometric mean cost of \$675.93 as the basis for the IPF PPS ECT payment per treatment in FY 2025, as discussed below. We proposed to update \$675.93 by the FY 2025 IPF PPS payment rate update of 2.7 percent (3.1 percent IPF market basket increase, reduced by the 0.4 percentage point productivity adjustment), and the wage index budget neutrality factor of 0.9998 for FY 2025, in alignment with our current standard methodology. We also proposed to update this amount based on more recent data of the market basket, productivity adjustment, and wage index budget neutrality factor.

To account for budget neutrality, as discussed in section IV.F of this final rule, we proposed to apply a refinement standardization factor to the FY 2025 IPF PPS Federal per diem base rate and to the ECT payment amount per treatment to account for this proposed change to the ECT payment amount per treatment and all proposed changes to the patient-level adjustment factors and to the ED adjustment factor for FY 2025. We noted that this proposed increase to the ECT per treatment amount would be associated with a minor decrease to the IPF Federal per diem base rate as a result of the refinement standardization factor (0.9514 instead of 0.9536). We estimated that this change would increase payments for IPFs that provide ECT, and would decrease payments for IPFs that do not provide ECT. However, we explained that the decrease in payments associated with this change would be no more than approximately 0.2 percent, which would be offset by various other proposed changes such as the proposed wage index changes, proposed revisions to the IPF PPS patient-level adjustments, and the proposed market basket increase for FY 2025.

We noted that we have monitored the provision of ECT through analysis of claims data since the beginning of the IPF PPS and have not observed any indicators that payment is inappropriately incentivizing the provision of ECT to IPF patients. We stated that we intend to continue monitoring the provision of ECT through further analysis of IPF PPS claims data. In addition, we presented a

detailed discussion of the distributional impacts of this proposed change and we welcomed comments regarding our analysis, including any comments that could inform our understanding of where ECT costs are allocated in cost reports in order to potentially inform improved collection of data on ECT treatment costs in the IPF setting. We also welcomed comments on whether it may be appropriate to collect additional ECT-specific costs on the hospital cost report. Lastly, we proposed that if more recent data became available, we would use such data, if appropriate, to determine the FY 2025 Federal per diem base rate and ECT payment per treatment for the FY 2025 IPF PPS final rule.

Comment: The majority of commenters supported our proposal to increase the ECT payment per treatment, noting that the increased payment would help protect access to this treatment for patients who need it. A few commenters suggested that we could phase in the increase over several years, thus mitigating a reduction to the base rate through the refinement standardization. One of these commenters suggested tying each smaller increase to a quality measure, thus providing additional oversight measures to monitor for unintended consequences, while another advocated for phasing in the increase over three years or phasing in the resulting budget neutrality factor over multiple years. One commenter recommended implementing a smaller increase until more detailed data on ECT costs is available in IPF cost reports.

Response: We appreciate the commenters' support for this proposal regarding the ECT payment per treatment. As we noted in the preamble to the FY 2025 proposed rule, the decrease in payments associated with this change would be no more than approximately 0.2 percent, or a reduction to the IPF federal per diem base rate of approximately \$2.03, which we noted would be offset for particular providers by various other proposed changes such as the proposed wage index changes, proposed revisions to the IPF PPS patient-level adjustments, and the proposed market basket increase for FY 2025. We do not agree that the effect of the increase in the ECT payment per treatment on the base rate is substantial enough to warrant phasing in over time. In response to the commenter who suggested tying increases to a quality measure, we thank you for your comment and will consider your suggestion when developing future measures. We will also continue monitoring ECT costs as we receive

more data on ancillary costs in the future.

Comment: One commenter noted that ECT costs are reported on cost report line 76, and requested that the outdated term “Electroshock Therapy” in the cost report instructions be changed to “Electroconvulsive Therapy” or ECT.

Response: We thank commenters for their suggestion and will consider revising the cost report terminology. We note that the Medicare Claims Processing Manual (CPM) 100–04; chapter 3, § 190.7.3, uses the suggested terminology.

Comment: Two commenters were critical of the use of ECT out of concern for patient safety or concern that the treatment is not sufficiently regulated.

Response: We appreciate commenters expressing their concerns; however, these comments are out of scope of this rule because our proposal did not relate to coverage of ECT or the practice of medicine. Rather, we proposed to refine the payment for a procedure paid for under the IPF PPS. We remind readers that CMS’s coverage requirements for ECT can be found at: <https://www.cms.gov/medicare-coverage-database/search-results.aspx?keyword=electroconvulsive+therapy&keywordType=starts&areald=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all>.

Final Decision: After consideration of the comments received, we are finalizing our proposal to use the pre-scaled and preadjusted CY 2024 OPBS geometric mean cost of \$675.93 as the basis for the IPF PPS ECT payment per treatment in FY 2025. Accordingly, we will apply the final FY 2025 IPF PPS payment rate update of 2.8 percent (3.3 percent IPF market basket percentage increase, reduced by the 0.5 percentage point productivity adjustment), the final refinement standardization factor of 0.9524, and the final wage index budget neutrality factor of 0.9996 for FY 2025, in alignment with our current standard methodology. A complete discussion of the final FY 2025 ECT payment per treatment and final refinement standardization factor is found in section II.B.3 of this final rule. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this final rule.

As we stated in the proposed rule, we intend to continue monitoring the provision of ECT through further analysis of IPF PPS claims data. (89 FR 23153)

IPFs must include a valid procedure code for ECT services provided to IPF beneficiaries to bill for ECT services, as described in our Medicare Claims

Processing Manual, Chapter 3, Section 190.7.3 (available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf>). There are no changes to the ECT procedure codes used on IPF claims in the final update to the ICD–10–PCS code set for FY 2025. Addendum B to this proposed rule shows the ECT procedure codes for FY 2025 and is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

3. Update of the Federal per Diem Base Rate and Electroconvulsive Therapy Payment per Treatment

The current (FY 2024) Federal per diem base rate is \$895.63 and the ECT payment per treatment is \$385.58. For the final FY 2025 Federal per diem base rate, we applied the payment rate update of 2.8 percent—that is, the final 2021-based IPF market basket percentage increase for FY 2025 of 3.3 percent reduced by the final productivity adjustment of 0.5 percentage point—the final wage index budget neutrality factor of 0.9996 (as discussed in section IV.D.1 of this final rule), and a final refinement standardization factor of 0.9524 (as discussed in section IV.F of this final rule) to the FY 2024 Federal per diem base rate of \$895.63, yielding a final Federal per diem base rate of \$876.53 for FY 2025. As discussed in section IV.B.2 of this final rule, we are finalizing our proposal to increase the ECT payment per treatment for FY 2025 in addition to our routine updates to the rate. We applied the 2.8 percent IPF market basket update, the 0.9996 wage index budget neutrality factor, and the 0.9524 refinement standardization factor to the final payment per treatment based on the CY 2024 OPBS geometric mean cost of \$675.93, yielding a final ECT payment per treatment of \$661.52 for FY 2025.

Section 1886(s)(4)(A)(i) of the Act requires that for RY 2014 and each subsequent RY, in the case of an IPF that fails to report required quality data with respect to such RY, the Secretary will reduce any annual update to a standard Federal rate for discharges during the RY by 2.0 percentage points. Therefore, we applied a 2.0 percentage point reduction to the annual update to the Federal per diem base rate and the proposed ECT payment per treatment as follows:

- For IPFs that fail to report required data under the IPFQR Program, we will apply a 0.8 percent payment rate update—that is, the final IPF market

basket increase for FY 2025 of 3.3 percent reduced by the productivity adjustment of 0.5 percentage point for an update of 2.8 percent, and further reduced by 2.0 percentage points in accordance with section 1886(s)(4)(A)(i) of the Act. We will also apply the refinement standardization factor of 0.9524 and the wage index budget neutrality factor of 0.9996 to the FY 2024 Federal per diem base rate of \$895.63, yielding a Federal per diem base rate of \$859.48 for FY 2025.

- For IPFs that fail to report required data under the IPFQR Program, we will apply the 0.8 percent annual payment rate update, the 0.9524 refinement standardization factor, and the 0.9996 wage index budget neutrality factor to the payment per treatment based on the CY 2024 OPBS geometric mean cost of \$675.93, yielding an ECT payment per treatment of \$648.65 for FY 2025.

C. Updates and Revisions to the IPF PPS Patient-Level Adjustment Factors

1. Overview of the IPF PPS Adjustment Factors and Revisions

The current (FY 2024) IPF PPS payment adjustment factors were derived from a regression analysis of 100 percent of the FY 2002 Medicare Provider and Analysis Review (MedPAR) data file, which contained 483,038 cases. For a more detailed description of the data file used for the regression analysis, we refer readers to the RY 2005 IPF PPS final rule (69 FR 66935 through 66936).

For FY 2025, we proposed to implement revisions to the methodology for determining payment rates under the IPF PPS. As we noted earlier in this FY 2025 IPF PPS final rule, section 1886(s)(5)(D) of the Act, as added by section 4125(a) of the CAA, 2023 requires that the Secretary implement revisions to the methodology for determining the payment rates under the IPF PPS for psychiatric hospitals and psychiatric units, effective for FY 2025. The revisions may be based on a review of the data and information collected under section 1886(s)(5)(A) of the Act. Accordingly, we proposed to revise the patient-level IPF PPS payment adjustment factors as discussed in section IV.C.4. of this final rule, effective for FY 2025. We explained that we developed proposed adjustment factors based on a regression analysis of IPF cost and claims data, which is discussed in greater detail in the following sections of this final rule. The primary sources of this analysis are CY 2019 through 2021 MedPAR files and Medicare cost report data (CMS

Form 2552–10, OMB No. 0938–0050)¹ from the FY 2019 through 2021 Hospital Cost Report Information System (HCRIS). For each year (2019 through 2021), if a provider did not have a Medicare cost report for that year, we used the provider's most recent available Medicare cost report prior to the year for which a Medicare cost report was missing, going back to as early as 2018. Section IV.C.3 of this final rule discusses the development of the proposed revised case-mix adjustment regression and the final case-mix regression analysis upon which we are basing our final revisions to the FY 2025 IPF PPS patient-level adjustment factors.

2. History of IPF PPS Cost and Claims Analyses

In the FY 2023 IPF PPS proposed rule (87 FR 19428 through 19429), we briefly discussed past analyses and areas of interest for future refinement, about which we previously solicited comments. CMS also released a technical report posted to the CMS website² accompanying the rule summarizing these analyses. In that same proposed rule, we described the results of the agency's latest analysis of the IPF PPS and solicited comments on certain topics from the report. We summarized the considerations and findings related to our analyses of the IPF PPS adjustment factors in the FY 2023 IPF PPS final rule (46864 through 46865).

In the FY 2024 IPF PPS proposed rule (88 FR 21269 through 21272), we requested information from the public to inform revisions to the IPF PPS required by the CAA, 2023. Specifically, we sought information about which data and information will be most appropriate and useful for the purposes of refining IPF PPS payments. We requested information related to the specific types of data and information mentioned in the CAA, 2023. We also solicited comments on the reporting of ancillary charges, such as labs and drugs, on IPF claims. Lastly, we presented and solicited comments on the latest results of our analysis of Social Drivers of Health (SDOH).

In response to the requests for information, commenters offered a number of suggestions for further analysis, including recommendations to consider adjusting payment for patients with sleep apnea, violent behavior, and patients that transfer from an acute care

unit. We discuss the analysis conducted and our findings as related to patient-level adjustment factors in section IV.C.3 of this final rule.

In the FY 2025 IPF PPS proposed rule, we explained that the primary goal in refining the IPF PPS payment adjustment factors is to pay each IPF an appropriate amount for the efficient delivery of care to Medicare beneficiaries. We stated that the system must be able to account adequately for each IPF's case-mix to allow for both fair distribution of Medicare payments and access to adequate care for those beneficiaries who require more costly care. We also noted that as required by section 1886(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, proposed revisions to the IPF PPS adjustment factors must be budget neutral. We explained that we applied a refinement standardization factor to the proposed IPF PPS payment rates to maintain budget neutrality for FY 2025.

3. Development of the Revised Case-Mix Adjustment Regression

In the proposed rule, we explained that to ensure that the IPF PPS continues to account adequately for each IPF's case-mix, we performed an extensive regression analysis of the relationship between the per diem costs and both patient and facility characteristics to identify those characteristics associated with statistically significant cost differences. We discuss the results of this regression analysis in section IV.C.3.e. of this final rule. We further discuss final policies related to the proposed revisions to the IPF PPS patient-level adjustment factors based on this regression analysis in section IV.C.4 of this final rule.

As we discussed in the proposed rule, we computed a per diem cost for each Medicare inpatient psychiatric stay, including routine operating, ancillary, and capital components using information from the CY 2019 through CY 2021 MedPAR files and data from the 2019 through 2021 Medicare cost reports, backfilling with Medicare cost reports from the most recent prior year when necessary.

We began with a 100-percent sample of the CY 2019 through CY 2021 MedPAR data files, which contain a total of 1,111,459 stays from 1,684 IPFs. We explained in the proposed rule that we applied several data restrictions and exclusions to obtain the set of data used for our regression analysis. The MedPAR data files used for this regression analysis contain a total of 806,611 stays from 1,643 IPFs, which reflect the removal of 41 providers and 304,848 stays with missing or erroneous

data. To include as many IPFs as possible in the regression, we used the cost report information for each provider corresponding to the year of claims, when available, and substituted the most recent prior available cost report information for routine cost and ancillary cost to charge ratios if the corresponding year's data was not available.

a. Data Sources

For the regression analysis, we stated in the proposed rule that we chose to use a combined set of CY 2019 through 2021 MedPAR data. Our analysis showed that using a combined set of data from multiple years yields the most stable and consistent result. We noted that when we looked at the results for each year individually, we found that some DRGs and comorbidity categories were not statistically significant due in part to small sample size. In addition, we noted that during FY 2020, the U.S. healthcare system undertook an unprecedented response to the Public Health Emergency (PHE) declared by the Secretary of the Department of Health and Human Services on January 31, 2020 in response to the outbreak of respiratory disease caused by a novel (new) coronavirus that has been named "SARS CoV 2" and the disease it causes, which has been named "coronavirus disease 2019" (abbreviated "COVID-19"). We stated that we believe the aggregated three-year regression serves to smooth the impact of changes in utilization driven by the COVID-19 PHE, as well as significant changes in staffing and labor costs that commenters noted in response to the FY 2023 and FY 2024 IPF PPS proposed rules. We also explained in the proposed rule that we used 2019 through 2021 Medicare cost report data to retain as many records as possible for analysis.

In addition, we explained that we used several other data sources to identify the IPF population for analysis and to construct variables in the regression model:

- *Provider of Services (POS) File:* The POS file contains facility characteristics including name, address, and types of services provided.

- *Provider Specific Data for Public Use Files for the IPF PPS:* The Provider Specific File (PSF) contains data used to calculate COLA factors and identify the Core-Based Statistical Area (CBSA). CBSA is used to match providers with corresponding wage index data, which is used to adjust the calculation of the Federal per diem base rate to account for geographic differences in costs.

- *Common Working File (CWF) Inpatient Claims Data:* The CWF

¹ https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202206-0938-017.

² <https://www.cms.gov/files/document/technical-report-medicare-program-inpatient-psychiatric-facilities-prospective-payment-system.pdf>.

contains data regarding ECT treatments provided during an IPF stay.

In the proposed rule, we noted that among the 1,643 providers included in the regression analysis sample, the majority had their most recent Medicare cost report information corresponding to the year of the MedPAR data file. Specifically, for the CY 2019 MedPAR data file, 99.5 percent (1,551 providers) used FY 2019 Medicare cost reports, and 0.5 percent (8 providers) used FY 2018 Medicare cost reports. For CY 2020, 99.7 percent (1,523 providers) used FY 2020 Medicare cost reports, and 0.3 percent (5 providers) used FY 2019 Medicare cost reports. For CY 2021, 97.6 percent (1,435 providers) used FY 2021 Medicare cost reports, and 2.4 percent (35 providers) used FY 2020 Medicare cost reports. We explained that this approach allowed us to use the most current and relevant cost report data, ensuring the robustness and accuracy of our analysis.

b. Trims and Assumptions

In the proposed rule, we explained that to identify the IPF population for analysis, we matched MedPAR records to facility-level information from Medicare cost reports, the POS file, and the PSF. We further explained that we included MedPAR stays that met the following criteria:

- Hospital CMS Certification Number (CCN) contains “40,” “41,” “42,” “43,” or “44” in the third and fourth position or a special unit code of “S” or “M” for psychiatric unit or psychiatric unit in a critical access hospital.
- Beneficiary primary payer code is equal to “Z” or blank, indicating Medicare is the primary payer.
- Group Health Organization (GHO) paid code is equal to zero or blank, indicating that a GHO has not paid the facility for the stay.
- National Claims History (NCH) claim type code is equal to “60,” an inpatient claim.
- Number of utilization days was greater than zero.

We noted in the proposed rule that we completed a series of trimming steps to remove missing and outlier data, to promote the accuracy and completeness of data included in the regression model. We stated that before any trims or exclusions were applied, there were 1,684 providers in the MedPAR data file. We described these trimming steps in detail in the proposed rule.

First, we matched facilities from the MedPAR dataset to the most recent Medicare cost report file available from CY 2018 to CY 2021, and excluded facilities that did not have a Medicare cost report available from 2018 to 2021.

If facilities had more than one Medicare cost report in a given year, we used the Medicare cost report representing the longest time span. We identified 1 provider in CY 2019, 5 providers in CY 2020, and 4 providers in CY 2021 that had no available Medicare cost report information. In total, we excluded data from 5 unique providers that had no available Medicare cost report information from CY 2019 to CY 2021.

Next, we trimmed facilities with extraordinarily high or low costs per day. We removed facilities with outlier routine per diem costs, defined as those falling outside of the range of the mean logarithm of routine costs per diem plus or minus 3.00 standard deviations. We also removed stays with outlier total per diem costs, defined as those falling outside the range of the mean per diem cost by facility type (psychiatric hospitals and psychiatric units) plus or minus 3.00 standard deviations. The average and standard deviations of the total per diem cost (routine and ancillary costs) were computed separately for stays in psychiatric hospitals and psychiatric units because we did not want to systematically exclude a larger proportion of cases from one type of facility. In applying these trims across all three data years used in our regression model, there were 104 providers with routine per diem costs outside 3.00 standard deviations from the mean, and 47 providers with total per diem costs outside 3.00 standard deviations from the mean. Specifically, this includes 24 providers in CY 2019, 41 providers in CY 2020, and 39 providers in CY 2021 excluded for outlier routine per diem costs. We identified 25 providers in CY 2019, 1 provider in CY 2020, and 21 providers in CY 2021 that we excluded for outlier total per diem costs. In total, we excluded data from 23 unique providers with outlier routine per diem costs and 8 unique providers with outlier total per diem costs.

We also removed stays at providers without a POS file or PSF. There were 5 providers without a POS file or PSF during the period CY 2019 to CY 2021; therefore, we excluded data from these 5 providers. Only 1 unique provider was entirely excluded with no POS file or PSF from CY 2019 to CY 2021. Additionally, 1 provider was excluded because no stays had one of the recognized IPF PPS DRGs assigned.

In summary, the application of these data preparation steps resulted in excluding 5 providers because they did not have a cost report available from 2018 to 2021, 23 providers with routine per diem costs outside 3.00 standard deviations from the mean, and 8

providers with total per diem costs outside 3.00 standard deviations from the mean. We also excluded 1 provider without a POS file or PSF, 1 provider with no stays with IPF PPS DRGs, and 3 providers based on IPF stays restrictions. In total, the exclusion of these 41 providers resulted in the removal of 304,848 stays from our original total of 1,111,459 stays.

In the proposed rule, we explained that we considered trimming stays from facilities where 95 percent or more of stays had no ancillary charges because we assumed that the cost data from these facilities were inaccurate or incomplete. We noted that this is the trimming methodology that we applied to the analysis described in the technical report released along with the FY 2023 IPF PPS proposed rule. As previously discussed, the IPF PPS regression model uses the sum of routine and ancillary costs as the dependent variable, and we assumed that data from facilities without ancillary charge data will be inadequate to capture variation in costs. We explained that when we examined the claims from 2018, which we used for prior analysis, this trimming step resulted in removing almost one-quarter of total stays from the unrestricted 2018 MedPAR dataset (82,491 out of 364,080 total stays). We stated that this trimming step also resulted in disproportionate exclusion of certain types of facilities, particularly freestanding psychiatric hospitals that were for-profit or government-operated, as well as all-inclusive rate providers. We noted that approximately 55 percent of stays from freestanding facilities would be removed, compared to just 0.3 percent of stays in psychiatric units. In the analysis described in the FY 2023 IPF PPS proposed rule (87 FR 19429), we attempted to address this disproportionate removal of stays by facility type by applying weights by facility type and ownership in the regression model to account for excluded providers and to avoid biasing the sample towards stays from providers in psychiatric units.

We explained that in response to the analysis described in the FY 2023 IPF PPS proposed rule (87 FR 19429), commenters raised concerns about the large number of stays excluded from the regression analysis, and questioned whether the ancillary charge data were truly missing, as all-inclusive rate providers are not required to report separate ancillary charges. We stated that we agree that this trimming step reduces the representativeness of the IPF population used in the regression model and may increase the potential

for bias of the regression coefficients used for payment adjustments. Furthermore, as discussed in section IV.E.4. of this final rule, we are clarifying cost reporting requirements and implementing operational changes that we believe will increase the accuracy of the cost information reported in the future. Specifically, we explain that CMS will issue instructions to the MACs and put in place edits for cost reporting periods beginning on or after October 1, 2024, ensuring that only government-owned or tribally owned IPF hospitals will be permitted to file an all-inclusive cost report. We further explain that all other IPF hospitals will be required to have a charge structure and to report ancillary costs and charges on their cost reports. We expect this change will support increased accuracy of future payment refinements to the IPF PPS.

In this year's proposed rule, we explained that when we examined the claims from CY 2019 to CY 2021, we observed that this trimming step would have resulted in a loss of a significant number of providers (324 providers in CY 2019, 330 providers in CY 2020, and 336 providers in CY 2021). Due to the concerns that commenters previously raised (which we summarized in the FY 2024 IPF PPS final rule (88 FR 51097 through 51098)), and to include as many claims as possible in the regression analysis, we explained that we did not trim stays from facilities with zero or minimal ancillary charges. As a result, we noted that we observed a significant reduction in data loss when comparing our latest regression model with the model described in the FY 2023 IPF PPS proposed rule. We further stated that by including, rather than trimming, facilities with low or no ancillary charge data, we prevented the loss of 288 providers across the three years, allowing for a more inclusive analysis. We noted that these providers accounted for approximately 194,673 stays included in our data set.

We clarified that the regression results presented in the proposed rule did not include the application of any trimming or subsequent weighting to account for the removal of stays from facilities with zero or minimal ancillary charges.

c. Calculation of the Dependent Variable

In the proposed rule, we explained that the IPF PPS regression model uses the natural logarithm of per diem total cost as the dependent variable. We stated that we computed a per diem cost for each Medicare inpatient psychiatric stay, including routine operating, ancillary, and capital components, using information from the combined CY 2019

through 2021 MedPAR file and data from the 2018 through 2021 Medicare cost reports. We explained that for each MedPAR CY, we examined the corresponding Medicare cost report, and if a provider's cost-to-charge ratio was missing from the matching year's cost report, we looked at the provider's cost report from the prior year to obtain the most recent cost-to-charge value for the provider. We noted that we applied a prior-year cost-to-charge ratio to 8 providers from the CY 2019 MedPAR claims, 5 providers from the CY 2020 MedPAR claims, and 35 providers from the CY 2021 MedPAR claims.

We further explained that to calculate the total cost per day for each inpatient psychiatric stay, routine costs were estimated by multiplying the routine cost per day from the IPF's Medicare cost report (Worksheet D–1, Part II, column 1, line 38) by the number of Medicare covered days in the MedPAR stay record. We explained that ancillary costs were estimated by multiplying each departmental cost-to-charge ratio (calculated by dividing the amount obtained from Worksheet C, columns 5, by the sum of Worksheet C, columns 6 and 7) by the corresponding ancillary charges in the MedPAR stay record. We stated that the total cost per day was calculated by summing routine and ancillary costs for the stay and dividing it by the number of Medicare covered days for each day of the stay.

As discussed in the proposed rule, we winsorized the distributions of the 17 ancillary cost centers from Worksheet C of the cost report at the 2nd and 98th percentiles to address extreme cost-to-charge ratios. That is, if the cost-to-charge ratio was missing and there was a charge on the claim, the cost-to-charge ratio was imputed to the calculated median value for each respective cost center.

In addition, we explained that the total cost per day (also referred to as per diem cost) was adjusted for differences in cost across geographic areas using the FY 2019 through 2021 IPF wage indices and COLAs corresponding to each MedPAR data year. We stated that we adjusted the labor-related portion of the per diem cost using the IPF wage index to account for geographic differences in labor cost and adjusted the non-labor portion of the per diem cost by the COLA adjustment factors for IPFs in Alaska and Hawaii. We stated that we used IPF PPS labor-related share and non-labor-related share finalized for each year, FY 2019 through FY 2021, to determine the amount of the per diem cost that is adjusted by the wage index and the COLA, respectively. We explained that we calculated the

adjusted cost using the following formula:

$$\text{Wage adjusted per diem cost} = \text{per diem cost} / (\text{wage index} * \text{labor-related share} + \text{COLA} * (1 - \text{labor-related share})).$$

d. Independent Variables

In the proposed rule, we stated that the independent variables in the regression model are patient-level and facility-level characteristics that affect the dependent variable in the model, which is per diem cost. As discussed in the following sections, we noted that the updated regression model for the proposed rule included adjustment-related variables and control variables. We explained that adjustment-related variables are used for adjusting payment, and we proposed to revise the IPF PPS patient-level adjustment factors based on the regression results for many of the adjustment-related variables in the model. We further explained that control variables are used to account for variation in the dependent variable that is associated with factors outside the adjustment factors of the payment model.

(1) Adjustment-Related Variables

Patient-level adjustment-related variables included in the regression model are variables for DRG assignment, comorbidity categories, age, and length of stay. We note that facility-level adjustment-related variables for rural status and teaching status are also included in the model; however, we did not propose revisions to the rural or teaching adjustments for FY 2025. We discuss the latest results of the regression analysis for facility-level adjustments in greater detail in section IV.A. of this final rule.

(2) Control Variables

The regression model used to determine IPF PPS payment adjustments in the RY 2005 IPF PPS final rule (69 FR 66922) included control variables to account for facilities' occupancy rate, a control variable to indicate if the patient received ECT, and a control variable for IPFs that do not bill for ancillary charges. In the proposed rule, we explained that the updated regression model for the FY 2025 IPF PPS proposed rule removed the occupancy control variables and the control variable for IPFs that do not bill for ancillary charges. In addition, we explained that we retained the control variable for patients receiving ECT and added control variables for the data year. We also explained that we added a control variable for the presence of ED

charges on the claim. We discuss considerations related to these control variables and others in the following paragraphs.

The 2004 regression model included two control variables for occupancy rate. One was a continuous variable for the facility's logarithmic-transformed occupancy rate. The other was a categorical variable indicating a facility had an occupancy rate below 30 percent. Both of these variables were found to be associated with statistically significant increases in cost. In the RY 2005 IPF PPS final rule, we adopted the structural approach and included these control variables in the regression. We explained that it was appropriate to control for variations in the occupancy rate in estimating the effects of the payment variables on per diem cost to avoid compensating facilities for inefficiency associated with underutilized fixed costs (69 FR 66934). As we discussed in the FY 2023 IPF PPS proposed rule, our analysis found that the occupancy control variables were associated with rural status. We solicited comments on the potential removal of the occupancy control variables from the model (87 FR 19429). In response, we received several comments in support of removing the occupancy control variables, due to the relationship between these control variables and the rural adjustment (87 FR 46865). Commenters cited the importance of rural IPFs as the primary points of care and access for many Medicare beneficiaries who cannot travel to urban areas for mental health services. As we discussed in the FY 2025 IPF PPS proposed rule, we considered the potential negative impact to rural facilities of retaining the occupancy control variables in the regression model. We stated that we agree with the commenters who noted the importance of maintaining stability in payments for rural IPFs; therefore, we did not include any occupancy control variables in our regression model.

In addition, we stated that we considered including a control variable for IPFs that do not bill for ancillary services. As we discussed in the RY 2005 IPF PPS final rule (69 FR 66936), we included variables in the regression to control for psychiatric hospitals that do not bill ancillary costs. However, at that time, the number of IPFs who did not bill for ancillary costs was relatively small and consisted mostly of government-operated facilities. As we discuss later in section IV.E.4 of this final rule, an increasing number of IPFs have stopped reporting ancillary charges on their claims, which means that

ancillary cost information is not available for stays at these IPFs.

We explained in the proposed rule that we considered whether to include a control variable for facilities that do not report ancillary charges. We stated that we considered that the inclusion of a control variable would only account for differences in the level of cost between IPFs with and without reported ancillary costs and would not facilitate comparison of costs between all IPFs in our sample. In addition, we noted that facilities that did not report ancillary charges also tended to have lower routine costs; that is, our analysis showed that these facilities will have overall lower costs per day, regardless of whether ancillary costs were considered in the cost variable. We explained that the inclusion of a control variable in the regression model would account for these differences in overall cost, which would impact the size of payment-related adjustment factors that are correlated with the prevalence of missing ancillary charge data. We stated that for this reason, in developing a regression model for proposing revisions to the IPF PPS, we did not include a control variable to account for facilities that report zero or minimal ancillary charges.

As noted earlier, the original model also included a control variable for the presence of ECT. This is because ECT is paid on a per-treatment basis under the IPF PPS. As discussed in more detail in section IV.B.2. of this FY 2025 IPF PPS final rule, we continue to observe that IPF stays with ECT have significantly higher costs per day. We proposed to continue paying for ECT on a per-treatment basis; therefore, we explained that we included a control variable to account for the additional costs associated with ECT, which will continue to be paid for outside the regression model.

Similarly, we stated that we included a control variable for stays with emergency department (ED)-related charges. The original model did not include an ED control variable, because ED costs were excluded from the dependent variable of IPF per diem costs. We explained that our regression model for the FY 2025 IPF PPS proposed rule includes all costs associated with each IPF stay, including ED costs. As we explained in the proposed rule, we proposed to calculate the ED adjustment in accordance with our longstanding methodology, separate from the regression model. However, we included a control variable for stays with ED charges to control for the additional costs associated with ED admissions, which are paid under the

ED adjustment outside the regression model.

Lastly, we stated that we included control variables for the data year. We stated that because the model used a combined set of data from 3 years, these control variables are included in the model to account for differences in cost levels between 2019, 2020, and 2021, which would be driven by economic inflation and other external factors unrelated to the independent variables in the regression model.

e. Regression Results

In the proposed rule, we presented the results of our regression model, which we noted includes a total of 806,611 stays, and had an r-squared value of 0.32340, meaning that the independent variables included in the regression model were able to explain approximately 32.3 percent of the variation in per diem cost among IPF stays.

In the proposed rule, we explained that except for the teaching variable, each of the adjustment factors we presented was the exponentiated regression coefficient of our regression model, which as we previously noted uses the natural logarithm of per diem total cost as the dependent variable. We stated that we presented the exponentiated regression results, as these most directly translate to the way that IPF PPS adjustment factors are calculated for payment purposes. That is, the exponentiated adjustment factors presented in the proposed rule represent a percentage increase or decrease in per diem cost for IPF stays with each characteristic. In the case of the teaching variable, we noted that the result presented in the proposed rule is the un-exponentiated regression coefficient. As discussed in section IV.D of this final rule, the current IPF PPS teaching adjustment is calculated as $1 + a$ facility's ratio of interns and residents to beds, raised to the power of 0.5150. We explained that the coefficient for teaching status presented in the proposed rule can be interpreted in the same way.

We explained that for certain categorical variables, including DRG, age, length of stay, and the year control variables, results for the reference groups were not shown. We stated that the DRG reference group is DRG 885, because this DRG represents the majority of IPF PPS stays. In addition, we explained that the age reference group is the Under 45 category, because this group is associated with the lowest costs after accounting for all other patient characteristics in the model. We further explained that the reference

group for length of stay is 10 days, which corresponds to the reference group used in the original regression model from the RY 2005 IPF PPS final rule. Lastly, we stated that the year control reference group is CY 2021. We stated that each of these reference groups effectively has an adjustment factor of 1.00 in the regression model.

Lastly, we stated that we considered the regression factors to be statistically significant when the p-value was less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***), as notated in the table presented in the proposed rule.

We received several comments regarding the regression methodology discussed in the proposed rule.

Comment: Two commenters expressed support for the regression methodology used to develop revised adjustment factors for the IPF PPS. In particular, MedPAC expressed support for the proposal to include stays at facilities with low or no ancillary charge information, as well as including multiple years of data, in the calculation of the updated patient-level adjustments for FY 2025. MedPAC further encouraged CMS to continue to monitor and update the weights as needed using the most recent data available.

Response: We appreciate the support from these commenters, and we intend to continue to monitor IPF PPS payments and costs to consider potential future updates as appropriate.

Comment: One commenter expressed concerns about CMS's piecemeal approach to implementing the updated coefficients. This commenter stated that CMS should update not only the patient-level adjustment factors as proposed but also the updated facility-level coefficients (*i.e.*, the teaching and rural adjustments) that were derived from the same regression model. This commenter further stated that if CMS did not plan to use these updated facility-level adjustments, it should have run a constrained regression, which would have resulted in different patient-level adjustment factors. From a technical perspective, this commenter stated that it is inappropriate to use patient-level and facility-level adjustments that were derived from separate regression analyses.

Response: We appreciate these methodological concerns from the commenter; however, we do not agree that the proposed approach is

technically inappropriate. Although the commenter asserted that CMS would not be using the regression-derived facility-level adjustments, this is not an accurate assertion. As we discussed in the proposed rule, we proposed a number of revisions to the patient-level adjustment factors as well as changes to the CBSA delineations. We proposed to maintain the existing facility-level adjustment factors for FY 2025 because we believe it is important to minimize the scope of changes that would impact payments to facilities in any single year. However, as we discussed in the proposed rule, CMS is considering using the regression-derived facility-level adjustment factors for payment in future years, and we solicited comments on potentially making such revisions in future rulemaking.

Regarding the suggestion to apply a constrained regression analysis, we do not believe this methodology would be appropriate. We note that a constrained regression analysis of the type the commenter suggested would apply mathematical constraints such that the coefficients for rural status and teaching status would remain at their current levels. A constrained regression analysis would therefore calculate the patient-level and control variables that minimize the sum of squared errors, given the constraints on the rural and teaching coefficients. We agree with the commenter's assertion that a constrained regression analysis would yield different patient-level adjustment factors for FY 2025. As a result, if CMS were to propose revisions to the facility-level adjustment factors in a future year, a constrained regression methodology of the type that the commenter recommended could result in further changes to the patient-level adjustment factors, which would be contrary to the goal of minimizing the impact of revisions in a single year, which CMS articulated in the proposed rule. Rather, in the case of the application of the regression-derived adjustment factors to the IPF PPS, we have controlled for aggregate changes in spending by applying a refinement standardization factor to the IPF PPS Federal per diem base rate. We believe that our proposed regression analysis appropriately incorporates the relevant payment variables and control variables into the regression model and produces results that can be implemented in accordance with our stated goals. We will take the

commenter's methodological suggestions into consideration to potentially inform future changes to the IPF PPS, if appropriate.

Final Decision: After consideration of the comments, we are finalizing our proposed regression methodology as discussed in the proposed rule.

We note that the regression results for this final rule have been updated based on more recent available data, as proposed. Specifically, we note that in reviewing the methodology used to calculate the IPF PPS regression model presented in the proposed rule, we discovered that the computer code incorrectly failed to assign several sleep apnea codes to the proposed Chronic Obstructive Pulmonary Disease and Sleep Apnea comorbidity category. As a result, our regression model underestimated the magnitude of the adjustment factor for this comorbidity category and slightly overestimated the magnitude of the adjustment factor for other independent variables in the model. We note that most of the changes in the adjustment factors in Table 2 are within the threshold of rounding, and therefore do not result in differences to the proposed adjustment factors for payment. We further discuss the impact of these changes to the adjustment factors in section IV.C.4 of this final rule.

This revised final model has an r-squared value of 0.32490, meaning that the independent variables included in the regression model were able to explain approximately 32.5 percent of the variation in per diem cost among IPF stays. We discuss the results of these changes to the final adjustment factors in section IV.C.4 of this final rule, and we discuss the final refinement standardization factor in section IV.F of this final rule.

Table 2 below shows the final calculated adjustment factors and significance level, as well as the number and percent of stays associated with each independent variable. Columns 6 and 7 of Table 2 show the lower and upper bounds of the 95-percent confidence interval (CI). For this final rule, we continue to consider the regression factors to be statistically significant when the p-value was less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***).

BILLING CODE 4120-01-P

Table 2: Final IPF PPS Per Diem Cost Regression Results with Data from CY 2019 through CY 2021

Description	Number of Stays	% of Stays	Adjustment Factors	Significance ¹	CI Lower Bound	CI Upper Bound
Degenerative nervous system disorders w MCC	4,287	0.5%	1.12489	***	1.08938	1.16156
Degenerative nervous system disorders w/out MCC	40,584	5.0%	1.11097	***	1.07794	1.14501
OR procedures with principal diagnosis of mental health	751	0.1%	1.28644	***	1.24458	1.32971
Acute adjustment reaction and psychosocial dysfunction	7,529	0.9%	1.07575	**	1.02333	1.13085
Depressive neuroses	23,566	2.9%	1.06118	***	1.03557	1.08742
Neuroses except depressive	10,143	1.3%	1.02063		0.96702	1.07722
Disorders of personality and impulse control	5,804	0.7%	1.16887	***	1.12856	1.21062
Organic disturbances and intellectual disability	55,842	6.9%	1.08295	***	1.05565	1.11096
Behavioral and developmental disorders	1,582	0.2%	1.07018	***	1.03507	1.10648
Other mental disorder diagnoses	321	0.0%	1.11902		0.92491	1.35388
Alcohol, Drug Abuse or Dependence, Left AMA	3,060	0.4%	0.86120	***	0.81681	0.90800
Alcohol, Drug Abuse or Dependence w rehab therapy	12,361	1.5%	0.89530	***	0.84211	0.95184
Alcohol, Drug Abuse or Dependence w/out rehab therapy w MCC	891	0.1%	1.01859		0.97787	1.06100
Alcohol, Drug Abuse or Dependence w/out rehab therapy w/out MCC	34,767	4.3%	0.94599	**	0.91487	0.97816
Poisoning and toxic effects of drugs w MCC	137	0.0%	1.19038	***	1.12466	1.25995

Description	Number of Stays	% of Stays	Adjustment Factors	Significance ¹	CI Lower Bound	CI Upper Bound
Poisoning and toxic effects of drugs w/out MCC	843	0.1%	1.11541	***	1.08072	1.15122
Signs and Symptoms w MCC	58	0.0%	1.12458	*	1.02823	1.22994
Signs and Symptoms w/out MCC	805	0.1%	1.09079	**	1.02257	1.16356
Age 45 to 54 years	121,498	15.1%	1.01879	***	1.01259	1.02503
Age 55 to 59 years	74,512	9.2%	1.04592	***	1.03588	1.05606
Age 60 to 64 years	68,136	8.4%	1.06370	***	1.05046	1.07711
Age 65 to 69 years	94,473	11.7%	1.08579	***	1.06899	1.10285
Age 70 to 79 years	126,280	15.7%	1.11488	***	1.09114	1.13913
Age over 79 years	87,442	10.8%	1.12706	***	1.09820	1.15668
Acute Renal Failure	19,064	2.4%	1.06069	***	1.03715	1.08476
Artificial Openings - Digestive & Urinary	3,713	0.5%	1.07499	***	1.05586	1.09448
Cardiac conditions	22,152	2.7%	1.04322	***	1.02774	1.05894
Conduct Disorder	5,113	0.6%	0.98279		0.93602	1.03189
Chronic Renal Failure	46,274	5.7%	1.07621	***	1.06277	1.08981
Coagulation Factor Deficit	492	0.1%	1.01240		0.97685	1.04925
Chronic Obstructive Pulmonary Disease	38,159	4.7%	1.08974	***	1.07602	1.10364
Developmental Disabilities	27,020	3.3%	1.01986		0.99450	1.04585
Uncontrolled Diabetes	21,939	2.7%	1.05120	***	1.03307	1.06964
Drug/Alcohol Induced Mental Disorders	59,437	7.4%	0.96118	**	0.93726	0.98571
Eating Disorder	2,812	0.3%	1.09375	***	1.05313	1.13594
Gangrene	223	0.0%	1.11914	***	1.05793	1.18389
Infectious diseases	38,562	4.8%	1.01603	.	0.99984	1.03247
Severe Protein Malnutrition	5,119	0.6%	1.16879	***	1.12359	1.21579
Oncology Treatment	12	0.0%	1.44281	***	1.20615	1.72590
Poisoning	5,966	0.7%	1.16022	***	1.13841	1.18245
Severe Musculoskeletal & Connective Tissue Disease	4,272	0.5%	1.04719	***	1.03039	1.06426
Tracheostomy	304	0.0%	1.09071	***	1.04508	1.13834
Intensive Management for High-Risk Behavior	19,884	2.5%	1.06991	***	1.03016	1.11119

Description	Number of Stays	% of Stays	Adjustment Factors	Significance ¹	CI Lower Bound	CI Upper Bound
ECT Indicator	12,654	1.6%	1.32498	***	1.27045	1.38186
ER Indicator	261,643	32.4%	1.38856	***	1.34548	1.43302
Rural	101,483	12.6%	1.19121	***	1.12331	1.26322
Teaching Status	155,458	19.3%	0.72479	***	0.57528	0.87430
Length of stay - 1 day	16,891	2.1%	1.27513	***	1.24347	1.30760
Length of stay - 2 days	28,370	3.5%	1.20144	***	1.17685	1.22655
Length of stay - 3 days	42,298	5.2%	1.14822	***	1.12761	1.16922
Length of stay - 4 days	48,187	6.0%	1.11626	***	1.09942	1.13336
Length of stay - 5 days	54,187	6.7%	1.08310	***	1.06794	1.09848
Length of stay - 6 days	59,215	7.3%	1.06029	***	1.04785	1.07288
Length of stay - 7 days	63,095	7.8%	1.02618	***	1.01510	1.03738
Length of stay - 8 days	51,491	6.4%	1.01666	***	1.00752	1.02589
Length of stay - 9 days	42,855	5.3%	1.00898	**	1.00215	1.01585
Length of stay - 11 days	35,092	4.4%	0.99518		0.98910	1.00130
Length of stay - 12 days	32,030	4.0%	0.99597		0.98951	1.00247
Length of stay - 13 days	32,356	4.0%	0.99852		0.98922	1.00792
Length of stay - 14 days	34,727	4.3%	0.99927		0.98427	1.01450
Length of stay - 15 days	24,919	3.1%	0.98916		0.97534	1.00318
Length of stay - 16 days	18,907	2.3%	0.98809		0.97394	1.00245
Length of stay - 17 days	16,128	2.0%	0.98984		0.97630	1.00356
Length of stay - 18 days	14,191	1.8%	0.98595	.	0.97172	1.00038
Length of stay - 19 days	13,085	1.6%	0.98825		0.97235	1.00441
Length of stay - 20 days	13,302	1.6%	0.98485	.	0.96832	1.00166
Length of stay - 21 days	12,628	1.6%	0.98519		0.96410	1.00673
Length of stay - greater or equal to 22 days	113,912	14.1%	0.98809		0.96064	1.01633
CY2019 Stay	330,574	41.0%	0.89868	***	0.88769	0.90982
CY2020 Stay	259,052	32.1%	0.94940	***	0.94054	0.95835

¹ Statistical significance based on p-value less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***)

4. Updates and Revisions to the IPF PPS Patient-Level Adjustments

The IPF PPS includes payment adjustments for the following patient-level characteristics: Medicare Severity Diagnosis Related Groups (MS-DRGs) assignment of the patient's principal diagnosis, selected comorbidities, patient age, and the variable per diem adjustments. We proposed to derive updated IPF PPS adjustment factors for FY 2025 using a regression analysis of data from the CY 2019 through 2021 MedPAR data files and Medicare cost report data from the 2018 through FY 2021 Hospital Cost Report Information System (HCRIS). In the proposed rule, however, we noted that we used more recent claims (specifically, the December 2023 update of the FY 2023 IPF PPS MedPAR claims) and cost data from the January 2024 update of the provider-specific file (PSF) to simulate payments to finalize the outlier fixed dollar loss threshold amount and to assess the impact of the IPF PPS updates. More information about the data used for the impact simulations is found in section VIII.C of this FY 2025 IPF PPS final rule. We explained that by adjusting for DRGs, comorbidities, age, and length of the stay, along with the facility-level variables and control variables in the model, we were able to explain approximately 32.3 percent of the variation in per diem cost among IPF stays.

In addition, we proposed routine coding updates for FY 2025 for our longstanding code first and IPF PPS comorbidities. Furthermore, as discussed in section IV.C.4.a.(2) of this final rule, we proposed to adopt a sub-regulatory process for future routine coding updates.

a. Updates and Revisions to MS-DRG Assignment

(1) Background

We believe it is important to maintain for IPFs the same diagnostic coding and DRG classification used under the IPPS for providing psychiatric care. For this reason, when the IPF PPS was implemented for cost reporting periods beginning on or after January 1, 2005, we adopted the same diagnostic code set (ICD-9-CM) and DRG patient classification system (MS-DRGs) that were utilized at the time under the IPPS. In the RY 2009 IPF PPS notice (73 FR 25709), we discussed CMS's effort to better recognize resource use and the severity of illness among patients. CMS adopted the new MS-DRGs for the IPPS in the FY 2008 IPPS final rule with comment period (72 FR 47130). In the RY 2009 IPF PPS notice (73 FR 25716),

we provided a crosswalk to reflect changes that were made under the IPF PPS to adopt the new MS-DRGs. For a detailed description of the mapping changes from the original DRG adjustment categories to the current MS-DRG adjustment categories, we refer readers to the RY 2009 IPF PPS notice (73 FR 25714).

The IPF PPS includes payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient's principal diagnosis. The DRG adjustment factors were expressed relative to the most frequently reported psychiatric DRG in FY 2002, that is, DRG 430 (psychoses). The coefficient values and adjustment factors were derived from the regression analysis discussed in detail in the RY 2004 IPF proposed rule (68 FR 66923; 66928 through 66933) and the RY 2005 IPF final rule (69 FR 66933 through 66960). Mapping the DRGs to the MS-DRGs resulted in the current 17 IPF MS-DRGs, instead of the original 15 DRGs, for which the IPF PPS provides an adjustment.

In the FY 2015 IPF PPS final rule which appeared in the August 6, 2014 **Federal Register** titled, "Inpatient Psychiatric Facilities Prospective Payment System—Update for FY Beginning October 1, 2014 (FY 2015)" (79 FR 45945 through 45947), we finalized conversions of the ICD-9-CM-based MS-DRGs to ICD-10-CM/PCS-based MS-DRGs, which were implemented on October 1, 2015. Further information on the ICD-10-CM/PCS MS-DRG conversion project can be found on the CMS ICD-10-CM website at <https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-ms-drg-conversion-project>.

(2) Adoption of Sub-Regulatory Process for Publication of Coding Changes

As discussed in the FY 2015 IPF PPS proposed rule (79 FR 26047) every year, changes to the ICD-10-CM and the ICD-10-PCS coding system have been addressed in the IPPS proposed and final rules. The changes to the codes are effective October 1 of each year and must be used by acute care hospitals as well as other providers to report diagnostic and procedure information. In accordance with § 412.428(e), we have historically described in the IPF PPS proposed and final rules the ICD-10-CM coding changes and DRG classification changes that have been discussed in the annual proposed and final hospital IPPS regulations. This has typically involved a discussion in the proposed rule about coding updates to be effective October 1 of each year, with a summary of comments in the final rule

along with a description of additional finalized codes for October.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date for ICD-10-CM diagnosis and ICD-10-PCS procedure code updates in addition to the annual October 1 update of ICD-10-CM diagnosis and ICD-10-PCS procedure codes, beginning with April 1, 2022. In that rule, we noted the intent of this April 1 implementation date is to allow flexibility in the ICD-10 code update process. Currently, as noted earlier in this final rule, the IPF PPS uses the IPPS DRG assignments, which are applied to IPF PPS claims; these DRG assignments reflect the change in process that the IPPS adopted for FY 2022. To maintain consistency with IPPS policy, we proposed to follow the same process beginning in FY 2025. This means that for routine coding updates that incorporate new or revised codes, we proposed to adopt these changes through a sub-regulatory process. Beginning in FY 2025, we will operationalize such coding changes in a Transmittal/Change Request, which would align with the way coding changes are announced under the IPPS.

For example, we proposed that for April 2025, we would adopt routine coding updates for the IPF PPS comorbidity categories, code first policy, ECT code list, and DRG assignment via sub-regulatory guidance. We stated that these coding updates would take effect April 1, 2025. We explained that in accordance with § 412.428(e), we would describe these coding changes, along with any coding updates that would be effective for October 1, 2025, in the FY 2026 IPF PPS proposed rule. We noted we would summarize and respond to any comments on these April and October coding changes in the FY 2026 IPF PPS final rule.

We further stated that this proposed update aims to allow flexibility in the ICD-10 code update process for the IPF PPS and reduce the lead time for making routine coding updates to the IPF PPS code first list, comorbidities, and ECT coding categories. In addition, we noted that the IPPS sub-regulatory process continues to manage DRG assignment changes which apply to the DRG assignments used in the IPF PPS. Finally, we clarified that we only anticipate applying this sub-regulatory process for routine coding updates. Any future substantive revisions to the IPF PPS DRG adjustments, comorbidities, code first policy, or ECT payment policy would be proposed through notice and comment rulemaking. We solicited public comments on this proposed rule.

We did not receive any comments on our proposal to adopt routine coding updates that incorporate new or revised codes through a sub-regulatory process. We are finalizing the use of a sub-regulatory process, as proposed.

(3) Routine Coding Updates for DRG Assignments

The diagnoses for each IPF MS-DRG will be updated as of October 1, 2024, using the final IPPS FY 2025 ICD-10-CM/PCS code sets. The FY 2025 IPPS/LTCH PPS final rule will include tables of the changes to the ICD-10-CM/PCS code sets that underlie the proposed FY 2025 IPF MS-DRGs. Both the FY 2025 IPPS final rule and the tables of final changes to the ICD-10-CM/PCS code sets, which underlie the FY 2025 MS-DRGs, will be available on the CMS IPPS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps>.

(4) Code First

As discussed in the ICD-10-CM Official Guidelines for Coding and Reporting, certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions, the ICD-10-CM has a coding convention that requires the underlying condition be sequenced first, followed by the manifestation. Wherever such a combination exists, there is a “use additional code” note at the etiology code, and a “code first” note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes (etiology followed by manifestation). In accordance with the ICD-10-CM Official Guidelines for Coding and Reporting, when a primary (psychiatric) diagnosis code has a code first note, the provider will follow the instructions in the ICD-10-CM Tabular List. The submitted claim goes through the CMS processing system, which will identify the principal diagnosis code as non-psychiatric and search the secondary codes for a psychiatric code to assign a DRG code for adjustment. The system will continue to search the secondary codes for those that are appropriate for comorbidity adjustment. For more information on the code first policy, we refer readers to the RY 2005 IPF PPS final rule (69 FR 66945). We also refer readers to sections I.A.13 and I.B.7 of the FY 2020 ICD-10-CM Coding Guidelines, which is available at https://www.cdc.gov/nchs/data/icd/10cmguidelinesFY2020_final.pdf. In the FY 2015 IPF PPS final rule, we provided a code first table for reference that highlights the same or similar

manifestation codes where the code first instructions apply in ICD-10-CM that were present in ICD-10-CM (79 FR 46009). In FY 2018, FY 2019, and FY 2020, there were no changes to the final ICD-10-CM codes in the IPF Code First table. For FY 2021 and FY 2022, there were 18 ICD-10-CM codes deleted from the final IPF Code First table. For FY 2023, there were 2 ICD-10-CM codes deleted and 48 ICD-10-CM codes added to the IPF Code First table. For FY 2024, there were no proposed changes to the Code First Table.

We proposed to continue our existing code first policy. We did not receive any comments on our proposal to continue the existing code-first policy, and we are finalizing the policy as proposed. As discussed in section IV.C.4.a.(2) of this final rule, we are also finalizing our proposal to adopt a sub-regulatory approach to handle the coding updates, which will remove the requirement to discuss coding updates in the **Federal Register** during regulatory updates prior to implementation and which will mirror the approach taken by the IPPS. The final FY 2025 Code First table is shown in Addendum B on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

(5) Revisions to MS-DRG Adjustment Factors

For FY 2025, we proposed to revise the payment adjustments for designated psychiatric DRGs assigned to the claim based on the patient’s principal diagnosis, following our longstanding policy of using the ICD-10-CM/PCS-based MS-DRG system. As discussed in the following paragraphs, we proposed to maintain DRG adjustments for 15 of the existing 17 IPF MS-DRGs for which we currently adjust payment in FY 2024. We proposed to replace two existing DRGs with two new DRGs to reflect changes in coding practices over time and proposing to add two DRGs that are associated with poisoning. We also proposed to revise the adjustment factors for the DRG adjustments based on the results of the regression analysis described in the proposed rule. In accordance with our longstanding policy, we proposed that psychiatric principal diagnoses that do not group to one of the 19 proposed designated MS-DRGs would still receive the Federal per diem base rate and all other applicable adjustments; however, the payment would not include an MS-DRG adjustment.

We proposed to implement all of these revisions to the DRG adjustments budget-neutrally, and we provided a

detailed discussion of the distributional impacts of these proposed changes. Lastly, we proposed that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 DRG adjustment factors.

(a) Replacement of DRGs

We proposed to remove DRGs 080 (Nontraumatic stupor & coma w MCC) and 081 (Nontraumatic stupor & coma w/o MCC), and to replace these with DRGs 947 (Signs and Symptoms w MCC) and 948 (Signs and Symptoms w/out MCC). As previously discussed, we observed that the number of cases in DRGs 080 and 081 have decreased significantly since 2004. We explained that we selected DRGs 947 and 948 as the most clinically appropriate replacements, because most of the ICD-10-CM codes that previously grouped to DRGs 080 or 081 now group to DRGs 947 or 948. We explained that the proposed adjustment factors for DRGs 947 and 948 would each be greater than the current DRG adjustment for DRGs 080 and 081. Therefore, we proposed that claims with DRGs 080 or 081 would still receive the Federal per diem base rate and all other applicable adjustments; however, the payment would not include an MS-DRG adjustment.

(b) Additions of DRGs

We proposed to recognize DRG adjustments for two DRGs associated with poisoning; specifically, DRGs 917 (Poisoning and toxic effects of drugs w MCC) and 918 (Poisoning and toxic effects of drugs w/out MCC). As we discussed in the proposed rule, we identified that a small but increasing number of IPF stays contain these poisoning-related DRG assignments, and that stays with these DRGs have increased costs per day that are statistically significant.

(c) Revisions to Adjustment Factors for Existing DRG Adjustments

We proposed to revise the adjustment factors for the remaining 15 of the existing 17 DRGs that currently receive a DRG adjustment in FY 2024. We stated that these revisions were based on the results of our latest regression analysis described in section IV.C.3 of the proposed rule.

We also stated that our analysis found that some of the adjustment factors in the regression model for DRGs that currently receive an adjustment are no longer statistically significant. Specifically, we found that the adjustment factors for DRG 882 (Neuroses except depressive), DRG 887 (Other mental disorder diagnoses), and

DRG 896 (Alcohol, Drug Abuse or Dependence w/out rehab therapy w MCC) were not statistically significant. We explained that for each of these DRGs, we examined whether the current adjustment factor falls within the confidence interval for our latest regression analysis. We stated that the current adjustment for DRG 882 is 1.02, and this falls within the confidence interval of 0.96798 to 1.07811 for the regression model discussed in the proposed rule. We stated that we believe it would be appropriate to maintain the current adjustment factor of 1.02 for DRG 882 because the latest regression results indicate that the current adjustment factor would be a reasonable approximation of the increased costs associated with DRG 882. However, we stated that for DRGs 887 and 896, the current adjustment factors (0.92 and 0.88, respectively) did not fall within the confidence interval for each of these DRGs. Therefore, we proposed to apply an adjustment factor of 1.00 for IPF stays with these DRGs.

(d) Summary of Comments on the Proposed MS-DRG Updates for FY 2025

We received comments regarding the proposed changes to the MS-DRG adjustments, which are summarized in the following paragraphs.

Comment: Several commenters expressed support for revising the DRG adjustments as proposed; however, a number of these commenters urged CMS to consider developing separate adjustment factors for IPF stays that are currently all grouped into DRG 885. Specifically, commenters expressed concern that a single DRG that accounts for 74.79% of stays does not appropriately capture differences in patient resource utilization between patients being treated for Bipolar Disorders and Schizophrenias (ICD 20–F31 diagnoses) and those patients being treated for Depressive Disorders and Unspecified Mood disorders (ICD F32–F39 diagnoses).

Response: We appreciate the support that commenters expressed for the proposed DRG revisions. Likewise, we appreciate concerns that commenters raised regarding subcategories of conditions within DRG 885. We agree with commenters about the importance of adjusting IPF PPS payment to recognize differences in resource utilization between patients with different conditions. However, contrary to the commenters’ suggestion, our analysis does not find that there are statistically significant differences in resources costs or cost per day when we

compare different groups of principal diagnoses within DRG 885.

Using the same regression model described in section IV.C.3 of this final rule, we added the following categorical variables:

- Bipolar Disorders and Schizophrenia—Stays with principal diagnosis in the ICD–10–CM code family of F20, F21, F22, F23, F24, F25, F26, F27, F28, F29, F30, or F31
- Depression and Mood Disorders—Stays with principal diagnosis in the ICD–10–CM code family of F32, F33, or F39; or with principal diagnosis of F349 or F3489.
- Other—All other DRG 885 stays.

For this analysis, we applied Bipolar Disorders and Schizophrenia as the reference group; therefore, there is no adjustment factor assigned in Table 3. The adjustment factors for other categories can be interpreted as the cost per day relative to the reference category. Table 3 also presents the significance level and confidence interval for each factor. We note that none of these factors is considered significant because the p-value was not less than or equal to the significance level of 0.05 (*), 0.01 (**), and 0.001 (***) for any of these factors.

Table 3: Analysis of Adjustment Factors for IPF Stays within DRG 885 Subcategories

Description	# of Stays CY 2019– CY 2021	% of Stays CY 2019– CY 2021	Adjustment Factors	Significance	CI Lower Bound	CI Upper Bound
Bipolar Disorders and Schizophrenia	438,269	54.33%	N/A	N/A	N/A	N/A
Depression and Mood Disorders	164,660	20.41%	0.99222		0.97308	1.01173
Other	351	0.04%	1.04685		0.96538	1.13520

Lastly, we acknowledge that even though there may be differences in total cost or differences in cost per day for treating patients with these conditions, other adjustment factors in the IPF PPS, such as the age adjustment or the variable per diem adjustment may

account for these differences in cost for such patients.
Final Decision: After consideration of the comments received, we are finalizing our proposal to revise the DRG adjustments based on the latest regression analysis. A detailed discussion of the distributional impacts

of this proposed change is found in section VIII.C of this final rule. Tables 4 through 6 summarize the final DRG changes based on the final regression analysis discussed in section IV.C.3.e of this FY 2025 IPF PPS final rule.

Table 4: Replacements for DRG Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Final Adjustment Factors
DRG 080- Nontraumatic stupor & coma w MCC	1.07	1	0.00%	N/A
DRG 081-Nontraumatic stupor & coma w/o MCC	1.07	1	0.00%	N/A
DRG 947-Signs and Symptoms w MCC	N/A	58	0.01%	1.12
DRG 948-Signs and Symptoms w/out MCC	N/A	805	0.10%	1.09

Table 5: Additions for DRG Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Final Adjustment Factors
DRG 917-Poisoning and toxic effects of drugs w MCC	N/A	137	0.02%	1.19
DRG 918-Poisoning and toxic effects of drugs w/out MCC	N/A	843	0.10%	1.12

Table 6: Updates to Existing DRG Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Final Adjustment Factors
DRG 056-Degenerative nervous system disorders w MCC	1.05	4,287	0.53%	1.12
DRG 057-Degenerative nervous system disorders w/out MCC	1.05	40,584	5.03%	1.11
DRG 876-OR procedure with principal diagnoses of mental illness	1.22	751	0.09%	1.29
DRG 880-Acute adjustment reaction and psychosocial dysfunction	1.05	7,529	0.93%	1.08
DRG 881-Depressive neuroses	0.99	23,566	2.92%	1.06
DRG 882-Neuroses except depressive	1.02	10,143	1.26%	1.02
DRG 883-Disorders of personality and impulse control	1.02	5,804	0.72%	1.17
DRG 884-Organic disturbances and intellectual disabilities	1.03	55,842	6.92%	1.08
DRG 885-Psychoses	1.00	603,280	74.79%	1.00
DRG 886-Behavioral and developmental disorders	0.99	1,582	0.20%	1.07
DRG 887-Other mental disorder diagnoses	0.92	321	0.04%	1.00
DRG 894-Alcohol, Drug Abuse or Dependence, Left AMA	0.97	3,060	0.38%	0.86
DRG 895-Alcohol, Drug Abuse or Dependence w rehab therapy	1.02	12,361	1.53%	0.90
DRG 896-Alcohol, Drug Abuse or Dependence w/out rehab therapy w MCC	0.88	891	0.11%	1.00
DRG 897-Alcohol, Drug Abuse or Dependence w/out rehab therapy w/out MCC	0.88	34,767	4.31%	0.95

BILLING CODE 4120-01-C

These changes to the DRG adjustments will be included in Addendum A, which is available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets>. The website includes the final DRG adjustment factors for FY 2025.

b. Payment for Comorbid Conditions**(1) Revisions to Comorbidity Adjustments**

The intent of the comorbidity adjustments is to recognize the increased costs associated with active comorbid conditions by providing additional payments for certain existing medical or psychiatric conditions that are expensive to treat.

Comorbidities are specific patient conditions that are secondary to the patient's principal diagnosis and that require active treatment during the stay. Diagnoses that relate to an earlier episode of care and have no bearing on the current hospital stay are excluded and must not be reported on IPF claims. Comorbid conditions must exist at the time of admission or develop subsequently, and affect the treatment received, LOS, or both treatment and LOS.

The current comorbidity adjustments were determined based on the regression analysis using the diagnoses reported by IPFs in FY 2002. The principal diagnoses were used to establish the DRG adjustments and were not accounted for in establishing the comorbidity category adjustments,

except where ICD-9-CM code first instructions applied. In a code first situation, the submitted claim goes through the CMS processing system, which identifies the principal diagnosis code as non-psychiatric and searches the secondary codes for a psychiatric code to assign an MS-DRG code for adjustment. The system continues to search the secondary codes for those that are appropriate for a comorbidity adjustment.

In our RY 2012 IPF PPS final rule (76 FR 26451 through 26452), we explained that the IPF PPS includes 17 comorbidity categories and identified the new, revised, and deleted ICD-9-CM diagnosis codes that generate a comorbid condition payment adjustment under the IPF PPS for RY 2012 (76 FR 26451).

As discussed in section IV.C.4.a.(1) of this final rule, it is our policy to maintain the same diagnostic coding set for IPFs that is used under the IPPS for providing the same psychiatric care. The 17 comorbidity categories formerly defined using ICD-9-CM codes were converted to ICD-10-CM/PCS in our FY 2015 IPF PPS final rule (79 FR 45947 through 45955). The goal for converting the comorbidity categories is referred to as replication, meaning that the payment adjustment for a given patient encounter is the same after ICD-10-CM implementation as it would be if the same record had been coded in ICD-9-CM and submitted prior to ICD-10-CM/PCS implementation on October 1, 2015. All conversion efforts were made with the intent of achieving this goal.

For each claim, an IPF may receive only one comorbidity adjustment within a comorbidity category, but it may receive an adjustment for more than one comorbidity category. Current billing instructions for discharge claims, on or after October 1, 2015, require IPFs to enter the complete ICD-10-CM codes for up to 24 additional diagnoses if they co-exist at the time of admission, or develop subsequently and impact the treatment provided.

As previously discussed in section IV.C.4.a.(2) of this final rule, we proposed to adopt an April 1 implementation date for ICD-10-CM diagnosis and ICD-10-PCS procedure code updates, in addition to the annual October 1 update, beginning with April 1, 2025 for the IPF PPS. For FY 2025 and future years, coding updates related to the IPF PPS comorbidity categories would be adopted following a sub-regulatory process as discussed earlier in this final rule.

For FY 2025, we proposed to revise the comorbidity adjustment factors based on the results of the 2019 through 2021 regression analysis described in section IV.C.3.e. of this final rule. We proposed additions and changes to the comorbidity categories for which we adjust payment based on our analysis of ICD-10-CM codes currently included in each category as well as public comments received in response to the FY 2022 and FY 2023 IPF PPS proposed rules.

Based on analysis of the ICD-10-CM codes, we considered the statistical significance of the adjustment factor and whether the current (FY 2024) adjustment factor fell within the confidence interval in the 2019 through

2021 regression to determine the FY 2025 IPF PPS proposed comorbidity categories and adjustment factors. As previously discussed for the DRG adjustment factors, when the regression factor is not statistically significant, but the current adjustment factor is within the confidence interval, we proposed to maintain the current adjustment factor. When a regression factor is not statistically significant and the current adjustment factor is not within the confidence interval, we proposed to remove the comorbidity category.

Specifically, we proposed to increase the adjustment factors for the Gangrene, Severe Protein Malnutrition, Oncology Treatment, Poisoning, and Tracheostomy comorbidity categories based on the adjustment factors derived from the regression analysis discussed in section IV.C.3 of this final rule. For these comorbidity categories, the regression results produced a statistically significant increase in the adjustment factors.

We did not receive any comments on our proposal to increase the adjustment factors for the Gangrene, Severe Protein Malnutrition, Oncology Treatment, Poisoning, and Tracheostomy comorbidity categories. We are finalizing the increased the adjustment factors for these comorbidity categories as proposed.

We proposed to remove the comorbidity categories for the Coagulation Factor Deficit, Drug/Alcohol Induced Mental Disorders, and Infectious Diseases adjustment factors because the regression factor for the ICD-10-CM codes associated with Coagulation Factor Deficit and Infectious Diseases were not statistically significant, and the current adjustment factors did not fall within the confidence intervals in the 2019 through 2021 regression.

The current adjustment factor for Drug/Alcohol Induced Mental Disorders is 1.03; however, the adjustment factor derived from our latest regression results was statistically significant at 0.96084, meaning payments would be reduced if we applied the regression-derived adjustment factor as a comorbidity adjustment for this category. To understand the drivers of changing costs for the Drug/Alcohol Induced Mental Disorders comorbidity category, we examined a subset of ICD-10-CM codes within the comorbidity category associated with opioid disorders which make up the majority of

stays that qualify for the current Drug/Alcohol Induced Mental Disorders comorbidity adjustment. These opioid disorder codes are listed in Table 7. When we separately analyzed these codes associated with opioid disorder, the results suggested that patients with opioid disorder are significantly less expensive than patients without opioid disorder. Because stays with opioid disorders make up the majority of stays in the Drug/Alcohol Induced Mental Disorders comorbidity category, we observe a statistically significant negative adjustment factor for the comorbidity category overall. The application of a comorbidity adjustment derived from our latest regression analysis would result in reduced payments for all stays in this comorbidity category. We do not believe it is appropriate to apply negative adjustment factors (that is, adjustment factors less than 1.00) for comorbidities because that would result in reduced rather than increased payments. Although we apply adjustment factors less than 1.00 for DRGs, this is because the DRG adjustment reflects the cost of stays relative to stays with the baseline DRG 885. In contrast, comorbidity adjustments reflect the cost relative to a stay with no comorbidities. A negative payment adjustment would not be consistent with the intent of a comorbidity adjustment, which is intended to provide additional payments to providers to account for the costs of treating patients with comorbid conditions. Therefore, we have not historically included any negative adjustment factors for comorbid conditions.

Therefore, we proposed to remove the Drug/Alcohol Induced Mental Disorders comorbidity category beginning in FY 2025. IPF stays that include these codes as a non-principal diagnosis would no longer receive the current Drug/Alcohol Induced Mental Disorders comorbidity category adjustment factor of 1.03; nor would they receive a reduction in payment. However, many IPF stays that include these ICD-10-CM diagnosis codes as a principal diagnosis would continue to receive a DRG adjustment. We refer readers to section IV.C.3.a of this final rule for a detailed discussion of proposed DRG adjustments under the IPF PPS.

BILLING CODE 4120-01-P

Table 7: ICD–10–CM Codes for Opioid Disorder

ICD–10–CM Code	Description
F1123	Opioid dependence with withdrawal
F1120	Opioid dependence, uncomplicated
F1124	Opioid dependence with opioid-induced mood disorder
F11259	Opioid dependence w opioid-induced psychotic disorder, unsp
F11229	Opioid dependence with intoxication, unspecified
F1193	Opioid use, unspecified with withdrawal
F11251	Opioid depend w opioid-induc psychotic disorder w hallucin
F11250	Opioid depend w opioid-induc psychotic disorder w delusions
F1129	Opioid dependence with unspecified opioid-induced disorder
F11288	Opioid dependence with other opioid-induced disorder
F11220	Opioid dependence with intoxication, uncomplicated
F11282	Opioid dependence with opioid-induced sleep disorder
F11921	Opioid use, unspecified with intoxication delirium
F11221	Opioid dependence with intoxication delirium
F11951	Opioid use, unsp w opioid-induc psych disorder w hallucin
F1114	Opioid abuse with opioid-induced mood disorder
F1194	Opioid use, unspecified with opioid-induced mood disorder
F11151	Opioid abuse w opioid-induced psychotic disorder w hallucin
F1113	Opioid abuse with withdrawal
F1110	Opioid abuse, uncomplicated
F1199	Opioid use, unsp with unspecified opioid-induced disorder
F11929	Opioid use, unspecified with intoxication, unspecified
F11922	Opioid use, unsp w intoxication with perceptual disturbance

BILLING CODE 4120–01–C

We believe removal of the Drug/Alcohol Induced Mental Disorders comorbidity category under the IPF PPS more appropriately aligns payment with resource use, as reflected in the latest regression results. As previously discussed in section IV.F of this final rule, all of these proposed revisions would be applied budget-neutrally. Therefore, we believe the removal of the Drug/Alcohol Induced Mental Disorders comorbidity adjustment would appropriately increase the IPF PPS Federal per diem base rate and thereby increase payment for IPF stays that are costlier. However, we solicited comments on whether a lack of ancillary charge data may be contributing to the results of our regression analysis as it relates to opioid disorders. We note that our analysis of the ICD–10–CM codes associated with opioid disorder also indicates that there is significant overlap between facility characteristics and stays including opioid disorder diagnoses. In particular, for-profit

freestanding IPFs were found to serve the majority of patients with opioid disorders. As discussed in section IV.E.4 of this final rule, our ongoing analysis has found an increase in the number of for-profit freestanding IPFs that are consistently reporting no ancillary charges or very minimal ancillary charges on their cost report. As a result, we noted that these IPFs do not report complete information on patient-level cost for the patients treated in these hospitals.

As stated previously, the regression factor for Drug/Alcohol Induced Mental Disorders was statistically significant, but is less than 1, meaning payments would be reduced if we applied it as a comorbidity adjustment. We stated that we were interested in understanding whether there is data and information that could better inform our understanding of the costs of treating these conditions. In addition, we stated that we were interested in understanding whether commenters

believe it may be more appropriate to maintain the existing Drug/Alcohol Induced Mental Disorders comorbidity category adjustment factor of 1.03, given that many providers that treat these patients also report minimal or no ancillary charges on their claims and cost reports. We noted that if we were to maintain the adjustment factor of 1.03 for these IPF stays, we expected it would have a negative impact on the refinement standardization factor, thereby slightly reducing the IPF PPS Federal per diem base rate and ECT per treatment amount.

Comment: Two commenters opposed the proposed removal of the Coagulation Factor Deficit and Infectious Disease comorbidity categories, stating that these comorbidities do result in increased resource use. Commenters explained that when patients test positive for infectious diseases after admission, the facility cannot discharge the patient due to the infectious disease. The commenters noted additional

resources are needed in these cases not only to treat the infected patient, but to prevent the spread of the infection to the rest of the patient population.

Response: We thank commenters for their feedback. However, the results of our regression analysis do not support a payment adjustment for coagulation factor deficit or infectious disease. As shown in Table 2, the adjustment factor derived from the regression is not statistically significant. This suggests that the cost of treating IPF patients with these conditions is not significantly different than treating IPF patients without these conditions. Therefore, removing these comorbidity categories more appropriately aligns payment with resource use.

Comment: A few commenters opposed the proposed removal of the Drug/Alcohol Induced Mental Disorders comorbidity category. The commenters stated that patients with drug- and alcohol-induced mental conditions are more complex to care for and therefore often require increased levels of care and medical management. One commenter expressed concern in regard to the proposed removal of the Drug/Alcohol Induced Mental Disorders comorbidity category, considering the prevalence of substance use disorders in society. Additionally, commenters expressed concern with CMS correlating a lack of ancillary cost data with lower cost associated with treating IPF patients with drug- and alcohol-induced mental disorders.

Response: We understand the commenters' concern for the overall prevalence of substance abuse disorders, and how patients with substance use disorder may require increased levels of care. As shown in Table 2, the adjustment factor derived from the regression is statistically significant, but is less than 1. This suggests that the cost of treating IPF patients with these conditions is lower than treating patients without these conditions, and therefore, removing this comorbidity category more appropriately aligns payment with resource use.

Additionally, we did not receive any public comments regarding data and information that could better inform our understanding of the costs of treating these conditions. We believe the best available data was used in the regression. We anticipate that CMS will gain additional cost information on the treatment of IPF patients with substance abuse disorders and we intend to analyze such data for consideration in future refinements of the IPF PPS.

Final Decision: After consideration of the comments received, we are finalizing our proposal for FY 2025 to

remove the Coagulation Factor Deficit, Infectious Disease, and Drug/Alcohol Induced Mental Disorders comorbidity categories. We note that we will continue to collect data on these comorbidity categories for consideration in future refinements of the IPF PPS. We encourage providers to report complete cost information for future analyses.

We also proposed to modify the Eating and Conduct Disorders comorbidity category and redesignate it as the Eating Disorders comorbidity category. That is, we proposed to remove conduct disorders from the codes eligible for a comorbidity adjustment. When we separately analyzed the ICD-10-CM codes for eating disorders (specifically, *F5000 Anorexia nervosa, unspecified*, *F5001 Anorexia nervosa, restricting type*, *F5002 Anorexia nervosa, binge eating/purging type*, and *F509 Eating disorder, unspecified*) and conduct disorders (*F631 Pyromania*, *F6381 Intermittent explosive disorder*, and *F911 Conduct disorder, childhood-onset type*), our regression results identified a positive, statistically significant adjustment factor associated with eating disorders. In contrast, conduct disorders had a negative and non-significant factor. These results suggest that eating disorders are associated with an increased level of resource, unlike conduct disorders, and that only eating disorders have an increase resource use at a level that is statistically significant. Based on these findings, we proposed to remove conduct disorders from the proposed newly designated Eating Disorders comorbidity category.

We did not receive any comments on our proposal to remove conduct disorders from the current Eating and Conduct Disorders comorbidity category. We are finalizing the newly designated Eating Disorders comorbidity category as proposed.

In addition, we proposed to modify the Chronic Obstructive Pulmonary Disease comorbidity category to include ICD-10-CM and ICD-10-PCS codes associated with sleep apnea (specifically, *G4733 Obstructive sleep apnea (adult) (pediatric)*, *5A09357 Assistance with Respiratory Ventilation, <24 Hrs, CPAP*, *Z9981 Dependence on supplemental oxygen*, and *Z9989 Dependence on other enabling machines and devices*). In response to the FY 2023 and FY 2024 IPF PPS proposed rules, commenters requested that CMS analyze the additional cost associated with patients with sleep apnea. Patients with sleep apnea often need to use a continuous positive airway pressure (CPAP) machine with a cord to manage their condition. Based

on the clinical expertise of CMS Medical Officers, we determined that patients with sleep apnea in the IPF setting would have increased ligature risk (that is, anything that could be used to attach a cord, rope, or other material for the purpose of hanging or strangulation), similar to the risk associated with patients in the IPF setting that have chronic obstructive pulmonary disease. We stated that we expect the additional staffing resources involved in treating IPF patients with sleep apnea would be similar to the resources involved in treating IPF patients with chronic obstructive pulmonary disease, as patients with chronic obstructive pulmonary disease may also require the presence of an additional device with a cord in the patient's room, such as a bilevel positive airway pressure (BiPAP) machine. We evaluated adding codes associated with sleep apnea to our regression model, on the basis of our expectation that we would observe higher costs associated with these codes that would be comparable to the costs associated with chronic obstructive pulmonary disease. The results of our 2019 through 2021 regression model suggest that sleep apnea is in fact associated with an increased level of resource use. Therefore, we proposed to redesignate the Chronic Obstructive Pulmonary Disease category as the Chronic Obstructive Pulmonary Disease and Sleep Apnea comorbidity category.

Comment: One commenter supported redesignating the Chronic Obstructive Pulmonary Disease category as the Chronic Obstructive Pulmonary Disease and Sleep Apnea comorbidity category. The commenter noted that patients using a CPAP machine require increased care and medical management due to the need for 1:1 staffing to prevent ligature issues.

Response: We appreciate the commenter's support for adding codes associated with sleep apnea to the Chronic Obstructive Pulmonary Disease comorbidity category. As discussed in section IV.C.4.b.(1), when including sleep apnea codes to the Chronic Pulmonary Disease comorbidity category, the adjustment factor was higher than the number published in the proposed rule. This further supports the commenters' assertion that the resource use for treating sleep apnea is higher than for patients without sleep apnea.

Final Decision: After consideration of the comment received, we are finalizing our proposal for FY 2025 to redesignate the Chronic Obstructive Pulmonary Disease category as the Chronic Obstructive Pulmonary Disease and Sleep Apnea comorbidity category.

Further, we analyzed costs associated with the ICD–10–CM codes in Table 8 that indicate high-risk behavior. In response to the FY 2023 and FY 2024 IPF PPS proposed rules, commenters requested that CMS analyze the additional cost associated with patients exhibiting violent behavior during their stay in an IPF. We considered these comments in coordination with CMS Medical Officers, and determined that patients exhibiting violent behavior would require more intensive management during an IPF stay. We determined that certain ICD–10–CM codes could describe the types of high-risk behaviors that require intensive management during an IPF stay. These could include patients exhibiting violent behavior as well as other high-risk, non-violent behaviors. We examined ICD–10–CM codes in the R45 code family (Symptoms and Signs Related to Emotional State) that could indicate high-risk behavior during an IPF stay, which would lead to increased

resource use. The regression analysis found that several codes, *R451 Restlessness and agitation*, *R454 Irritability and anger*, and *R4584 Anhedonia* codes are associated with a statistically significant adjustment factor. In other words, patients presenting with restlessness and agitation, irritability and anger, or anhedonia are more costly than patients who do not present these conditions. Therefore, we proposed to add a new comorbidity category recognizing the costs associated with Intensive Management for High-Risk Behavior.
Comment: Two commenters supported the proposed addition of a new comorbidity category recognizing the costs associated with Intensive Management for High-Risk Behavior. One commenter recommended that CMS include codes for *R456 Violent Behavior*, *R4585 Homicidal and suicidal ideations*, *R45850 Homicidal ideation*, and *R45851 Suicidal ideation* into the proposed Intensive Management for

High-Risk Behavior comorbidity category.
Response: We appreciate the commenters' support regarding adding a new comorbidity category recognizing the costs associated with Intensive Management for High-Risk Behavior. As discussed in the proposed rule, we analyzed costs associated with the ICD–10–CM codes including *R456 Violent Behavior*, *R4585 Homicidal and suicidal ideations*, *R45850 Homicidal ideation*, and *R45851 Suicidal ideation*. The results of our regression analysis, as presented in the table below, found that these codes are not associated with a statistically significant positive adjustment factor, meaning, the cost of treating IPF patients with these conditions is not significantly higher than treating IPF patients without these conditions. Therefore, adding these codes to the Intensive Management for High-Risk Behavior comorbidity category would not align payment with resource use.

Table 8: Analysis of Adjustment Factors for Additional High Risk Behavior Codes

Description	# of Stays CY 2019– CY 2021	% of Stays CY 2019– CY 2021	Adjustment Factors	Significance	CI Lower Bound	CI Upper Bound
<i>R456 Violent Behavior</i>	6,184	0.8%	0.97869		0.92757	1.03261
<i>R45850 Homicidal ideation</i>	39,856	4.9%	0.92641	***	0.91254	0.94049
<i>R45851 Suicidal ideation</i>	264,551	32.8%	0.95828	***	0.94077	0.97612

Final Decision: After consideration of the comments received, we are finalizing our proposal to add a new

comorbidity category recognizing the costs associated with Intensive

Management for High-Risk Behavior to include the codes indicated in Table 9.
BILLING CODE 4120–01–P

Table 9: ICD–10–CM Codes for High-Risk Behavior Analyzed

ICD–10–CM Code	Description	Proposed Action for FY 2025 Intensive Management for High-Risk Behavior Comorbidity Category
R45	Symptoms and signs involving emotional state	
R450	Nervousness	
R451	Restlessness and agitation	Add
R452	Unhappiness	
R453	Demoralization and apathy	
R454	Irritability and anger	Add
R455	Hostility	
R456	Violent behavior	
R457	State of emotional shock and stress, unspecified	
R458	Other symptoms and signs involving emotional state	
R4581	Low self-esteem	
R4582	Worries	
R4583	Excessive crying of child, adolescent or adult	
R4584	Anhedonia	Add
R4585	Homicidal and suicidal ideations	
R45850	Homicidal ideations	
R45851	Suicidal ideations	
R4586	Emotional lability	
R4587	Impulsiveness	
R4589	Other symptoms and signs involving emotional state	

BILLING CODE 4120–01–C

Lastly, we proposed to maintain the adjustment factors for the Developmental Disabilities and Uncontrolled Diabetes comorbidity categories. Based on the regression analysis, the Developmental Disabilities comorbidity category adjustment factor was not statistically significant; however, the current adjustment factor is within the confidence interval. As discussed in section IV.C.3.a of this final rule, a non-statistically significant adjustment factor within the confidence interval indicates that the current adjustment factor would be a reasonable approximation of the increased costs. The Uncontrolled Diabetes comorbidity category adjustment factor did not change from the current adjustment factor based on the 2019 through 2021 regression.

We did not receive any comments on our proposal to maintain the adjustment factors for the Developmental

Disabilities and Uncontrolled Diabetes comorbidity categories. We are finalizing maintaining these adjustment factors, as proposed.

We also proposed to decrease the adjustment factors for the following comorbidity categories: Renal Failure—Acute, Artificial Openings—Digestive & Urinary, Cardiac conditions, Renal Failure—Chronic, Chronic Obstructive Pulmonary Disease, and Severe Musculoskeletal & Connective Tissue Diseases.

The regression analysis found the Renal Failure—Acute, Artificial Openings—Digestive & Urinary, Cardiac conditions, Renal Failure—Chronic, Chronic Obstructive Pulmonary Disease, and Severe Musculoskeletal & Connective Tissue Diseases comorbidity categories resulted in a statistically significant adjustment factor. While payment would still be increased when the claim includes one of these

comorbidity categories, the proposed adjustment factors for FY 2025 would be less than the current adjustment factors for these categories.

We did not receive any comments on our proposal to decrease the adjustment factors for the following comorbidity categories: Renal Failure—Acute, Artificial Openings—Digestive & Urinary, Cardiac conditions, Renal Failure—Chronic, Chronic Obstructive Pulmonary Disease, and Severe Musculoskeletal & Connective Tissue Diseases. We are finalizing a decrease to these adjustment factors, as proposed.

The FY 2025 comorbidity adjustment factors are displayed in Table 10, and can be found in Addendum A, available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets>.

BILLING CODE 4120–01–P

Table 10: Comparison of FY 2024 and FY 2025 IPF PPS Comorbidity Category Adjustments

Description	Current Adjustment Factor	FY 2025 Adjustment Factor
Renal Failure, Acute	1.11	1.06
Artificial Openings – Digestive & Urinary	1.08	1.07
Cardiac Conditions	1.11	1.04
Renal Failure, Chronic	1.11	1.08
Coagulation Factor Deficit	1.13	N/A
Chronic Obstructive Pulmonary Disease	1.12	N/A
Chronic Obstructive Pulmonary Disease and Sleep Apnea	N/A	1.09
Developmental Disabilities	1.04	1.04
Uncontrolled Diabetes	1.05	1.05
Drug/Alcohol Induced Mental Disorders	1.03	N/A
Eating and Conduct Disorders	1.12	N/A
Eating Disorders	N/A	1.09
Gangrene	1.10	1.12
Infectious Diseases	1.07	N/A
Severe Protein Malnutrition	1.13	1.17
Oncology Treatment	1.07	1.44
Poisoning	1.11	1.16
Severe Musculoskeletal & Connective Tissue Diseases	1.09	1.05
Tracheostomy	1.06	1.09
Intensive Management for High-Risk Behavior	N/A	1.07

BILLING CODE 4120-01-C

As discussed in section IV.F of this final rule, we proposed to implement revisions to the comorbidity category adjustments budget-neutrally. A detailed discussion of the distributional impacts of these changes is found in section VIII.C of this final rule.

(2) Coding Updates for FY 2025

For FY 2025, we proposed to add 2 ICD-10-CM/PCS codes to the Oncology Treatment comorbidity category. The FY 2025 comorbidity codes are shown in Addenda B, available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets>.

In accordance with the policy established in the FY 2015 IPF PPS final rule (79 FR 45949 through 45952), we reviewed all new FY 2025 ICD-10-CM codes to remove codes that were site “unspecified” in terms of laterality from the FY 2023 ICD-10-CM/PCS codes in instances where more specific codes are available. As we stated in the FY 2015 IPF PPS final rule, we believe that specific diagnosis codes that narrowly

identify anatomical sites where disease, injury, or a condition exists should be used when coding patients’ diagnoses whenever these codes are available. We finalized in the FY 2015 IPF PPS rule, that we would remove site “unspecified” codes from the IPF PPS ICD-10-CM/PCS codes in instances when laterality codes (site specified codes) are available, as the clinician should be able to identify a more specific diagnosis based on clinical assessment at the medical encounter. There were no proposed changes to the FY 2025 ICD-10-CM/PCS codes, therefore, we did not propose to remove any of the new codes.

c. Patient Age Adjustments

As explained in the RY 2005 IPF PPS final rule (69 FR 66922), we analyzed the impact of age on per diem cost by examining the age variable (range of ages) for payment adjustments. In general, we found that the cost per day increases with age. The older age groups are costlier than the under 45 age group, the differences in per diem cost increase for each successive age group, and the

differences are statistically significant. While our regression analysis of CY 2019 through CY 2021 data supports maintaining a payment adjustment factor based on age as was established in the RY 2005 IPF PPS final rule, the results suggest that revisions to the adjustment factor for age are warranted.

For FY 2025, we proposed to revise the patient age adjustments as shown in Addendum A of this final rule, which is available on the CMS website at (see <https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets>). We proposed to adopt the patient age adjustments derived from the regression model using a blended set of 2019 through 2021 data, as discussed in section IV.C.3 of this final rule. Table 11 summarizes the current and proposed patient age adjustment factors for FY 2025. As discussed in section IV.F of this final rule, we proposed to implement this revision to the patient age adjustments budget-neutrally. A detailed discussion of the distributional impacts of this change is found in section VIII.C of this final rule.

We solicited comments on these proposed revisions to the patient age adjustment factors. Lastly, we proposed that if more recent data become

available, we would use such data, if appropriate, to determine the final FY 2025 patient age adjustment factors.

We did not receive any comments on our proposal. We are finalizing the revisions to the patient age adjustment factors as proposed.

Table 11: Updates to Patient Age Adjustments

Age (in years)	Current Adjustment Factors	# of Stays CY 2019- CY 2021	% of Stays CY 2019- CY 2021	Adjustment Factors
Under 45	1.00	234,270	29.04%	1.00
45 and under 50	1.01			
50 and under 55	1.02			
45 and under 55	N/A	121,498	15.06%	1.02
55 and under 60	1.04	74,512	9.24%	1.05
60 and under 65	1.07	68,136	8.45%	1.06
65 and under 70	1.10	94,473	11.71%	1.09
70 and under 75	1.13			
75 and under 80	1.15			
70 and under 80	N/A	126,280	15.66%	1.11
80 and over	1.17	87,442	10.84%	1.13

d. Variable per Diem Adjustments

We explained in the RY 2005 IPF PPS final rule (69 FR 66946) that the regression analysis indicated that per diem cost declines as the LOS increases. The variable per diem adjustments to the Federal per diem base rate account for ancillary and administrative costs that occur disproportionately in the first days after admission to an IPF. As discussed in the RY 2005 IPF PPS final rule, where a complete discussion of the variable per diem adjustments can be found, we used a regression analysis to estimate the average differences in per diem cost among stays of different lengths (69 FR 66947 through 66950). As a result of this analysis, we established variable per diem adjustments that begin on day 1 and decline gradually until day 21 of a patient's stay. For day 22 and thereafter, the variable per diem adjustment remains the same each day for the remainder of the stay. However, the adjustment applied to day 1 depends upon whether the IPF has a qualifying ED. If an IPF has a qualifying ED, it receives a 1.31 adjustment factor for day 1 of each stay. If an IPF does not have a qualifying ED, it receives a 1.19

adjustment factor for day 1 of the stay. The ED adjustment is explained in more detail in section IV.D.4 of this final rule.

For FY 2025, we proposed to revise the variable per diem adjustment factors as indicated in the table below, and shown in Addendum A to this rule, which is available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/tools-and-worksheets>. We proposed to increase the adjustment factors for days 1 through 9. As shown in Table 12, the results of the latest regression analysis indicate that there is not a statistically significant decrease in cost per day after day 10; therefore, we proposed that days 10 and above will receive a 1.00 adjustment. Table 12 summarizes the current and proposed variable per diem adjustment factors for FY 2025. As discussed in section IV.F of this final rule, we proposed to implement this revision to the variable per diem adjustments budget-neutrally. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this final rule.

We solicited comments on these proposed revisions to the variable per

diem adjustment factors. Lastly, we proposed that if more recent data become available, we will use such data, if appropriate, to determine the final FY 2025 variable per diem adjustment factors.

Comment: Two commenters supported the proposed revisions to the variable per diem adjustments, noting that these revisions reflect increased costs early in a stay.

Response: We thank the commenters for their support. As discussed in section IV.C.4.b.(1) of this final rule, we have updated our regression analysis to account for a programming error that inadvertently excluded certain sleep apnea codes from the regression model. The results of the latest regression analysis increase the adjustment factor for the first day of the stay. This result further supports the commenters' assertion that there are increased costs early in an IPF stay.

Final Decision: After consideration of the comments received, we are finalizing the revision of the IPF variable per diem adjustment factors as shown in Table 12.

Table 12: Updates to Variable Per Diem Adjustments

Description	Current Adjustment Factors	# of Stays CY 2019–CY 2021	% of Stays CY 2019–CY 2021	Adjustment Factors
Length of stay - 1 day without ED	1.19	17,141	2.09%	1.28
Length of stay - 1 day with a qualified ED	1.31	N/A	N/A	1.54
Length of stay - 2 days	1.12	28,370	3.52%	1.20
Length of stay - 3 days	1.08	42,298	5.24%	1.15
Length of stay - 4 days	1.05	48,187	5.97%	1.12
Length of stay - 5 days	1.04	54,187	6.72%	1.08
Length of stay - 6 days	1.02	59,215	7.34%	1.06
Length of stay - 7 days	1.01	63,095	7.82%	1.03
Length of stay - 8 days	1.01	51,491	6.38%	1.02
Length of stay - 9 days	1.00	42,855	5.31%	1.01
Length of stay – greater than or equal to 10 days	1.00 – 0.92	400,022	49.59%	1.00

D. Updates to the IPF PPS Facility-Level Adjustments

The IPF PPS includes facility-level adjustments for the wage index, IPFs located in rural areas, teaching IPFs, cost of living adjustments for IPFs located in Alaska and Hawaii, and IPFs with a qualifying ED. We proposed to use the existing regression-derived facility-level adjustment factors established in the RY 2005 IPF final rule and did not propose changes to the facility-level adjustment factors for rural location and teaching status for FY 2025. As discussed in the following sections, we proposed updates to the FY 2025 IPF PPS wage index. In addition, we proposed to update the ED adjustment for FY 2025 to reflect more recent cost and claims data.

1. Wage Index Adjustment

a. Background

As discussed in the RY 2007 IPF PPS final rule (71 FR 27061), and the RY 2009 IPF PPS (73 FR 25719) and RY 2010 IPF PPS notices (74 FR 20373), to provide an adjustment for geographic wage levels, the labor-related portion of an IPF's payment is adjusted using an appropriate wage index. Currently, an IPF's geographic wage index value is determined based on the actual location of the IPF in an urban or rural area, as defined in § 412.64(b)(1)(ii)(A) and (C).

Due to the variation in costs and because of the differences in geographic wage levels, in the RY 2005 IPF PPS

final rule, we required that payment rates under the IPF PPS be adjusted by a geographic wage index. We proposed and finalized a policy to use the unadjusted, pre-floor, pre-reclassified IPPS hospital wage index to account for geographic differences in IPF labor costs. We implemented use of the pre-floor, pre-reclassified IPPS hospital wage data to compute the IPF wage index since there was not an IPF-specific wage index available. We believe that IPFs generally compete in the same labor market as IPPS hospitals, and therefore, the pre-floor, pre-reclassified IPPS hospital wage data should be reflective of labor costs of IPFs. We believe this pre-floor, pre-reclassified IPPS hospital wage index to be the best available data to use as proxy for an IPF-specific wage index. As discussed in the RY 2007 IPF PPS final rule (71FR 27061 through 27067), under the IPF PPS, the wage index is calculated using the IPPS wage index for the labor market area in which the IPF is located, without considering geographic reclassifications, floors, and other adjustments made to the wage index under the IPPS. For a complete description of these IPPS wage index adjustments, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41390). Our wage index policy at § 412.424(a)(2) provides that we use the best Medicare data available to estimate costs per day, including an

appropriate wage index to adjust for wage differences.

When the IPF PPS was implemented in the RY 2005 IPF PPS final rule, with an effective date of January 1, 2005, the pre-floor, pre-reclassified IPPS hospital wage index that was available at the time was the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index. Historically, the IPF wage index for a given RY has used the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY as its basis. This has been due in part to the pre-floor, pre-reclassified IPPS hospital wage index data that were available during the IPF rulemaking cycle, where an annual IPF notice or IPF final rule was usually published in early May. This publication timeframe was relatively early compared to other Medicare payment rules because the IPF PPS follows a RY, which was defined in the implementation of the IPF PPS as the 12-month period from July 1 to June 30 (69 FR 66927). Therefore, the best available data at the time the IPF PPS was implemented was the pre-floor, pre-reclassified IPPS hospital wage index from the prior FY (for example, the RY 2006 IPF wage index was based on the FY 2005 pre-floor, pre-reclassified IPPS hospital wage index).

In the RY 2012 IPF PPS final rule, we changed the reporting year timeframe for IPFs from a RY to FY, which begins October 1 and ends September 30 (76 FR 26434 through 26435). In that FY 2012 IPF PPS final rule, we continued

our established policy of using the pre-floor, pre-reclassified IPPS hospital wage index from the prior year (that is, from FY 2011) as the basis for the FY 2012 IPF wage index. This policy of basing a wage index on the prior year's pre-floor, pre-reclassified IPPS hospital wage index has been followed by other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. By continuing with our established policy, we remained consistent with other Medicare payment systems.

In FY 2020, we finalized the IPF wage index methodology to align the IPF PPS wage index with the same wage data timeframe used by the IPPS for FY 2020 and subsequent years. Specifically, we finalized the use of the pre-floor, pre-reclassified IPPS hospital wage index from the FY concurrent with the IPF FY as the basis for the IPF wage index. For example, the FY 2020 IPF wage index was based on the FY 2020 pre-floor, pre-reclassified IPPS hospital wage index rather than on the FY 2019 pre-floor, pre-reclassified IPPS hospital wage index.

We explained in the FY 2020 proposed rule (84 FR 16973), that using the concurrent pre-floor, pre-reclassified IPPS hospital wage index will result in the most up-to-date wage data being the basis for the IPF wage index. We noted that it would also result in more consistency and parity in the wage index methodology used by other Medicare payment systems. We indicated that the Medicare skilled nursing facility (SNF) PPS already used the concurrent IPPS hospital wage index data as the basis for the SNF PPS wage index. We proposed and finalized similar policies to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index data in other Medicare payment systems, such as hospice and inpatient rehabilitation facilities. Thus, the wage adjusted Medicare payments of various provider types are based upon wage index data from the same timeframe. For FY 2025, we proposed to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index.

In the FY 2023 IPF PPS final rule (87 FR 46856 through 46859), we finalized a permanent 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, and we stated that we will apply this cap in a budget neutral manner. In addition, we finalized a policy that a new IPF will be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied because a new IPF

will not have a wage index in the prior FY. We amended the IPF PPS regulations at § 412.424(d)(1)(i) to reflect this permanent cap on wage index decreases. We refer readers to the FY 2023 IPF PPS final rule for a more detailed discussion about this policy.

For FY 2025, we proposed to apply the IPF wage index adjustment to the labor-related share of the national IPF PPS base rate and ECT payment per treatment. The proposed labor-related share of the IPF PPS national base rate and ECT payment per treatment is 78.8 percent in FY 2025. This percentage reflects the labor-related share of the 2021-based IPF market basket for FY 2025 and is 0.1 percentage point higher than the FY 2024 labor-related share (see section IV.A.3 of this final rule). We received several comments on this proposal, which are discussed in the following paragraphs.

Comment: Several commenters requested CMS revise the IPF wage index methodology. Specifically, a few commenters suggested CMS revise the policy so that the post-reclassification and post-floor hospital IPPS wage index is used to calculate the wage index for IPFs. The commenter believes that the continued use of the pre-reclassification and pre-floor hospital inpatient wage index is unreasonable because it places IPFs at a disadvantage in the labor markets in which they operate relative to hospitals in the same markets. Other commenters suggested CMS exercise its authority to refine the IPF PPS by applying the pre-floor, pre-reclassified IPPS hospital wage index for the CBSA in which the nearest IPPS hospital is located where the pre-floor, pre-reclassified IPPS hospital wage index for the CBSA in which the IPF is located only includes data from a closed IPPS hospital. Commenters stated they believe the closed hospital data is more likely to be unreliable such that the application of the pre-floor, pre-reclassified IPPS hospital wage index would result in an inappropriately deflated wage index value. Commenters further noted that the closure of the only IPPS hospital in the CBSA would suggest that the community is currently underserved, and would make it particularly appropriate to ensure that aberrant wage index data does not serve as an impediment to new IPF services in a community. One commenter urged CMS to apply an out-migration adjustment (OMA) to IPFs to account for the employment of hospital employees who reside in one county but commute to work in a county with a higher wage index.

Response: We appreciate the commenters' recommendations. We did

not propose the specific policies suggested by commenters, but we will take them into consideration to potentially inform future rulemaking. We do not believe that the continued use of the pre-reclassification and pre-floor hospital inpatient wage index for FY 2024 is unreasonable or that this policy puts IPFs at a disadvantage relative to hospitals in the labor markets in which they operate. As we have previously discussed in the RY 2007 final rule (71 FR 27066), we believe that the actual location of an IPF (as opposed to the location of affiliated providers) is most appropriate for determining the wage adjustment because the prevailing wages in the area in which the IPF is located influence the cost of a case. In that same RY 2007 final rule (71 FR 27066), we also stated that we believe the "rural floor" is required only for the acute care hospital payment system because section 4410 of the Balanced Budget Act of 1997 (Pub. L. 105–33) applies specifically to acute care hospitals and not excluded hospitals and excluded units. As we have previously discussed, the IPF wage index is intended to be a relative measure of the value of labor in prescribed labor market areas (87 FR 46857). There are a variety of reasons why our longstanding IPF wage index policy have not applied floors or reclassifications, which, as we previously noted, are not applied to the IPF wage index by statute. For example, applying floors and reclassifications to the IPF wage index would significantly increase administrative burden, both for IPFs and for CMS, associated with IPFs reclassifying from one CBSA to another, and it would significantly increase the complexity of the methodology. Furthermore, because floors and reclassifications would be applied budget-neutrally under the wage index, these policies would increase the wage index for some IPFs while reducing IPF PPS payments for all other IPFs, which would upset the long-settled expectations with which IPFs across the country have been operating. For these reasons, we believe using the pre-floor, pre-reclassified IPPS hospital wage index is the most appropriate data to use as a proxy for an IPF wage index.

Regarding the suggestion to apply the wage index for the CBSA of the nearest IPPS hospital in cases when an IPF's CBSA includes only a closed IPPS hospital, we disagree with the commenter that wage data from a hospital that has closed is more likely to be unreliable and that such data would inappropriately deflate the wage index for that CBSA. Rather, following

the longstanding methodology for calculating the wage index, wage data from the period during which the hospital was open would be comparable to wage data from the same period for hospitals located in other geographical areas, and would provide an appropriate relative measure of the value of labor in that CBSA's labor market area compared to others. We do not believe that such wage data or the wage index of a CBSA in this situation would serve as an impediment for either new or existing IPF services in a community. In addition, we recognize that in some cases, the closure of the only IPPS hospital in the CBSA could suggest that the community is underserved; however, in other cases, the lack of an IPPS hospital could be due to other factors, such as when an area's only IPPS hospital converts to another hospital type such as a critical access hospital. We note that at this time, there is only one urban CBSA with no IPPS hospitals; however, there are also no IPFs located in this CBSA.

Lastly, as discussed in the FY 2024 IPPS proposed rule (88 FR 26966), in constructing the proposed FY 2024 wage index, wage data was included for facilities that were IPPS hospitals in FY 2020, inclusive of those facilities that have since terminated their participation in the Medicare program as hospitals, as long as those data did not fail any of our edits for reasonableness. These edits excluded providers with aberrant data that should not be included in the wage index. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages.

We appreciate the commenter's suggestion to apply an out-migration adjustment to IPFs to account for employment of hospital staff who commute to work in counties with a higher wage index. However, we note that the out-migration adjustment is applied to the IPPS hospital wage index under section 1886(d)(13) of the Act, which is a statutory provision that specifically applies to subsection (d) hospitals paid under the IPPS. As discussed in the prior paragraph, CMS does not believe it is appropriate for the IPF PPS to apply an out-migration adjustment that is not statutorily required, because such a policy would increase administrative burden and have distributional impacts on IPFs.

Comment: One commenter encouraged CMS to consider developing and applying a low wage index hospital policy for rural and low wage index IPFs similar to the policy in place for the IPPS wage index to ensure that IPFs in low wage index and rural areas, which typically draw from the same labor pool as IPPS hospitals, have adequate resources to continue to provide access to care.

Response: We appreciate the suggestions from commenters; however, we did not propose to apply a low-wage index policy for the IPF PPS wage index and are not finalizing such a methodology. As we noted in the FY 2025 IPF PPS proposed rule, our longstanding methodology for the IPF wage index is derived from IPPS wage data, that is, the pre-reclassified and pre-floor IPPS wage index. Thus, to the extent that increasing wage index values under the IPPS for low-wage index hospitals results in those hospitals increasing employee compensation, this increase would be reflected in the IPPS wage data upon which the IPF wage index is based and would be expected to result in higher wage indices for these areas under the IPF PPS. We further note that IPPS wage index values are based on historical data and typically lag by four years. As a result, the hospital cost report data for FY 2021 would reflect any changes in employee compensation driven by the IPPS low-wage index hospital policy, and under our proposal, this data would become the basis for the IPF wage index in FY 2025. Therefore, any effects of these changes would be extended to the IPF setting.

Final Decision: After consideration of the comments received, we are finalizing our proposal for FY 2025 to continue to use the concurrent pre-floor, pre-reclassified IPPS hospital wage index as the basis for the IPF wage index. We will apply the IPF wage index adjustment to the labor-related share of the national base rate and ECT payment per treatment. The labor-related share of the national rate and ECT payment per treatment will change from 78.7 percent in FY 2024 to 78.8 percent in FY 2025. This percentage reflects the labor-related share of the 2021-based IPF market basket for FY 2025 (see section IV.A.5 of this final rule).

b. Office of Management and Budget (OMB) Bulletins

(1) Background

The wage index used for the IPF PPS is calculated using the unadjusted, pre-reclassified and pre-floor IPPS wage

index data and is assigned to the IPF based on the labor market area in which the IPF is geographically located. IPF labor market areas are delineated based on the Core-Based Statistical Area (CBSAs) established by the OMB.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. These bulletins contain information regarding CBSA changes, including changes to CBSA numbers and titles. OMB bulletins may be accessed online at <https://www.whitehouse.gov/omb/information-for-agencies/bulletins/>. In accordance with our established methodology, the IPF PPS has historically adopted any CBSA changes that are published in the OMB bulletin that corresponds with the IPPS hospital wage index used to determine the IPF wage index and, when necessary and appropriate, has proposed and finalized transition policies for these changes.

In the RY 2007 IPF PPS final rule (71 FR 27061 through 27067), we adopted the changes discussed in the OMB Bulletin No. 03-04 (June 6, 2003), which announced revised definitions for Metropolitan Statistical Areas (MSAs), and the creation of Micropolitan Statistical Areas and Combined Statistical Areas. In adopting the OMB CBSA geographic designations in RY 2007, we did not provide a separate transition for the CBSA-based wage index since the IPF PPS was already in a transition period from TEFRA payments to PPS payments.

In the RY 2009 IPF PPS notice, we incorporated the CBSA nomenclature changes published in the most recent OMB bulletin that applied to the IPPS hospital wage index used to determine the current IPF wage index and stated that we expected to continue to do the same for all the OMB CBSA nomenclature changes in future IPF PPS rules and notices, as necessary (73 FR 25721).

Subsequently, CMS adopted the changes that were published in past OMB bulletins in the FY 2016 IPF PPS final rule (80 FR 46682 through 46689), the FY 2018 IPF PPS rate update (82 FR 36778 through 36779), the FY 2020 IPF PPS final rule (84 FR 38453 through 38454), and the FY 2021 IPF PPS final rule (85 FR 47051 through 47059). We direct readers to each of these rules for more information about the changes that were adopted and any associated transition policies.

As discussed in the FY 2023 IPF PPS final rule, we did not adopt OMB Bulletin 20–01, which was issued March 6, 2020, because we determined this bulletin had no material impact on the IPF PPS wage index. This bulletin creates only one Micropolitan statistical area, and Micropolitan areas are considered rural for the IPF PPS wage index. That is, the constituent county of the new Micropolitan area was considered rural effective as of FY 2021 and would continue to be considered rural if we adopted OMB Bulletin 20–01.

Finally, on July 21, 2023, OMB issued Bulletin 23–01, which revises the CBSA delineations based on the latest available data from the 2020 census. This bulletin contains information regarding updates of statistical area changes to CBSA titles, numbers, and county or county equivalents.

(2) Proposed Implementation of New Labor Market Area Delineations

We believe it is important for the IPF PPS to use, as soon as is reasonably possible, the latest available labor market area delineations to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We believe that using the most current delineations will increase the integrity of the IPF PPS wage index system by creating a more accurate representation of geographic variations

in wage levels. In the FY 2025 IPF PPS proposed rule, we explained that we have carefully analyzed the impacts of adopting the new OMB delineations and find no compelling reason to delay implementation. Therefore, we proposed to implement the new OMB delineations as described in the July 21, 2023, OMB Bulletin No. 23–01, effective beginning with the FY 2025 IPF PPS wage index. We proposed to adopt the updates to the OMB delineations announced in OMB Bulletin No. 23–01 effective for FY 2025 under the IPF PPS.

As previously discussed, we finalized a 5-percent permanent cap on any decrease to a provider's wage index from its wage index in the prior year. For more information on the permanent 5-percent cap policy, we refer readers to the FY 2023 IPF PPS final rule (87 FR 46856 through 46859). In addition, we proposed to phase out the rural adjustment for IPFs that are transitioning from rural to urban based on these CBSA revisions, as discussed in section IV.D.1.c. of this final rule.

(a) Micropolitan Statistical Areas

OMB defines a “Micropolitan Statistical Area” as a CBSA associated with at least one urban cluster that has a population of at least 10,000, but less than 50,000 (75 FR 37252). We refer to these as Micropolitan Areas. After extensive impact analysis, consistent with the treatment of these areas under the IPPS as discussed in the FY 2005

IPPS final rule (69 FR 49029 through 49032), we determined the best course of action was to treat Micropolitan Areas as “rural” and include them in the calculation of each state's IPF PPS rural wage index. We refer readers to the FY 2007 IPF PPS final rule (71 FR 27064 through 27065) for a complete discussion regarding treating Micropolitan Areas as rural. We did not propose any changes to this policy for FY 2025.

(b) Change to County-Equivalents in the State of Connecticut

The June 6, 2022, Census Bureau Notice (87 FR 34235 through 34240), OMB Bulletin No. 23–01 replaced the 8 counties in Connecticut with 9 new “Planning Regions.” Planning regions now serve as county-equivalents within the CBSA system. In the proposed rule, we explained that we have evaluated the changes and are proposed to adopt the planning regions as county equivalents for wage index purposes. We stated that we believe it is necessary to adopt this migration from counties to planning region county-equivalents to maintain consistency with OMB updates. We provided the following crosswalk for each county in Connecticut with the current and proposed FIPS county and county-equivalent codes and CBSA assignments.

Table 13: Change to County-Equivalents in the State of Connecticut

FIPS	Current County	Current CBSA	Proposed FIPS	Proposed Planning Region Area (County Equivalent)	Proposed CBSA
09003	HARTFORD	25540	09110	CAPITOL	25540
09015	WINDHAM	49340	09150	NORTHEASTERN CONNECTICUT	7
09005	LITCHFIELD	7	09160	NORTHWEST HILLS	7
09001	FAIRFIELD	14860	09190	WESTERN CONNECTICUT	14860
09001	FAIRFIELD	14860	09120	GREATER BRIDGEPORT	14860
09011	NEW LONDON	35980	09180	SOUTHEASTERN CONNECTICUT	35980
09013	TOLLAND	25540	09110	CAPITOL	25540
09009	NEW HAVEN	35300	09140	NAUGATUCK VALLEY	47930
09009	NEW HAVEN	35300	09170	SOUTH CENTRAL CONNECTICUT	35300
09007	MIDDLESEX	25540	09130	LOWER CONNECTICUT RIVER VALLEY	25540

(c) Urban Counties That Will Become Rural Under the Revised OMB Delineations

As previously discussed, we proposed to implement the new OMB labor market area delineations (based upon

OMB Bulletin No. 23–01) beginning in FY 2025. We stated that our analysis shows a total of 53 counties (and county equivalents) and 15 providers are located in areas that were previously considered part of an urban CBSA but would be considered rural beginning in

FY 2025 under these revised OMB delineations. Table 14 lists the 53 urban counties that we noted would be rural if we finalized our proposal to implement the revised OMB delineations.
BILLING CODE 4120–01–P

Table 14: Counties Previously Considered Part of an Urban CBSA that Would Become Rural Areas Under Revised OMB Delineations

County Code	County/County Equivalent	State	Current CBSA	Labor Market Area
01129	WASHINGTON	AL	33660	Mobile, AL
05025	CLEVELAND	AR	38220	Pine Bluff, AR
05047	FRANKLIN	AR	22900	Fort Smith, AR-OK
05069	JEFFERSON	AR	38220	Pine Bluff, AR
05079	LINCOLN	AR	38220	Pine Bluff, AR
10005	SUSSEX	DE	41540	Salisbury, MD-DE
13171	LAMAR	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA
16077	POWER	ID	38540	Pocatello, ID
17057	FULTON	IL	37900	Peoria, IL
17077	JACKSON	IL	16060	Carbondale-Marion, IL
17087	JOHNSON	IL	16060	Carbondale-Marion, IL
17183	VERMILION	IL	19180	Danville, IL
17199	WILLIAMSON	IL	16060	Carbondale-Marion, IL
18121	PARKE	IN	45460	Terre Haute, IN
18133	PUTNAM	IN	26900	Indianapolis-Carmel-Anderson, IN
18161	UNION	IN	17140	Cincinnati, OH-KY-IN
21091	HANCOCK	KY	36980	Owensboro, KY
21101	HENDERSON	KY	21780	Evansville, IN-KY
22045	IBERIA	LA	29180	Lafayette, LA
24001	ALLEGANY	MD	19060	Cumberland, MD-WV
24047	WORCESTER	MD	41540	Salisbury, MD-DE
25011	FRANKLIN	MA	44140	Springfield, MA
26155	SHIAWASSEE	MI	29620	Lansing-East Lansing, MI
27075	LAKE	MN	20260	Duluth, MN-WI
28031	COVINGTON	MS	25620	Hattiesburg, MS
31051	DIXON	NE	43580	Sioux City, IA-NE-SD
36123	YATES	NY	40380	Rochester, NY
37049	CRAVEN	NC	35100	New Bern, NC
37077	GRANVILLE	NC	20500	Durham-Chapel Hill, NC
37085	HARNETT	NC	22180	Fayetteville, NC
37087	HAYWOOD	NC	11700	Asheville, NC
37103	JONES	NC	35100	New Bern, NC
37137	PAMLICO	NC	35100	New Bern, NC
42037	COLUMBIA	PA	14100	Bloomsburg-Berwick, PA
42085	MERCER	PA	49660	Youngstown-Warren-Boardman, OH-PA
42089	MONROE	PA	20700	East Stroudsburg, PA
42093	MONTOUR	PA	14100	Bloomsburg-Berwick, PA

County Code	County/County Equivalent	State	Current CBSA	Labor Market Area
42103	PIKE	PA	35084	Newark, NJ-PA
45027	CLARENDON	SC	44940	Sumter, SC
48431	STERLING	TX	41660	San Angelo, TX
49003	BOX ELDER	UT	36260	Ogden-Clearfield, UT
51113	MADISON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV
51175	SOUTHAMPTON	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
51620	FRANKLIN CITY	VA	47260	Virginia Beach-Norfolk-Newport News, VA-NC
54035	JACKSON	WV	16620	Charleston, WV
54043	LINCOLN	WV	16620	Charleston, WV
54057	MINERAL	WV	19060	Cumberland, MD-WV
55069	LINCOLN	WI	48140	Wausau-Weston, WI
72001	ADJUNTAS	PR	38660	Ponce, PR
72055	GUANICA	PR	49500	Yauco, PR
72081	LARES	PR	10380	Aguadilla-Isabela, PR
72083	LAS MARIAS	PR	32420	Mayagüez, PR
72141	UTUADO	PR	10380	Aguadilla-Isabela, PR

BILLING CODE 4120-01-C

We proposed that the wage data for all providers located in the counties listed above would now be considered rural, beginning in FY 2025, when calculating their respective state's rural wage index. This rural wage index value would also be used under the IPF PPS. We recognize that rural areas typically have lower area wage index values than urban areas, and providers located in these counties may experience a negative impact in their IPF payment due to the proposed adoption of the revised OMB delineations. However, we noted that providers located in these

counties would receive a rural adjustment beginning in FY 2025, which would mitigate the impact of decreases to the wage index for these providers. In addition, we explained that the permanent 5-percent cap on wage index decreases under the IPF PPS would further mitigate large wage index decreases for providers in these areas.

(d) Rural Counties That Would Become Urban Under the Revised OMB Delineations

As previously discussed, we proposed to implement the new OMB labor

market area delineations (based upon OMB Bulletin No. 23-01) beginning in FY 2025. We stated that analysis of these OMB labor market area delineations shows that a total of 54 counties (and county equivalents) and 10 providers are located in areas that were previously considered rural but will now be considered urban under the revised OMB delineations. Table 15 lists the 54 rural counties that we stated would be urban if we finalized our proposal to implement the revised OMB delineations.

BILLING CODE 4120-01-P

Table 15: Counties that Would Gain Urban Status Under Revised OMB Delineations

County Code	County/County Equivalent	State	New CBSA	Labor Market Area
01087	Macon	AL	12220	Auburn-Opelika, AL
01127	Walker	AL	13820	Birmingham, AL
12133	Washington	FL	37460	Panama City-Panama City Beach, FL
13187	Lumpkin	GA	12054	Atlanta-Sandy Springs-Roswell, GA
15005	Kalawao	HI	27980	Kahului-Wailuku, HI
17053	Ford	IL	16580	Champaign-Urbana, IL
17127	Massac	IL	37140	Paducah, KY-IL
18159	Tipton	IN	26900	Indianapolis-Carmel-Greenwood, IN
18179	Wells	IN	23060	Fort Wayne, IN
20021	Cherokee	KS	27900	Joplin, MO-KS
21007	Ballard	KY	37140	Paducah, KY-IL
21039	Carlisle	KY	37140	Paducah, KY-IL
21127	Lawrence	KY	26580	Huntington-Ashland, WV-KY-OH
21139	Livingston	KY	37140	Paducah, KY-IL
21145	Mc Craken	KY	37140	Paducah, KY-IL
21179	Nelson	KY	31140	Louisville/Jefferson County, KY-IN
22053	Jefferson Davis	LA	29340	Lake Charles, LA
22083	Richland	LA	33740	Monroe, LA
26015	Barry	MI	24340	Grand Rapids-Wyoming-Kentwood, MI
26019	Benzie	MI	45900	Traverse City, MI
26055	Grand Traverse	MI	45900	Traverse City, MI
26079	Kalkaska	MI	45900	Traverse City, MI
26089	Leelanau	MI	45900	Traverse City, MI
27133	Rock	MN	43620	Sioux Falls, SD-MN
28009	Benton	MS	32820	Memphis, TN-MS-AR
28123	Scott	MS	27140	Jackson, MS
30007	Broadwater	MT	25740	Helena, MT
30031	Gallatin	MT	14580	Bozeman, MT
30043	Jefferson	MT	25740	Helena, MT
30049	Lewis and Clark	MT	25740	Helena, MT
30061	Mineral	MT	33540	Missoula, MT
32019	Lyon	NV	39900	Reno, NV
37125	Moore	NC	38240	Pinehurst-Southern Pines, NC
38049	McHenry	ND	33500	Minot, ND
38075	Renville	ND	33500	Minot, ND
38101	Ward	ND	33500	Minot, ND
39007	Ashtabula	OH	17410	Cleveland, OH
39043	Erie	OH	41780	Sandusky, OH
41013	Crook	OR	13460	Bend, OR

County Code	County/County Equivalent	State	New CBSA	Labor Market Area
41031	Jefferson	OR	13460	Bend, OR
42073	Lawrence	PA	38300	Pittsburgh, PA
45087	Union	SC	43900	Spartanburg, SC
46033	Custer	SD	39660	Rapid City, SD
47081	Hickman	TN	34980	Nashville-Davidson--Murfreesboro--Franklin, TN
48007	Aransas	TX	18580	Corpus Christi, TX
48035	Bosque	TX	47380	Waco, TX
48079	Cochran	TX	31180	Lubbock, TX
48169	Garza	TX	31180	Lubbock, TX
48219	Hockley	TX	31180	Lubbock, TX
48323	Maverick	TX	20580	Eagle Pass, TX
48407	San Jacinto	TX	26420	Houston-Pasadena-The Woodlands, TX
51063	Floyd	VA	13980	Blacksburg-Christiansburg-Radford, VA
51181	Surry	VA	47260	Virginia Beach-Chesapeake-Norfolk, VA-NC
55123	Vernon	WI	29100	La Crosse-Onalaska, WI-MN

BILLING CODE 4120-01-C

We proposed that when calculating the area wage index, beginning with FY 2025, the wage data for providers located in these counties would be included in their new respective urban CBSAs. Typically, providers located in an urban area receive a wage index value higher than or equal to providers located in their state's rural area. We also noted that providers located in these areas would no longer be considered rural beginning in FY 2025. We refer readers to section IV.D.1.c of

this final rule for a discussion of the proposed policy to phase out the payment of the rural adjustment for providers in these areas.

(e) Urban Counties That Would Move to a Different Urban CBSA Under the New OMB Delineations

In the proposed rule, we noted that in certain cases adopting the new OMB delineations would involve a change only in CBSA name and/or number, while the CBSA continues to encompass the same constituent counties. For

example, CBSA 10540 (Albany-Lebanon, OR) would experience a change to its name, and become CBSA 10540 (Albany, OR), while its one constituent county would remain the same. Table 16 shows the current CBSA code and our proposed CBSA code where we proposed to change either the name or CBSA number only. We did not further discuss these proposed changes in the proposed rule, because they are inconsequential changes with respect to the IPF PPS wage index.

BILLING CODE 4120-01-P

Table 16: Current CBSAs and their New CBSA Codes and Titles

Current CBSA Code	Current CBSA Title	CBSA Code	CBSA Title
10540	Albany-Lebanon, OR	10540	Albany, OR
12420	Austin-Round Rock-Georgetown, TX	12420	Austin-Round Rock-San Marcos, TX
12540	Bakersfield, CA	12540	Bakersfield-Delano, CA
15260	Brunswick, GA	15260	Brunswick-St. Simons, GA
16540	Chambersburg-Waynesboro, PA	16540	Chambersburg, PA
16984	Chicago-Naperville-Evanston, IL	16984	Chicago-Naperville-Schaumburg, IL
19430	Dayton-Kettering, OH	19430	Dayton-Kettering-Beavercreek, OH
19740	Denver-Aurora-Lakewood, CO	19740	Denver-Aurora-Centennial, CO
21820	Fairbanks, AK	21820	Fairbanks-College, AK
22660	Fort Collins, CO	22660	Fort Collins-Loveland, CO
23224	Frederick-Gaithersburg-Rockville, MD	23224	Frederick-Gaithersburg-Bethesda, MD
24860	Greenville-Anderson, SC	24860	Greenville-Anderson-Greer, SC
25940	Hilton Head Island-Bluffton, SC	25940	Hilton Head Island-Bluffton-Port Royal, SC
26380	Houma-Thibodaux, LA	26380	Houma-Bayou Cane-Thibodaux, LA
29820	Las Vegas-Henderson-Paradise, NV	29820	Las Vegas-Henderson-North Las Vegas, NV
31020	Longview, WA	31020	Longview-Kelso, WA
34740	Muskegon, MI	34740	Muskegon-Norton Shores, MI
35840	North Port-Sarasota-Bradenton, FL	35840	North Port-Bradenton-Sarasota, FL
36084	Oakland-Berkeley-Livermore, CA	36084	Oakland-Fremont-Berkeley, CA
36540	Omaha-Council Bluffs, NE-IA	36540	Omaha, NE-IA
39340	Provo-Orem, UT	39340	Provo-Orem-Lehi, UT
39540	Racine, WI	39540	Racine-Mount Pleasant, WI
41620	Salt Lake City, UT	41620	Salt Lake City-Murray, UT
42680	Sebastian-Vero Beach, FL	42680	Sebastian-Vero Beach-West Vero Corridor, FL
42700	Sebring-Avon Park, FL	42700	Sebring, FL
44420	Staunton, VA	44420	Staunton-Stuarts Draft, VA
44700	Stockton, CA	44700	Stockton-Lodi, CA
47220	Vineland-Bridgeton, NJ	47220	Vineland, NJ
48300	Wenatchee, WA	48300	Wenatchee-East Wenatchee, WA
48424	West Palm Beach-Boca Raton-Boynton Beach, FL	48424	West Palm Beach-Boca Raton-Delray Beach, FL

We explained that in some cases, if we adopt the new OMB delineations, counties would shift between existing and new CBSAs, changing the constituent makeup of the CBSAs. We stated that we consider this type of

change, where CBSAs are split into multiple new CBSAs, or a CBSA loses one or more counties to another urban CBSA to be significant modifications.

Table 17 lists the urban counties that we stated would move from one urban

CBSA to another newly proposed or modified CBSA if we adopted the new OMB delineations.

BILLING CODE 4120-01-P

Table 17: Urban Counties That Would Move to a New or Modified CBSA Under Revised OMB Delineations

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
06039	MADERA	CA	31460	Madera, CA	23420	Fresno, CA
11001	THE DISTRICT	DC	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
12053	HERNANDO	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12057	HILLSBOROUGH	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12101	PASCO	FL	45300	Tampa-St. Petersburg-Clearwater, FL	45294	Tampa, FL
12103	PINELLAS	FL	45300	Tampa-St. Petersburg-Clearwater, FL	41304	St. Petersburg-Clearwater-Largo, FL
12119	SUMTER	FL	45540	The Villages, FL	48680	Wildwood-The Villages, FL
13013	BARROW	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13015	BARTOW	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13035	BUTTS	GA	12060	Atlanta-Sandy Springs-	12054	Atlanta-Sandy Springs-Roswell, GA

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
				Alpharetta, GA		
13045	CARROLL	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13057	CHEROKEE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13063	CLAYTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13067	COBB	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13077	COWETA	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13085	DAWSON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13089	DE KALB	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13097	DOUGLAS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13113	FAYETTE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13117	FORSYTH	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13121	FULTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
13135	GWINNETT	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13143	HARALSON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13149	HEARD	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13151	HENRY	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13159	JASPER	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13199	MERIWETHER	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13211	MORGAN	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13217	NEWTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13223	PAULDING	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	31924	Marietta, GA
13227	PICKENS	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13231	PIKE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
13247	ROCKDALE	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13255	SPALDING	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
13297	WALTON	GA	12060	Atlanta-Sandy Springs-Alpharetta, GA	12054	Atlanta-Sandy Springs-Roswell, GA
18073	JASPER	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
18089	LAKE	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
18111	NEWTON	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
18127	PORTER	IN	23844	Gary, IN	29414	Lake County-Porter County-Jasper County, IN
21163	MEADE	KY	21060	Elizabethtown-Fort Knox, KY	31140	Louisville/Jefferson County, KY-IN
22103	ST. TAMMANY	LA	35380	New Orleans-Metairie, LA	43640	Slidell-Mandeville-Covington, LA
25015	HAMPSHIRE	MA	44140	Springfield, MA	11200	Amherst Town-Northampton, MA
24009	CALVERT	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	30500	Lexington Park, MD
24017	CHARLES	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24033	PRINCE GEORGES	MD	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	47764	Washington, DC-MD
24037	ST. MARYS	MD	15680	California-Lexington Park, MD	30500	Lexington Park, MD
37019	BRUNSWICK	NC	34820	Myrtle Beach-	48900	Wilmington, NC

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
				Conway-North Myrtle Beach, SC-NC		
34009	CAPE MAY	NJ	36140	Ocean City, NJ	12100	Atlantic City-Hammonton, NJ
34023	MIDDLESEX	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
34025	MONMOUTH	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
34029	OCEAN	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
34035	SOMERSET	NJ	35154	New Brunswick-Lakewood, NJ	29484	Lakewood-New Brunswick, NJ
36027	DUTCHESS	NY	39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY
36071	ORANGE	NY	39100	Poughkeepsie-Newburgh-Middletown, NY	28880	Kiryas Joel-Poughkeepsie-Newburgh, NY
39035	CUYAHOGA	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39055	GEAUGA	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39085	LAKE	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39093	LORAIN	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39103	MEDINA	OH	17460	Cleveland-Elyria, OH	17410	Cleveland, OH
39123	OTTAWA	OH	45780	Toledo, OH	41780	Sandusky, OH
72023	CABO ROJO	PR	41900	San Germán, PR	32420	Mayagüez, PR
72059	GUAYANILLA	PR	49500	Yauco, PR	38660	Ponce, PR
72079	LAJAS	PR	41900	San Germán, PR	32420	Mayagüez, PR
72111	PENUELAS	PR	49500	Yauco, PR	38660	Ponce, PR
72121	SABANA GRANDE	PR	41900	San Germán, PR	32420	Mayagüez, PR
72125	SAN GERMAN	PR	41900	San Germán, PR	32420	Mayagüez, PR

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
72153	YAUCO	PR	49500	Yauco, PR	38660	Ponce, PR
47057	GRAINGER	TN	34100	Morristown, TN	28940	Knoxville, TN
51510	ALEXANDRIA CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51013	ARLINGTON	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51043	CLARKE	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51047	CULPEPER	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51059	FAIRFAX	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51600	FAIRFAX CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51610	FALLS CHURCH CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51061	FAUQUIER	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51630	FREDERICKSBURG CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51107	LOUDOUN	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51683	MANASSAS CITY	VA	47894	Washington-Arlington-Alexandria,	11694	Arlington-Alexandria-Reston, VA-WV

County Code	County Name	State	Current CBSA	Current CBSA Name	CBSA Code	CBSA Name
				DC-VA-MD-WV		
51685	MANASSAS PARK CITY	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51153	PRINCE WILLIAM	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51157	RAPPAHANNOCK	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51177	SPOTSYLVANIA	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51179	STAFFORD	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
51187	WARREN	VA	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV
53061	SNOHOMISH	WA	42644	Seattle-Bellevue-Kent, WA	21794	Everett, WA
55059	KENOSHA	WI	29404	Lake County-Kenosha County, IL-WI	28450	Kenosha, WI
54037	JEFFERSON	WV	47894	Washington-Arlington-Alexandria, DC-VA-MD-WV	11694	Arlington-Alexandria-Reston, VA-WV

BILLING CODE 4120-01-C

We stated in the proposed rule that we identified 68 IPF providers located in the affected counties listed in Table 17. We noted that if providers located in these counties move from one CBSA to another under the revised OMB delineations, there may be impacts, either negative or positive, upon their specific wage index values.

(f) Summary of Comments on the Proposed CBSA Updates for FY 2025

We received mixed comments on the proposal to adopt the revised CBSA delineations. Several commenters recognized the impact of these delineation changes, and some commenters were supportive of this action, while others voiced concerns. In addition, we received comments

regarding the permanent 5-percent cap on wage index decrease.

Comment: MedPAC agreed with the 5-percent cap policy and additionally recommended applying a cap on wage index increases of more than 5-percent.

Response: We thank MedPAC for their support and appreciate the suggestion to apply a cap on wage index changes of more than 5-percent to increases in the wage index. However, as we noted in

the FY 2023 IPF PPS proposed rule (87 FR 19424), we believe applying a 5-percent cap on all wage index decreases would support increased predictability about IPF PPS payments for providers, enabling them to more effectively budget and plan their operations. That is, we proposed to cap decreases because we believe that a provider would be able to more effectively budget and plan when there is predictability about its expected minimum level of IPF PPS payments in the upcoming fiscal year. We did not propose to limit wage index increases because we do not believe such a policy is needed to enable IPFs to more effectively budget and plan their operations. Therefore, we believe it is appropriate for providers that experience an increase in their wage index value to receive that wage index value.

Comment: One commenter stated that while they appreciate the 5-percent cap, CMS should implement a 3-year transition period to updated OMB CBSA delineations as we have done in previous OMB CBSA updates.

Response: We appreciate the commenter's feedback; however, we do not agree. In FY 2021 (85 FR 47059), we implemented a 2-year transition to mitigate any negative effects of wage index changes by applying a 5-percent cap on any decrease in an IPF's wage index from the IPF's final wage index from FY 2020.

In the FY 2022 IPF PPS final rule (86 FR 42616 through 42617), we stated that we continued to believe that applying the 5-percent cap transition policy in year one provided an adequate safeguard against any significant payment reductions associated with the adoption of the revised CBSA delineations in FY 2021, allowed for sufficient time to make operational changes for future FYs, and provided a reasonable balance between mitigating some short-term instability in IPF payments and improving the accuracy of the payment adjustment for differences in area wage levels.

In FY 2023 (87 FR 46856 through 46859), we finalized a permanent 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year. Effective for FY 2025, the adoption of the updates to the OMB delineations announced in OMB Bulletin No. 23–01 will be subject to the 5-percent cap on wage index decreases policy.

As discussed in the FY 2023 IPF PPS final rule (87 FR 46856 through 46859), we continue to believe this methodology will maintain the IPF PPS wage index as a relative measure of the value of labor in prescribed labor market areas,

increase predictability of IPF PPS payments for providers, and mitigate instability and significant negative impacts to providers resulting from significant changes to the wage index. Therefore, we do not believe implementing a transition period to updated OMB CBSA delineations effective for FY 2025 is appropriate.

Comment: One commenter recommended that CMS apply the wage index 5-percent cap in a non-budget neutral manner.

Response: CMS did not propose any new policies this year pertaining to the 5-percent cap, and accordingly, we are not finalizing any new policies in this final rule. In accordance with our longstanding policy under the IPF PPS, we updated the wage index in such a way that total estimated payments to IPFs for FY 2025 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the IPF PPS rates. We applied the wage index cap in a budget-neutral manner in accordance with this overall budget neutrality policy for the IPF PPS wage index so that wage index changes do not increase aggregate Medicare spending. In the FY 2023 IPF PPS proposed rule (87 FR 19423 through 19425), we noted that applying a 5-percent cap on all wage index decreases would have a very small effect on the wage index budget neutrality factor for FY 2023. We explained that we anticipate that in the absence of proposed policy changes, most providers will not experience year to-year wage index declines greater than 5-percent in any given year and that we expect the impact to the wage index budget neutrality factor in future years will continue to be minimal.

Comment: One commenter stated that both OMB guidance and the Metropolitan Areas Protection and Standardization (MAPS) Act (Pub. L. 117–219) support that, if CMS chooses to adopt new OMB delineations, CMS must fully explain why reliance on the updated CBSAs as set forth by OMB is appropriate for purposes of the FY 2025 wage index adjustments. The commenter asserted that CMS has not provided rationale for why relying on the updated CBSAs is appropriate. Rather than simply adopting the OMB CBSAs by default, the commenter stated that CMS must make a fact-specific determination of those CBSAs' suitability for Medicare reimbursement purposes, including whether it would be appropriate to use additional data to modify OMB's delineation to ensure that such changes are appropriate for purposes of defining regional labor markets for IPF workers.

Response: We acknowledge the commenter's concerns about adopting CBSA changes by default. We do not agree with the commenter's assertion that CMS has not provided rationale for the proposed adoption of the revised CBSA delineations for FY 2025. The MAPS Act specifically states that “this act limits the automatic application of, and directs the Office of Management and Budget (OMB) to provide information about, changes to the standards for designating a core-based statistical area (CBSA) . . .” We believe our proposed rule meets the requirements of the MAPS Act, because we have not automatically applied the revised CBSAs outlined in OMB Bulletin 23–01. Rather, as we noted in the proposed rule, we proposed the adoption of the revised CBSA delineations because we believe it is important for the IPF PPS to use, as soon as is reasonably possible, the latest available labor market area delineations to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions. We also stated that using the most current delineations would increase the integrity of the IPF PPS wage index system by creating a more accurate representation of geographic variations in wage levels.

With respect to the suggestion that CMS consider whether it would be appropriate to use additional data to modify OMB's delineation to ensure that such changes are appropriate for purposes of defining regional labor markets for IPF workers, we do not believe use of such additional data is appropriate. As we have previously discussed in the RY 2007 final rule (71 FR 27066) and as we noted earlier in this final rule, we believe that the actual location of an IPF (as opposed to the location of affiliated providers) is most appropriate for determining the wage adjustment, because the prevailing wages in the area in which the IPF is located influence the cost of a case. Accordingly, we do not believe it would be appropriate to use additional data to modify OMB's delineations for the same reasons we previously stated with regard to floors or reclassifications. For example, using additional data to modify OMB's CBSA delineations would significantly increase administrative burden, both for IPFs and for CMS, associated with particular geographical areas or even individual IPFs moving from one CBSA to another, and it would significantly increase the complexity of the methodology.

Furthermore, because all CBSA delineation changes would be applied budget-neutrally under the wage index,

these policies would increase the wage index for some IPFs while reducing IPF PPS payments for all other IPFs, which would be a departure from our longstanding policies that IPFs have relied on for many years. For these reasons, we continue to believe it is important for the IPF PPS to use the latest available labor market area delineations based on the latest available CBSA delineations established by OMB as soon as is reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

Comment: One commenter requested that CMS provide a wage index table with the FY 2025 IPF final rule that provides the wage index for each hospital by the Hospital CMS Certification Number (CCN), similar to the Case-Mix Index and Wage Index Table by CCN published for the IPPS rule.

Response: We appreciate the commenter's interest in requesting that CMS publish information about wage index changes at the provider level. However, if CMS were to include a provider-level wage index table for the IPF PPS in rulemaking, we would be concerned that it could create confusion if providers' details change after a file has been published alongside the IPF PPS proposed or final rule, as this information can change throughout the year.

We note that the MACs maintain, on an ongoing basis, detailed information about the location, including the applicable wage index, for each IPF. The MACs also have information as to whether the 5-percent cap is applicable for each individual IPF. IPFs can contact their MACs for provider specific wage index information and any related questions. We note that CMS has provided instructions to the MACs on applying the 5-percent cap policy (see publication 100–04 Medicare Claims Processing Manual, chapter 3).

Final Decision: After consideration of the comments received, we are finalizing our proposal to update the IPF PPS wage index for FY 2025 to reflect the CBSA delineations based on OMB Bulletin 23–01. As we did not propose any changes to our established 5-percent wage index cap policy, we are not finalizing any changes to that policy for FY 2025. We refer readers to section IV.D.1.C of this final rule for a discussion about the proposed 3-year transition policy for providers affected by the loss of the IPF PPS rural adjustment in FY 2025.

c. Adjustment for Rural Location

In the RY 2005 IPF PPS final rule, (69 FR 66954), we provided a 17-percent payment adjustment for IPFs located in a rural area. This adjustment was based on the regression analysis, which indicated that the per diem cost of rural facilities was 17-percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. This 17-percent adjustment has been part of the IPF PPS each year since the inception of the IPF PPS. As discussed earlier in this rule, we proposed a number of revisions to the patient-level adjustment factors as well as changes to the CBSA delineations. In order to minimize the scope of changes that would impact providers in any single year, we proposed to use the existing regression-derived adjustment factor, which was established in RY 2005, for FY 2025 for IPFs located in a rural area as defined at § 412.64(b)(1)(ii)(C). See the RY 2005 IPF PPS final rule (69 FR 66954) for a complete discussion of the adjustment for rural locations. However, as discussed in the section IV.A of this FY 2025 IPF PPS final rule, we have completed analysis of more recent cost and claims and solicited comments on those results in the FY 2025 IPF PPS proposed rule.

As we explained in the proposed rule, the adoption of OMB Bulletin No. 23–01 in accordance with our established methodology would determine whether a facility is classified as urban or rural for purposes of the rural payment adjustment in the IPF PPS. Overall, we stated that we believe implementing updated OMB delineations would result in the rural payment adjustment being applied where it is appropriate to adjust for higher costs incurred by IPFs in rural locations. However, we noted we recognize that implementing these changes would have distributional effects among IPF providers, and that some providers would experience a loss of the rural payment adjustment because of our proposals. Therefore, we explained that we believe it would be appropriate to consider, as we have in the past, whether a transition period should be used to implement these proposed changes.

In the proposed rule, we explained that prior changes to the CBSA delineations have included a phase-out policy for the rural adjustment for IPFs transitioning from rural to urban status. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and

Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census. We adopted these new OMB CBSA delineations in the FY 2016 IPF final rule (80 FR 46682 through 46689), and identified 105 counties and 37 IPFs that will move from rural to urban status due to the new CBSA delineations. To reduce the impact of the loss of the 17-percent rural adjustment, we adopted a budget-neutral 3-year phase-out of the rural adjustment for existing FY 2015 rural IPFs that became urban in FY 2016 and that experienced a loss in payments due to changes from the new CBSA delineations. These IPFs received two-thirds of the rural adjustment for FY 2016 and one-third of the rural adjustment in FY 2017. For FY 2018, these IPFs did not receive a rural adjustment.

For subsequent adoptions of OMB Bulletin No. 15–01 for FY 2018 (82 FR 36779 through 36780), OMB Bulletin 17–01 for FY 2020 (84 FR 38453 through 38454), and OMB Bulletin 18–04 for FY 2021 (85 FR 47053 through 47059), we identified that fewer providers were affected by these changes than by the changes relating to the adoption of OMB Bulletin 13–01. We did not phase out the rural adjustment when adopting these delineation changes.

In the FY 2025 IPF PPS proposed rule, we explained that for facilities located in a county that transitioned from rural to urban in Bulletin 23–01, we considered whether it will be appropriate to phase out the rural adjustment for affected providers consistent with our past practice of using transition policies to help mitigate negative impacts on hospitals of OMB Bulletin proposals that have a material effect on a number of IPFs. We noted that adoption of the updated CBSAs in Bulletin 23–01 would change the status of 10 IPF providers currently designated as “rural” to “urban” for FY 2025 and subsequent fiscal years. As such, we explained that these 10 newly urban providers would no longer receive the 17-percent rural adjustment. Consistent with the transition policy adopted for IPFs in FY 2016 (80 FR 46682 through 46689), we proposed a 3-year budget neutral phase-out of the rural adjustment for IPFs located in the 54 rural counties that would become urban under the new OMB delineations, given the potentially significant payment impacts for these IPFs. We stated that we believe a phase-out of the rural adjustment transition period for these 10 IPFs specifically is appropriate because we expect these IPFs would experience a steeper and more abrupt reduction in their

payments compared to other IPFs. Therefore, we proposed to phase out the rural adjustment for these providers to reduce the impact of the loss of the FY 2024 rural adjustment of 17-percent over FYs 2025, 2026, and 2027. We explained that this policy would allow IPFs that are classified as rural in FY 2024 and would be classified as urban in FY 2025 to receive two-thirds of the rural adjustment for FY 2025. For FY 2026, these IPFs would receive one-third of the rural adjustment. For FY 2027, these IPFs would not receive a rural adjustment. We explained that we believe a 3-year budget-neutral phase-out of the rural adjustment for IPFs that transition from rural to urban status under the new CBSA delineations would best accomplish the goals of mitigating the loss of the rural adjustment for existing FY 2024 rural IPFs. We stated that the purpose of the gradual phase-out of the rural adjustment for these providers is to mitigate potential payment reductions and promote stability and predictability in payments for existing rural IPFs that may need time to adjust to the loss of their FY 2024 rural payment adjustment or that experience a reduction in payments solely because of this redesignation. We stated that this policy would be specifically for rural IPFs that become urban in FY 2025. We did not propose a transition policy for urban IPFs that become rural in FY 2025 because these IPFs would receive the full rural adjustment of 17-percent beginning October 1, 2024. We solicited comments on this proposed policy.

We received comments on the proposal to maintain the 17-percent rural adjustment for FY 2025, and the proposal to establish a 3-year budget-neutral transition policy for rural IPFs that become urban in FY 2025. We discuss these comments below. In addition, we refer readers to section V.A of this final rule for a discussion of comments received in response to a request for information about potential future revisions to the IPF PPS facility-level adjustments.

Comment: Several commenters expressed support for maintaining the existing 17-percent rural adjustment for FY 2025, with one commenter agreeing with the importance of mitigating the scope of changes in the payment system in one year. In contrast, one commenter suggested CMS update the rural adjustment for FY 2025 to use the regression-derived adjustment factor as discussed in section IV.C of this final rule. This commenter stated that the impact to facilities of revising the rural adjustment would be relatively small and recommended that CMS adopt a

transition policy for all changes to mitigate the impact in a single year. This commenter recommended re-running the regression analysis with more current data before proposing a revision of the rural location adjustment in the future.

Response: We appreciate the comments regarding the proposal to maintain the existing 17-percent rural adjustment for FY 2025. Based on the informational impact analysis discussed in section IV.A of the proposed rule, we have identified that potential changes to the rural adjustment for FY 2025 would have distributional impacts for individual providers, although the overall impact would be budget neutral (that is, 0 percent overall impact). We continue to believe that the most appropriate approach to maintain stability in payments for FY 2025 is to maintain the existing rural adjustment factor, as proposed. We appreciate the thoughtful recommendations for methodological considerations and will take them into consideration for potential future revisions to the rural adjustment.

Comment: Two commenters expressed support for phasing in changes related to the revised CBSA delineations, including the proposal to phase out the rural adjustment for IPFs that would become urban in FY 2025.

Response: We appreciate the support from commenters.

Final Decision: After consideration of the comments received, we are finalizing our proposals to maintain the current 17-percent adjustment for IPFs located in rural areas, and to phase out the rural adjustment for IPFs that will become urban in FY 2025 because of the adoption of the revised CBSA delineations based on OMB Bulletin 23–01. We will apply two-thirds of the rural adjustment for these providers for FY 2025 and one-third of the rural adjustment for FY 2026. For FY 2027, these IPFs will not receive a rural adjustment.

d. Wage Index Budget Neutrality Adjustment

Changes to the wage index are made in a budget neutral manner so that updates do not increase expenditures. Therefore, for FY 2025, we proposed to continue to apply a budget neutrality adjustment in accordance with our existing budget neutrality policy. This policy requires us to update the wage index in such a way that total estimated payments to IPFs for FY 2025 are the same with or without the changes (that is, in a budget neutral manner) by applying a budget neutrality factor to the IPF PPS rates. We proposed a budget

neutrality factor of 0.9998 in to ensure that the rates reflect the FY 2025 update to the wage indexes (based on the FY 2021 hospital cost report data) and the labor-related share in a budget neutral manner.

Finally, we note that in the April 3, 2024 IPF PPS proposed rule (89 FR 23188), there was a technical error in describing the calculation of the FY 2025 proposed wage index budget neutrality factor. We erroneously stated that on that page that the wage index budget neutrality factor was 0.9995; however, the correct wage index budget neutrality factor base rate was 0.9998, as discussed in section I.B of the same proposed rule (89 FR 23147) and in Addendum A to the proposed rule. To be clear, this error only affected the description of the wage index budget neutrality factor in section IV.D.1.d of the FY 2025 IPF PPS proposed rule, and the calculations themselves, as well as the rates indicated in the proposed rule, were correct and consistent with our longstanding methodology for updating the IPF Federal per diem base rate and ECT payment per treatment.

For this FY 2025 IPF PPS final rule, we use the following steps to ensure that the rates reflect the FY 2025 update to the wage indexes (based on FY 2021 hospital cost report data) and the labor-related share in a budget-neutral manner:

Step 1: Simulate estimated IPF PPS payments, using the FY 2024 IPF wage index values (available on the CMS website) and labor-related share (as published in the FY 2024 IPF PPS final rule (88 FR 51054)).

Step 2: Simulate estimated IPF PPS payments using the FY 2025 IPF wage index values (available on the CMS website), and the FY 2025 labor-related share (based on the latest available data as discussed previously).

Step 3: Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2025 budget neutral wage adjustment factor of 0.9996.

Step 4: Apply the FY 2025 budget neutral wage adjustment factor from step 3 to the FY 2024 IPF PPS Federal per diem base rate after the application of the IPF market basket increase reduced by the productivity adjustment described in section IV.A of this final rule to determine the FY 2025 IPF PPS Federal per diem base rate. As discussed in section IV.F of this final rule, we are also applying a refinement standardization factor to determine the FY 2025 IPF PPS Federal per diem base rate.

2. Teaching Adjustment

Background

In the RY 2005 IPF PPS final rule, we implemented regulations at § 412.424(d)(1)(iii) to establish a facility-level adjustment for IPFs that are, or are part of, teaching hospitals. The teaching adjustment accounts for the higher indirect operating costs experienced by hospitals that participate in graduate medical education (GME) programs. The payment adjustments are made based on the ratio of the number of fulltime equivalent (FTE) interns and residents training in the IPF and the IPF's average daily census.

Medicare makes direct GME payments (for direct costs such as resident and teaching physician salaries, and other direct teaching costs) to all teaching hospitals including those paid under a PPS and those paid under the TEFRA rate-of-increase limits. These direct GME payments are made separately from payments for hospital operating costs and are not part of the IPF PPS. The direct GME payments do not address the estimated higher indirect operating costs teaching hospitals may face.

The results of the regression analysis of FY 2002 IPF data established the basis for the payment adjustments included in the RY 2005 IPF PPS final rule. The results showed that the indirect teaching cost variable is significant in explaining the higher costs of IPFs that have teaching programs. We calculated the teaching adjustment based on the IPF's "teaching variable," which is $(1 + [\text{the number of FTE residents training in the IPF's average daily census}])$. The teaching variable is then raised to the 0.5150 power to result in the teaching adjustment. This formula is subject to the limitations on the number of FTE residents, which are described in this section of this final rule.

We established the teaching adjustment in a manner that limited the incentives for IPFs to add FTE residents for the purpose of increasing their teaching adjustment. We imposed a cap on the number of FTE residents that may be counted for purposes of calculating the teaching adjustment. The cap limits the number of FTE residents that teaching IPFs may count for the purpose of calculating the IPF PPS teaching adjustment, not the number of residents teaching institutions can hire or train. We calculated the number of FTE residents that trained in the IPF during a "base year" and used that FTE resident number as the cap. An IPF's FTE resident cap is ultimately determined based on the final

settlement of the IPF's most recent cost report filed before November 15, 2004 (69 FR 66955). A complete discussion of the temporary adjustment to the FTE cap to reflect residents due to hospital closure or residency program closure appears in the RY 2012 IPF PPS proposed rule (76 FR 5018 through 5020) and the RY 2012 IPF PPS final rule (76 FR 26453 through 26456).

In the regression analysis that informed the RY 2004 IPF PPS final rule, the logarithm of the teaching variable had a coefficient value of 0.5150. We converted this cost effect to a teaching payment adjustment by treating the regression coefficient as an exponent and raising the teaching variable to a power equal to the coefficient value. We note that the coefficient value of 0.5150 was based on the regression analysis holding all other components of the payment system constant. A complete discussion of how the teaching adjustment was calculated appears in the RY 2005 IPF PPS final rule (69 FR 66954 through 66957) and the RY 2009 IPF PPS notice (73 FR 25721).

We proposed to retain the coefficient value of 0.5150 for the teaching adjustment to the Federal per diem base rate as we did not propose refinements to the facility-level payment adjustments for rural location or teaching status for FY 2025. As noted earlier, given the scope of changes to the wage index and patient-level adjustment factors, we believe this will minimize the total impacts to providers in any given year. We refer readers to section V.A of this final rule for a discussion of comments received in response to a request for information about potential future revisions to the IPF PPS facility-level adjustments.

Comment: Several commenters expressed support for maintaining the existing teaching adjustment for FY 2025, with one commenter agreeing with the importance of mitigating the scope of changes in the payment system in one year. In contrast, one commenter recommended CMS update the rural adjustment for FY 2025 to use the regression-derived adjustment factor as discussed in section IV.C of this final rule. This commenter stated that the impact to facilities of revising the rural adjustment would be relatively small, and recommended that CMS adopt a transition policy for all changes to mitigate the impact in a single year. This commenter recommended re-running the regression analysis with more current data before proposing a revision of the teaching adjustment in the future.

Response: We thank the commenters for their support. Based on the informational impact analysis discussed in section IV.A of the proposed rule, we have identified that potential changes to the teaching adjustment for FY 2025 would potentially have distributional impacts for individual providers, although the overall impact would be budget neutral (that is, 0 percent overall impact). We continue to believe that the most appropriate approach to maintain stability in payments for FY 2025 is to maintain the existing teaching adjustment factor, as proposed. We appreciate the thoughtful recommendations for methodological considerations and will take this into consideration for potential future revisions to the teaching adjustment.

Comment: Two commenters requested that CMS allow affiliation agreements for IPFs, which would permit a facility to share its training cap with other facilities, or that CMS revise the definition of a new training program to allow an originating training facility that closes to transfer its existing program to a new facility. One commenter requested CMS provide teaching cap increases to IPFs who receive section 126 and section 4122 psychiatry residency under the CAA, 2021 and CAA, 2023, respectively. This commenter additionally stated that CMS should remove the teaching cap altogether, citing a national shortage of psychiatrists and their analysis of 2021 and 2022 HCRIS data indicating that IPFs nationally are training 600 residents above their caps.

Response: We appreciate the commenter's suggestion regarding potential changes to the IPF teaching adjustment to recognize new residency slots under the CAA, 2023 and the CAA, 2021. The CAA, 2021 and CAA, 2023 established resident slots for direct medical education and indirect medical education, which are paid under the IPPS. Section 126 of the CAA, 2021 and Section 4122 of the CAA, 2023 specifically pertain to section 1886(h) and section 1886(d)(5)(B) of the Act, which do not pertain to the IPF PPS. We will take this comment into consideration to potentially inform future rulemaking for the IPF PPS.

Regarding the commenter's suggestion to recognize affiliation agreements, we did not propose to recognize affiliation agreements for the IPF PPS teaching adjustment and are not making a change to this policy. As we previously stated in the RY 2005 IPF PPS final rule (69 FR 66956), our intent is not to affect affiliation agreements and rotational arrangements for hospitals that have residents that train in more than one

hospital. We have not implemented a provision concerning affiliation agreements specifically pertaining to the FTE caps used in the teaching adjustment under the IPF PPS.

Final Decision: After consideration of the comments received, we are finalizing as proposed to calculate the teaching adjustment according to our existing methodology and to maintain the existing coefficient value for FY 2025.

3. Cost of Living Adjustment for IPFs Located in Alaska and Hawaii

The IPF PPS includes a payment adjustment for IPFs located in Alaska and Hawaii based upon the area in which the IPF is located. As we explained in the RY 2005 IPF PPS final rule, the FY 2002 data demonstrated

that IPFs in Alaska and Hawaii had per diem costs that were disproportionately higher than other IPFs. As a result of this analysis, we provided a COLA in the RY 2005 IPF PPS final rule. We refer readers to the FY 2024 IPF PPS final rule for a complete discussion of the currently applicable COLA factors (88 FR 51088 through 51089).

We adopted a new methodology to update the COLA factors for Alaska and Hawaii for the IPF PPS in the FY 2015 IPF PPS final rule (79 FR 45958 through 45960). For a complete discussion, we refer readers to the FY 2015 IPF PPS final rule.

We also specified that the COLA updates will be determined every 4 years, in alignment with the IPPS market basket labor-related share update

(79 FR 45958 through 45960). Because the labor-related share of the IPPS market basket was updated for FY 2022, the COLA factors were updated in FY 2022 IPPS/LTCH rulemaking (86 FR 45547). As such, we also finalized an update to the IPF PPS COLA factors to reflect the updated COLA factors finalized in the FY 2022 IPPS/LTCH rulemaking effective for FY 2022 through FY 2025 (86 FR 42621 through 42622). This is reflected in Table 18 below. We proposed to maintain the COLA factors in Table 18 for FY 2025 in alignment with the policy described in this paragraph.

We did not receive any comments on our proposal; we are finalizing the COLA factors for IPFs located in Alaska and Hawaii as proposed.

Table 18: IPF PPS Cost-of-Living Adjustment Factors: IPFs Located in Alaska and Hawaii

Area	FY 2022 through FY 2025
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

The final IPF PPS COLA factors for FY 2025 are also shown in Addendum A to this rule, which is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientPsychFacilPPS/tools.html>.

4. Adjustment for IPFs With a Qualifying ED

The IPF PPS includes a facility-level adjustment for IPFs with qualifying EDs. As defined in § 412.402, qualifying emergency department means an emergency department that is staffed and equipped to furnish a comprehensive array of emergency services and meets the requirements of 42 CFR 489.24(b) and § 413.65.

We provide an adjustment to the Federal per diem base rate to account for the costs associated with maintaining a full-service ED. The

adjustment is intended to account for ED costs incurred by a psychiatric hospital with a qualifying ED, or an excluded psychiatric unit of an IPPS hospital or a critical access hospital (CAH), and the overhead cost of maintaining the ED. This payment applies to all IPF admissions (with one exception which we describe in this section), regardless of whether the patient was admitted through the ED. The ED adjustment is made on every qualifying claim except as described in this section of this final rule. As specified at § 412.424(d)(1)(v)(B), the ED adjustment is not made when a patient is discharged from an IPPS hospital or CAH, and admitted to the same IPPS hospital's or CAH's excluded psychiatric unit. We clarified in the RY 2005 IPF PPS final rule (69 FR 66960) that an ED adjustment is not made in this case because the costs associated

with ED services are reflected in the DRG payment to the IPPS hospital or through the reasonable cost payment made to the CAH.

For FY 2025, we proposed to update the adjustment factor from 1.31 to 1.53 for IPFs with qualifying EDs using the same methodology used to determine ED adjustments in prior years. We proposed that those IPFs with a qualifying ED would receive an adjustment factor of 1.53 as the variable per diem adjustment for day 1 of each patient stay. If an IPF does not have a qualifying ED, we proposed that it would receive an adjustment factor of 1.27 as the variable per diem adjustment for day 1 of each patient stay. We proposed to apply this revision to the ED adjustment budget-neutrally by applying a refinement standardization factor, and we presented a detailed discussion of the distributional impacts

of this proposed change (89 FR 23154 through 23172).

We solicited comment on this proposal. We also discussed alternative analysis of adjustment factors based on source of admission, which we did not propose to adopt. Lastly, we proposed that if more recent data become available, we would use such data, if appropriate, to determine the FY 2025 ED adjustment factor.

Comment: One commenter erroneously stated that CMS proposed to maintain the existing adjustment factor for IPFs with a qualified ED, and expressed support for doing so, but did not provide a rationale.

Response: We appreciate the comment, but we believe the commenter may have misunderstood the proposal. We proposed to increase the variable per diem adjustment factor for IPFs that have a qualified ED to 1.53, which we believe would appropriately adjust IPF PPS payments to account for differences in costs between IPFs without a qualified ED and those with a qualified ED.

Final Decision: After consideration of the comments received, we are finalizing the proposed revision to the ED adjustment factor following the proposed methodology. Thus, we are finalizing our proposal to use the following steps, as used in prior years, to calculate the updated ED adjustment factor. (A complete discussion of the steps involved in the calculation of the ED adjustment factors can be found in the RY 2005 IPF PPS final rule (69 FR 66959 through 66960) and the RY 2007 IPF PPS final rule (71 FR 27070 through 27072).)

Step 1: Estimate the proportion by which the ED costs of a stay will increase the cost of the first day of the stay. Using the IPFs with ED admissions in years 2019 through 2021, we divided the average ED cost per stay when admitted through the ED (\$519.97) by the average cost per day (\$1,338.93), which equals 0.39.

Step 2: Adjust the factor estimated in step 1 to account for the fact that we will pay the higher first day adjustment for all cases in the qualifying IPFs, not just the cases admitted through the ED. Since on average, 66 percent of the cases in IPFs with ED admissions are admitted through the ED, we multiplied 0.39 by 0.66, which equals 0.26.

Step 3: Add the adjusted factor calculated in the previous 2 steps to the variable per diem adjustment derived from the regression equation that we used to derive our other payment adjustment factors. As discussed in section IV.C.4.d. of this final rule, the first day payment factor for FY 2025 is

1.28. Adding 0.26, we obtained a first day variable per adjustment for IPFs with a qualifying ED equal to 1.54.

The ED adjustment is incorporated into the variable per diem adjustment for the first day of each stay for IPFs with a qualifying ED. A detailed discussion of the distributional impacts of this proposed change is found in section VIII.C of this final rule.

E. Other Payment Adjustments and Policies

1. Outlier Payment Overview

The IPF PPS includes an outlier adjustment to promote access to IPF care for those patients who require expensive care and to limit the financial risk of IPFs treating unusually costly patients. In the RY 2005 IPF PPS final rule, we implemented regulations at § 412.424(d)(3)(i) to provide a per case payment for IPF stays that are extraordinarily costly. Providing additional payments to IPFs for extremely costly cases strongly improves the accuracy of the IPF PPS in determining resource costs at the patient and facility level. These additional payments reduce the financial losses that would otherwise be incurred in treating patients who require costlier care; therefore, reduce the incentives for IPFs to under-serve these patients. We make outlier payments for discharges where an IPF's estimated total cost for a case exceeds a fixed dollar loss threshold amount (multiplied by the IPF's facility-level adjustments) plus the federal per diem payment amount for the case.

In instances when the case qualifies for an outlier payment, we pay 80 percent of the difference between the estimated cost for the case and the adjusted threshold amount for days 1 through 9 of the stay (consistent with the median LOS for IPFs in FY 2002), and 60 percent of the difference for day 10 and thereafter. The adjusted threshold amount is equal to the outlier threshold amount adjusted for wage area, teaching status, rural area, and the COLA adjustment (if applicable), plus the amount of the Medicare IPF payment for the case. We established the 80 percent and 60 percent loss sharing ratios because we were concerned that a single ratio established at 80 percent (like other Medicare PPSs) might provide an incentive under the IPF per diem payment system to increase LOS to receive additional payments.

After establishing the loss sharing ratios, we determined the current fixed dollar loss threshold amount through payment simulations designed to

compute a dollar loss beyond which payments are estimated to meet the 2 percent outlier spending target. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier payments represent 2 percent of total estimated IPF PPS payments.

2. Update to the Outlier Fixed Dollar Loss Threshold Amount

In accordance with the update methodology described in § 412.428(d), we proposed to update the fixed dollar loss threshold amount used under the IPF PPS outlier policy. Based on the regression analysis and payment simulations used to develop the IPF PPS, we established a 2 percent outlier policy, which strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the federal per diem base rate for all other cases that are not outlier cases. We proposed to maintain the established 2 percent outlier policy for FY 2025.

Our longstanding methodology for updating the outlier fixed dollar loss threshold involves using the best available data, which is typically the most recent available data. We note that for FY 2022 and FY 2023 only, we made certain methodological changes to our modeling of outlier payments, and we discussed the specific circumstances that led to those changes for those years (86 FR 42623 through 42624; 87 FR 46862 through 46864). We direct readers to the FY 2022 and FY 2023 IPF PPS proposed and final rules for a more complete discussion.

We proposed to update the IPF outlier threshold amount for FY 2025 using FY 2023 claims data and the same methodology that we have used to set the initial outlier threshold amount each year beginning with the RY 2007 IPF PPS final rule (71 FR 27072 and 27073). Based on an analysis of the December 2023 update of FY 2023 IPF claims, we estimated that IPF outlier payments as a percentage of total estimated payments would be approximately 2.1 percent in FY 2024. Therefore, we proposed to update the outlier threshold amount to \$35,590 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2025. We noted that the proposed rule update would be an increase from the FY 2024 threshold of \$33,470. Lastly, we proposed that if more recent data become available for the FY 2025 IPF PPS final rule, we would use such data as appropriate to determine the final outlier fixed dollar loss threshold amount for FY 2025.

Comment: Three commenters wrote that CMS should seek alternatives to the calculation of the outlier fixed dollar loss threshold. Two commenters suggested that CMS remove IPFs with extremely high or low costs per day, as we did in FY 2022 and FY 2023. One commenter suggested that CMS establish a new outlier baseline that increases each year based on the market basket update or using three-year rolling average to calculate the fixed dollar loss threshold.

Response: We appreciate the suggestions from commenters regarding the financial impact of the outlier threshold on IPFs and the use of alternative methodologies for estimating the outlier threshold. We are not finalizing any of the alternative methodologies that commenters suggested because we believe the proposed methodology, which follows our longstanding methodology, is the most technically appropriate for maintaining outlier payments at 2 percent of total IPF PPS payments in FY 2025.

Regarding the suggestion to limit increases to the outlier threshold to no more than the market basket update, we are concerned that this methodology would not be technically appropriate for the IPF PPS outlier policy. As discussed earlier in this section, the longstanding IPF PPS 2-percent outlier policy was established based on the regression analysis and payment simulations used to develop the IPF PPS. We have previously explained that the 2-percent outlier policy strikes an appropriate balance between protecting IPFs from extraordinarily costly cases while ensuring the adequacy of the Federal per diem base rate for all other cases that are not outlier cases. Each year when we update the IPF PPS, we simulate payments using the latest available data to compute the fixed dollar loss threshold so that outlier payments represent 2 percent of total estimated IPF PPS payments. For this FY 2025 IPF PPS final rule, we have simulated payments using the latest available data, and these payment simulations indicate that an increase to the outlier fixed dollar loss threshold is necessary to maintain outlier payments at 2 percent of total payments. We are concerned that limiting increases to the outlier fixed dollar loss threshold to no more than the market basket update percentage would not appropriately target outlier payments such that they remain at 2 percent of total IPF PPS payments. Moreover, such a policy would increase outlier payments above the 2-percent target for FY 2025. Likewise, a methodology in which CMS

would calculate the IPF PPS outlier threshold based on a three-year rolling average would not effectively target outlier payments at 2 percent of total IPF PPS payments. This is because the outlier threshold in FY 2023 and FY 2024 are lower than the threshold level that our payment simulations suggest would most effectively target outlier payments at 2 percent. Therefore, if we were to use a rolling average to calculate the FY 2025 IPF PPS outlier threshold, such a methodology would likely result in outlier payments that exceed the target.

Final Decision: After consideration of the comments received, we are finalizing our proposal to update the fixed dollar loss threshold amount used under the IPF PPS outlier policy. For this FY 2025 IPF PPS rulemaking, consistent with our longstanding practice, based on an analysis of the latest available data (the March 2024 update of FY 2023 IPF claims) and rate increases, we believe it is necessary to update the fixed dollar loss threshold amount to maintain an outlier percentage that equals 2 percent of total estimated IPF PPS payments. Based on an analysis of these updated data, we estimate that IPF outlier payments as a percentage of total estimated payments are approximately 2.3 percent in FY 2024. Therefore, we are finalizing an update to the outlier threshold amount to \$38,110 to maintain estimated outlier payments at 2 percent of total estimated aggregate IPF payments for FY 2025.

3. Update to IPF Cost-to-Charge Ratio Ceilings

Under the IPF PPS, an outlier payment is made if an IPF's cost for a stay exceeds a fixed dollar loss threshold amount plus the IPF PPS amount. To establish an IPF's cost for a particular case, we multiply the IPF's reported charges on the discharge bill by its overall cost-to-charge ratio (CCR). This approach to determining an IPF's cost is consistent with the approach used under the IPPS and other PPSs. In the RY 2004 IPPS final rule (68 FR 34494), we implemented changes to the IPPS policy used to determine CCRs for IPPS hospitals, because we became aware that payment vulnerabilities resulted in inappropriate outlier payments. Under the IPPS, we established a statistical measure of accuracy for CCRs to ensure that aberrant CCR data did not result in inappropriate outlier payments.

As indicated in the RY 2005 IPF PPS final rule (69 FR 66961), we believe that the IPF outlier policy is susceptible to the same payment vulnerabilities as the IPPS; therefore, we adopted a method to

ensure the statistical accuracy of CCRs under the IPF PPS. Specifically, we adopted the following procedure in the RY 2005 IPF PPS final rule:

- Calculated two national ceilings, one for IPFs located in rural areas and one for IPFs located in urban areas.
- Computed the ceilings by first calculating the national average and the standard deviation of the CCR for both urban and rural IPFs using the most recent CCRs entered in the most recent Provider Specific File (PSF) available.

For FY 2025, we proposed to continue following this methodology to update the FY 2025 national median and ceiling CCRs for urban and rural IPFs based on the CCRs entered in the latest available IPF PPS PSF, and we proposed that if more recent data became available, we would use such data to calculate the rural and urban national median and ceiling CCRs for FY 2025. We did not receive any comments on this proposal, and we are finalizing it as proposed.

To determine the final rural and urban ceilings, we multiplied each of the standard deviations by 3 and added the result to the appropriate national CCR average (either rural or urban). The final upper threshold CCR for IPFs in FY 2025 is 2.3181 for rural IPFs, and 1.8287 for urban IPFs, based on current CBSA-based geographic designations. If an IPF's CCR is above the applicable ceiling, the ratio is considered statistically inaccurate, and we assign the appropriate national (either rural or urban) median CCR to the IPF.

We apply the national median CCRs to the following situations:

- New IPFs that have not yet submitted their first Medicare cost report. We continue to use these national median CCRs until the facility's actual CCR can be computed using the first tentatively or final settled cost report.
- IPFs whose overall CCR is in excess of three standard deviations above the corresponding national geometric mean (that is, above the ceiling).
- Other IPFs for which the Medicare Administrative Contractor (MAC) obtains inaccurate or incomplete data with which to calculate a CCR.

Specifically, for FY 2025, for each of the three situations listed above, using the most recent CCRs entered in the CY 2023 PSF, we estimate a national median CCR of 0.5720 for rural IPFs and a national median CCR of 0.4200 for urban IPFs. These calculations are based on the IPF's location (either urban or rural) using the current CBSA-based geographic designations. A complete discussion regarding the national median CCRs appears in the RY 2005

IPF PPS final rule (69 FR 66961 through 66964).

4. Requirements for Reporting Ancillary Charges and All-Inclusive Status Eligibility Under the IPF PPS

a. Background

As discussed in section IV.E.4.b of this final rule, to analyze variation in cost between patients with different characteristics, it is crucial for us to have complete cost information about each patient, including data on ancillary services provided. Currently, IPFs and psychiatric units are required to report ancillary charges on cost reports. As specified at 42 CFR 413.20, hospitals are required to file cost reports on an annual basis and maintain sufficient financial records and statistical data for proper determination of costs payable under the Medicare program.

However, our ongoing analysis has found a notable increase in the number of IPFs, specifically for-profit freestanding IPFs, that appear to be erroneously identifying on form CMS–2552–10, Worksheet S–2, Part I, line 115, as eligible for filing all-inclusive cost reports. These hospitals identifying as eligible for filing all-inclusive cost reports (indicating that they have one charge covering all services) are consistently reporting no ancillary charges or very minimal ancillary charges and are not using charge information to apportion costs in their cost report. Generally, based on the nature of IPF services and the conditions of participation applicable to IPFs, we expect to see ancillary services and correlating charges, such as labs and drugs, on most IPF claims.³

In the FY 2016 IPF PPS final rule (80 FR 46693 through 46694), we discussed analysis conducted to better understand IPF industry practices for future IPF PPS refinements. This analysis revealed that in 2012 to 2013, over 20 percent of IPF stays show no reported ancillary charges, such as laboratory and drug charges, on claims. In the FY 2016 IPF PPS final rule (80 FR 46694), FY 2017 IPF PPS final rule (81 FR 50513), FY 2018 IPF PPS final rule (82 FR 36784), FY 2019 IPF PPS final rule (83 FR 38588), and FY 2020 IPF PPS final rule (84 FR 38458), we reminded providers that we only pay the IPF for services furnished to a Medicare beneficiary who is an inpatient of that IPF, except for

certain professional services, and payments are considered to be payments in full for all inpatient hospital services provided directly or under arrangement (see 42 CFR 412.404(d)), as specified in 42 CFR 409.10.

On November 17, 2017, we issued Transmittal 12, which made changes to the hospital cost report form CMS–2552–10 (OMB No. 0938–0050) and included cost report level 1 edit 10710S, effective for cost reporting periods ending on or after August 31, 2017. Edit 10710S required that cost reports from psychiatric hospitals include certain ancillary costs or the cost report will be rejected. On January 30, 2018, we issued Transmittal 13, which changed the implementation date for Transmittal 12 to be for cost reporting periods ending on or after September 30, 2017. CMS suspended edit 10710S effective April 27, 2018, pending evaluation of the application of the edit to all-inclusive rate providers. We issued Transmittal 15 on October 19, 2018, reinstating the requirement that cost reports from psychiatric hospitals, except all-inclusive rate providers, include certain ancillary costs. This requirement is still currently in place. For details, we refer readers to see these Transmittals, which are available on the CMS website at <https://www.cms.gov/medicare/regulations-guidance/transmittals>.

Under IPF PPS regulations at § 412.404(e), all inpatient psychiatric facilities paid under the IPF PPS must meet the recordkeeping and cost reporting requirements as specified at § 413.24. Historically, in accordance with § 413.24(a)(1), most hospitals that were approved to file all-inclusive cost reports were Indian Health Services (IHS) hospitals, government-owned psychiatric and acute care hospitals, and nominal charge hospitals. Although IPFs are no longer reimbursed on the basis of reasonable costs, we continue to expect that most IPFs, other than government-owned or tribally owned IPFs, should report cost data that is based on an approved method of cost finding and on the accrual basis of accounting. The option to elect to file an all-inclusive rate cost report is limited to providers that do not have a charge structure and that, therefore, must use an alternative statistic to apportion costs associated with services rendered to Medicare beneficiaries.

Current cost reporting rules allow hospitals that do not have a charge structure to file an all-inclusive cost report using an alternative cost allocation method. We refer readers to the Provider Reimbursement Manual (PRM) 15–1; chapter 22, § 2208 for detailed information on the

requirements to file an alternative method.

b. Challenges Related to Missing IPF Ancillary Cost Data

In general, most providers allocate their Medicare costs using costs and charges as described at § 413.53(a)(1)(i) and referred to as the Departmental Method, which is the ratio of beneficiary charges to total patient charges for the services of each ancillary department. For cost reporting periods beginning on or after October 1, 1982, the cost report uses the Departmental Method to apportion the cost of the department to the Medicare program. Added to this amount is the cost of routine services for Medicare beneficiaries, determined based on a separate average cost per diem for all patients for general routine patient care areas as required at § 413.53(a)(1)(i) and (e); and 15–1, chapter 22, § 2200.1.⁴

We use cost-to-charge ratios (CCRs) from Medicare cost reports as the method of establishing reasonable costs for hospital services and as the basis for ratesetting for several hospital prospective payment systems. In general, detailed ancillary cost and charge information is necessary for accurate Medicare ratesetting. When hospitals identify as all-inclusive, they are excluded from ratesetting because they do not have CCRs but use an alternative basis for apportioning costs. When hospitals erroneously identify as all-inclusive but have a charge structure, data that is necessary for accurate Medicare ratesetting is improperly excluded.

Since the issuance of Transmittal 15, we have continued to identify an increase in the number of IPFs, specifically for-profit freestanding IPFs, that appear to be erroneously identifying on form CMS–2552–10, Worksheet S–2, Part I, line 115, as filing all-inclusive cost reports. In conjunction with the FY 2023 IPF PPS proposed rule (87 FR 19428 through 19429), we posted a report on the CMS website that summarizes the results of the latest analysis of more recent IPF cost and claim information for potential IPF PPS adjustments and requested comments about the results summarized in the report. The report showed that approximately 23 percent of IPF stays were trimmed from the data set used in

³ IPFs are subject to all hospital conditions of participation, including 42 CFR 482.25, which specifies that “The hospital must have pharmaceutical services that meet the needs of the patients,” and 482.27, which specifies that “The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients.”

⁴ IPFs are subject to all hospital conditions of participation, including 42 CFR 482.25, which specifies that “The hospital must have pharmaceutical services that meet the needs of the patients,” and 482.27, which specifies that “The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients.”

that analysis because they were stays at facilities where fewer than 5-percent of their stays had ancillary charges. The report is available on the CMS website at <https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-psychiatric-facility/ipf-reports-and-educational-resources>.

Section 4125 of the CAA, 2023 authorizes the Secretary to collect data and information, specifically including charges related to ancillary services, as appropriate to inform revisions to the IPF PPS.

In the FY 2024 IPF PPS proposed rule (88 FR 21270 through 21272), we included a request for information (RFI) related to the reporting of charges for ancillary services, such as labs and drugs, on IPF claims. We were interested in better understanding IPF industry practices pertaining to the billing and provision of ancillary services to inform statutorily mandated IPF PPS refinements. We stated that we were considering whether to require charges for ancillary services to be reported on claims and potentially reject claims if no ancillary services are reported, and whether to consider payment for such claims to be inappropriate or erroneous and subject to recoupment.

In response to the comment solicitation, we received a comment from MedPAC regarding facilities that do not report ancillary charges on most or any of their claims. MedPAC stated that it is not known: whether IPFs fail to report ancillary charges separately because they were appropriately bundled with all other charges into an all-inclusive per diem rate; if no ancillary charges were incurred because the IPF cares for a patient mix with lower care needs or inappropriately fails to furnish the kinds of care reflected in ancillary charges when medically necessary; or if ancillary charges for services furnished during the IPF stay are inappropriately billed outside of the IPF base rate (unbundling). MedPAC recommended CMS conduct further investigation into the lack of certain ancillary charges and whether IPFs are providing necessary care and appropriately billing for inpatient psychiatric services under the IPF PPS.

MedPAC also encouraged CMS to require the reporting of ancillary charges and clarify the requirements related to IPFs' "all-inclusive-rate" hospital status. MedPAC noted that it observed in cost report data that IPFs that previously were not all-inclusive-rate hospitals have recently changed to an all-inclusive-rate status. MedPAC noted that the timing of many of these changes appears to correspond to CMS's

transmittals requiring ancillary services to be reported on cost reports for IPFs that do not have an all-inclusive rate.

Other commenters, including IPFs and hospital associations, responded to the RFI stating that the lack of ancillary charges on claims does not indicate a lack of services being provided. The commenters strongly opposed any claim-level editing and stated that reporting ancillary charges at the claim level would be inefficient and burdensome, particularly for government and IHS all-inclusive hospitals.

c. Clarification of Eligibility Criteria for the Option To Elect To File an All-Inclusive Cost Report

After taking into consideration the feedback we received from both MedPAC and IPF providers, for FY 2025 (89 FR 23193 through 23194) we clarified the eligibility criteria to be approved to file all-inclusive cost reports. We explained that only government-owned or tribally owned facilities are able to satisfy these criteria, and thus only these facilities will be permitted to file an all-inclusive cost report for cost reporting periods beginning on or after October 1, 2024.

We reminded readers that in order to be approved to file an all-inclusive cost report, hospitals must either have an all-inclusive rate (one charge covering all services) or a no-charge structure.⁵ We clarified that this does not mean any hospital can elect to have an all-inclusive rate or no-charge structure. Our longstanding policy as discussed in the PRM 15–1, chapter 22, § 2208.1, only allows a hospital to use an all-inclusive rate or no charge structure if it has never had a charge structure in place. In addition, we clarified that our expectation is that any new IPF would have the ability to have a charge structure under which it could allocate costs and charges. As previously stated, only a government-owned or tribally owned facility will be able to satisfy these criteria and will be eligible to file its cost report using an all-inclusive rate or no charge structure.

We stated that for cost reporting periods beginning on or after October 1, 2024, we will issue instructions to the MACs and put in place edits to operationalize our longstanding policy that only government-owned or tribally owned IPF hospitals are permitted to file an all-inclusive cost report. We explained that all other IPF hospitals must have a charge structure and must report ancillary costs and charges on their cost reports. IPFs that have

previously filed an all-inclusive cost report erroneously will no longer be able to do so. We further noted that to the extent government-owned or tribally owned hospitals can report ancillary charges on their cost reports, we strongly encourage them to do so to allow CMS to review and analyze complete and accurate data.

We stated that we believe clarifying the current eligibility criteria to be approved to file all-inclusive cost reports and implementing these operational changes will appropriately require freestanding IPFs with the ability to have a charge structure, that is, all IPFs other than those which are government-owned or tribally owned, to track and report ancillary charge information. In addition, we stated that we expect that more IPFs reporting ancillary charge information will result in an increase of IPFs having a CCR, which will in turn result in an increased number of IPFs being included in ratesetting. Therefore, we explained that we believe these operational changes will improve the quality of data reported, which will result in increased accuracy of future payment refinements to the IPF PPS.

Furthermore, we explained that we believe collecting charges of ancillary services from freestanding IPFs supports the directive for competition under the Executive Order on Promoting Competition in the American Economy as it facilitates accurate payment, cost efficiency, and transparency.⁶ We received several comments regarding this clarification and the operational changes discussed in the FY 2025 IPF PPS proposed rule.

Comment: Overall, commenters understood the clarification that only a government-owned or tribally owned facility will be able to satisfy these criteria and will be eligible to file its cost report using an all-inclusive rate or no charge structure. However, many commenters requested that CMS be lenient with facilities as they transition, and extend the date for compliance to October 1, 2026. A few commenters stated that reporting ancillary costs would require major changes to internal systems to efficiently track ancillary costs.

Response: We appreciate commenters' understanding of the importance of reporting ancillary costs on cost reports. As discussed in the proposed rule, the requirement that cost reports from psychiatric hospitals, except all-inclusive rate providers, include certain

⁵ PRM 15–1, chapter 22, § 2208.1.

⁶ <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09executive-order-on-promoting-competition-in-the-american-economy/>.

ancillary costs is currently in place. For a hospital to be eligible to file an all-inclusive cost report, they must require the use of an alternative statistic to apportion costs associated with services rendered to Medicare beneficiaries due to not having a charge structure. These requirements have been discussed through prior rulemaking, transmittals, a technical report, and MedPAC meetings and reports.

We remind readers that implementing the proposed operational changes to limited all-inclusive cost reporting would, at the earliest, affect cost reports submitted after October 1, 2025. This means that affected IPFs would have at least one year to make operational changes. While we acknowledge the concerns from commenters regarding systems changes needed to track ancillary costs, we believe putting in place edits for cost reporting periods beginning on or after October 1, 2024, to operationalize our longstanding policy provides IPF hospitals sufficient time to generally track and submit the ancillary cost and charge information.

Comment: Some commenters noted that the absence of ancillary costs on cost reports does not correlate to the assumption that ancillary services were not provided to the patient. The commenters stated that filing all-inclusive cost reports is a matter of efficiency to reduce administrative burden and cost. Commenters also expressed that they do not believe reporting ancillary costs has a direct influence on payment.

Response: We understand the lack of reported ancillary costs may not necessarily correlate with the services not being provided; however, based on the nature of IPF services and the conditions of participation applicable to IPFs, we expect to see ancillary services and correlating charges, such as labs and drugs, on most IPF claims. We believe IPFs are providing these necessary services to patients; however, the information currently reported does not provide evidence to this effect. In regard to commenters who stated that filing all-inclusive cost reports is a business decision for efficiency and to reduce administrative burden, filing correct cost reports should not be a new burden as this has always been required under Medicare. Furthermore, as mentioned above, we believe maintaining an accurate charge structure would be part of a business's accounting for reordering and restocking pharmaceuticals at a minimum, as well as more accurate payment for the purposes of outlier payments. As we mention above, these requirements have been discussed through prior

rulemaking, transmittals, a technical report, and MedPAC meetings and reports.

Further, we disagree with the commenters' assertion that reporting ancillary costs does not have a direct influence on payment. As discussed in section IV.C.3.c of this final rule, we analyzed ancillary cost and charge data to inform our proposed FY 2025 refinements to the IPF PPS. In addition, in section III.C.4.b of this final rule, we solicited comments on whether a lack of ancillary charge data may be contributing to the results of our regression analysis as it relates to opioid use disorders. For future refinements of the IPF PPS, such as those related to the patient assessment instrument as discussed in section V.B. of this final rule, the quality of the analyses of patient-level costs that CMS performs will ultimately depend on the quality of data that IPFs report.

Final Decision: After consideration of the comments received, we are putting in place operational edits to allow only those freestanding IPFs that are government-owned, IHS- or tribally owned facilities, to submit an all-inclusive cost report, effective for cost reporting periods beginning on or after October 1, 2024. Therefore, all other IPFs are required to have a charge structure and must report costs and charges for inpatient psychiatric services. We believe that collecting, and subsequently analyzing, detailed ancillary data from additional IPF hospitals will allow us to increase the accuracy of the IPF PPS.

F. Refinement Standardization Factor

Section 1886(s)(5)(D)(iii) of the Act, as added by section 4125(a) of the CAA, 2023, states that revisions in payment implemented pursuant to section 1886(s)(5)(D)(i) for a rate year shall result in the same estimated amount of aggregate expenditures under this title for psychiatric hospitals and psychiatric units furnished in the rate year as would have been made under this title for such care in such rate year if such revisions had not been implemented. We interpret this to mean that revisions in payment adjustments implemented for FY 2025 (and for any subsequent fiscal year) must be budget neutral.

Historically, we have maintained budget neutrality in the IPF PPS using the application of a standardization factor, which is codified in our regulations at § 412.424(c)(5) to account for the overall positive effects resulting from the facility-level and patient-level adjustments. As discussed in section IV.B.1 of this final rule, section 124(a)(1) of the BBRA required that we

implement the IPF PPS in a budget neutral manner. In other words, the amount of total payments under the IPF PPS, including any payment adjustments, must be projected to be equal to the amount of total payments that would have been made if the IPF PPS were not implemented. Therefore, we calculated the standardization factor by setting the total estimated IPF PPS payments, taking into account all of the adjustment factors under the IPF PPS, to be equal to the total estimated payments that would have been made under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97-248) methodology had the IPF PPS not been implemented. A step-by-step description of the methodology used to estimate payments under the TEFRA payment system appears in the RY 2005 IPF PPS final rule (69 FR 66926).

We believe the budget neutrality requirement of section 4125(a) of the CAA, 2023 is consistent with our longstanding methodology for maintaining budget neutrality under the IPF PPS. Therefore, for FY 2025, we proposed to apply a refinement standardization factor in accordance with our existing policy at § 412.424(c)(5). This policy requires us to update IPF PPS patient-level adjustment factors, ED adjustment, and ECT per treatment amount as proposed in FY 2025 IPF PPS proposed rule, in such a way that total estimated payments to IPFs for FY 2025 are the same with or without the changes (that is, in a budget neutral manner) by applying a refinement standardization factor to the IPF PPS rates. We proposed to apply a refinement standardization factor of 0.9514 to the IPF PPS federal per diem base rate and ECT per treatment amount to maintain budget neutrality.

We did not receive any comments on our proposed methodology for applying a refinement standardization factor. We are finalizing our proposal to use the following steps to ensure that the rates reflect the FY 2025 update to the patient-level adjustment factors (as previously discussed in section IV.C and IV.D of this final rule, and summarized in Addendum A) in a budget neutral manner:

Step 1: Simulate estimated IPF PPS payments using the FY 2024 IPF patient-level and facility-level adjustment factor values and FY 2024 ECT payment per treatment (available on the CMS website).

Step 2: Simulate estimated IPF PPS payments using the FY 2025 IPF patient-level and facility-level adjustment factor values (see Addendum A of this final rule, which

is available on the CMS website) and ECT per treatment amount based on the CY 2022 geometric mean cost for ECT under the OPPS.

Step 3: Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the final FY 2025 refinement standardization factor of 0.9524.

Step 4: Apply the FY 2025 refinement standardization factor from step 3 to the FY 2024 IPF PPS Federal per diem base rate and ECT per treatment amount (based on the CY 2022 geometric mean cost for ECT under the OPPS), after the application of the wage index budget neutrality factor and the IPF market basket increase reduced by the productivity adjustment described in section IV.A of this final rule to determine the FY 2025 IPF PPS Federal per diem base rate and FY 2025 ECT payment amount per treatment.

V. Requests for Information (RFI) To Inform Future Revisions to the IPF PPS in Accordance With the CAA, 2023

In the FY 2025 IPF PPS proposed rule, we requested information on two main topics to inform future revisions to the IPF PPS, in accordance with the CAA, 2023. First, we requested information regarding potential revisions to the IPF PPS facility-level adjustments. Second, we requested information regarding the development of a patient assessment instrument under the IPFQR program.

A. Request for Information Regarding Revisions to IPF PPS Facility-Level Adjustments

In section IV of the FY 2025 IPF PPS proposed rule (89 FR 23194 through 23200), we described the results of our latest analysis and requested public comment on them. Specifically, we presented the latest results of our analysis of the adjustments for rural location and teaching status, as well as a potential new adjustment for safety net population. We explained that the potential inclusion of a safety net adjustment could affect the magnitude of the adjustment factors for rural and teaching status, and we noted that future additional data and analysis may produce results that differ from those presented in the proposed rule. Lastly, we presented informational data about the distributional impacts of adopting such adjustment factors for the IPF PPS. We refer readers to the proposed rule for detailed description and explanation of these regression analyses and results.

In the proposed rule, we solicited comments on the following topics:

- Would it be appropriate to consider proposing revisions to the IPF PPS facility-level adjustments for rural

location and teaching status in the future based on the results of our latest regression analysis?

- Should we consider adjusting payment using MedPAC's Medicare Safety Net Index (MSNI) formula with adaptations, as described in the proposed rule? What, if any, changes to the methodology should we consider for the IPF setting? For example, should we develop a separate payment adjustment for each component (that is, the low-income ratio, uncompensated care ratio, and Medicare dependency ratio)?

- We note that our construction of the MSNI did not scale or index facility-level variables to a national standard or median value. We anticipate that doing so would result in less of a change to the IPF Federal per diem base rate but would still result in comparable distributional impacts (that is, IPFs with lower MSNIs would receive lower payments, and IPFs with higher MSNIs would receive higher payments). Should we consider scaling or indexing the MSNI to a national average MSNI for all IPFs?

- Is MedPAC's MSNI formula, as adapted, an accurate and appropriate measure of the extent to which an IPF acts as a safety-net hospital for Medicare beneficiaries?

- Should additional data be collected through the cost report to improve the calculation of MSNI, such as collecting UCC and revenue at the IPF unit level?

- Is the current cost report data submitted by IPFs sufficiently valid and complete to support the implementation of an MSNI payment? We note our concerns about the low or non-existent amounts reported for uncompensated care for freestanding IPFs and the use of hospital-level UCC and revenue amounts to calculate the UCC ratio for IPF units.

- What administrative burden or challenges might providers face in reporting their UCC and low-income patient stays?

- Would IPFs have the information necessary to report their low-income patient stays to CMS for the purpose of the MSNI calculation? What challenges might IPFs face in gathering and reporting this information?

- In the FY 2023 IPPS proposed rule, CMS noted that, when calculating the MSNI, the following circumstances may be encountered: new hospitals (for example, hospitals that begin participation in the Medicare program after the available audited cost report data), hospital mergers, hospitals with multiple cost reports and/or cost reporting periods that are shorter or longer than 365 days, cost reporting periods that span fiscal years, and

potentially aberrant data. How should CMS consider addressing these circumstances when calculating the MSNI for IPFs?

Comment: Several commenters supported refinements to the rural location and teaching status adjusters as described in the RFI. Some commenters recommended CMS continue to analyze more recent data to ensure that the updated regression model will have similar outcomes.

Response: We appreciate the information and feedback provided and will take these comments into consideration for future rulemaking.

Comment: Several commenters supported the development of a payment adjustment for safety net population. Two of these commenters expressed concerns that the available data is insufficient for implementation of an adjustment for MSNI as described in the RFI.

The majority of commenters who responded to the RFI about a payment adjustment for MSNI opposed the addition of this adjustment factor under the construction presented in the proposed rule because of insufficient data to support the adjustment because of the substantial decrease to the base rate or because of the redistribution of resources away from IPFs with a low MSNI. Several of these commenters, concerned that the adjustment would substantially decrease the base rate, noted that a decrease of this size would have unintended consequences such as further reducing access to care. Some commenters noted concerns that the inclusion of an MSNI adjustment would reduce the size of the rural adjustment, while other commenters noted that the adjustment would reduce the teaching adjustment. A couple of commenters recommended developing a DSH payment for IPFs as an alternative to MSNI. About half of these commenters advocated for an MSNI adjustment that is not budget neutral (*i.e.* that comes from an additional funding source), while one advocated for separate payment adjustments for each factor of MSNI (the low-income ratio, uncompensated care ratio, and Medicare dependency ratio). One of these commenters suggested a bonus value-based payment tied to quality measures for facilities serving high proportions of dually eligible beneficiaries.

MedPAC supported CMS's efforts to develop an adjustment factor based on MSNI. They recommended that CMS analyze whether a facility's low-income subsidy (LIS) and Medicare share of days are correlated with higher costs and lower profit margins, noting that factors that are important for identifying

safety-net acute care hospitals may not be exactly the same for IPFs. They also recommend that CMS require IPFs to report uncompensated care before implementing an adjustment factor including uncompensated care. MedPAC further advocated for investigation of an appropriate cap on changes; they suggest normalizing MSNI and basing each IPF's adjustment on the difference between the IPF's MSNI and the national MSNI.

Response: We appreciate the information and feedback provided and will take these comments into consideration for future rulemaking.

B. Request for Information (RFI)—Patient Assessment Instrument Under IPFQR Program (IPF PAI) To Improve the Accuracy of the PPS

Section 4125(b)(1) of CAA, 2023 amended section 1886(s)(4) of the Act, by inserting a new paragraph (E), to require IPFs participating in the IPFQR Program to collect and submit to the Secretary certain standardized patient assessment data, using a standardized patient assessment instrument (PAI) developed by the Secretary, for RY 2028 (FY 2028) and each subsequent rate year. IPFs must submit such data with respect to at least the admission to and discharge of an individual from the IPF, or more frequently as the Secretary determines appropriate. For IPFs to meet this new data collection and reporting requirement for RY 2028 and each subsequent rate year, the Secretary must implement a standardized PAI that collects data with respect to the following categories: functional status; cognitive function and mental status; special services, treatments, and interventions for psychiatric conditions; medical conditions and comorbidities; impairments; and other categories as determined appropriate by the Secretary. This IPF-PAI must enable comparison of the patient assessment data across all IPFs which submit these data. In other words, the data must be standardized such that data from IPFs participating in the IPFQR Program can be compared; the IPF-PAI each IPF administers must be made up of identical questions and identical sets of response options to which identical standards and definitions apply.

As we develop the IPF-PAI, in accordance with these new statutory requirements, we seek to collect information that will help us achieve the following goals: (1) improve the quality of care in IPFs, (2) improve the accuracy of the IPF PPS in accordance with section 4125(b)(2) of CAA, 2023,

and (3) improve health equity.⁷ In the Request for Information (RFI) we included in the FY 2025 IPF PPS proposed rule (89 FR 23200 through 23204), we solicited comments for development of this IPF-PAI, in accordance with these new statutory requirements, and to achieve these goals.

The RFI consisted of four sections. The first section discussed a general framework or set of principles for development of the IPF-PAI. The second section outlined potential approaches that could be used to develop the items or data elements that make up the PAI. This section also discussed patient assessment data elements in use in PAIs for skilled nursing facilities and other healthcare settings that could potentially be adapted for use in the IPF-PAI. The third section outlined potential approaches that could be used to collect patient assessment data. Finally, the fourth section solicited public comment on the principles and approaches listed in the first three sections and sought other input regarding the IPF-PAI.

1. Framework for Development of the IPF-PAI

We considered similar legislatively derived PAIs previously implemented for certain post-acute care (PAC) providers to inform the goals and guiding principles for the IPF-PAI because of similarities of section 4125(b) of CAA, 2023 to the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185, October 6, 2014), codified at section 1899B of the Act. Similar to section 4125(b) of CAA, 2023, section 1899B of the Act requires certain PAC providers, specifically home health agencies (HHAs), skilled nursing facilities (SNFs), inpatient rehabilitation facilities (IRFs), and long-term care hospitals (LTCHs), to submit certain standardized patient assessment data (as set forth at section 1899B(b)(1)(B)) using a standardized PAI under the PAC providers' respective quality reporting programs. While IPFs are acute care providers and not PAC providers, given the similarities between the CAA, 2023 and section 1899B of the Act, we considered the goals and guiding principles that we followed to implement section 1899B of the Act for certain PAC providers and examined

their applicability and appropriateness for IPFs.

We previously identified four key considerations when assessing Standardized Patient Assessment Data Elements for the PAC PAIs to collect: (1) Overall clinical relevance; (2) Interoperable exchange to facilitate care coordination during transitions in care; (3) Ability to capture medical complexity and risk factors that can inform both payment and quality; and (4) Scientific reliability and validity, general consensus agreement for its usability.⁸ For the reasons discussed in the following subsections, we believe that these considerations are also appropriate for the development of the IPF-PAI. In addition, we seek to balance the need to collect meaningful patient data to improve care with the need to minimize administrative burden. The remainder of this section describes each of these considerations in the context of the IPF-PAI. As we discuss in section V.B.4.a of this final rule, we solicited comment on these considerations.

a. Overall Clinical Relevance

In each category of assessment required by section 1886(s)(4)(E)(ii), as added by section 4125(b) of CAA, 2023, (functional status; cognitive function and mental status; special services, treatments, and interventions for psychiatric conditions; medical conditions and comorbidities; impairments, and other categories as determined appropriate by the Secretary), we seek to establish Standardized Patient Assessment Data Elements that providers can use to support high quality care and outcomes in the IPF setting. As we evaluate Standardized Patient Assessment Data Elements in PAIs designed for other care settings, we intend to work with CMS Medical Officers, including

⁸ We refer readers to the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal fiscal year 2020 final rule (84 FR 38767); the Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal fiscal year 2020 and Updates to the IRF Quality Reporting Program final rule (84 FR 39110), the Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements CY 2020 final rule (84 FR 60567), and the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and fiscal year 2020 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals final rule (84 FR 42537).

⁷ For more information on our strategic goals to improve health equity by expanding the collection, reporting, and analysis of standardized data, we refer readers to Priority 1 of our Framework for Health Equity at <https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework>.

psychiatrists, to consider the clinical relevance for IPF patients as a determining factor in whether an item merits inclusion in the IPF-PAI. For an example of a PAI in use in another setting, we refer readers to the IRF-PAI instrument available at <https://www.cms.gov/files/document/irf-pai-version-40-eff-10012022-final.pdf>. We are particularly interested in learning about specific instruments and tools in each area of assessment that have high clinical relevance in the IPF setting and welcomed comments regarding Standardized Patient Assessment Data Elements that may not be clinically relevant to the IPF setting.

To ensure the clinical relevance of the instrument across a diverse group of IPF patients, we are considering structuring the assessment with conditional questions, so that certain sets of questions are only indicated if the questions are relevant to the patient. Furthermore, we note that some data elements may only be appropriate for collection at certain times during the patient's stay (for example, only at admission or only at discharge). We solicited comments regarding the most effective structure to employ in the development of the IPF-PAI.

b. Interoperability

Interoperability is a key priority and initiative at CMS. Across the organization, we aim to promote the secure exchange, access, and use of electronic health information to support better informed decision making and a more efficient healthcare system. As a part of this effort, we make interoperability a priority for standardized data collection. We intend to ensure that the IPF-PAI meets Health Level 7® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) standards.

As part of our interoperability considerations, we are interested in whether Standardized Patient Assessment Data Elements already in use in the CMS Data Element Library (DEL)⁹ are appropriate and clinically relevant for the IPF setting. Based on our analysis of IPF PPS claims submitted in CY 2021, approximately 8,000 admissions to IPFs were individuals transferred from SNFs or IRFs. We are interested in whether Standardized Patient Assessment Data Elements already used in the DEL can be used to better support interoperability between providers, given the high number of transfers.

c. Ability To Capture Medical Complexity and Risk Factors

We intend to expand our efforts to refine the IPF PPS to increase the accuracy of the payment system by better identifying patient characteristics that best predict resource use during an IPF stay. To identify Standardized Patient Assessment Data Elements that would help predict resource use, we intend to evaluate Standardized Patient Assessment Data Elements for their ability to explain medical complexity, the need for special services and treatments, and to measure case-mix differences that impact costs. It is our expectation that an IPF-PAI that effectively differentiates treatment needs between patients will also help IPFs plan and distribute their resources. Our hope is that the IPF-PAI can therefore integrate with IPFs' business practices. In addition, Standardized Patient Assessment Data Elements that capture patient risk factors can contribute to quality of care and patient safety.

d. Scientific Reliability and Validity

Standardized Patient Assessment Data Elements considered for inclusion in the IPF-PAI must be scientifically reliable and valid in IPF settings.¹⁰ We intend to draw on our significant experience in development of quality measures in the IPFQR Program and development of Standardized Patient Assessment Data Elements for other PAIs, such as the IRF-PAI and the Minimum Data Set (MDS) (the PAI for SNFs), in our development of Standardized Patient Assessment Data Elements for the IPF-PAI.¹¹ It is important to note that the statutorily required timeframe for implementation of the IPF-PAI for RY 2028 limits our ability to develop and test a full battery of new Standardized Patient Assessment Data Elements for the launch of the IPF-PAI. We anticipate the need and opportunity for

incremental revisions to the IPF-PAI in the future.

We anticipate that our development process for new Standardized Patient Assessment Data Elements will include working with teams of researchers for each category including a group of advisors made up of clinicians and academic researchers for each team with expertise in IPFs. We expect to convene a Technical Expert Panel (TEP) to provide expert input on new and existing Standardized Patient Assessment Data Elements that merit consideration for inclusion and testing, including environmental scans and reviews of scientific literature. In an ideal scenario, Standardized Patient Assessment Data Elements would be tested in a representative sample of IPFs for appropriateness in different IPF settings and across a range of patients. Standardized Patient Assessment Data Elements would be tested for inter-rater (that is, consistency in results regardless of who is administering the assessment) and inter-organizational reliability, for validity in all IPF settings, for internal consistency, and for breadth of application among a range of IPF patients. We anticipate that Standardized Patient Assessment Data Elements would also need to be tested for their ability to detect differences among patients and costs of treatment. Due to the constraints of the statutorily required implementation timeframe, it may not be possible to complete all testing before launching the IPF-PAI.

The process for scientifically testing each question and set of responses is lengthy and resource-intensive. This process is based on the steps for quality measure development described in the Blueprint Measure Lifecycle,¹² developed by the CMS Measures Management System. These steps include literature review and environmental scanning; various levels of field testing to understand the "real world" performance of the data elements; and iterative expert and interested parties engagement to include broader perspectives on topics, candidate data elements, and interpretation of testing results. If appropriate, using data currently collected by IPFs or Standardized Patient Assessment Data Elements that have been tested and validated for use in other clinical settings can reduce these timeframes because test data are already available.

¹⁰ CMS' guidelines for data element identification and evaluation, including definitions of scientific acceptability (i.e., reliability and validity) are described in the Blueprint Measure Lifecycle, available at: <https://mmshub.cms.gov/measure-lifecycle/measure-testing/overview>.

¹¹ For more information on other PAIs, we refer readers to <https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-rehabilitation/pai> (for the IRF-PAI), to <https://www.cms.gov/medicare/quality/home-health/oasis-data-sets> (for the OASIS data set for HHAs), to <https://www.cms.gov/medicare/quality/long-term-care-hospital/lth-care-data-set-lth-grp-manual> (for the CARE data set for LTCHs), and to <https://www.cms.gov/medicare/quality/nursing-home-improvement/resident-assessment-instrument-manual> (for the Minimum Data Set (MDS) Resident Assessment Instrument (RAI)).

¹² <https://mmshub.cms.gov/blueprint-measure-lifecycle-overview>.

⁹ <https://del.cms.gov/DELWeb/pubHome>.

e. Administrative Burden

In evaluating Standardized Patient Assessment Data Elements for inclusion in the IPF–PAI, we are considering the burden of data collection through the PAI and aiming to minimize additional burden by considering whether any data that is currently collected through IPFQR Program measures or on IPF claims could be collected as Standardized Patient Assessment Data Elements to avoid duplication of data that IPFs are already reporting. We are also considering how collecting some data for some IPFQR Program measures through the IPF–PAI and collecting other data through the Hospital Quality Reporting (HQR) system would affect the reporting burden for participating IPFs. Licensing, permissions costs, or copyright restrictions that would add to administrative costs and burdens are also a consideration as we evaluate existing PAIs and mechanisms or tools for submitting IPF–PAI data.

As we develop the IPF–PAI, we are interested in receiving information about how to find a balance between collecting the most relevant and useful information and the administrative burden of administering the assessment and submitting the assessment data.

2. Elements of the IPF–PAI

Section 1886(s)(4)(E)(ii) of the Act, added by section 4125(b)(1)(C) of the CAA, 2023, requires that the standardized patient assessment data to be collected in the IPF–PAI must be with respect to six enumerated categories.

a. Functional Status

The first enumerated category of data for the IPF–PAI is functional status. Section 1886(s)(4)(E)(ii)(I) of the Act provides that functional status may include mobility and self-care at admission to a psychiatric hospital or unit and before discharge from a psychiatric hospital or unit. We note that information in this category is generally found in a patient's discharge summary and are interested in learning about standardized elements that correspond to functional status as relevant to IPFs. In the FY 2025 IPF PPS proposed rule, we stated our interest in learning about assessments that may be currently in use in the IPF setting and meet criteria for inclusion in the IPF–PAI (89 FR 23202).

b. Cognitive Function and Mental Status

The second enumerated category of data for the IPF–PAI is cognitive function and mental status. Section 1886(s)(4)(E)(ii)(II) of the Act provides that cognitive function may include the

ability to express ideas and to understand, and mental status may include depression and dementia. We note that in the IPF setting, a patient's diagnoses, which can be abstracted from their medical chart, provide some information related to this category. We are aware that IPFs may be currently assessing cognitive function using existing instruments. In the FY 2025 IPF PPS proposed rule, we stated our interest in hearing from IPFs about which instruments are currently in use to measure cognitive function in IPFs and which have high clinical relevance for the IPF setting (89 FR 23202).

c. Special Services, Treatments, and Interventions

The third enumerated category of data for the IPF–PAI is special services, treatments, and interventions for psychiatric conditions. Section 1886(s)(4)(E)(ii)(III) of the Act neither addresses what these terms mean nor provides any illustrative examples. As discussed in section VII.C. of this rule, the IPFQR Program already collects information about the use of restraint and seclusion through quality measures (Hospital Based Inpatient Psychiatric Services (HBIPS)-2, Hours of Physical Restraint, and HBIPS-3, Hours of Seclusion Use), while claims include information about ECT treatments provided. Other areas of interest in this category may include high-cost medications, use of chemical restraints, one-to-one observation, and high-cost technologies. In the FY 2025 IPF PPS proposed rule, we stated our interest in whether these or any other special services, treatments, or interventions should be considered for inclusion in the IPF–PAI (89 FR 23202 through 23203).

d. Medical Conditions and Comorbidities

The fourth enumerated category of data for the IPF–PAI is medical conditions and comorbidities. Section 1886(s)(4)(E)(ii)(IV) of the Act provides that medical conditions and comorbidities may include diabetes, congestive heart failure, and pressure ulcers. We note that IPF claims record a significant number of medical conditions and comorbidities to receive the payment adjustment for comorbidities in the IPF PPS and conditions that are relevant to the IPF stay. In reviewing Standardized Patient Assessment Data Elements listed in this category in PAIs in use in PAC settings, we observed that these PAIs include Standardized Patient Assessment Data Elements regarding pain interference in this category, such as the effect of pain

on sleep, pain interference with therapy activities, and pain interference with day-to-day activities. In the FY 2025 IPF PPS proposed rule, we stated our interest in learning from commenters whether these existing data elements from the PAC settings would be clinically relevant for inclusion in this category for the IPF–PAI (89 FR 23203).

e. Impairments

The fifth enumerated category of data for the IPF–PAI is impairments. Section 1886(s)(4)(E)(ii)(V) of the Act provides that impairments may include incontinence and an impaired ability to hear, see, or swallow. PAIs in use in other settings include Standardized Patient Assessment Data Elements regarding hearing and vision (for example, Section B, “Hearing, Speech, and Vision” of the IRF–PAI Version 4.2 (Effective October 1, 2024)).¹³ In the FY 2025 IPF PPS proposed rule, we stated our interest both in whether Standardized Patient Assessment Data Elements regarding additional impairments merit consideration for the IPF–PAI, and whether the Standardized Patient Assessment Data Elements regarding hearing and vision included in the IRF–PAI are appropriate for the IPF setting (89 FR 23203). We note that the Standardized Patient Assessment Data Element categories are not intended to be duplicative, so we would seek to avoid any overlap in measuring cognitive deficits in the Cognitive Function category with the Impairments category.

f. Other Categories Deemed Appropriate

The sixth enumerated category of data for the IPF–PAI is other categories as determined appropriate by the Secretary. We believe this provision allows for flexibility to include additional areas in the IPF–PAI.

One of our strategic priorities, as laid out in the CMS Strategic Plan,¹⁴ reflects our deep commitment to improvements in health equity by addressing the health disparities that underlie our health system. In line with that strategic priority, in the FY 2025 IPF PPS proposed rule, we stated our interest in Standardized Patient Assessment Data Elements that would provide insight about any demographic factors (for example, race, national origin, primary language, ethnicity, sexual orientation, and gender identity) as well as Social Drivers of Health (SDOH) (for example, housing status and food security)

¹³ <https://www.cms.gov/files/document/irf-pai-version-42-effective-10-01-24.pdf>.

¹⁴ The CMS Strategic Plan. Available at <https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan>. Accessed February 20, 2024.

associated with underlying inequities (89 FR 23203). We also stated our interest in whether there are Standardized Patient Assessment Data Elements that would provide insight into special interventions that IPFs are providing to support patients after discharge which could serve to potentially reduce the incidence of readmissions (89 FR 23203).

We note that, beginning with mandatory reporting of CY 2025 data for FY 2027 payment determination, the IPFQR Program includes the Screening for SDOH measure, which assesses the percentage of patients, aged 18 years and over at the time of admission, who are screened for five specific health-related social needs (HRSNs) (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) but which does not require reporting of that information at the patient-level (88 FR 51117). Furthermore, we note that PAIs adopted for the PAC settings discussed previously include collection of SDOH data under section 1899B(b)(1)(B)(vi) of the Act, which contains a similar provision for other categories deemed appropriate by the Secretary.¹⁵

We note that, if we deem it appropriate to add a SDOH category for the IPF-PAI and these SDOH data are included as Standardized Patient Assessment Data Elements in the PAI, they could potentially be used to risk adjust or stratify measures collected for the IPFQR Program. In the FY 2025 IPF PPS proposed rule, we stated our interest in learning whether using some of these SDOH data adopted in other PAIs to risk adjust or stratify these measures would make the measures in

the IPFQR Program more meaningful (89 FR 23203).

3. Implementation of the PAI—Data Submission

We plan to develop flexible methods for providers to submit IPF-PAI data to CMS, including batch uploads in specified formats and a portal for submission of files. We welcomed public comment on tools and methods for submission of data that balance administrative burden and ease of use.

4. Request for Information on IPF-PAI

In the FY 2025 IPF PPS proposed rule, we requested information from the public to inform the selection of Standardized Patient Assessment Data Elements to be collected on the IPF-PAI and the implementation process (89 FR 23203). We sought information about PAIs IPFs currently use upon admission and discharge, as well as information about how IPFs estimate resource needs to determine capacity before a patient is admitted. We also sought information about methods for IPFs to submit patient assessment data and the potential administrative burden on IPFs, Medicare Administrative Contractors (MACs), and CMS. Finally, we sought input on the relationship between the IPF-PAI and the measures within the IPFQR Program.

We solicited comment on the following topics:

a. Principles for Selecting Standardized Patient Assessment Data Elements

- To what extent do you agree with the principles for selecting and developing Standardized Patient Assessment Data Elements for the IPF-PAI?
- What, if any, principles should CMS eliminate from the Standardized Patient Assessment Data Element selection criteria?
- What, if any, principles should CMS add to the Standardized Patient Assessment Data Element selection criteria?

Comment: Several commenters were supportive of the idea of implementing a patient assessment for the IPF setting. They saw potential for an IPF-PAI to capture patient characteristics and costs more accurately through standardized assessment and believed that data from the IPF-PAI could support improvement in payment models, quality of care, and health equity. Some commenters expressed general concerns about the IPF-PAI, citing challenges with PAIs used in other provider types and the burden that a standardized patient assessment could place on providers.

Several commenters recommended CMS include data elements that reflect resource use in the IPF-PAI, and a few commenters stated the belief that data elements in the IPF-PAI should be selected with consideration of their ability to capture quality of care or support quality improvement efforts. A commenter stated that CMS should not collect any additional information that would not ultimately impact IPF payments.

Several commenters suggested ways that CMS should approach instrument development to minimize administrative burdens related to the PAI, such as leveraging or aligning with current IPFQR requirements and other common, existing IPF workflows, and focusing on data elements that are easy to collect and assessment instruments that are already in widespread use, rather than developing de novo tools. A commenter recommended that CMS compare the content of the IPF-PAI to other required data submissions in order to reduce duplicative data entry. A commenter recommended that CMS attempt to align data elements, data collection time periods, and measures between the IPFQR Program and The Joint Commission, a national accrediting body that establishes quality and safety standards for health care organizations.¹⁶ To mitigate burden, several commenters recommended that CMS be judicious when selecting data elements for the IPF-PAI, prioritizing data elements that could be auto-populated from a facility's electronic health record (EHR). A commenter stated that it is important for CMS to only consider standardized tools that are in the public domain and that do not incur costs of utilization for inclusion in the IPF-PAI.

Several commenters agreed with CMS that data elements selected for the IPF-PAI should have demonstrated scientific acceptability, including testing that

¹⁵ For further information detailing the rationale for adopting SDOH Standardized Patient Assessment Data Elements in these settings, we refer readers to the Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities; Updates to the Quality Reporting Program and Value-Based Purchasing Program for Federal fiscal year 2020 final rule (84 FR 38805 through 38817); the Medicare Program; Inpatient Rehabilitation Facility (IRF) Prospective Payment System for Federal fiscal year 2020 and Updates to the IRF Quality Reporting Program final rule (84 FR 39149 through 38161), the Medicare and Medicaid Programs; CY 2020 Home Health Prospective Payment System Rate Update; Home Health Value-Based Purchasing Model; Home Health Quality Reporting Requirements; and Home Infusion Therapy Requirements CY 2020 final rule (84 FR 60597 through 60608), and the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and fiscal year 2020 Rates; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Promoting Interoperability Programs Requirements for Eligible Hospitals and Critical Access Hospitals final rule (84 FR 42577 through 42588).

¹⁶ IPFs can receive accreditation from The Joint Commission, formerly known as on The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), through an independent survey process and period reporting of quality measure data. Psychiatric hospitals participating in Medicare that are accredited under The Joint Commission's consolidated standards for adult psychiatric facilities are deemed to meet Medicare's requirements for hospitals (with the exception of the special medical record and staffing requirements). Accreditation by The Joint Commission is not a requirement for participating in Medicare, but many IPFs maintain accredited status and must submit quality measure data to The Joint Commission as well as to CMS. More information on the process of deeming IPFs to have met Medicare's requirements is available in Appendix AA of the State Operations Manual available at: https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/som107ap_aa_psys_hospitals.pdf.

shows them to be reliable and valid. A few commenters noted the importance of inter-rater reliability and suggested this could be bolstered during implementation by providing clear guidance to individuals administering the assessment. A commenter recommended ongoing monitoring of IPF-PAI data after the IPF-PAI is implemented, including an audit plan for ensuring accuracy of reported data and periodic reassessment of inter-rater reliability. Several commenters noted the importance of testing the IPF-PAI in IPFs, specifically in a diverse set of IPFs, to ensure relevance, validity, and reliability in this setting.

Several commenters described unique characteristics of IPF patients and limitations of IPFs and recommended that CMS prioritize appropriateness for IPFs when developing the IPF-PAI. Several commenters noted concerns that leveraging data elements used in post-acute care or with geriatric populations would not be appropriate for the majority of IPF patients. A few commenters recommended that CMS select data elements that would be applicable to diverse patient populations and facility types. A commenter noted the importance of using standardized data elements in the IPF-PAI that apply to the broadest range of patients, focusing, for example, on function rather than symptoms, as measures of function apply to all patients while measurement of specific symptomology would need to be tailored to patients' conditions.

Some commenters noted that patients in IPFs may be unwilling or unable to complete any patient interviews to inform data elements. A commenter recommended that testing be conducted with IPFs to understand these dynamics and inform policies on acceptable completion rates.

Several commenters stated concerns about the timeline for development and implementation of the IPF-PAI. To accomplish its goals while minimizing burden to providers, a few commenters recommended that CMS start with a basic tool that is limited in scope while meeting the statutory requirements, then expand the tool as additional data elements are tested for validity and reliability. A commenter suggested that CMS identify what is already being collected by IPFs and require reporting of these data elements, rather than developing a new tool.

Many commenters noted the importance of engaging with experts and other interested parties in the development of the IPF-PAI. A few commenters suggested that CMS engage with specific interested parties,

including mental health specialty societies, psychiatric mental health nurses, and software vendors. A commenter recommended that CMS engage with the provider community to solicit their comments before finalizing the IPF-PAI. A commenter suggested that CMS form a working group that meets quarterly in order to incorporate and respond to feedback from interested parties.

Regarding CMS intention to design the IPF-PAI to be interoperable, a commenter recommended that CMS align the IPF-PAI with United States Core Data for Interoperability (USCDI), while another commenter stated support for CMS commitment to interoperability for the IPF-PAI, specifically for data on social risk factors and HRSNs. Several commenters noted that IPFs did not receive funding to adopt certified EHR technology and suggested that CMS consider how the implementation of the IPF-PAI would affect providers without EHRs.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF-PAI.

b. Patient Assessments Recommended for Use in the IPF-PAI

- Are there PAIs currently available for use, or that could be adapted or developed for use in the IPF-PAI, to assess patients': (1) functional status; (2) cognitive function and mental status; (3) special services, treatments, and interventions for psychiatric conditions; (4) medical conditions and comorbidities; (5) impairments; (6) health disparities; or (7) other areas not mentioned in this RFI?

We summarize the comments we received regarding existing assessment instruments or data elements in current use with respect to each patient assessment topic in sections V.B.4.c through V.B.4.h of this rule. We include the names of the instruments that commenters identified in the summaries of comments that pertain to each topic area in sections V.B.4.c through V.B.4.h of this rule.

c. Functional Status Standardized Patient Assessment Data Elements

- What aspects of function are most predictive of medical complexity or increased resource needs to treat a patient in the IPF setting?

- Which of the Standardized Patient Assessment Data Elements related to mobility (that is, the ability to toilet transfer, walk 10 feet, car transfer, walk 10 feet on an uneven surface, 1 step up (that is, a curb), 4 steps up, 12 steps up,

and pick up an object) currently collected by PAC settings in their respective PAIs are clinically relevant in the IPF setting? Do they otherwise meet the principles for inclusion in the IPF-PAI?

Comment: A few commenters described aspects of functional status that would be appropriate to capture using the IPF-PAI. These include being wheelchair bound, ability to toilet transfer, ability to walk 10 feet, requiring assistance with walking, being designated as at risk of falls, and requiring 1-on-1 supervision for any reason. A commenter recommended assessing patients' abilities to complete activities of daily living (ADLs) and instrumental activities of daily living (IADLs). We note that ADLs typically refer to ambulating, feeding, dressing, personal hygiene, continence, and toileting and IADLs typically refer to transportation, managing finances, shopping and meal preparation, housekeeping, communication (for example, using the telephone), and managing medications.¹⁷ A commenter offered several examples of public domain measures of physical and social function from the National Institute of Health's Patient-Reported Outcomes Measurement Information System (PROMIS), including Physical Function, Ability to Participate in Social Roles and Activities, Companionship, Friendship, and Social Isolation.¹⁸ A commenter shared two assessments that capture a patient's risk for falls: the Edmonson Fall Risk Assessment Tool¹⁹ and the Morse Fall Scale.²⁰

A few commenters stated that the standardized patient assessment data elements on functional status that CMS presented for comment were not relevant to the IPF patient population. They stated that IPF patients are generally younger and have fewer functional impairments than the post-acute and geriatric populations for which these data elements were developed. A commenter suggested that these data elements would only be appropriate for geriatric psychiatry patients, and that the IPF-PAI could

¹⁷ Mlinac, M.E., & Feng, M.C. (2016). Assessment of activities of daily living, self-care, and independence. *Archives of Clinical Neuropsychology*, 31(6), 506–516.

¹⁸ For information about the PROMIS data elements, we refer readers to: <https://www.healthmeasures.net/explore-measurement-systems/promis>.

¹⁹ Edmonson, D., Robinson, S., & Hughes, L. (2011). Development of the Edmonson psychiatric fall risk assessment tool. *Journal of psychosocial nursing and mental health services*, 49(2), 29–36.

²⁰ Watson, B.J., Salmoni, A.W., & Zecevic, A.A. (2016). The use of the Morse Fall Scale in an acute care hospital. *Clin Nurs Stud*, 4(2), 32–40.

skip these questions for non-geriatric patients.

A commenter stated concerns about the accuracy of provider-assessed functional assessments, in the event that data on functional assessments would be used in payment models (that is, facilities would be paid more for patients with poor functional status), as providers would have an incentive to assess patients as more functionally impaired than they might be. Another commenter stated support for the standardized assessment of functional status, and stated their belief that functional status is the only topic appropriate for standardized patient assessment due to the clinical diversity of IPF patients.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF-PAI.

d. Cognitive Function and Mental Status Standardized Patient Assessment Data Elements

- What aspects of cognitive function and mental status are most predictive of medical complexity or increased resource needs to treat a patient in the IPF setting?

- What components or instruments are used to assess cognitive function, mental status, or a combination thereof upon admission? What, if any, differences are there between assessments administered at admission and at discharge? What are the components of the mental status assessments administered at admission and discharge?

Comment: Several commenters stated that mental status examination is a typical practice in IPFs, with key aspects including appearance and behavior, speech, thought process and content, affect and mood, cognition, perception, judgement, insight, and suicidal ideation and suicide-related behaviors. Several commenters recommended that CMS ensure IPFs and treating clinicians have discretion over the approach to conducting mental status examinations, noting that the mental status examination should be tailored to the patient, and stated concerns about the IPF-PAI introducing a standardized approach to this typically individualized process. Several commenters recommended considering assessment of suicidal ideation and suicide-related behaviors, homicidality and homicidal ideation, aggression, agitation, and unpredictable behavior, as these are markers of patient acuity and predictive of resource use. Additionally, a commenter

recommended assessing for psychosis and insomnia, sharing their belief that patients experiencing these states require more resources.

Several commenters stated a belief that assessment of cognitive function is not appropriate for most IPF patients, specifically for patients who do not show signs of cognitive impairment. These commenters stated that cognitive impairment is most common in older adults and questioned the value of universal screening for cognitive impairment for the IPF population.

Commenters shared the names of several assessments on the topics of cognitive function and mental status, including the St. Louis University Mental Status Exam,²¹ the Mini-Mental State Exam,²² the Montreal Cognitive Assessment,²³ the Cohen-Mansfield Agitation Inventory,²⁴ the Geriatric Depression Scale,²⁵ the Patient Health Questionnaire (PHQ-9),²⁶ and the Beck Depression Inventory.²⁷ A commenter recommended that the IPF-PAI contain only a single item to address the Cognitive Function and Mental Status category, such as “Does the patient have a co-morbid neurocognitive disorder?” A commenter recommended including a standardized suicide risk assessment in the IPF-PAI, recommending the Columbia-Suicide Severity Rating Scale.²⁸

A commenter stated concerns about the time required to collect standardized

assessments of cognitive function and mental status. This commenter noted that, although individual assessments may be brief, when combined with other data elements, this could make the IPF-PAI very long.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF-PAI.

e. Special Services, Treatments, and Interventions for Psychiatric Conditions Standardized Patient Assessment Data Elements

- What special services, treatments, and interventions are most predictive of increased resource intensity during an IPF stay?

- Do data currently collected as part of the IPFQR Program related to special services and treatments (such as HBIPS-2 Hours of Physical Restraint Use and HBIPS-3 Hours of Seclusion Use) meet the criteria for inclusion in the IPF-PAI?

Comment: Several commenters shared thoughts on the special services, treatments, and interventions that they have found to be most predictive of resource intensity. These include supervision or observation needs (for example, one-to-one observation and continuous visual observation), unit restrictions, restraint or seclusion episodes, features of medication (for example, polypharmacy, medication management needs, use of long-acting injectable medication or clozapine, high-cost medications, and emergency medications), fall risk management, the need for any treatments that occur outside of the IPF (for example, dialysis), and the patient being involuntarily hospitalized. Several commenters described the resource intensity impacts of patients who require higher than usual levels of observation at any point during their stay. Regarding medications, a few commenters described how long-acting injectable medications and clozapine are often reserved for patients for whom other medications are not effective or not acceptable, and their use often correlates with patients who are not attaining symptom control quickly, and therefore require more staff attention and supervision. Regarding involuntary hospitalization, a commenter noted the staffing resources required to comply with the administrative and legal processes, such as accompanying the patient to court proceedings. This commenter recommended that CMS include in the IPF-PAI a data element to capture when a patient requires legal hearing(s) related to involuntary hospitalization or treatment over

²¹ Shwartz, S.K., Morris, R.D., & Penna, S. (2019). Psychometric properties of the Saint Louis University mental status examination. *Applied Neuropsychology: Adult*, 26(2), 101–110.

²² Tombaugh, T.N., McDowell, I., Kristjansson, B., & Hubley, A.M. (1996). Mini-Mental State Examination (MMSE) and the Modified MMSE (3MS): a psychometric comparison and normative data. *Psychological Assessment*, 8(1), 48.

²³ Freitas, S., Simões, M.R., Marôco, J., Alves, L., & Santana, I. (2012). Construct validity of the montreal cognitive assessment (MoCA). *Journal of the International Neuropsychological Society*, 18(2), 242–250.

²⁴ Cohen-Mansfield, J. (1986). Cohen-Mansfield Agitation Inventory. *International Journal of Geriatric Psychiatry*.

²⁵ Wancata, J., Alexandrowicz, R., Marquart, B., Weiss, M., & Friedrich, F. (2006). The criterion validity of the Geriatric Depression Scale: a systematic review. *Acta Psychiatrica Scandinavica*, 114(6), 398–410.

²⁶ Löwe, B., Unützer, J., Callahan, C.M., Perkins, A.J., & Kroenke, K. (2004). Monitoring depression treatment outcomes with the Patient Health Questionnaire-9. *Medical care*, 42(12), 1194–1201.

²⁷ Dozois, D.J., Dobson, K.S., & Ahnberg, J.L. (1998). A psychometric evaluation of the Beck Depression Inventory-II. *Psychological assessment*, 10(2), 83.

²⁸ Posner, K., Brown, G.K., Stanley, B., Brent, D.A., Yershova, K.V., Oquendo, M.A., . . . & Mann, J. J. (2011). The Columbia-Suicide Severity Rating Scale: initial validity and internal consistency findings from three multisite studies with adolescents and adults. *American journal of psychiatry*, 168(12), 1266–1277.

objection (for example, being administered medication).

A commenter recommended that CMS include recreational therapy as a distinct and separate service to be collected in the IPF-PAI.

A commenter noted concerns that treatments and interventions cannot be assessed in a standardized way in the IPF-PAI because they are different for every patient. Another commenter recommended that CMS not require that minutes of therapy time be tracked on the IPF-PAI, as they believe this would be resource intensive and have little value.

A commenter noted that IPFs already collect and submit patient data relevant to this category through the IPFQR Program's Tobacco Use Treatment Provided or Offered at Discharge measure (TOB-3)²⁹ and suggested that CMS consider existing data reporting to meet the requirement for patient assessment for this topic.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF-PAI.

f. Medical Conditions and Comorbidities Standardized Patient Assessment Data Elements

- Is the Standardized Patient Assessment Data Element regarding pain interference (effect on sleep, interference with therapy activities, interference with day-to-day activities) currently collected by PAC settings in their respective PAIs clinically relevant in the IPF setting? Does it otherwise meet the criteria for inclusion in the IPF-PAI?

- Do the medical conditions and comorbidities coded on IPF claims meet the criteria for inclusion in the IPF-PAI?

Comment: Commenters provided feedback on the types of medical conditions and comorbidities that would be appropriate to be assessed in the IPF setting.

Commenters shared a list of common comorbidities that could be collected in the IPF-PAI, including chronic lower respiratory diseases, diseases of esophagus/stomach, metabolic disorders, hypertensive diseases, and episodic and paroxysmal disorders (for example, insomnia, migraine). A commenter agreed that the Standardized Patient Assessment Data Element regarding pain interference (effect on sleep, interference with therapy activities, interference with day-to-day

activities)³⁰ is clinically relevant in the IPF setting.

A commenter recommended three topics to include in this domain: presence of medical conditions requiring standing medication, medical/surgical consult required, and need for medical testing/procedure. This commenter described how the need for patients to leave the IPF to receive specialized care creates additional staffing demand. Another commenter recommended that the IPF-PAI include psychiatric diagnoses, medical comorbidities, and levels of intervention required, as these impact resources. Another commenter noted that allowing for the documentation of multiple psychiatric comorbidities would help to capture the resource costs to treat these complex patients.

A few commenters stated concerns or challenges. A commenter noted concerns that standardizing assessment of comorbidities would be difficult, as assessment requires individualized consideration. Another commenter noted that IPFs already collect and submit patient data relevant to this category through the IPFQR Program's Screening for Metabolic Disorders measure³¹ and suggested that CMS consider existing data reporting to meet the requirement for patient assessment for this topic.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF-PAI.

g. Impairments Standardized Patient Assessment Data Elements

- Are Standardized Patient Assessment Data Elements related to impairments (that is, the ability to hear and see in adequate light) currently collected PAC settings in their respective PAIs clinically relevant in the IPF setting? Do they otherwise meet the principles for inclusion in the IPF-PAI?

- What impairments are most predictive of increased resource intensity during an IPF stay?

Comment: Several commenters stated agreement with CMS that hearing and

vision impairments would be clinically relevant to the IPF setting and are a reason for increased resource use when caring for patients with these impairments. A commenter disagreed that hearing and vision impairments were relevant to the IPF population, arguing that these are conditions that primarily affect older adults. Another commenter, in the context of recommending that CMS minimize data collection burden, suggested a single "yes/no" item: Is the patient hard of hearing or visually impaired?

Several commenters suggested assessing more global concepts of impairment, stating that the ability to participate in life and perform daily functions is clinically relevant for the IPF population.

A commenter recommended that the IPF-PAI also assess functional neurologic impairments such as incontinence and dysphagia.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF-PAI.

h. Other Categories of Standardized Patient Assessment Data Elements

- What other assessment elements would contribute to the clinical utility of the IPF-PAI?

- What other assessment elements would best capture medical complexity in the interest of refining and improving the accuracy of the IPF PPS?

- What other assessment elements would inform CMS' understanding of health equity for IPF patients?

- Are there special interventions that IPFs provide which support patients after discharge, and which could serve to reduce the incidence of hospital readmissions for psychiatric conditions? What, if any, assessment elements would inform CMS' understanding of such interventions?

Comment: Regarding assessment elements to inform CMS' understanding of health equity, several commenters suggested that CMS should consider collecting information about a patient's social risk factors in the IPF-PAI. Some commenters provided specific recommendations regarding which social risk factors would be most important to gather information on, or overarching principles to guide selection of social risk factors. However, several commenters cautioned against collecting information pertaining to SDOH through the IPF-PAI.

³⁰ The Pain Interference standardized patient assessment data elements are currently collected in four other PAIs: the IRF-PAI for IRFs (<https://www.cms.gov/medicare/payment/prospective-payment-systems/inpatient-rehabilitation/pai>), the OASIS data set for HHAs (<https://www.cms.gov/medicare/quality/home-health/oasis-data-sets>), the CARE data set for LTCHs (<https://www.cms.gov/medicare/quality/long-term-care-hospital/ltr-care-data-set-ltr-care-manual>), and the Minimum Data Set (MDS) Resident Assessment Instrument (RAI) for SNFs (<https://www.cms.gov/medicare/quality/nursing-home-improvement/resident-assessment-instrument-manual>).

³¹ <https://qualitynet.cms.gov/ipf/ipfqr/measures>.

²⁹ <https://qualitynet.cms.gov/ipf/ipfqr/measures>.

Regarding other topics that could be included in the IPF-PAI, a commenter recommended that the assessment include data elements related to whether an individual has identified and is participating in activities that promote enjoyment, engagement, and social interaction with others. Another commenter recommended that CMS consider quality of life, such as measured by the World Health Organization's Quality-of-Life Scale (WHOQOL-BREF).³² This commenter also recommended that CMS consider a global measure of psychiatric functioning, such as the Behavior and Symptom Identification Scale (BASIS),³³ which assesses psychosocial symptoms and can be used to measure outcomes.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF-PAI.

i. Implementation

- We anticipate that IPFs will need to make changes to systems and processes and train staff in order to administer the assessment and submit assessment data by the implementation date. What operational or practical limitations would IPFs face in making those necessary changes? Are there particular categories of Standardized Patient Assessment Data Elements that would be more or less feasible for IPFs to operationalize? We are particularly interested in impacts to facilities of varying sizes and ownership characteristics.

- What forms of training and guidance would be most useful for CMS to provide to support IPFs in the implementation of the IPF-PAI?

Comment: Many commenters described challenges that they believe IPFs will face when implementing the IPF-PAI, focusing on workflow, staffing resources, and technological constraints.

Several commenters recommended that CMS engage with the EHR and other software vendors that would be likely to support IPFs' implementation of the IPF-PAI. Two commenters recommended that CMS allow ample time for software vendors to develop data collection and reporting tools for IPFs; a commenter recommended at

least 18 months between finalizing technical specifications and implementation, while another recommended 2 years. A commenter recommended that CMS commit to making updates to the IPF-PAI no more than once per year. A commenter recommended that CMS develop the IPF-PAI in such a way that it could be populated from the patient's record in the EHR at the time of discharge.

Regarding implementation at the facility level, a few commenters recommended clarifying what training and guidance that would be provided to IPFs in advance of implementation and suggested that thorough training and clear instructions for completing the IPF-PAI will be important to support data quality.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF-PAI.

j. Relationship to the IPFQR Program

- Would having some measures which require data submission through the HQR system and having other measures, which require data collection and submission through the IPF-PAI increase operational complexity or administrative burden? If so, how would you recommend mitigating this complexity or burden?

- Would any of the current chart-abstracted measures be easier to report through the IPF-PAI? If so, which measures?

- Would any of the current measures in the program be more meaningful if they were stratified or risk-adjusted using data from the required patient assessment categories or other categories not specified by the CAA, 2023 that should be added to the IPF-PAI?

- What new measure concepts, which would use data collected through Standardized Patient Assessment Data Elements in the IPF-PAI, should we consider?

Comment: Several commenters stated concerns about the prospect of needing to submit patient data to two systems, if, for example, IPFs continue using the existing process for submitting patient-level data for the IPFQR Program's measures, but the IPF-PAI data submission is accomplished through a different process. They recommended that CMS incorporate the IPF-PAI into the existing patient level XML submission process. In addition, they recommended against moving current chart-abstracted quality measures to the IPF-PAI, due to concerns that the IPF-PAI is intended to be collected for all

patients, not just the sample that are currently the target of chart abstraction.

Another commenter stated concerns about duplication of data collection or data entry between existing IPFQR Program measures and the IPF-PAI. However, that commenter suggested that it would be appropriate to move data reporting to the IPF-PAI for a few of the current IPFQR Program measures.

Response: We thank commenters for their responses to this comment solicitation. We will take these comments into consideration in the development of the IPF-PAI.

VI. Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program

A. Background and Statutory Authority

The Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program is authorized by section 1886(s)(4) of the Act, and it applies to psychiatric hospitals and psychiatric units paid by Medicare under the IPF PPS (see section II.A. of this final rule for a detailed discussion of entities covered under the IPF PPS). Section 1886(s)(4)(A)(i) requires the Secretary to reduce by 2 percentage points the annual update to the standard Federal rate for discharges occurring during such rate year³⁴ for any IPF that does not comply with quality data submission requirements under IPFQR program, set forth in section 1886(s)(4)(C) of the Act, with respect to an applicable rate year.

Section 1886(s)(4)(C) of the Act requires IPFs to submit to the Secretary data on quality measures specified by the Secretary under section 1886(s)(4)(D) of the Act. Except as provided in section 1886(s)(4)(D)(ii) of the Act, section 1886(s)(4)(D)(i) of the Act requires that any measure specified by the Secretary must have been endorsed by the consensus-based entity (CBE) with a contract under section

³⁴ We note that the statute uses the term "rate year" (RY). However, beginning with the annual update of the inpatient psychiatric facility prospective payment system (IPF PPS) that took effect on July 1, 2011 (RY 2012), we aligned the IPF PPS update with the annual update of the ICD codes, effective on October 1 of each year. This change allowed for annual payment updates and the ICD coding update to occur on the same schedule and appear in the same **Federal Register** document, promoting administrative efficiency. To reflect the change to the annual payment rate update cycle, we revised the regulations at 42 CFR 412.402 to specify that, beginning October 1, 2012, the IPF PPS RY means the 12-month period from October 1 through September 30, which we refer to as a "fiscal year" (FY) (76 FR 26435). Therefore, with respect to the IPFQR Program, the terms "rate year," as used in the statute, and "fiscal year" as used in the regulation, both refer to the period from October 1 through September 30. For more information regarding this terminology change, we refer readers to section III of the RY 2012 IPF PPS final rule (76 FR 26434 through 26435).

³² Whoqol Group. (1998). Development of the World Health Organization WHOQOL-BREF quality of life assessment. *Psychological medicine*, 28(3), 551–558.

³³ Eisen, S.V., Normand, S.L., Belanger, A.J., Spiro III, A., & Esch, D. (2004). The revised behavior and symptom identification scale (BASIS-R): reliability and validity. *Medical care*, 42(12), 1230–1241.

1890(a) of the Act. Section 1886(s)(4)(D)(ii) of the Act provides 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 CBE 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.

Section 4125(b)(1) of CAA, 2023 amended section 1886(s)(4) of the Act, by inserting a new paragraph (E), to require IPFs participating in the IPFQR Program to collect and submit to the Secretary certain standardized patient assessment data, using a standardized patient assessment instrument (PAI) developed by the Secretary, for RY 2028 (FY 2028) and each subsequent rate year. We refer readers to section V.B of this final rule in which we discuss responses to our solicitation of public comment on the development of this PAI.

We refer readers to the FY 2019 IPF PPS final rule (83 FR 38589) for a discussion of the background and statutory authority of the IPFQR Program. We have codified procedural requirements and reconsideration and appeals procedures for IPFQR Program decisions in our regulations at 42 CFR 412.433 and 412.434. Consistent with previous IPFQR Program regulations, we refer to both inpatient psychiatric hospitals and psychiatric units as “facilities” or “IPFs.” This usage follows the terminology in our IPF PPS regulations at § 412.402.

For additional information on procedural requirements related to statutory authority, participation and withdrawal, data submission, quality measure retention and removal, extraordinary circumstances exceptions, and public reporting we refer readers to 42 CFR 412.433 Procedural requirements under the IPFQR Program.

For the IPFQR Program, we refer to the year in which an IPF would receive the 2-percentage point reduction to the annual update to the standard Federal rate as the *payment determination year*. An IPF generally meets IPFQR Program requirements by submitting data on specified quality measures in a specified time and manner during a *data submission period* that occurs prior to the payment determination year. These data reflect a period prior to the data submission period during which the IPF furnished care to patients; this period is known as the *performance period*. For example, for a measure for which CY 2025 is the performance period which is

required to be submitted in CY 2026 and affects FY 2027 payment determination, if an IPF did not submit the data for this measure as specified during CY 2026 we would reduce by 2-percentage points that IPF’s update for the FY 2027 payment determination year (even if the IPF meets all other IPFQR Program requirements for the FY 2027 payment determination).

B. Measure Adoption

We strive to put patients and caregivers first, ensuring they are empowered to partner with their clinicians in their healthcare decision making using information from data driven insights that are increasingly aligned with meaningful quality measures. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, and affordability of care while paying particular attention to improving clinicians’ and beneficiaries’ experiences when interacting with our programs. In combination with other efforts across HHS, we believe the IPFQR Program helps to incentivize IPFs to improve healthcare quality and value while giving patients and providers the tools and information needed to make the best individualized decisions. Consistent with these goals, our objective in selecting quality measures for the IPFQR Program is to balance the need for information on the full spectrum of care delivery and the need to minimize the burden of data collection and reporting. We have primarily focused on measures that evaluate critical processes of care that have significant impact on patient outcomes and support CMS and HHS priorities for improved quality and efficiency of care provided by IPFs. When possible, we also propose to incorporate measures that directly evaluate patient outcomes and experience. We refer readers to the CMS National Quality Strategy,³⁵ the Behavioral Health Strategy,³⁶ the Framework for Health Equity,³⁷ and the

Meaningful Measures Framework³⁸ for information related to our priorities in selecting quality measures.

1. Measure Selection Process

Section 1890A(a) of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the CBE contracted under 1890(a) of the Act, to solicit input from multi-stakeholder groups on the selection of quality and efficiency measures for the IPFQR Program. Before being proposed for inclusion in the IPFQR Program, measures are placed on a list of Measures Under Consideration (MUC list), which is published annually. Following publication on the MUC list, a multi-stakeholder group convened by the CBE reviews the measures under consideration for the IPFQR Program, among other federal programs, and provides input on those measures to the Secretary. Under the Partnership for Quality Measurement (PQM), which is convened by the entity which currently holds the contract under 1890(a) of the Act, this process is known as the Pre-Rulemaking Measure Review (PRMR). We consider the input and recommendations provided by this multi-stakeholder group in selecting all measures for the IPFQR Program, including the 30-Day Risk-Standardized All-Cause Emergency Department (ED) Visit Following an IPF Discharge measure discussed in this final rule.

2. Adoption of the 30-Day Risk-Standardized All-Cause ED Visit Following an IPF Discharge Measure Beginning With the CY 2025 Performance Period/FY 2027 Payment Determination

a. Background

We have consistently stated our commitment to identifying measures that examine the care continuum for patients with mental health conditions and substance use disorders and to quantify outcomes following IPF-discharge (see for example, the adoption of the Medication Continuation Following Hospitalization in an IPF measure in the FY 2020 IPF PPS Final Rule, 84 FR 38460 through 38462). Post-discharge outcomes are an important part of our measurement strategy because patient-centered discharge planning and coordination of care for patients with any combination of mental health conditions and substance use disorders improves long-term outcomes,

³⁵ Schreiber, M, Richards, A, et al. (2022). The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality. Available at: <https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality>.

³⁶ CMS. (2022). CMS Behavioral Health Strategy. Available at <https://www.cms.gov/cms-behavioral-health-strategy>.

³⁷ CMS. (2022). CMS Framework for Health Equity 2022–2032. Available at <https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf>.

³⁸ CMS. (2023). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at <https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-20>. Accessed on March 20, 2024.

including reducing readmissions and other post-discharge acute care services.^{39 40}

Although not all post-discharge acute care visits are preventable, there are actions that the IPF can take to maximize the chance for patients' successful community reintegration.⁴¹ For example, care transition models to reduce the need for additional acute care following an inpatient stay have been adapted to the inpatient psychiatric setting. To implement these models, IPFs may need to consider how to include the patient and their caregivers, including family, in discharge planning, how to communicate with post-discharge providers, and how to ensure whole-person care for patients during and following their discharge.⁴² Specifically, IPFs may need to assist patients in connecting with outpatient providers, such as coordinating with the patient and their caregiver to schedule the patient's first post-discharge follow-up appointment, arranging for the patient's intensive outpatient (IOP) care, or connecting to peer support services. Additionally, IPFs may need to identify and address barriers patients may face in accessing medications and adhering to scheduled post-discharge follow-up appointments. Barriers may include financial factors, transportation, and childcare, which may necessitate support from social services, beginning during hospitalization and continuing after discharge.^{43 44} Barriers may also

include the patient's concerns regarding the stigmatization associated with seeking care post-discharge. This can be addressed through treatment provided during the IPF stay.^{45 46} Improvements in patient experience of care and patient-centeredness of care have been associated with improved follow-up post-discharge and a reduction in patients requiring post-discharge acute care.^{47 48} In summary, by proactively addressing potential barriers to post-discharge care, improving patient experience of care and patient-centeredness of care, and implementing care transition models, IPFs can reduce the need for post-discharge acute care.

The IPFQR Program currently has three measures that assess post-discharge outcomes: (1) Follow-up After Psychiatric Hospitalization (FAPH); (2) Medication Continuation Following Inpatient Psychiatric Discharge; and (3) Thirty Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization (CBE #2860, the IPF Unplanned Readmission measure). Each of these measures serves a unique role in assessing care coordination and post-discharge outcomes.

The FAPH measure, which we adopted in the FY 2022 IPF PPS Final Rule (86 FR 42640 through 42645), uses Medicare FFS claims to determine the percentage of inpatient discharges from an IPF stay for which the patient received a follow-up visit for treatment of mental illness. The FAPH measure represents an important component of post-discharge care coordination, specifically the transition of care to an outpatient provider. However, this measure does not quantify patient outcomes.

The Medication Continuation Following Inpatient Psychiatric

review of the literature. *Community Mental Health Journal*, 55(8), 1255–1274. doi:10.1007/s10597-019-00413-9.

⁴⁵ Allen, E.M., Call, K.T., Beebe, T.J., McAlpine, D.D., & Johnson, P.J. (2017). Barriers to Care and Healthcare Utilization among the Publicly Insured. *Medical Care*, 55(3), 207–214. doi:10.1097/MLR.0000000000000644.

⁴⁶ Mutschler, C., Lichtenstein, S., Kidd, S.A., & Davidson, L. (2019). Transition experiences following psychiatric hospitalization: A systematic review of the literature. *Community Mental Health Journal*, 55(8), 1255–1274. doi:10.1007/s10597-019-00413-9.

⁴⁷ Donisi V, Tedeschi F, Wahlbeck K, Haaramo P, Amadeo F. Pre-discharge factors predicting readmissions of psychiatric patients: a systematic review of the literature. *BMC Psychiatry*. 2016 Dec 16;16(1):449. doi:10.1186/s12888-016-1114-0. PMID: 27986079; PMCID: PMC5162092.

⁴⁸ Morgan C Shields, Mara A G Hollander, Alisa B Busch, Zohra Kantawala, Meredith B Rosenthal, Patient-centered inpatient psychiatry is associated with outcomes, ownership, and national quality measures, *Health Affairs Scholar*, Volume 1, Issue 1, July 2023, qxad017, <https://doi.org/10.1093/haschl/qxad017>.

Discharge measure, which we adopted in FY 2020 IPF PPS Final Rule (84 FR 38460 through 38465), assesses whether patients admitted to IPFs with diagnoses of Major Depressive Disorder (MDD), schizophrenia, or bipolar disorder filled at least one evidence-based medication prior to discharge or during the post-discharge period. Medication continuation is important for patients discharged from the IPF setting with these disorders because of significant negative outcomes associated with non-adherence to medication regimes. However, this measure does not quantify patient outcomes with respect to the use of acute care services post-discharge.

The IPF Unplanned Readmission measure, which we adopted in the FY 2017 IPF PPS Final Rule (81 FR 57241 through 57246), assesses outcomes associated with worsening condition, potentially due to insufficient discharge planning and post-discharge care coordination, by assessing post-discharge use of acute care. The IPF Unplanned Readmission measure estimates the incidence of unplanned, all-cause readmissions to IPFs or short-stay acute care hospitals following discharge from an eligible IPF index admission. A readmission is defined as any admission that occurs within 3 to 30 days after the discharge date from an eligible index admission to an IPF, except those considered planned.⁴⁹ However, this measure does not quantify the proportion of patients 18 and older with an ED visit, without subsequent admission, within 30 days of discharge from an IPF. Without collecting this information in a measure, we believe there is a gap in our understanding regarding patients' successful reintegration into their communities following their IPF discharge.

To further understand this gap, we analyzed post-discharge outcomes using claims data. In this analysis, we determined that, for patients discharged from IPFs, the risk-adjusted rate of ED visits after an IPF discharge between June 1, 2019 and July 31, 2021 (excluding the first two quarters of 2020 due to the COVID-19 public health emergency) was 20.7 percent. The rate of readmissions captured under the IPF Unplanned Readmission measure for this same period was 20.1 percent.⁵⁰ This means that approximately 40 percent of patients discharged from an IPF had either an ED visit or an

⁴⁹ <https://p4qm.org/measures/2860>.

⁵⁰ As depicted in the April 2023 file available at <https://data.cms.gov/provider-data/archived-data/hospitals>.

³⁹ Nelson, E.A. Maruish, M.E., Axler, J.L. Effects of Discharge Planning with Outpatient Appointments on Readmission Rates. <https://ps.psychiatryonline.org/doi/10.1176/appi.ps.51.7.885>.

⁴⁰ Steffen S, Kösters M, Becker T, Puschner B. Discharge planning in mental health care: a systematic review of the recent literature. *Acta Psychiatr Scand*. 2009 Jul;120(1):1–9. doi: 10.1111/j.1600-0447.2009.01373.x. Epub 2009 Apr 8. PMID: 19486329.

⁴¹ Haselden, M., Corbeil, T., Tang, F., Olsson, M., Dixon, L.B., Essock, S.M., Wall, M.M., Radigan, M., Frimpong, E., Wang, R., Lamberti, S., Schneider, M., & Smith, T.E. (2019). Family Involvement in Psychiatric Hospitalizations: Associations With Discharge Planning and Prompt Follow-Up Care. *Psychiatric Services*, 70(10), 860–866. <https://doi.org/10.1176/appi.ps.201900028>.

⁴² Pincus, Harold. Care Transition Interventions to Reduce Psychiatric Re-Hospitalizations. National Association of State Mental Health Program Directors. 2015. Available at https://nasnmhp.org/sites/default/files/Assessment%20%233_Care%20Transitions%20Interventions%20toReduce%20Psychiatric%20Rehospitalization.pdf. Accessed on January 23, 2024.

⁴³ Allen, E.M., Call, K.T., Beebe, T.J., McAlpine, D.D., & Johnson, P.J. (2017). Barriers to Care and Healthcare Utilization among the Publicly Insured. *Medical Care*, 55(3), 207–214. doi:10.1097/MLR.0000000000000644.

⁴⁴ Mutschler, C., Lichtenstein, S., Kidd, S.A., & Davidson, L. (2019). Transition experiences following psychiatric hospitalization: A systematic

unplanned readmission within 30-days of IPF discharge, but only about half of those visits are being captured in the publicly reported IPF Unplanned Readmission measure. Visits to an ED within 30 days of discharge from an IPF (regardless of whether that visit results in a hospital readmission, observation stay, discharge, or patient leaving without being seen) often indicate deteriorating or heightened mental or physical health needs. That is, these visits often represent a patient seeking care for symptoms that were present during the patient's stay in the IPF, regardless of whether the symptom was the reason for the admission, that have become worse for the patient in the time since discharge. Therefore, we believe that IPFs and the public would benefit from having these data made publicly available to inform care decisions and quality improvement efforts. Specifically, members of the public could use these data to inform care decisions and IPFs could use these data to compare their performance to that of similar IPFs. For example, by having these data publicly reported, IPFs could compare their performance with that of other IPFs with similar patient populations, a comparison which is not possible without this measure. If IPFs identified that other IPFs with similar patient populations had better rates of post-discharge ED visits (that is, other IPFs had fewer patients seek care in an ED within 30 days of discharge from the IPF), the IPF could identify a need to evaluate discharge planning and post-discharge care coordination to identify process changes which could improve outcomes.

To address this gap, we developed and proposed the inclusion of the new, claims-based 30-Day Risk-Standardized All-Cause ED Visit Following an IPF Discharge measure (the IPF ED Visit measure) in the IPFQR Program beginning with the CY 2025 performance period/FY 2027 payment determination. The IPF ED Visit measure aims to provide information to patients, caregivers, other members of the public, and IPFs about the proportion of patients who seek care in ED in the 30 days following discharge from an IPF but are not admitted as an inpatient to an acute care hospital or IPF. This measure would assess the proportion of patients 18 and older with an ED visit, including observation stays, for any cause, within 30 days of discharge from an IPF, without subsequent admission.

We recognize that not all post-discharge ED visits are preventable, nor are all post-discharge ED visits associated with the initial IPF

admission. However, we developed an all-cause ED visit rate, as opposed to a more narrowly focused measure of ED admissions for mental health or substance use concerns, for three primary reasons. First, such a measure aligns most closely with the IPF Unplanned Readmission measure as this measure is also an all-cause measure. Second, an all-cause measure emphasizes the importance of whole-person care for patients. Whole-person care, during the inpatient stay and through referral at discharge, includes addressing the conditions that may jeopardize a patient's health, but are not the reason for admission to the IPF, if the IPF has reason to identify these conditions during the course of treatment. For example, if an IPF were to identify through metabolic screening that a patient has diabetes, it would be appropriate for that IPF to recommend appropriate follow-up for that patient, such as with a primary care provider, endocrinologist, or dietician. Such post-discharge coordination of care could prevent the patient from seeking acute care after discharge from the IPF for complications of diabetes, such as diabetic ketoacidosis. Third, this measure includes ED visits for all conditions because patients visiting the ED may do so for physical symptoms associated with a mental health condition or substance use disorder. An example is a patient with anxiety that presents to the ED with chest pain and shortness of breath. If the clinician documents the primary diagnosis as chest pain (R07.9) or shortness of breath (R06.02), the patient would not be included in a mental health and substance use-specific IPF ED Visit measure, despite their history of anxiety (F41.9), a potential contributor to their presenting symptoms at the ED. We recognize that it is possible that such a visit may not be related to the patient's anxiety. However, while not all acute care visits after discharge from an IPF are preventable or necessarily related to the quality of care provided by the IPF, there is evidence that improvements in the quality of care for patients in the IPF setting can reduce rates of patients seeking acute care after discharge from an IPF, representing an improved outcome for patients.⁵¹

⁵¹ See for instance Chung, D.T., Ryan, C.J., Hadzi-Pavlovic, D., Singh, S.P., Stanton, C., & Large, M.M. (2017). Suicide rates after discharge from psychiatric facilities: A systematic review and meta-analysis. *JAMA Psychiatry*, 74(7), 694–702. <https://doi.org/10.1001/jamapsychiatry.2017.1044> or Durbin, J., Lin, E., Layne, C., et al. (2007). Is readmission a valid indicator of the quality of inpatient psychiatric care? *Journal of Behavioral Health Services Research*, 34, 137–150. doi:10.1007/s11414-007-9055-5.

Additionally, we considered whether 30 days was an appropriate timeframe for this measure. That is, we sought to identify whether a measure that assessed post-discharge ED visits over a period shorter or longer than 30 days would be more appropriate. Because IPFs are already familiar with interpreting data for the 30-day period in the IPF Unplanned Readmission measure, we determined that it would be appropriate to maintain the 30-day period for the IPF ED Visit measure. Additionally, by maintaining the same timeframe as the IPF Unplanned Readmission measure, we can provide IPFs and patients with a more complete picture of acute care among IPF patients after discharge from the IPF.

Pursuant to the Meaningful Measures 2.0 Framework (a CMS initiative that identifies priority domains for measures within CMS Programs⁵²), this measure addresses the “Seamless Care Coordination” and the “Person-Centered Care” quality domains by encouraging facilities to provide patient-centric discharge planning and support post-discharge care transitions. The IPF ED Visit measure also aligns with the CMS National Quality Strategy Goals⁵³ of “Engagement” and “Outcomes and Alignment.” It supports outcomes and alignment because this measure provides a quantified estimate of one post-discharge outcome that patients may experience, that is, a post-discharge acute care visit that does not result in an admission. It also supports the Behavioral Health Strategy⁵⁴ domains of “Quality of Care” and “Equity and Engagement” because engaging patients to improve post-discharge outcomes is an element of providing quality care. Furthermore, similar to the Meaningful Measures domain of “Person-Centered Care,” this measure supports the Universal Foundation domain of “Person-Centered Care.”

b. Overview of Measure

The IPF ED Visit measure was developed with input from clinicians, patients, and policy experts; the measure was subject to the pre-rulemaking process required by section 1890A of the Act, as discussed further in section VI.B.1 of this rule. Consistent

⁵² <https://www.cms.gov/medicare/quality/meaningful-measures-initiative/meaningful-measures-2.0>.

⁵³ Schreiber, M., Richards, A., et al. (2022). The CMS National Quality Strategy: A Person-Centered Approach to Improving Quality. Available at: <https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality>.

⁵⁴ CMS. (2022). CMS Behavioral Health Strategy. Available at <https://www.cms.gov/cms-behavioral-health-strategy>.

with the key elements of the CMS Measure Development Lifecycle,⁵⁵ we began with measure conceptualization during which we performed a targeted literature review and solicited input from a behavioral health technical expert panel (TEP). This allowed us to ensure that this topic addresses a gap that is important to interested parties. After confirming this, we developed the measure specifications for the IPF ED Visit measure. With these specifications, we issued a 30-day call for public comment⁵⁶ and performed empirical testing using claims data, including modeling for risk-adjustment. After refining the measure specifications based on testing and public comment, we performed an equity analysis in which we tested the risk-adjustment methodology to ensure that the measure does not reflect access issues related to patient demographics instead of quality of care. By following the Measure Development Lifecycle, we sought to ensure that this is a vetted, valid, reliable, and ready-to-implement claims-based measure which would assess the proportion of patients 18 and older with an ED visit, including observation stays, for any cause, within 30 days of discharge from an IPF, without subsequent admission. By using the same definitions of index admission and patient populations as those used in the IPF Unplanned Readmission measure, we have designed the IPF ED Visit measure to complement the IPF Unplanned Readmission measure to the extent possible. We have also sought to minimize administrative burden by developing this as a claims-based measure so that it adds no information collection burden to clinicians and staff working in the IPF setting.

(1) Measure Calculation

The focus population for this measure is adult Medicare FFS patients with a discharge from an IPF. The measure is based on all eligible index admissions from the focus population. An eligible index admission is defined as any IPF admission for which the patient meets the following criteria: (1) age 18 or older at admission; (2) discharged alive from an IPF; (3) enrolled in Medicare FFS Parts A and B during the 12 months before the admission date, the month of

admission, and at least one month after the month of discharge from the index admission (that is, the original stay in an IPF); and (4) discharged with a principal diagnosis that indicates a psychiatric disorder. Excluded from the measure are patients discharged against medical advice (AMA) from the IPF index admission (because the IPF may not have had the opportunity to conduct full discharge planning for these patients); patients with unreliable data regarding death, demographics, or a combination thereof in their claims record (because these data are unreliable, they may lead to inaccuracies in the measure calculation); patients who expired during the IPF stay (because post-discharge care is not applicable to these patients); patients with a discharge resulting in a transfer to another care facility (because the receiving care facility would be responsible for discharge planning for these patients); and patients discharged but readmitted within 3 days of discharge, also known as an interrupted stay (because interrupted stays are often reflective of patient needs outside of the IPF, such as treatment for another condition).

To calculate the measure, we proposed to use the following data sources which are all available from Medicare administrative records and data submitted by providers through the claims process: (1) Medicare beneficiary and coverage files, which provide information on patient demographic, enrollment, and vital status information to identify the measure population and certain risk factors; (2) Medicare FFS Part A records, which contain final action claims submitted by acute care and critical access hospitals, IPFs, home health agencies, and skilled nursing facilities to identify the measure population, readmissions, and certain risk factors; and (3) Medicare FFS Part B records, which contain final action claims submitted by physicians, physician assistants, clinical social workers, nurse practitioners, and other outpatient providers to identify certain risk factors. To ensure that diagnoses result from encounters with providers trained to establish diagnoses, we proposed that this measure will not use claims for services such as laboratory tests, medical supplies, or other ambulatory services. Index admissions and ED visits would be identified in the Medicare FFS Part A records. Comorbid conditions for risk-adjustment would be identified in the Medicare Part A and Part B records in the 12 months prior to admission, including the index admission. Demographic and FFS

enrollment data would be identified in the Medicare beneficiary and coverage files.

To calculate the IPF ED Visit measure, we proposed that CMS would: (1) identify all IPF admissions in the one-year performance period; (2) apply inclusion and exclusion criteria to identify index admissions; (3) identify ED visits and observation stays within 30 days of discharge from each index admission; (4) identify risk factors in the 12 months prior to index admission and during the index admission; and (5) run hierarchical logistic regression to compute the risk-standardized ED visit rate for each IPF.⁵⁷ This hierarchical logistic regression would allow us to apply the risk-adjustment factors developed in measure testing to ensure that measure results are comparable across IPFs regardless of the clinical complexity of each IPF's patient population.

(2) Pre-Rulemaking Measure Review and Measure Endorsement

As required under section 1890A of the Act, the CBE established the Partnership for Quality Measurement (PQM) to convene clinicians, patients, measure experts, and health information technology specialists to participate in the pre-rulemaking process and the measure endorsement process. The pre-rulemaking process, also called the Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration (MUC List) by one of several committees convened by the PQM for the purpose of providing multi-stakeholder input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the IPFQR Program. The PRMR process includes opportunities for public comment through a 21-day public comment period, as well as public listening sessions. The PQM posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within five days of the close of the public comment period.⁵⁸ More details regarding the PRMR process may be found in the CBE's Guidebook of Policies and Procedures

⁵⁵ <https://mmshub.cms.gov/blueprint-measure-lifecycle-overview>.

⁵⁶ We note that in the FY 2025 IPF PPS proposed rule we incorrectly stated that this call for comments was issued in the **Federal Register**. It was actually posted on the measure lifecycle's public comment page (available at: <https://mmshub.cms.gov/get-involved/public-comments/overview>) and communicated through subregulatory channels.

⁵⁷ For an example of the hierarchical logistic risk-adjustment algorithm, we refer readers to the algorithm for the IPF Unplanned Readmission measure at <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/hospitalqualityinits/downloads/inpatient-psychiatric-facility-readmission-measure.zip>.

⁵⁸ These materials are available at the PRMR section of the PQM website: <https://p4qm.org/PRMR>.

for Pre-Rulemaking Measure Review and Measure Set Review, including details of the measure review process in Chapter 3.⁵⁹

The CBE-established PQM also conducts the measure endorsement and maintenance (E&M) process to ensure measures submitted for endorsement are evidence-based, reliable, valid, verifiable, relevant to enhanced health outcomes, actionable at the caregiver-level, feasible to collect and report, and responsive to variations in patient characteristics, such as health status, language capabilities, race or ethnicity, and income level, and are consistent across types of health care providers, including hospitals and physicians (see section 1890(b)(2) of the Act). The PQM convenes several E&M project groups twice yearly, formally called E&M Committees, each comprised of an E&M Advisory Group and an E&M Recommendations Group, to vote on whether a measure meets certain quality measure criteria. More details regarding the E&M process may be found in the E&M Guidebook, including details of the measure endorsement process in the section titled, “Endorsement and Review Process.”⁶⁰

As part of the PRMR process, the IPF ED Visit measure was reviewed during the PRMR Hospital Recommendation Group meeting on January 18, 2024. For the voting procedures of the PRMR and E&M process, the PQM utilized the Novel Hybrid Delphi and Nominal Group (NHDNG) multi-step process, which is an iterative consensus-building approach aimed at a minimum of 75 percent agreement among voting members, rather than a simple majority vote, and supports maximizing the time spent to build consensus by focusing discussion on measures where there is disagreement. For example, the PRMR Hospital Recommendation Group can reach consensus and have the following voting results: (A) Recommend, (B) Recommend with conditions (with 75 percent of the votes cast as recommend with conditions or 75 percent between recommend and recommend with conditions), and (C) Do not recommend. If no voting category reaches 75 percent or greater (including the combined [A] Recommend and [B] Recommend with conditions) the PRMR Hospital Recommendation Group is considered

not to have come to consensus and the voting result is “Consensus not reached.” Consensus not reached signals continued disagreement amongst the committee despite being presented with perspectives from public comment, committee member feedback and discussion, and highlights the multi-faceted assessments of quality measures. More details regarding the PRMR voting procedures may be found in Chapter 4 of the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review.⁶¹ More details regarding the E&M voting procedures may be found in the PQM Endorsement and Maintenance (E&M) Guidebook.⁶² The PRMR Hospital Recommendation Group⁶³ reached consensus and recommended including this measure in the IPFQR Program with conditions.

Seven members of the group recommended adopting the measure into the IPFQR program without conditions; eleven members recommended adoption with conditions; and one committee member voted not to recommend the measure for adoption. Taken together, 94.73 percent of the votes were between recommend & recommend with conditions.

The conditions specified by the PRMR Hospital Recommendation Group were: (1) that the measure be considered for endorsement by a consensus-based entity; and (2) further consideration of how the measure addresses 72-hour transfers to the ED. We have taken those considerations into account and proposed this measure for adoption because we believe we have adequately addressed the concerns raised by those considerations.

To address the first condition, we have submitted the measure to the CBE for consideration. For more information on submission to and consideration by the CBE we refer readers to section VI.B.2.b.(3) of this rule.

The second voting condition requested that we further consider how the measure addresses 72-hour transfers to the ED because of concerns that IPFs may appear to have worse performance if “interrupted stays” are not excluded from the measure. An “interrupted stay” occurs when a patient is discharged from an IPF and readmitted to the same IPF within 72 hours. This frequently occurs when a patient needs medical treatment that is beyond the scope of the IPF, such as care in an ED for an emergent health issue. We believe that

this concern is sufficiently addressed in the ED Visit measure’s specifications because these “interrupted stays” are excluded from the measure, as described in section VI.B.2.b.(1) of this rule. This exclusion is defined as an index admission with a readmission on Days 0, 1, or 2 post-discharge. In other words, patients transferred to the ED and subsequently readmitted to the IPF within 72 hours are excluded from the measure. Therefore “interrupted stays” are excluded from the measure as per the group’s recommendation.

(3) CBE Endorsement

Section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act (that is, the CBE). After a measure has been submitted to the CBE, the committee responsible for reviewing the measure evaluates the measure on five domains: (1) Importance; (2) Feasibility; (3) Scientific Acceptability (that is, reliability and validity); (4) Equity; and (5) Use and Usability. Committee members evaluate whether the measure the domain is “Met”, “Not Met but Addressable” or “Not Met” for each measure using a set of criteria provided by the CBE.⁶⁴ When a measure is submitted it is assigned to one of the CBE’s projects based on where in the patient’s healthcare experience the measure has the most relevance. The five projects are (1) Primary Prevention; (2) Initial Recognition and Management; (3) Management of Acute Events, Chronic Disease, Surgery, Behavioral Health; (4) Advanced Illness and Post-Acute Care; and (5) Cost and Efficiency.

The measure developer submitted the measure for CBE endorsement consideration in the Fall 2023 review cycle. The measure was assigned to the Cost and Efficiency Project. The CBE Cost and Efficiency Endorsement committee met on January 31, 2024 and did not reach consensus regarding the IPF ED Visit measure, with 60.6 percent voting in favor of endorsement or endorsement with conditions and the remaining members voting to not endorse, which is below the 75 percent threshold necessary for the endorsement of the measure, as described in VI.B.2.b. During the Cost and Efficiency Endorsement committee’s meeting, members of the committee discussed whether an all-cause measure was appropriate and whether IPFs are able to

⁵⁹ https://p4qm.org/sites/default/files/2023-09/Guidebook-of-Policies-and-Procedures-for-Pre-Rulemaking-Measure-Review-%28PRMR%29-and-Measure-Set-Review-%28MSR%29-Final_0.pdf.

⁶⁰ The Partnership for Quality Measurement. (October 2023). Endorsement and Maintenance (E&M) Guidebook. Available at: https://p4qm.org/sites/default/files/2023-12/Del-3-6-Endorsement-and-Maintenance-Guidebook-Final_0_0.pdf.

⁶³ We note that the PRMR Hospital Recommendation Group was previously the Measure Applications Partnership (MAP) Hospital Workgroup under the pre-rulemaking process followed by the previous CBE.

⁶⁴ <https://p4qm.org/EM>.

implement interventions to reduce post-discharge acute care.⁶⁵

As discussed in section VI.B.2.a of this final rule, an all-cause measure complements the IPF Unplanned Readmission measure, emphasizes whole-person care, and captures visits to the ED for patients with physical symptoms associated with mental health conditions. Additionally, evidence shows that there are interventions that reduce post-discharge acute care. These include adopting care transition models, proactively connecting patients with post-discharge providers, identifying and addressing patients' barriers to post-discharge care, and focusing on providing patient-centered care and improving patient experience of care.

Although section 1886(s)(4)(D)(i) of the Act generally requires that measures specified by the Secretary shall be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(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 a measure that has been endorsed or adopted by a consensus organization identified by the Secretary.

We have determined that this is an appropriate topic for the adoption of a measure absent CBE endorsement because where possible we focus on measures that assess patient outcomes. Unplanned use of acute care after discharge from an IPF is often associated with worsening condition, potentially due to insufficient discharge planning and post-discharge care coordination. While the IPFQR Program currently has a measure that assesses unplanned readmissions after discharge from an IPF, there is a gap in the measure set with respect to unplanned ED visits without a subsequent admission to an acute care hospital or IPF. The IPF ED Visit measure fills that gap. We also reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures that assess outcomes that solely result in a patient's ED visit after the patient's discharge from an IPF. The only endorsed measure that we identified that addresses an IPF patient seeking

acute care after discharge is the IPF Unplanned Readmission measure. As we discussed previously, the IPF Unplanned Readmission measure does not assess ED visits that do not result in an admission. Therefore, we believe that the IPF ED Visit measure is an important complement to the IPF Unplanned Readmission measure. We did not find any other measures that assess post-discharge ED visits without a subsequent admission, and therefore the exception in section 1886(s)(4)(D)(ii) of the Act applies.

c. Data Collection, Submission, and Reporting

Because all data used to calculate the IPF ED Visit measure are available on Medicare claims, this measure requires no additional data collection or submission by IPFs. We proposed to adopt the ED Visit Measure with a reporting period beginning with data from CY 2025 performance period/FY 2027 payment determination year.

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: Several commenters supported adoption of the IPF ED Visit measure. Some commenters stated that this measure would improve prioritization of discharge planning and provide a more comprehensive understanding of IPF patients' acute care needs following a discharge, which is a critical period for this patient population. Other commenters stated that this measure may serve as an important tool to assess the quality of care in IPFs for beneficiaries, policymakers, and other interested parties. A commenter also noted that these data are not available from the current readmission measure in the IPFQR Program (that is, the Thirty Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization—the IPF Unplanned Readmission measure) because that measure does not capture ED visits. A commenter noted that this measure may promote improved discharge planning, patient engagement, and improved referrals to social services, which could help patients avoid relying on EDs for care for chronic conditions, which could, in turn, reduce overcrowding in EDs. This commenter also stated that this is particularly important for the IPF patient population because they are at high risk of experiencing gaps in the care continuum leading to readmissions and poor outcomes.

Response: We thank these commenters for their support.

Comment: Several commenters expressed concern that this measure does not account for patient characteristics that could affect the likelihood of the patient needing acute care following discharge from the IPF. These commenters were specifically concerned that IPFs that treat patients with high levels of unmet social needs (including inability to afford medication, lack of a home, lack of access to communications technology for accessing less acute care—such as a phone for calling emergency hotlines or other resources) may appear to perform worse on the measure (that is, have more patients seeking care in the ED within 30 days of discharge) than IPFs that treat patients with fewer unmet social needs. A commenter stated that patients who receive care in IPFs have an increased risk for violence and victimization, which may affect their use of EDs.

Response: We agree with commenters that the prevalence of unmet social needs is high among patients receiving care in IPFs, and that the prevalence of these needs may be higher in some IPFs when compared to others. We further agree that patient factors, including unmet social needs and an increased risk for violence or victimization, increase a patient's risk of needing emergency care. We note that data on the Screen Positive Rate for SDOH measure (which includes information about the patient's risk of interpersonal violence), which we finalized in the FY 2024 IPF PPS final rule (88 FR 51117 through 51121), will be publicly reported starting with the FY 2027 payment determination (the same period for which we are adopting the IPF ED Visit measure). With both measures being implemented and publicly reported at same time, IPFs and other interested parties will be able to compare performance on this IPF ED Visit measure across IPFs with similar rates of patients who screen positive for social needs under the Screen Positive Rate for SDOH measure.

We reiterate that the goal of this measure is to reduce rates of 30-day post-discharge ED visits in comparison to other similarly situated IPFs and that we seek to achieve this by publicly reporting IPF performance on this measure. We note that the IPF ED Visit measure is not intended to allow comparisons between post-discharge outcomes of patients discharged from IPFs and patients discharged from other facility types.

We also note that, as part of the measure development and testing process, the measure developer performed an equity analysis in which

⁶⁵ For information about the Cost and Efficiency endorsement review we refer readers to the meeting summary, available at <https://p4qm.org/sites/default/files/Cost%20and%20Efficiency/material/EM-Cost-and-Efficiency-Fall2023-Endorsement-Meeting-Summary.pdf>.

they tested the risk-adjustment methodology to ensure that the measure does not reflect access issues related to patient demographics instead of quality of care. The equity analysis involved comparing a model that included both SDOH and clinical risk-factors against a model that included only clinical risk factors. The model that included both SDOH and clinical risk-factors had only marginally better predictive accuracy than the model with only clinical risk-factors, suggesting that the impact of SDOH on the outcome is relatively small compared to the clinical risk-factors.⁶⁶ Furthermore, we have concerns about holding IPFs to different standards for the outcomes of their patients of diverse sociodemographic status because we do not want to mask potential disparities or minimize incentives to improve the outcomes of disadvantaged populations. The measure developer's equity testing verified that the measure provides information about the quality of care provided in the IPF, even for IPFs that treat patients with different demographic characteristics.⁶⁷ Therefore, we do not expect results on this measure to be driven by an IPF's patient case-mix or prevalence of unmet social needs within that IPF. However, we will continue to monitor measure results to ensure that they reflect IPF quality of care.

Comment: Several commenters expressed concern that by including an all-cause measure we will not accurately represent the quality of care provided by IPFs. These commenters noted that there are reasons that patients seek emergency care that are unrelated to the care provided by the IPF, including accidents or physical health needs unrelated to the patient's behavioral health condition. Some commenters expressed concern that the use of an all-cause measure, instead of a more narrowly specified measure such as the potentially preventable admissions measures used in post-acute care settings (specifically, IRFs, SNFs, LTCHs, and HHAs) or the ED Visits Following Outpatient Chemotherapy measure in the Hospital Outpatient Quality Reporting Program, implies that IPFs have more accountability for patients than other care settings.

⁶⁶ For more information regarding this equity testing, we refer readers to the "Equity" tab of the information submitted to the CBE for review and available during the pre-rulemaking review. This is available at: <https://p4qm.org/measures/4190>.

⁶⁷ For more information regarding this equity testing, we refer readers to the "Equity" tab of the information submitted to the CBE for review and available during the pre-rulemaking review. This is available at: <https://p4qm.org/measures/4190>.

Response: We recognize that not all post-discharge ED visits are preventable, nor are all post-discharge ED visits associated with the initial IPF admission. Therefore, we do not expect rates for the IPF ED Visit measure to be zero. However, because engaging patients to improve post-discharge outcomes is an important element of providing quality care, we seek to develop and implement measures that assess this post-discharge outcome.

While there are many circumstances that may cause a patient to seek emergency care that are unrelated to the IPF, approximately 40 percent of Medicare beneficiaries discharged from IPFs seek acute care treatment in hospitals within 30 days of their discharge from the IPF, with approximately half of those patients being admitted to an inpatient hospital and half of those patients receiving treatment in the emergency department without a subsequent admission.⁶⁸ In 2021, approximately 4 percent of Medicare beneficiaries visited an ED each month with or without a subsequent admission,⁶⁹ which is significantly lower than the percentage of discharged IPF patients visiting an ED. While we recognize that many patients discharged from IPFs are more clinically complex than the general Medicare population, we also believe that there is opportunity to close the gap in ED utilization between IPF patients and the Medicare beneficiary population at-large.

Furthermore, we developed an all-cause measure for the three reasons previously discussed: (1) to align with the IPF Unplanned Readmissions measure; (2) to emphasize whole-person care; and (3) to ensure that patients who visit the ED for symptoms related to their behavioral health condition or that could have been appropriately addressed by the IPF during the patient's stay or at discharge are included in the measure. These reasons continue to be important elements of assessing and reporting on post-discharge use of acute care.

We recognize that other CMS quality reporting and value-based purchasing programs have developed measures that assess the use of acute care services for more narrowly defined groups of patients or that focus on "potentially preventable" use of acute care services. However, we note that other programs

⁶⁸ We refer readers to the FY 2025 IPF PPS proposed rule for more information regarding these calculations (89 FR 23207).

⁶⁹ CDC, Emergency Department Visit Rates by Selected Characteristics: United States, 2021. Accessed at <https://www.cdc.gov/nchs/data/databriefs/db478.pdf>.

have developed measures that more broadly assess outcomes after discharge. For example, the Hospital Inpatient Quality Reporting Program (IQR) Program has two measures that broadly assess outcomes after discharge: (1) the Hybrid Hospital-Wide Unplanned Readmission (HWR) measure⁷⁰ and (2) the Hybrid Hospital-Wide Mortality (HWM) measure.⁷¹ The Hospital Outpatient Quality Reporting Program has one measure, the Surgery Measure (OP-36).⁷²

We note that unmanaged behavioral health conditions can present in many ways including physical and mental symptoms. During an ED visit it is possible that the relationship between the presenting condition and the patient's behavioral health condition may not be assessed and documented. Therefore, we chose to develop a more broadly specified measure than some of the measures in use in other programs. This does not imply that IPFs have more control over or accountability for use of acute care than other care providers. It is a consequence of the complexity of the patients that seek care in IPFs. We reiterate we do not expect IPFs to achieve zero post-discharge acute care visits.

We believe that commenters may have been concerned regarding financial accountability for patients seeking emergency care after discharge from an IPF. We note that the IPFQR Program is a pay-for-reporting program. CMS only has the authority under section 1886(s)(4)(A) to apply a financial penalty if an IPF fails to submit data on a quality measure in the form and manner, and at a time, specified by CMS. CMS does not otherwise adjust payments based on the IPF's performance on the measures adopted in the IPFQR Program.

Comment: A commenter stated that IPFs do not have the appropriate health information technology (HIT) to electronically connect with local partners. These commenters stated that

⁷⁰ This measure evaluates whether a patient has an unplanned readmission within 30 days of discharge. For more addition on this measure, we refer readers to the hybrid measures section of the QualityNet website: <https://qualitynet.cms.gov/inpatient/measures/hybrid>.

⁷¹ This measure estimates a hospital-level 30-day risk-standardized mortality rate, which is defined as death from any cause within 30 days after the index admission date. For more information on this measure, we refer readers to the hybrid measures section of the QualityNet website: <https://qualitynet.cms.gov/inpatient/measures/hybrid>.

⁷² This measure estimates facility-specific risk-standardized hospital visits within seven days of hospital outpatient surgery. For more information on this measure, we refer readers to the surgery measure section of the QualityNet website: <https://qualitynet.cms.gov/outpatient/measures/surgery>.

this makes it more difficult for IPFs to engage in meaningful cross-setting discharge and follow-up care coordination.

Response: We understand that many IPFs have limited access to certified electronic health record technology (CEHRT)⁷³ and that this impacts their access to interoperable communications with other healthcare providers. However, there are many strategies for comprehensive discharge planning that do not rely on interoperable electronic systems. For example, the Agency for Healthcare Research and Quality (AHRQ) has the Include-Discuss-Educate-Assess-Listen (IDEAL) discharge planning guide which does not require any use of HIT.⁷⁴ We therefore believe that performance on this measure is not directly dependent on an IPF's technological capabilities.

Comment: Several commenters expressed concern that patients may not have access to post-discharge care other than through the ED. Commenters noted the following reasons for lack of access to lower acuity care: (1) underserved communities may not have lower acuity care available; (2) communal living settings may have policies that restrict access to lower acuity care settings; and (3) long wait times for outpatient appointments. A few commenters stated that utilization of the ED without subsequent admissions may demonstrate that patients are seeking medical care before their condition becomes so severe that inpatient care is required, and is therefore positive. A commenter stated that this measure may restrict patient access to EDs.

Response: While we agree that patients seeking medical care before their condition becomes so severe that inpatient care is required is preferable to patients needing to be readmitted, we disagree that seeking that care in the ED is a positive indication. Receiving care in the ED without an admission indicates that either the patient's condition has become urgent, or the patient is receiving lower-acuity care in the ED. A preferable outcome would be for the patient to be able to receive care in the community setting without

having to use emergency services for low acuity care and improved care management.

Receiving lower acuity care in the ED can be time-consuming for the patient and can lead to increased spending and unnecessary testing and treatment,⁷⁵ and patients receiving care in EDs are at particularly high risk for adverse events.⁷⁶ Furthermore, patients receiving lower acuity care in the ED can lead to ED crowding, which can affect the ED's ability to provide care to higher acuity patients, and reduce the overall quality of care provided by the ED.⁷⁷ To avoid the potential risks associated with lower acuity care provided in the ED, guiding patients to other available resources, to the extent possible, is part of high quality discharge planning and post-discharge care coordination.

However, we recognize that EDs are valuable resources, which provide necessary care for urgent needs, and that there are areas in which EDs may be the only source of care available to patients. We also recognize that there are many situations in which care in an ED is clinically appropriate and not related to the care provided by the discharging IPF. We reiterate that the IPF ED Visit measure is designed to provide information regarding how IPFs perform relative to similar IPFs, including IPFs in the same geographic areas and shared community resources. The goal of this measure is to reduce rates of 30-day post-discharge ED visits in comparison to other similarly situated IPFs, but there is no expectation that IPFs would reach zero 30-day post-discharge ED visits.

Regarding the concern that this measure may restrict access to EDs following discharge from an IPF, we note that the intention of this measure is not for IPFs to discourage patients from seeking care in EDs when appropriate. Rather, we believe that IPFs play an important role in helping

patients understand purposes of, and how to access, all levels of care within their communities, and that it is also their responsibility to help patients understand when to seek treatment in an ED setting. We also reiterate that, while lower scores on this measure are better, we would not expect IPFs to reach zero ED visits following discharge because there are circumstances that require the use of the ED.

Comment: A few commenters recommended that CMS develop a risk adjustment strategy for this measure. Another commenter stated that IPFs may refuse to admit patients who have complex medical needs because of the increased possibility that these patients would later seek emergency care and reflect poorly on the discharging IPF.

Response: As described in the FY 2025 IPF PPS proposed rule, this measure is risk-adjusted (89 FR 23208). The steps to calculate this measure are: (1) identify all IPF admissions in the one-year performance period; (2) apply inclusion and exclusion criteria to identify index admissions; (3) identify ED visits and observation stays within 30 days of discharge from each index admission; (4) identify risk factors in the 12 months prior to index admission and during the index admission; and (5) run hierarchical logistic regression to compute the risk-standardized ED visit rate for each IPF. We developed the hierarchical logistic regression model to understand which clinical patient characteristics had effects on the patients' risk of needing care in the ED within 30 days of discharge from the IPF. This analysis allows us to ensure that the measure results are comparable across IPFs regardless of the clinical complexity of each IPF's patient population. The hierarchical logistic regression model was provided for CBE review and was available to the public at the time of publication of the FY 2025 IPF PPS proposed rule. For more information on this model we refer readers to <https://p4qm.org/sites/default/files/2023-10/Copy%20of%20Risk-model-specifications.xlsx>. Because this measure is risk adjusted for patient complexity, IPFs that admit patients with complex medical needs do not increase their risk of appearing to perform poorly on this measure.

Comment: Some commenters were concerned that IPFs may be penalized for factors outside of their control.

Response: We note that the IPFQR Program is a pay-for-reporting program. We only have the authority under section 1886(s)(4)(A) of the Act to apply a financial penalty if an IPF fails to submit data on a quality measure in the

⁷³ We note that CEHRT refers to EHR technology that qualifies for use in the Medicare Promoting Interoperability Program, though it is used by a variety of health care providers that do not participate in that Program. For more information about CEHRT, we refer readers to: <https://www.cms.gov/medicare/regulations-guidance/promoting-interoperability-programs/certified-ehr-technology>.

⁷⁴ Agency for Healthcare Research and Quality (AHRQ) Accessed at https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/systems/hospital/engagingfamilies/strategy4/Strat4_Tool_1_IDEAL_chklst_508.pdf.

⁷⁵ Uscher-Pines L, Pines J, Kellermann A, Gillen E, Mehrotra A. Emergency department visits for nonurgent conditions: systematic literature review. *Am J Manag Care*. 2013 Jan;19(1):47–59. PMID: 23379744; PMCID: PMC4156292.

⁷⁶ Pini R, Ralli ML, Shanmugam S. Emergency Department Clinical Risk. 2020 Dec 15. In: Donaldson L, Ricciardi W, Sheridan S, et al., editors. *Textbook of Patient Safety and Clinical Risk Management* [internet]. Cham (CH): Springer; 2021. Chapter 15. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK585618/> doi: 10.1007/978-3-030-59403-9_15.

⁷⁷ Sartini M, Carbone A, Demartini A, Giribone L, Oliva M, Spagnolo AM, Cremonesi P, Canale F, Cristina ML. Overcrowding in Emergency Department: Causes, Consequences, and Solutions—A Narrative Review. *Healthcare* (Basel). 2022 Aug 25;10(9):1625. doi: 10.3390/healthcare10091625. PMID: 36141237; PMCID: PMC9498666.

form and manner, and at a time, CMS specifies. We do not otherwise adjust or penalize payments based on the IPF's performance on the measures adopted in the IPFQR Program.

We understand commenters may be concerned about the impact of public reporting of IPF's performance on this measure as required by section 1886(s)(4)(F) of the Act, such as patients seeking care at higher performing IPFs. We reiterate that the goal of this measure is to reduce rates of 30-day post-discharge ED visits in comparison to other similarly situated IPFs and that we seek to achieve this by publicly reporting IPF performance on this measure. In addition, because the IPF ED Visit measure is risk standardized, it provides a tool for comparing IPFs that treat clinically different patient populations. Furthermore, by comparing IPFs which treat patients with similar levels of unmet social needs (by comparing IPFs which report similar rates on the Screen Positive for SDOH measure), patients would be able to use the IPF ED Visit measure as an element of their care decisions. We note that IPFs that experience extraordinary events, such as natural disasters, which affect their ability to submit required measure data under the IPFQR Program could request an extraordinary circumstances exception in accordance with our regulation at § 412.433(f).

Comment: A few commenters recommended that, for the IPFQR Program, CMS should only develop and adopt quality measures specific to the provision of inpatient psychiatric care. A few commenters recommended that CMS develop quality measures that focus on factors within the IPF's control, such as a discharge planning measure or a follow-up after discharge measure to better assess discharge planning and care coordination. Some commenters recommended development of condition-specific measures to assess post-discharge use of acute care. A commenter recommended assessing care coordination through use of a patient experience survey.

Response: Regarding the recommendation that CMS should only develop and adopt quality measures specific to the provision of inpatient psychiatric care, we note that helping patients successfully reintegrate into their communities upon discharge is an important element of the provision of high-quality inpatient psychiatric care. However, we believe the commenter is recommending that we more narrowly focus measures on actions performed by the IPF while the patient is receiving care at the facility.

Consistent with the CMS National Quality Strategy's Focus on a health care system that promotes quality outcomes,⁷⁸ we focus on measures that assess outcomes where possible. We recognize that one limitation of measures that assess outcomes is that outcomes are the result of numerous factors, many beyond providers' control.⁷⁹ We considered other ways of assessing discharge planning and care coordination. However, we chose to develop this measure instead of a discharge planning measure because it more directly assesses the outcome we wish to achieve (improved reintegration into communities after discharge) and can be calculated using data that IPFs already provide. We note that we already have the Follow-Up After Psychiatric Hospitalization (FAPH) measure⁸⁰ in the IPFQR Program. For more information about the FAPH measure and how the IPF ED Visit measure complements we refer readers to our discussion in section VI.B.2.a. of this final rule.

Regarding the recommendation that we include care transition questions in a patient experience measure, we agree that the patient's experience of being prepared to successfully reintegrate into the community is an important element of discharge planning and care coordination. We note that the Psychiatric Inpatient Experience (PIX) survey measure, which we finalized in the FY 2024 IPF PPS final rule (88 FR 51121 through 51128), includes a treatment effectiveness domain, including questions related to the patient's perspective of whether their care experience has prepared them to transition back into the community. However, the patient's perspective at time of discharge is only one element of a complex set of elements that lead to a successful reintegration into the community, including, for example, the appropriateness and completeness of documentation and whether recommendations for outpatient care appropriately account for the patient's ability to access this care.

⁷⁸ CMS, CMS Quality in Motion: Acting on the CMS National Quality Strategy. April 2024. Available at: <https://www.cms.gov/files/document/quality-motion-cms-national-quality-strategy.pdf>.

⁷⁹ Agency for Healthcare Research and Quality, Types of Health Care Quality Measures. Access May 30, 2024. Available at: <https://www.ahrq.gov/talking-quality/measures/types.html#:~:text=Outcome%20measures%20may%20seem%20to,>

[%20many%20beyond%20providers'%20control.](https://www.ahrq.gov/talking-quality/measures/types.html#:~:text=Outcome%20measures%20may%20seem%20to,%20many%20beyond%20providers'%20control.)
⁸⁰ For more information about this measure, we refer readers to the codebook, available at: https://qualitynet.cms.gov/files/6675efeba629e067996f932d?filename=FY25_IPFQR_FAPH_Codebook.xlsx.

Comment: Some commenters were concerned about the lack of CBE endorsement, specifically expressing the belief that the CBE's lack of consensus on whether to endorse the measure indicated that the measure was not reliable or valid. A commenter recommended the inclusion of experts in the measure development process, including individuals involved in providing care in IPFs. A commenter stated the belief that the measure developer misinterpreted the statistical significance of the measure in reliability and validity testing. Other commenters stated that the measure specifications do not provide a clear connection between evidence-based interventions and measure outcomes. A commenter stated the belief that adopting this measure, despite lack of CBE endorsement, with the sole justification that there is no endorsed measure that addresses this topic is an insufficient justification for adopting a measure that is not endorsed by the CBE.

Response: We agree that it is important to adopt measures that are reliable and valid and have been reviewed by clinical experts. Through the development and testing of this measure, which we described in the FY 2025 IPF PPS proposed rule (89 FR 23208) and in more detail in the measure information submitted for CBE review⁸¹ as discussed in the FY 2025 IPF PPS proposed rule (89 FR 23209 through 23210), it meets these criteria.

Specifically, the measure developer tested the measure for reliability using a bootstrapped test-retest approach (which is a statistical method for testing using a single data set)⁸² and calculated the intra-class correlation coefficient (ICC) which reflects correlation and agreement between measurements. The mean ICC obtained by through this method was 0.690 with a range of 0.683 through 0.756.⁸³ Generally, ICC values between 0.5 and 0.75 are considered moderate and between 0.75 and 0.9 are considered good.⁸⁴ Therefore this measure is in the high-moderate to low-good range of reliability, which is

⁸¹ Available at Partnership for Quality Measurement. <https://p4qm.org/measures/4190>.

⁸² PennState, Eberly College of Science, Applied Statistics. Available at <https://online.stat.psu.edu/stat500/lesson/11/11.2/11.2.1>.

⁸³ Information available on the Partnership for Quality Measurement measure page, available at <https://p4qm.org/measures/4190>.

⁸⁴ Koo TK, Li MY. A Guideline of Selecting and Reporting Intraclass Correlation Coefficients for Reliability Research. J Chiropr Med. 2016 Jun;15(2):155–63. doi: 10.1016/j.jcm.2016.02.012. Epub. 2016 Mar. 31. Erratum in: J. Chiropr. Med. 2017 Dec;16(4):346. PMID: 27330520; PMCID: PMC4913118.

sufficiently reliable for adoption into the IPFQR Program.

To test the validity, the measure developer assessed the relationship between the IPF ED Visit measure rate and the IPF Unplanned Readmission measure rate. The measure developer also performed hypothesis-driven validity testing to determine if performance rates among subgroups of patients (including based on sex, race/ethnicity, dual eligibility status, and patients with a longer length of stay) were consistent with empirical literature regarding ED usage among these patients. There was a positive relationship between facility rates on the IPF ED Visit measure and the IPF Unplanned Readmissions measure and there were small differences in the ED measure rate across the patient subgroups they evaluated in the direction consistent with expectations based on literature.⁸⁵ These results demonstrate the validity of the measure. Furthermore, as part of the standard measure development process⁸⁶ the measure developer convened a Technical Expert Panel (TEP) representing a diverse set of viewpoints (89 FR 23208) to ensure that the measure would address a gap that is important to interested parties. We further note that, while the measure did not meet the 75 percent threshold required for endorsement, the majority (60.6 percent) of the CBE committee did support endorsement, or endorsement with conditions.

⁸⁵ Information available on the Partnership for Quality Measurement measure page, available at <https://p4qm.org/measures/4190>.

⁸⁶ CMS. Blueprint Measure Lifecycle. Available at <https://mmshub.cms.gov/blueprint-measure-lifecycle-overview>.

Regarding the concern that the measure developer misinterpreted the statistical data, we have assessed the results achieved in testing to be consistent with appropriate statistical methods.

While there is limited research focused entirely on reducing ED visits without subsequent admission following discharge from an IPF, the literature that exists, as well as literature on reducing readmissions following IPF discharge, show clear links between steps IPFs can take and reduced use of acute care after discharge from the IPF. Additionally, IPFs can play a role in care coordination by arranging follow-up appointments for patients, ensuring medications are available at discharge, assisting patients with accessing medications from external providers, and engaging the patients' social support system. Patients who missed their first post-IPF discharge follow-up appointment had a 140 percent increased risk of readmission,⁸⁷ which indicates the importance of providing sufficient patient education and post-discharge support to ensure the patient is able to keep their first post-IPF discharge follow-up appointment.

When we propose a measure that is not endorsed by the CBE, we must evaluate whether the exception in 1886(s)(4)(D)(ii) of the Act applies. This exception 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

⁸⁷ Hamilton, J.E., Rhoades, H., Galvez, J. et al. (2015). Factors differentially associated with early readmission at a university teaching psychiatric hospital. *Journal of Evaluation in Clinical Practice*, 21(4), 572–578.

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 a measure that has been endorsed or adopted by a consensus organization identified by the Secretary. We stated in the proposed rule that there are no measures that address this topic that have been adopted by the CBE to explain why the second part of this exception applies to this measure (89 FR 23210). We are adopting the IPF ED Visit measure because it is a measure that has been tested for feasibility, validity, and reliability, which was developed with input from a diverse set of experts, that will provide data that patients and their families can use to inform care decisions and IPFs can use to drive quality improvement activities. We gave due consideration to measures endorsed by the CBE and there were no measures that address this important outcome.

Final Decision: After consideration of the comments we received, we are finalizing our proposal to adopt the IPF ED Visit measure beginning with the CY 2025 performance period/FY 2027 payment determination as proposed.

C. Summary of IPFQR Program Measures for the FY 2027 Payment Determination for the IPFQR Program

We are adopting one new measure for the FY 2027 payment determination for the IPFQR Program. With the adoption of this measure, the FY 2027 IPFQR Program measure set includes 16 mandatory and one voluntary measure. Table 19 sets forth the measures in the FY 2027 IPFQR Program.

BILLING CODE 4120-01-P

TABLE 19: IPFQR PROGRAM MEASURE SET FOR THE FY 2027 PAYMENT DETERMINATION FOR THE IPFQR PROGRAM

CBE #	Measure ID	Measure
Required Measures		
0640	HBIPS-2	Hours of Physical Restraint Use
0641	HBIPS-3	Hours of Seclusion Use
N/A	FAPH	Follow-Up After Psychiatric Hospitalization
N/A*	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention
N/A*	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge
N/A*	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge
1659	IMM-2	Influenza Immunization
N/A*	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A	N/A	Screening for Metabolic Disorders
2860	N/A	Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility
N/A	N/A	30-Day Risk-Standardized All-Cause Emergency Department Visit Following an Inpatient Psychiatric Facility Discharge measure ¹
3205*	Med Cont.	Medication Continuation Following Inpatient Psychiatric Discharge
N/A	N/A	Modified COVID-19 Healthcare Personnel (HCP) Vaccination Measure
N/A	Facility Commitment	Facility Commitment to Health Equity
N/A	Screening for SDOH	Screening for Social Drivers of Health
N/A	Screen Positive	Screen Positive Rate for Social Drivers of Health
Voluntary Measure		
N/A	PIX Survey	Psychiatric Inpatient Experience Survey ²

* Measure is no longer endorsed by the CBE but was endorsed at the time of adoption. We note that although section 1886(s)(4)(D)(i) of the Act generally requires measures specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

¹ Measure finalized for adoption in Section VI.B.2. of this final rule.

² We note that the PIX measure will become mandatory for the FY 2028 payment determination, as finalized in the FY 2024 IPF PPS Final Rule (88 FR 51128).

BILLING CODE 4120-01-C

D. Retention of Data Submission Requirements for the FY 2027 Payment Determination and Subsequent Years

Section 1886(s)(4)(C) of the Act requires the submission of quality data in a form and manner, and at a time, specified by the Secretary. In the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2013 Rates; Hospitals'

Resident Caps for Graduate Medical Education Payment Purposes; Quality Reporting Requirements for Specific Providers and for Ambulatory Surgical Centers (FY 2013 IPPS/LTCH PPS) final rule (77 FR 53655), we specified that data must be submitted between July 1 and August 15 of the calendar year preceding a given payment determination year (for example, data were required to be submitted between July 1, 2015 and August 15, 2015 for the FY 2016 payment determination). In the Medicare Program; Hospital Inpatient

Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Payment Policies Related to Patient Status (FY 2014 IPPS/LTCH PPS) final rule (78 FR 50899), we clarified that this policy applied to all future years of data submission for the IPFQR Program unless we changed the policy through future rulemaking.

In the FY 2018 IPF PPS final rule (82 FR 38472 through 38473) we updated this policy by stating that the data submission period will be a 45-day period beginning at least 30 days following the end of the data collection period and that we will provide

notification of the exact dates through subregulatory means.

In the FY 2022 IPF PPS Final Rule (86 FR 42658 through 42661), we finalized voluntary patient-level data reporting for the FY 2023 payment determination and mandatory patient-level data

reporting for chart-abstracted measures within the IPFQR Program beginning with FY 2024 payment determination and subsequent years. The measures currently in the IPFQR Program affected by this requirement are set forth in Table 20.

TABLE 20: IPFQR PROGRAM MEASURES REQUIRING PATIENT-LEVEL DATA SUBMISSION

CBE #	Measure ID	Measure
Required Measures		
0640	HBIPS-2	Hours of Physical Restraint Use (numerator only)
0641	HBIPS-3	Hours of Seclusion Use (numerator only)
N/A*	SUB-2 and SUB-2a	Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention
N/A*	SUB-3 and SUB-3a	Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge
N/A*	TOB-3 and TOB-3a	Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge
1659	IMM-2	Influenza Immunization
N/A*	N/A	Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)
N/A	N/A	Screening for Metabolic Disorders

* Measure is no longer endorsed by the CBE but was endorsed at the time of adoption. We note that although section 1886(s)(4)(D)(i) of the Act generally requires measures specified by the Secretary be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(s)(4)(D)(ii) states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We attempted to find available measures for each of these clinical topics that have been endorsed or adopted by a consensus organization and found no other feasible and practical measures on the topics for the IPF setting.

As we have gained experience with patient-level data submission for the IPFQR program, during the voluntary data submission period for FY 2023 (which occurred in CY 2022) and the first mandatory data submission period for FY 2024 (which occurred in CY 2023), we have observed that annual data submission periods require IPFs to store large volumes of patient data to prepare for transmission to CMS. Furthermore, the volume of data associated with all IPFs reporting a full year of patient-level data during one data submission period creates the risk that systems will be unable to handle the volume of data.

We have reviewed how other quality reporting programs that require patient-level data submission address these concerns and determined that the Hospital Inpatient Quality Reporting (IQR) Program (78 FR 50811) and the

Hospital Outpatient Quality Reporting (OQR) Program (72 FR 66872) both require quarterly submission of patient-level data. As we considered requiring quarterly reporting for the IPFQR Program, we also determined that increasing the frequency of data submission would allow additional analysis of measure trends over time. In the FY 2025 IPF PPS proposed rule, we stated that having additional data points (from additional quarters of data) could allow for more nuanced analyses of the IPFQR Program's measures (89 FR 23212). We stated that specifically, we would be able to better identify quarterly highs or lows that may be less apparent when data are combined over a full year. We recognized that, if we updated data reporting requirements to require reporting four times per year instead of once per year, then IPFs would need to meet four incremental

deadlines instead of one deadline, and that this increased the risk that an individual IPF may fail to submit data specified for the measures and not receive its full market basket update. However, we believe that this risk is low because IPFs already have experience submitting some data required by the IPFQR Program on a more frequent basis. Specifically, the COVID-19 Healthcare Personnel (HCP) Vaccination Measure is currently reported into the CDC's National Healthcare Safety Network (NHSN) for one week per month resulting in a quarterly measure result (as originally adopted in the FY 2022 IPF PPS final rule (86 FR 42636) and restated in the FY 2024 IPF PPS final rule (88 FR 51131 through 51132). In addition, if this proposal for quarterly data submission were finalized, data submission for each calendar quarter would have been required during a

period of at least 45 days beginning
three months after the end of the
calendar quarter. Table 21 summarizes

the deadlines we proposed for the CY
2025 and CY 2026 performance periods:

TABLE 21: QUARTERLY SUBMISSION DEADLINES FOR CY 2025 AND CY 2026 PERFORMANCE PERIODS, AS PROPOSED

Performance Period	Submission Deadline
January 1, 2025- March 31, 2025 (Q1 2025)	November 15, 2025
April 1, 2025 – June 30, 2025 (Q2 2025)	November 15, 2025
July 1, 2025 – September 30, 2025 (Q3 2025)	February 15, 2026
October 1, 2025 – December 31, 2025 (Q4 2025)	May 15, 2026
January 1, 2026- March 31, 2026 (Q1 2026)	August 15, 2026
April 1, 2026 – June 30, 2026 (Q2 2026)	November 15, 2026
July 1, 2026 – September 30, 2026 (Q3 2026)	February 15, 2027
October 1, 2026 – December 31, 2026 (Q4 2026)	May 15, 2027

Furthermore, we proposed that all data which continue to be reported on an annual basis (that is, non-measure data, aggregate measures, and attestations) would have been required to be reported concurrently with the data from the fourth quarter of the applicable year. For example, data reflecting the entirety of CY 2025 (that is, non-measure data, aggregate measures, and attestations) would have been required by the Q4 2025 submission deadline (that is, May 15, 2026).

We received public comments on this proposal. The following is a summary of the comments we received and our responses.

Comment: A few commenters supported our proposal to transition to quarterly submission of patient-level data. A commenter agreed that this may reduce the risk that systems are unable to handle the data volume and increase the data available for trend analysis.

Response: We thank these commenters for their support.

Comment: Several commenters expressed concerns regarding the proposed timeline of requiring quarterly submission of patient level data beginning with the CY 2025 performance period. Some of these commenters expressed concern that IPFs would not be able to update processes and systems to meet the November 15, 2025 submission deadline

for the first quarter of the CY 2025 performance period (January 1, 2025– March 31, 2025). Other commenters stated that the CMS Specifications Manual releases are often delayed from discharge dates, which affects when IPFs can abstract data to prepare for submission. A commenter stated that transitioning to quarterly reporting may affect the ability of newly certified IPFs to successfully participate in the IPFQR Program due to the time it takes to receive notice of accreditation.

Response: After reviewing the concerns raised by commenters regarding the challenges of transitioning to quarterly reporting, we agree with commenters that these challenges would affect some IPFs’ ability to report data for the CY 2025 performance period (that is, the FY 2027 payment determination). Therefore, we are not finalizing this proposal at this time.

If we propose to adopt quarterly reporting in the future, we will consider the transition time required for IPFs to update their submissions, evaluate the timing of the CMS Specifications Manual with respect to reporting deadlines, and ensure that newly certified facilities are able to participate in the IPFQR Program.

Comment: Several commenters recommended that CMS delay adoption of this policy. Some of these commenters recommended a stepped approach in which CMS gradually

transitions to quarterly reporting. A commenter recommended only requiring data submission twice annually. A few commenters recommended delaying adoption of this policy until CMS and IPFs have more experience with patient-level data submission and to decrease financial risk to IPFs.

Response: We thank these commenters for their recommendations. We are not finalizing this proposal at this time. If we propose more frequent reporting in the future, we will consider these approaches to more frequent reporting in any future rulemaking.

Comment: A few commenters expressed concern that this proposal would quadruple IPF’s information collection burden.

Response: We understand commenters’ concerns that there would be an increase in reporting burden associated with increasing the required frequency of reporting patient-level data. We note that we are not finalizing this proposal at this time. However, we disagree that increasing from annual reporting to quarterly reporting would quadruple the information collection burden. We note that reviewing patient medical records to determine which patients are included in numerators and denominators for each measure is the portion of measure submission which entails the highest information collection burden, and that changing the

frequency with which data are to be reported would have no impact on the number of patients for whom IPFs are required medical records to calculate measure results.

Comment: Several commenters expressed concern that the increase in staff time spent reporting would reduce staff availability for patient care duties. A commenter expressed that this data reporting frequency would be more burdensome for IPFs than quarterly reporting is for other healthcare providers because IPFs experience more challenges related to outdated HIT. Some commenters recommended that CMS provide financial support, potentially by increasing payment rates for IPFs, for the increased reporting frequency due to the increased burden it would require. Several commenters expressed concern that this increased reporting frequency would disproportionately increase IPF costs relative to benefits that more frequent reporting would provide.

Response: We understand commenters' concerns that there would be an increase in reporting burden associated with increasing the required frequency of reporting patient-level data. We recognize that IPFs have faced more barriers in adopting and updating HIT than acute care hospitals, and that this may affect their ability to abstract, store, and submit quality measure data on a more frequent basis. We note that we are not finalizing this proposal at this time. However, we disagree with commenters regarding the impact this proposed increase in reporting frequency would have. As previously discussed, reporting the information to CMS is a small portion of the total information collection burden associated with participating in the IPFQR Program. Therefore, we believe that the increase in reporting frequency would have a relatively small impact on IPFs' reporting burden and that this impact would not meaningfully affect IPFs' ability to provide patient care. We also do not believe that the increase in reporting frequency would significantly increase the cost of reporting and therefore we do not believe that an increase in payment to account for this increase would be necessary or appropriate. However, we will consider the potential impact on reporting burden to ensure that the benefits of more frequent collection outweigh the increase in costs of participation if we propose quarterly reporting in future rulemaking.

Comment: A commenter requested clarification regarding whether data submission for the PIX survey measure

would be included in the transition to quarterly data submission.

Response: We are not finalizing our proposal to transition to quarterly reporting. If we propose a transition to quarterly reporting in future rulemaking, we will state what data is included in that proposal at that time.

Comment: A few commenters provided recommendations for actions to take prior to transitioning to quarterly data submission. These actions were: (1) ensure alignment of IPFQR submission deadlines with deadlines for other CMS quality reporting programs; (2) reduce the number of program measures; (3) reduce the number of measures which require manual abstraction or submission; and (4) align measures across programs, as feasible and appropriate.

Response: We thank commenters for these recommendations. We will consider these recommendations as we evaluate the IPFQR Program for future transition to quarterly data submission.

Comment: Some commenters expressed concern that the accuracy of the data submitted may be compromised unless non-measure data and aggregate measures were also submitted quarterly. These commenters stated that updates to billing and medical records could occur after the submission of quarterly patient-level data that could create inconsistencies between the data submitted on a quarterly basis and that submitted on an annual basis. These commenters provided an example of their concern, specifically that denominator for the Hours of Physical Restraint Use (Hospital-Based Inpatient Psychiatric Services—HBIPS–2) and Hours of Seclusion Use (HBIPS–3) measures⁸⁸ is included in the non-measure data set and therefore these measures would be particularly susceptible to data inaccuracies. A few commenters stated that because of the relatively small number of patients served by IPFs (compared to patients served by acute care hospitals) quarterly sample sizes would likely be too small to perform improved trend analysis with the increased frequency of data submission.

Response: We agree with commenters that ensuring that the data we publicly report are accurate and complete is an important part of the IPFQR Program. We recognize commenters' concerns that, without additional guidance regarding timing of data abstraction and reporting with respect to billing and

medical record updates, there is a potential to create discrepancies between data submitted on a quarterly basis and data submitted on an annual basis. We further agree with commenters that this could be particularly concerning regarding the HBIPS–2 and HBIPS–3 measures because the denominators for these measures would be included in the annually reported data set and the numerators would be included in the quarterly reported data set. We understand commenters' concern that the relatively small sample sizes may be too small to perform improved trend analysis. We note that we are not finalizing this proposal at this time. We will consider these recommendations as we evaluate the IPFQR Program for future transition to quarterly data submission.

Final Decision: After consideration of the comments we received, we are not finalizing our proposal to modify data submission requirements, beginning with the FY 2027 payment determination, to transition to quarterly data submission for patient-level data.

VII. 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.

This final rule refers to associated information collections that are not discussed in the regulation text contained in this document.

The following changes will be submitted to OMB for review under control number 0938–1171 (CMS–10432). We did not propose changes that would change any of the data collection instruments that are currently approved under that control number.

⁸⁸ For more information on the HBIPS–2 and HBIPS–3 measures we refer readers to the IPF Specifications Manual available at: https://qualitynet.cms.gov/files/6675e252a629e067996f9205?filename=IPF_SpecMan_v1.3.pdf.

A. Wage Estimates

In the FY 2024 IPF PPS final rule, we utilized the median hourly wage rate for Medical Records Specialists, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the IPFQR Program (88 FR 51145). While the most recent data from the BLS reflects a mean hourly wage of \$24.65 per hour for all medical records specialists, \$26.06 is the mean hourly wage for “general medical and surgical hospitals,” which is an industry within medical records specialists.⁸⁹ We believe the industry of “general medical and surgical hospitals” is more specific to the IPF setting for use in our calculations than other industries that fall under medical records specialists, such as “office of physicians” or “nursing care facilities (skilled nursing facilities).” We calculated the cost of indirect costs, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($\$26.06 \times 2 =$

\$52.12) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to IPFs using a wage plus benefits estimate of \$52.12 per hour throughout the discussion in this section of this rule for the IPFQR Program.

Some of the activities previously finalized for the IPFQR Program require beneficiaries to undertake tasks such as responding to survey questions on their own time. In the FY 2024 IPF PPS final rule, we estimated the hourly wage rate for these activities to be \$20.71/hr (88 FR 51145). We updated the estimate to a post-tax wage of \$24.04/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time.⁹⁰ To derive the costs for beneficiaries, we used a measurement of the usual weekly earnings of wage and salary workers of \$1,118, divided by 40 hours to calculate an hourly pre-tax wage rate of \$27.95/hr.⁹¹ The rate is

adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,⁹² resulting in the post-tax hourly wage rate of \$24.04/hr. Unlike our State and private sector wage adjustments, we did not adjust beneficiary wages for fringe benefits and other indirect costs since the individuals’ activities, if any, would occur outside the scope of their employment.

B. Previously Finalized IPFQR Estimates

We finalized provisions that impact policies beginning with the FY 2027 payment determination. For the purposes of calculating burden, we attribute the costs to the year in which the costs begin. Under our previously finalized policies, data submission for the measures that affect the FY 2027 payment determination occurs during CY 2026 and generally reflects care provided during CY 2025. Our currently approved burden for CY 2025 is set forth in Table 22.

BILLING CODE 4120-01-P

⁹⁰ <https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework>.

⁹¹ <https://www.bls.gov/news.release/pdf/wkyeng.pdf>. Accessed January 1, 2024.

⁹² <https://www.census.gov/library/stories/2023/09/median-household-income.html>. Accessed January 2, 2024.

⁸⁹ Medical Records Specialists (*bls.gov*).

TABLE 22: PREVIOUSLY IPFQR PROGRAM FOR CY 2025

Measure/Response Description	Number Respondents	Number of Responses/ Respondent	Total Annual Responses	Time per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Applicable Wage Rate (\$/hr)	Cost per Facility (\$)	Total Annual Cost (\$)
Hours of Physical Restraint Use	1,596	1,261	2,012,556	0.25	315	503,139	44.86	14,142	22,570,816
Hours of Seclusion Use	1,596	1,261	2,012,556	0.25	315	503,139	44.86	14,142	22,570,816
Follow-Up After Psychiatric Hospitalization	1,596	0	0	0	0	0	44.86	0	0
Alcohol Use Brief Intervention Provided or Offered and SUB-2a Alcohol Use Brief Intervention	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Alcohol and Other Drug Use Disorder Treatment Provided or Offered at Discharge and SUB-3a Alcohol and Other Drug Use Disorder Treatment at Discharge	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Tobacco Use Treatment Provided or Offered at Discharge and TOB-3a Tobacco Use Treatment at Discharge	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Influenza Immunization	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Transition Record with Specified Elements Received by Discharged Patients (Discharges from an Inpatient Facility to Home/Self Care or Any Other Site of Care)	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576

Measure/Response Description	Number Respondents	Number of Responses/ Respondent	Total Annual Responses	Time per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Applicable Wage Rate (\$/hr)	Cost per Facility (\$)	Total Annual Cost (\$)
Screening for Metabolic Disorders	1,596	609	971,964	0.25	152	242,991	44.86	6,830	10,900,576
Thirty-Day All-Cause Unplanned Readmission Following Psychiatric Hospitalization in an Inpatient Psychiatric Facility	1,596	0	0	0	0	0	44.86	0	0
30-Day Risk-Standardized All-Cause Emergency Department Visit Following an Inpatient Psychiatric Facility Discharge measure	1,596	0	0	0	0	0	44.86	0	0
Medication Continuation Following Inpatient Psychiatric Discharge	1,596	0	0	0	0	0	44.86	0	0
Modified COVID-19 Healthcare Personnel (HCP) Vaccination Measure	1,596	0	0	0	0	0	44.86	0	0
Facility Commitment to Health Equity	1,596	1	1,596	0.167	0	267	44.86	7	11,957
Screening for Social Drivers of Health (Data Submission)	798	1	798	0.167	0	133	44.86	7	5,978
Screen Positive Rate for Social Drivers of Health	798	1	798	0.167	0	133	44.86	7	5,978
Non Measure Data Collection	1,596	4	6,384	0.5	2	3,192	44.86	90	143,193
<i>Subtotal for Medical Records Specialists</i>	<i>1,596</i>	<i>6,183</i>	<i>9,866,472</i>	<i>Varies</i>	<i>1,547</i>	<i>2,467,949</i>	<i>44.86</i>	<i>69,376</i>	<i>110,712,195</i>
Screening for Social Drivers of Health (Patient Screening)	1,596	1,261	2,012,556	0.033	42	66,414	20.71	862	1,375,441
Psychiatric Inpatient Experience Survey	798	300	239,400	0.121	36	28,967	20.71	752	599,915
<i>Subtotal for Individuals</i>	<i>1,596</i>	<i>1,561</i>	<i>2,251,956</i>	<i>Varies</i>	<i>78</i>	<i>95,382</i>	<i>20.71</i>	<i>1,614</i>	<i>1,975,356</i>
Totals	1,596	7,744	12,118,428	3.155	1,624	2,563,331	804.04	70,990	112,687,551

BILLING CODE 4120-01-C**C. Updates Due to More Recent Information**

In section VI.A of this final rule, we described our updated wage rates which

increase from \$44.86/hr to \$52.12/hr (an increase of \$7.26/hr) for activities performed by Medical Records Specialists and from \$20.71/hr to \$24.04/hr (an increase of \$3.33/hr) for

activities performed by individuals. The effects of these updates are set forth in Table 23.

TABLE 23: EFFECTS OF WAGE RATE UPDATES

Measure/Response Description	Total Annual Responses	Time Per Response (hrs)	Time per Facility (hrs)	Total Annual Time (hrs)	Change in Applicable Wage Rate (\$/hr)	Change in Cost per Facility (\$)	Change in Total Annual Cost (\$)
Subtotal for Medical Records Specialists	9,866,472	Varies	1,547	2,467,949	7.26	11,228	17,919,245
Subtotal for Individuals	2,251,956	Varies	78	95,382	3.33	259	414,083
Totals	12,118,428	Varies	1,624	2,563,331	Varies	11,487	18,333,328

D. Updates Due to Policies in This Final Rule

In section VI.B.2 of this final rule, we are adopting the 30-Day Risk-Standardized All-Cause ED Visit Following an IPF Discharge (IPF ED Visit) measure beginning with the CY 2025 performance period/FY 2027 payment determination. As described in section VI.B.2.c. of this final rule, we will calculate the IPF ED Visit measure using Medicare claims that IPFs and other providers submit for payment. Since this is a claims-based measure, there is no additional burden outside of submitting a claim. The claim submission is approved by OMB under control number 0938–0050 (CMS–2552–10). This rule does not warrant any changes under that control number.

In Section VI.D. of this final rule, we are not finalizing our proposal to require IPFs to submit data on chart-abstracted measures quarterly. Because we are not finalizing this proposal it will have no effect on information collection burden.

E. Consideration of Burden Related to Clarification of Eligibility Criteria for the Option To Elect To File an All-Inclusive Cost Report

As discussed in section IV.E.4 of this final rule, we clarified the eligibility criteria to be approved to file all-inclusive cost reports. Only government-owned, IHS, and tribally owned facilities are able to satisfy these criteria, and thus only these facilities will be permitted to file an all-inclusive cost report for cost reporting periods beginning on or after October 1, 2024.

We do not estimate any change in the burden associated with the hospital cost report (CMS–2552–10) OMB control

number 0938–0050. We anticipate that IPFs which are currently filing all-inclusive cost reports, but are not government-owned or tribally owned, will not incur additional burden related to the submission of the cost report. The approved burden estimate associated with the submission of the hospital cost report includes the same amount of burden for the submission of an all-inclusive cost report as for the submission of a cost report with a charge structure.

We recognize that these IPFs will be required to track ancillary costs and charges using a charge structure; however, we expect that any burden associated with this tracking will be part of the normal course of a hospital's activities.

F. Submission of PRA-Related Comments

We have submitted a copy of the final rule's information collection requirements to OMB for their review. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed above, please visit the CMS website at <https://www.cms.gov/regulationsand-guidance/legislation/paperworkreductionactof1995/pra-listing>, or call the Reports Clearance Office at 410–786–1326.

We invited public comments on these potential information collection requirements.

Comment: We summarized comments on the proposed information collection burden associated with the proposed transition to quarterly reporting in Section VI.D. of this final rule.

Response: As noted in Section VI.D. of this final rule, we are not finalizing our proposal to require IPFs to submit data on chart-abstracted measures quarterly. Because we are not finalizing this proposal it will have no effect on information collection burden.

VIII. Regulatory Impact Analysis

A. Statement of Need

This rule finalizes updates to the prospective payment rates for Medicare inpatient hospital services provided by IPFs for discharges occurring during FY 2025 (October 1, 2024 through September 30, 2025). We are finalizing our proposal to apply the 2021-based IPF market basket increase for FY 2025 of 3.3 percent, reduced by the productivity adjustment of 0.5 percentage point as required by section 1886(s)(2)(A)(i) of the Act for a final total FY 2025 payment rate update of 2.8 percent. In this final rule, we are finalizing our proposal to update the outlier fixed dollar loss threshold amount, update the IPF labor-related share, adopt new CBSA delineations based on OMB Bulletin 23–01, and update the IPF wage index to reflect the FY 2025 hospital inpatient wage index. Section 1886(s)(4) of the Act requires IPFs to report data in accordance with the requirements of the IPFQR Program for purposes of measuring and making publicly available information on health care quality; and links the quality data submission to the annual applicable percentage increase.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and

Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866, as amended by Executive Order 14094, defines a “significant regulatory action” as an action that is likely to result in a rule that may: (1) have an annual effect on the economy of \$200 million or more (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impacts of entitlements, 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 Executive Order 12866. In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1) of Executive Order 12866. We estimate that the total impact of these changes for FY 2025 payments compared to FY 2024 payments will be a net increase of approximately \$65 million. This reflects a \$75 million increase from the update to the payment rates (+\$90 million from the 2nd quarter 2024 IGI forecast of the 2021-based IPF market basket of 3.3 percent, and –\$15 million for the productivity adjustment of 0.5 percentage point), as well as a \$10 million decrease as a result of the

update to the outlier threshold amount. Outlier payments are estimated to change from 2.3 percent in FY 2024 to 2.0 percent of total estimated IPF payments in FY 2025.

Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is not significant per section 3(f)(1) as measured by the \$200 million or more in any 1 year, but does meet the criteria under 5 U.S.C. 804(2) (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996, also known as the Congressional Review Act). Nevertheless, because of the potentially substantial impact to IPF providers, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined that this rulemaking is “significant.” Therefore, OMB has reviewed the final regulations, and the Departments have provided the following assessment of their impact.

C. Detailed Economic Analysis

In this section, we discussed the historical background of the IPF PPS and the impact of the final rule on the Federal Medicare budget and on IPFs.

1. Budgetary Impact

As discussed in the RY 2005 and RY 2007 IPF PPS final rules, we applied a budget neutrality factor to the Federal per diem base rate and ECT payment per treatment to ensure that total estimated payments under the IPF PPS in the implementation period would equal the amount that would have been paid if the IPF PPS had not been implemented. This budget neutrality factor included the following components: outlier adjustment, stop-loss adjustment, and the behavioral offset. As discussed in the RY 2009 IPF PPS notice (73 FR 25711), the stop-loss adjustment is no longer applicable under the IPF PPS.

As discussed in section IV.D.1.d of this final rule, we are updating the wage index and labor-related share, as well as update the CBSA delineations based on OMB Bulletin 23–01, in a budget neutral manner by applying a wage index budget neutrality factor to the Federal per diem base rate and ECT payment per treatment. In addition, as discussed in section IV.F of this final rule, we are applying a refinement standardization factor to the Federal per diem base rate and ECT payment per treatment to account for the proposed revisions to the ECT per treatment amount, ED adjustment, and patient-level adjustment factors (as previously

discussed in sections IV.B, IV.C, and IV.D of this final rule, and summarized in Addendum A), which must be made budget-neutrally. Therefore, the budgetary impact to the Medicare program of the final rule will be due to the final market basket update for FY 2025 of 3.3 percent (see section IV.A.2 of this final rule) reduced by the productivity adjustment of 0.5 percentage point required by section 1886(s)(2)(A)(i) of the Act and the update to the outlier fixed dollar loss threshold amount.

We estimate that the FY 2025 impact will be a net increase of \$65 million in payments to IPF providers. This reflects an estimated \$75 million increase from the update to the payment rates and a \$10 million decrease due to the update to the outlier threshold amount to set total estimated outlier payments at 2.0 percent of total estimated payments in FY 2025. This estimate does not include the implementation of the required 2.0 percentage point reduction of the productivity-adjusted market basket update factor for any IPF that fails to meet the IPF quality reporting requirements (as discussed in section IV.B.2. of this final rule).

2. Impact on Providers

To show the impact on providers of the changes to the IPF PPS discussed in this final rule, we compared estimated payments under the IPF PPS rates and factors for FY 2025 versus those under FY 2024. We determined the percent change in the estimated FY 2025 IPF PPS payments compared to the estimated FY 2024 IPF PPS payments for each category of IPFs. In addition, for each category of IPFs, we have included the estimated percent change in payments resulting from the update to the outlier fixed dollar loss threshold amount; the revisions to the patient-level adjustment factors, ED adjustment, and ECT per treatment amount; the updated wage index data including the labor-related share and the changes to the CBSA delineations; and the market basket increase for FY 2025, as reduced by the productivity adjustment according to section 1886(s)(2)(A)(i) of the Act.

To illustrate the impacts of the final FY 2025 changes in this rule, our analysis begins with FY 2023 IPF PPS claims (based on the 2023 MedPAR claims, March 2024 update). We estimated FY 2024 IPF PPS payments using these 2023 claims, the finalized FY 2024 IPF PPS Federal per diem base rate and ECT per treatment amount, and the finalized FY 2024 IPF PPS patient and facility level adjustment factors (as published in the FY 2024 IPF PPS final

rule (88 FR 51054)). We then estimated the FY 2024 outlier payments based on these simulated FY 2024 IPF PPS payments using the same methodology as finalized in the FY 2024 IPF PPS final rule (88 FR 51090 through 51092) where total outlier payments are maintained at 2 percent of total estimated FY 2024 IPF PPS payments.

Each of the following changes is added incrementally to this baseline

model in order for us to isolate the effects of each change:

- The update to the outlier fixed dollar loss threshold amount.
- The revisions to patient-level adjustment factors, ED adjustment, and the ECT per treatment amount.
- The FY 2025 IPF wage index, the changes to the CBSA delineations, and the FY 2025 labor-related share (LRS).
- The market basket increase for FY 2025 of 3.3 percent reduced by the

productivity adjustment of 0.5 percentage point in accordance with section 1886(s)(2)(A)(i) of the Act for a payment rate update of 2.8 percent.

Our column comparison in Table 24 illustrates the percent change in payments from FY 2024 (that is, October 1, 2023, to September 30, 2024) to FY 2025 (that is, October 1, 2024, to September 30, 2025) including all the final payment policy changes.

BILLING CODE 4120-01-P

TABLE 24: FY 2025 IPF PPS PAYMENT IMPACTS

[Percent Change in columns 3 through 6]					
Facility by Type	Number of Facilities	Outlier	Refinement of Patient-Level Adjustments and ECT	Wage Index FY25, LRS, and 5% Cap	Total Percent Change ¹
(1)	(2)	(3)	(4)	(5)	(6)
All Facilities	1,419	-0.3	0.0	0.0	2.5
Total Urban	1,162	-0.3	0.0	-0.2	2.3
Urban unit	645	-0.4	0.5	-0.6	2.3
Urban hospital	517	-0.1	-0.5	0.2	2.5
Total Rural	257	-0.1	-0.3	1.4	3.8
Rural unit	197	-0.1	0.1	1.1	4.0
Rural hospital	60	-0.2	-1.1	2.1	3.6
By Type of Ownership:					
Freestanding IPFs					
Urban Psychiatric Hospitals					
Government	119	-0.5	1.1	-0.6	2.7
Non-Profit	97	-0.1	-0.1	-0.3	2.3
For-Profit	301	0.0	-0.9	0.6	2.5
Rural Psychiatric Hospitals					
Government	30	-0.3	1.6	-0.3	3.9
Non-Profit	12	-0.5	-1.5	0.3	1.0
For-Profit	18	0.0	-2.3	3.7	4.2
IPF Units					
Urban					
Government	93	-0.8	0.8	-0.1	2.7
Non-Profit	430	-0.4	0.7	-0.9	2.1
For-Profit	122	-0.2	-0.5	0.1	2.3
Rural					
Government	44	-0.1	-0.1	0.7	3.4
Non-Profit	113	-0.2	0.4	1.2	4.2
For-Profit	40	-0.1	-0.1	1.3	3.9
By Teaching Status:					
Non-teaching	1,217	-0.2	-0.2	0.3	2.7
Less than 10% interns and residents to beds	100	-0.5	0.6	-1.1	1.9
10% to 30% interns and residents to beds	76	-0.6	1.2	-1.2	2.2

More than 30% interns and residents to beds	26	-0.7	1.2	-0.1	3.2
By Region:					
New England	99	-0.4	0.9	-1.5	1.8
Mid-Atlantic	191	-0.4	0.3	-1.7	0.9
South Atlantic	228	-0.2	0.4	1.3	4.4
East North Central	225	-0.2	0.0	0.5	3.2
East South Central	140	-0.1	-0.2	2.6	5.0
West North Central	95	-0.5	1.1	0.0	3.4
West South Central	213	-0.1	-1.2	1.6	3.2
Mountain	102	-0.2	-0.3	0.8	3.1
Pacific	126	-0.3	-0.5	-1.8	0.1
By Bed Size:					
Psychiatric Hospitals					
Beds: 0-24	87	-0.1	-0.9	0.8	2.5
Beds: 25-49	86	0.0	-1.3	1.3	2.7
Beds: 50-75	91	-0.1	-0.4	0.9	3.2
Beds: 76 +	313	-0.1	-0.3	0.0	2.3
Psychiatric Units					
Beds: 0-24	440	-0.2	0.0	0.3	2.9
Beds: 25-49	229	-0.3	0.5	-0.7	2.3
Beds: 50-75	103	-0.4	0.7	0.1	3.2
Beds: 76 +	70	-0.7	0.6	-1.2	1.5

¹ This column includes the impact of the updates in columns (3) through (6) above, and of the IPF market basket percentage for FY 2025 of 3.3 percent, reduced by 0.5 percentage point for the productivity adjustment as required by section 1886(s)(2)(A)(i) of the Act.

BILLING CODE 4120-01-C

3. Impact Results

Table 24 displays the results of our analysis. The table groups IPFs into the categories listed here based on characteristics provided in the Provider of Services file, the IPF PSF, and cost report data from the Healthcare Cost Report Information System:

- Facility Type.
- Location.
- Teaching Status Adjustment.
- Census Region.
- Size.

The top row of the table shows the overall impact on the 1,419 IPFs included in the analysis. In column 2, we present the number of facilities of each type that had information available in the PSF, had claims in the MedPAR dataset for FY 2023. We note that providers are assigned urban or rural status in Table 24 based on the current CBSA delineations for FY 2024.

In column 3, we present the effects of the update to the outlier fixed dollar loss threshold amount. We estimate that IPF outlier payments as a percentage of total IPF payments are 2.3 percent in FY

2024. Therefore, we adjusted the outlier threshold amount to set total estimated outlier payments equal to 2.0 percent of total payments in FY 2025. The estimated change in total IPF payments for FY 2025, therefore, includes an approximate 0.3 percent decrease in payments because we would expect the outlier portion of total payments to decrease from approximately 2.3 percent to 2.0 percent.

The overall impact of the estimated decrease to payments due to updating the outlier fixed dollar loss threshold (as shown in column 3 of Table 24), across all hospital groups, is a 0.3 percent decrease. The largest decrease in payments due to this change is estimated to be 0.8 percent for urban government-owned IPF units.

In column 4, we present the effects of the revisions to the patient-level adjustment factors, ED adjustment, and ECT per treatment amount and the application of the refinement standardization factor that is discussed in section IV.F of this final rule. These revisions are budget neutral; therefore, there is no projected change in aggregate payments to IPFs, as indicated in the

first row of column 4. We estimate the largest payment increases would be 1.6 percent for rural government-owned IPF hospitals. Conversely, we estimate that rural for-profit IPF hospitals would experience the largest payment decrease of -2.3 percent. Payments to IPF units in urban areas would increase by 0.5 percent, and payments to IPF units in rural areas would increase by 0.1 percent.

In column 5, we presented the effects of the budget-neutral update to the IPF wage index, the LRS, and the changes to the CBSA delineations for FY 2025. In addition, this column includes the application of the 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year as finalized in the FY 2023 IPF PPS final rule (87 FR 46856 through 46859). The change in this column represents the effect of using the concurrent hospital wage data as discussed in section IV.D.1.a of this final rule. That is, the impact represented in this column reflects the update from the FY 2024 IPF wage index to the FY 2025 IPF wage index, which includes basing the FY 2025 IPF wage index on the FY 2025

pre-floor, pre-reclassified IPPS hospital wage index data, applying a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year, and updating the LRS from 78.7 percent in FY 2024 to 78.8 percent in FY 2025. We note that there is no projected change in aggregate payments to IPFs, as indicated in the first row of column 5; however, there will be distributional effects among different categories of IPFs. For example, we estimate the largest increase in payments to be 3.7 percent for rural for-profit IPF hospitals, and the largest decrease in payments to be -1.8 percent for IPFs located in the Pacific region.

Overall, IPFs are estimated to experience a net increase in payments of 2.5 percent as a result of the updates in this final rule. IPF payments are estimated to increase by 2.3 percent in urban areas and 3.8 percent in rural areas. The largest payment increase is estimated at 5.0 percent for IPFs located in the East South Central region.

4. Effect on Beneficiaries

Under the FY 2025 IPF PPS, IPFs will continue to receive payment based on the average resources consumed by patients for each day. Our longstanding payment methodology reflects the differences in patient resource use and costs among IPFs, as required under section 124 of the BBRA. We expect that updating IPF PPS rates in this rule will improve or maintain beneficiary access to high quality care by ensuring that payment rates reflect the best available data on the resources involved in inpatient psychiatric care and the costs of these resources. We continue to expect that paying prospectively for IPF services under the FY 2025 IPF PPS will enhance the efficiency of the Medicare program.

As discussed in sections V.B.2 of this final rule, we expect that the additional IPFQR Program measure will support improving discharge planning and care coordination to decrease the likelihood that a patient will need to seek emergency care within 30 days of discharge from an IPF.

5. Effects of the Updates to the IPFQR Program

In section V.B.2. of the rule, we are adopting the 30-Day Risk-Standardized All-Cause ED Visit Following an Inpatient Psychiatric Facility Discharge measure beginning with data from the CY 2025 performance period for the FY 2027 payment determination.

We do not believe this update will impact providers' workflows or information systems to collect or report

the data because this measure is calculated by CMS using information that IPFs already submit as part of the claims process. There may be some effects of this measure on IPF workflows and clinical processes to improve care coordination and discharge planning to improve performance on the measure.

We are not finalizing our proposal to adopt a quarterly data submission requirement for measures for which we require patient-level data. We do not believe there will be any effect of maintaining our previously finalized policy.

In accordance with section 1886(s)(4)(A) of the Act, we will apply a 2-percentage point reduction to the FY 2025 market basket update for IPFs that have failed to comply with the IPFQR Program requirements for FY 2025, including reporting on the mandatory measures. For the FY 2024 payment determination, of the 1,568 IPFs eligible for the IPFQR Program, 194 IPFs did not receive the full market basket update because of the IPFQR Program; 42 of these IPFs chose not to participate and 152 did not meet the requirements of the program.

We intended to closely monitor the effects of the IPFQR Program on IPFs and help facilitate successful reporting outcomes through ongoing education, national trainings, and a technical help desk.

6. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret the proposed rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will be directly impacted and will review this final rule, we assume that the total number of unique commenters on the most recent IPF proposed rule will be the number of reviewers of the final rule. For this FY 2025 IPF PPS final rule, the most recent IPF proposed rule was the FY 2025 IPF PPS proposed rule, and we received 67 unique comments on the proposed rule. We acknowledged that this assumption may understate or overstate the costs of reviewing the final rule. It is possible that not all commenters reviewed the FY 2025 IPF proposed rule in detail, and it is also possible that some reviewers chose not to comment on that proposed rule. For these reasons, we thought that the number of commenters would be a fair estimate of the number of reviewers who are directly impacted by this final rule. We solicited comments on this assumption.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule; therefore, for the purposes of our estimate, we assume that each reviewer reads approximately 50 percent of this final rule.

Using the May, 2023 mean (average) wage information from the BLS for medical and health service managers (Code 11-9111), we estimated that the cost of reviewing this final rule is \$129.28 per hour, including other indirect costs <https://www.bls.gov/oes/current/oes119111.htm>. Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 154 minutes (2.57 hours) for the staff to review half of this final rule, which contains a total of approximately 77,000 words. For each IPF that reviews the final rule, the estimated cost is $(2.57 \times \$129.28)$ or \$332.25. Therefore, we estimate that the total cost of reviewing this final rule is \$22,260.75 $(\$332.25 \times 67 \text{ reviewers})$.

D. Alternatives Considered

The statute gives the Secretary discretion in establishing an update methodology to the IPF PPS. We continued to believe it is appropriate to routinely update the IPF PPS so that it reflects the best available data about differences in patient resource use and costs among IPFs, as required by the statute. Therefore, we proposed and are finalizing updates to: the IPF PPS using the methodology published in the RY 2005 IPF PPS final rule (our "standard methodology") pre-floor, pre-reclassified IPPS hospital wage index as its basis, along with the proposed changes to the CBSA delineations. Additionally, we apply a 5-percent cap on any decrease to a provider's wage index from its wage index in the prior year. Lastly, we are finalizing our proposal to revise the patient-level adjustment factors, ED adjustment, and to increase the ECT per treatment amount for FY 2025 (reflecting the pre-scaled and pre-adjusted CY 2024 OPPS geometric mean cost).

E. Accounting Statement

As required by OMB Circular A-4 (available at www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), in Table 25, we have prepared an accounting statement showing the classification of the expenditures associated with the updates to the IPF wage index and payment rates in this final rule. Table 25 provides our best estimate of the increase in Medicare payments under the IPF PPS as a result of the changes presented in this final rule and is based on 1,419 IPFs that had

data available in the PSF and claims in our FY 2023 MedPAR claims dataset. Lastly, Table 25 also includes our best

estimate of the costs of reviewing and understanding this final rule.

TABLE 25: Accounting Statement: Classification of Estimated Costs, Savings, and Transfers

Category	Primary estimate (\$million/year)		
		Year dollars	Period covered
Regulatory Review Costs	0.22	2024	FY 2025
Annualized Monetized Transfers from Federal Government to IPF Medicare Providers	65	2024	FY 2025

F. Regulatory Flexibility Act

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, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. The great majority of hospitals and most other

health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the Small Business Administration (SBA) definition of a small business (having revenues of less than \$47 million in any 1 year).

According to the SBA's website at <http://www.sba.gov/content/small-business-size-standards>, IPFs falls into the North American Industrial

Classification System (NAICS) code 622210, Psychiatric and Substance Abuse hospitals. The SBA defines small Psychiatric and Substance Abuse hospitals as businesses having less than \$47 million.

As discussed earlier in this final rule, the only costs imposed by this final rule are the regulatory review costs, which we estimate at \$22,260.75 per IPF.

BILLING CODE 4120-01-P

TABLE 26: NAICS 622210 Psychiatric and Substance Abuse Hospitals Size Standards

NAICS (6-digit)	Industry Subsector Description	SBA Size Standard/Small Entity Threshold	Total Small Businesses
622210	Psychiatric and Substance Abuse Hospitals	\$47 Million	213

Source: US Census 2017 SUSB

TABLE 27: Concentration Ratios (NAICS 622210) Psychiatric and Substance Abuse Hospitals

Firm Size (by Receipts)	Firm Count	% of Small Firms	Average Revenue
SMALL HOSPITALS	213	100.0%	\$ 20,634,779.34
<100,000	0	0	
100,000-499,999	4	1.9%	\$ 250,750
500,000-999,999	5	2.3%	\$ 713,000
1,000,000-2,499,999	3	1.4%	\$ 1,249,000
2,500,000-4,999,999	13	6.1%	\$ 3,870,077
5,000,000-7,499,999	10	4.7%	\$ 5,523,800
7,500,000-9,999,999	12	5.6%	\$ 7,507,917
10,000,000-14,999,999	23	10.8%	\$ 12,227,391
15,000,000-19,999,999	27	12.7%	\$ 14,432,111
20,000,000-24,999,999	21	9.9%	\$ 19,257,762
25,000,000-29,999,999	21	9.9%	\$ 26,277,000
30,000,000-34,999,999	23	10.8%	\$ 28,937,261
35,000,000-39,999,999	21	9.9%	\$ 35,550,095
40,000,000-49,999,999	30	14.1%	\$ 38,400,433
LARGE HOSPITALS			
Receipts > 49 million	181	NA	\$ 104,798,552.49

Source: US Census 2017 SUSB

Table 28: (NAICS 622210) Psychiatric and Substance Abuse Hospitals Impacts on Small Entities

Firm Size (by Receipts)	Avg. Annual Revenue	Annualized Cost per Firm	% of Small Firms	Revenue Test
All Hospitals	\$ 125,433,331.83	\$22,260.75	N/A	0.02%
Small Hospitals	\$ 20,634,779.34	\$22,260.75	100%	0.1%
<100,000	0	0	0	
100,000-499,999	\$ 250,750	\$22,260.75	1.9%	8.8%
500,000-999,999	\$ 713,000	\$22,260.75	2.3%	3.1%
1,000,000-2,499,999	\$ 1,249,000	\$22,260.75	1.4%	1.8%
2,500,000-4,999,999	\$ 3,870,077	\$22,260.75	6.1%	0.6%
5,000,000-7,499,999	\$ 5,523,800	\$22,260.75	4.7%	0.4%
7,500,000-9,999,999	\$ 7,507,917	\$22,260.75	5.6%	0.3%
10,000,000-14,999,999	\$ 12,227,391	\$22,260.75	10.8%	0.2%
15,000,000-19,999,999	\$ 14,432,111	\$22,260.75	12.7%	0.2%
20,000,000-24,999,999	\$ 19,257,762	\$22,260.75	9.9%	0.1%
25,000,000-29,999,999	\$ 26,277,000	\$22,260.75	9.9%	0.1%
30,000,000-34,999,999	\$ 28,937,261	\$22,260.75	10.8%	0.1%
35,000,000-39,999,999	\$ 35,550,095	\$22,260.75	9.9%	0.1%
40,000,000-49,999,999	\$ 38,400,433	\$22,260.75	14.1%	0.1%

Source: US Census 2017 SUSB

According to Table 26, 213 psychiatric and substance abuse hospitals can be considered small according to the SBA. As we stated earlier, the SBA defines small Psychiatric and Substance Abuse hospitals as businesses having less than \$47 million. Note, Tables 26 and 27 show revenue more than \$49.9 million since the data does not provide the exact estimate for \$47 million. Table 27 shows that there are 181 Psychiatric and Substance Abuse hospitals that earn revenue in excess of \$49 million.

The Department of Health and Human Services generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. For the purposes of the RFA, we estimate that only 0.1 percent of small Psychiatric and Substance Abuse hospitals are small entities as that term is used in the RFA.

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. According to Table 27, we believe that this threshold will not be reached, 0.1 percent, by the requirements in this final rule. Therefore, the Secretary has certified that this final rule will have a *de minimis* economic impact on the small entities.

Since there is not a significant impact on a substantial number of small entities, the Secretary has certified that this final rule will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. As discussed in section VIII.C.2 of this final rule, the rates and policies set forth in this final rule will not have an adverse impact on the rural hospitals based on the data of the 197 rural excluded psychiatric units and 60 rural psychiatric hospitals in our database of 1,419 IPFs for which data were available. Therefore, the Secretary has determined that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

G. Unfunded Mandate Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA)

also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately \$183 million. This final rule does not mandate any requirements for state, local, or tribal governments, or for the private sector. This final rule will 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 \$183 million in any 1 year.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 24, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–16909 Filed 7–31–24; 4:15 pm]

BILLING CODE 4120–01–P



FEDERAL REGISTER

Vol. 89

Wednesday,

No. 152

August 7, 2024

Part IV

Department of Agriculture

Food Safety and Inspection Service

9 CFR Part 381

Salmonella Framework for Raw Poultry Products; Proposed Rule

DEPARTMENT OF AGRICULTURE**Food Safety and Inspection Service****9 CFR Part 381**

[Docket No. FSIS–2023–0028]

RIN 0583–AD96

Salmonella Framework for Raw Poultry Products

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Proposed rule and Proposed Determination.

SUMMARY: FSIS is announcing its proposed determination that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products contaminated with certain *Salmonella* levels and serotypes are adulterated within the meaning of the Poultry Products Inspection Act (PPIA). The proposed determination would establish final product standards based on these *Salmonella* levels and serotypes and would prevent raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products that contain *Salmonella* at the levels and serotypes that would render them adulterated from entering commerce. FSIS is also proposing to revise the regulations that require that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation to clarify that these procedures must include a microbial monitoring program (MMP) that incorporates statistical process control (SPC) monitoring methods, to require sampling at rehang instead of pre-chill, and to require that all establishments conduct paired sampling at rehang and post-chill.

DATES: Comments on this proposal must be received on or before October 7, 2024.

ADDRESSES: FSIS invites interested persons to submit comments on this document. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to: <https://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400

Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.

- *Hand- or courier-delivered submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2023–0028. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <https://www.regulations.gov>.

Docket: Go to the Federal eRulemaking Portal at <https://www.regulations.gov> for access to the rulemaking docket, including any background documents and the plain-language summary of the proposed rule of not more than 100 words in length required by the Providing Accountability Through Transparency Act of 2023. For in-person access to background documents or comments received, call (202) 720–5046 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT:

Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, FSIS, USDA; Telephone: (202) 205–0495.

SUPPLEMENTARY INFORMATION:**Executive Summary**

FSIS is responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled. In support of this mission, FSIS established a *Salmonella* verification testing program in 1996 as part of the “Pathogen Reduction; Hazard Analysis and Critical Control Point Systems” (PR/HACCP) final rule (61 FR 38805). Among other things, the PR/HACCP final rule established *Salmonella* pathogen reduction performance standards for raw product to allow FSIS to verify whether establishments have effective process controls to address *Salmonella*. The current performance standards for young chicken and turkey carcasses, raw chicken parts, and comminuted chicken and turkey products are represented as a fraction of the maximum number of allowable *Salmonella*-positive results over a targeted number of samples collected and analyzed in a 52-week moving window. FSIS categorizes establishments based on the *Salmonella* verification sampling results and posts the performance categorization of all

establishments subject to the performance standards on the FSIS website. FSIS uses *Salmonella* performance standard categorization as a basis to prioritize in-depth evaluations of failing establishments' food safety systems, including their HACCP plan and sanitation Standard Operating Procedures (SOPs).

While the results of FSIS' *Salmonella* verification sampling show that the current prevalence-based performance standards approach has been effective in reducing the proportion of poultry products contaminated with *Salmonella*, these measures have yet to have an observable impact on human illness rates. The estimated rate of human *Salmonella* infections from all sources has remained consistent over the last two decades, with over 1.3 million illnesses estimated in the United States each year. Additionally, while current *Salmonella* performance standards are designed to achieve the Department of Health and Human Services' Healthy People Initiative¹ targets for foodborne illness reduction, the 2010 and 2020 Healthy People targets for a reduction in *Salmonella* infections from all sources were not met. The Healthy People 2030 target is to reduce *Salmonella* infections from all sources to a national case rate of no more than 11.5 per 100,000 consumers per year. To reach this 2030 target, *Salmonella* illnesses must be reduced by 25 percent.

Poultry is among the leading sources of *Salmonella* foodborne illness acquired domestically in the United States.² Therefore, on October 19, 2021, FSIS announced that it was mobilizing a stronger, and more comprehensive effort to reduce *Salmonella* illnesses associated with poultry products. In the

¹ Launched by the U.S. Department of Health and Human Services (HHS) in 1980, the Healthy People Initiative sets out to create widely accessible plans to help organizations, communities and individuals improve public health. Each decade, HHS releases new goals after evaluating the successes and areas of growth from the previous ten years. They monitor the progress toward Healthy People's objectives using high-quality data and feedback., the HHS benchmark continues to focus on reducing poultry-based *Salmonella* infections by 25 percent, a goal that has not been reached over the last decade. The Healthy People 2030 objectives were released on August 18, 2020.

² Interagency Food Safety Analytics Collaboration (FSAC). Foodborne illness source attribution estimates for 2020 for *Salmonella*, *Escherichia coli* O157, and *Listeria monocytogenes* using multi-year outbreak surveillance data, United States. GA and DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, U.S. Department of Agriculture's Food Safety and Inspection Service. 2022. Available at: https://www.cdc.gov/ifsac/php/annual-reports/?CDC_AAref_Val=https://www.cdc.gov/foodsafety/ifsac/annual-reports.html.

announcement, FSIS stated that it had initiated several activities designed to gather data and information to inform and support future actions related to this new effort. FSIS charged the National Committee on Microbiological Criteria for Food (NACMCF) to provide guidance on the types of microbiological criteria the Agency might use to better prevent *Salmonella* infections associated with poultry products. The Agency also conducted a risk profile for pathogenic *Salmonella* subtypes in poultry and developed two quantitative risk assessments—one for *Salmonella* in chicken and one for *Salmonella* in turkey. Additionally, FSIS conducted an exploratory sampling program for young chicken carcasses to generate microbial data to help inform future policies and added quantification to its *Salmonella* testing program.

In addition to initiating these activities, on October 17, 2022, FSIS shared with stakeholders a draft regulatory framework that the Agency was considering for a new strategy to control *Salmonella* in poultry products and announced that FSIS would be hosting a virtual public meeting on November 3, 2022, to discuss the framework. The three components under consideration in the draft framework included:

Component One. Requiring that establishments characterize *Salmonella* as a hazard reasonably likely to occur at receiving and requiring that incoming flocks be tested for *Salmonella* before entering an establishment.

Component Two. Enhancing establishment process control monitoring and FSIS verification.

Component Three. Implementing an enforceable final product standard that would define whether certain raw poultry products contaminated with certain levels and/or serotypes of *Salmonella* are adulterated.

The draft framework under consideration also addressed cross-cutting issues associated with testing for *Salmonella*, considerations for small and very small establishments, and data sharing. At the November 2022 public meeting, stakeholders presented oral comments on the three separate components of the draft framework and the cross-cutting issues. Stakeholders also had an opportunity to submit written comments to FSIS by December 16, 2022.

After carefully evaluating the written comments and other stakeholder input provided on the October 2022 draft framework, along with new studies and information that have become available since the Agency made the October 2022 draft framework available to the

public, FSIS is proposing a new regulatory framework targeted at reducing *Salmonella* illnesses associated with poultry products. The proposed regulatory framework reflects the draft framework with some modifications.

First, consistent with Component Three of the October 2022 draft framework, FSIS is proposing final product standards that would define whether certain raw poultry products contaminated with certain *Salmonella* levels and serotypes are adulterated as defined in the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*). Specifically, FSIS has tentatively determined that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey are adulterated if they contain any type of *Salmonella* at or above 10 colony forming units/per milliliter or gram (10 cfu/mL(g)) in analytical portion (*i.e.*, mL of rinsate or gram of product) and contain any detectable level of at least one of the *Salmonella* serotypes of public health significance identified for that commodity. The proposed *Salmonella* serotypes of public health significance identified for raw chicken carcasses, chicken parts, and comminuted chicken are Enteritidis, Typhimurium, and I 4,[5],12:i:-, and for raw comminuted turkey are Hadar, Typhimurium, and Muenchen. These are the most highly virulent *Salmonella* serotypes associated with these products identified in the FSIS chicken and turkey risk assessments.

The *Salmonella* serotypes of public health significance will likely change over time as the serotypes commonly associated with human illnesses change. FSIS would continue to track annual targets for reducing the proportion of poultry samples that contain *Salmonella* serotypes of public health significance as well as data on rates for additional serotypes commonly associated with human illness to inform future revisions to the *Salmonella* serotypes of public health significance. Should FSIS finalize the proposed final product standards, the Agency intends to further evaluate and, if necessary, refine these standards as advances in science and technology related to pathogen levels, serotypes, and virulence genes become available. If FSIS finalizes the proposed final product standards, the Agency intends to re-evaluate the serotypes of public health concern every 3–5 years at a minimum and whenever new information on *Salmonella* serotypes associated with human illness become available. When evaluating the serotypes, FSIS would consider, among other things, outbreak illness data,

foodborne illness surveillance data, product testing data, and animal testing data. FSIS would publicly announce any modifications to the final products standards in the **Federal Register**. FSIS requests comments on this proposed timeline for re-evaluating serotypes of public health concern.

Should FSIS finalize these proposed standards, the Agency intends to conduct a routine sampling and verification testing program for *Salmonella* in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey in which the Agency would collect samples of raw final products and analyze them for *Salmonella* levels and serotypes to determine whether the final product is adulterated. Under the proposed *Salmonella* verification testing program, FSIS intends to only collect and analyze samples of the final raw poultry products produced by an establishment, *i.e.*, chicken carcasses to be shipped in commerce as whole chickens, chicken parts to be shipped in commerce as chicken parts, comminuted chicken to be shipped in commerce as comminuted chicken products, and comminuted turkey to be shipped in commerce as comminuted turkey products. Under this proposed determination, chicken parts subject to the final product standards would include legs, thighs, breasts, wings, quarters, and halves.

When FSIS tests a product sample for adulterants, establishments must maintain control of products tested for adulterants to ensure that the products do not enter commerce while waiting for receipt of the test results. Thus, if FSIS finalizes its proposed routine *Salmonella* verification testing program for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, establishments that produce these raw products would need to control and maintain the integrity of the sampled lot pending the availability of test results. If test results detect *Salmonella* at a level of 10 cfu/mL(g) or higher and at least one *Salmonella* serotype of public health significance, FSIS would consider products represented by the sampled lots to be adulterated and would issue a non-compliance record (NR). Therefore, all products in the lot represented by the sample would be prohibited from entering commerce. If any product from the lot represented by the product samples has entered and remains available in commerce, FSIS would request that the producing establishment recall the implicated products. Depending on the circumstances, in addition to issuing an NR, FSIS could take other appropriate

enforcement action as authorized in 9 CFR part 500 because the establishment would have produced and shipped adulterated product. Such actions may include immediately suspending inspection or issuing a Notice of Intended Enforcement (NOIE).

As FSIS implements the final product standards verification sampling program, the Agency has tentatively decided to phase out all current *Salmonella* performance standards for poultry. Thus, when the proposed final product verification sampling program is fully implemented, FSIS has tentatively decided that it would no longer use *Salmonella* sampling results to categorize establishments that produce poultry products and would no longer publish these establishments' performance standards categories on the FSIS website. The Agency is requesting comments on this issue.

Consistent with Component Two of the initial proposed framework, FSIS is proposing to revise the regulations in 9 CFR 381.65(g) and (h) that require that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation and maintain records documenting those procedures. FSIS is proposing to amend these regulations to establish new requirements pertaining to how establishments monitor and document whether their processes for preventing microbial contamination are in control. The proposed revisions are intended to clarify existing regulatory requirements related to process control monitoring in 9 CFR 381.65(g) and (h).

Under this proposal, establishments would be required to incorporate statistical process control (SPC) monitoring principles into their microbial monitoring programs (MMPs). The proposed revisions would require that establishments use only validated and fit for purpose microbial sampling and analysis procedures, generate and record statistically meaningful microbial monitoring data, set benchmarks by which to evaluate microbial monitoring data, and otherwise define the statistical methods the establishment will use to evaluate the recorded data against the predefined limits. To offset the costs associated with this proposal, eligible very small (VS) and very low volume (VLV) establishments would have access to laboratory services provided by FSIS at no charge to analyze the establishments' microbial monitoring samples for them.

FSIS is further proposing to revise the regulations to ensure that establishments comply with the

corrective action provisions required under HACCP as they apply to the establishment's MMP. FSIS is proposing to specifically require establishments to, at a minimum, implement written corrective actions, including a root cause assessment, when microbial monitoring results deviate from the predefined criteria in the MMP, the other process control monitoring results, or the process control determination made for the entire HACCP system.

FSIS has developed new guidance to help establishments meet the proposed updated sampling and analysis requirements under 9 CFR 381.65(g). The new guidance includes a SPC sampling plan based on paired sampling for Aerobic Count (AC) at the rehang and post-chill locations, with a one-sided process control statistical model that charts and calculates against minimum monitoring criteria at the minimum required frequency. Establishments that incorporate the guidance into their MMPs would not be required to provide FSIS with additional scientific or technical information to support their chosen statistical methods. FSIS also is proposing to make available to all poultry slaughter establishments an electronic spreadsheet file that is pre-programmed to calculate the monitoring measures for the guidance sampling plan as results are entered.

In addition, FSIS is proposing to amend the recordkeeping requirements under 9 CFR 381.65(h) to require that establishments submit their microbial monitoring sampling results to FSIS electronically. FSIS is developing a web portal that will allow external partners to securely upload sampling information and submit it to FSIS electronically in a machine-readable format.³ Should FSIS finalize this proposal, the Agency would provide a template that establishments could use to record and submit their monthly results. Establishments that use the template to record the microbial monitoring results may upload their completed template into the portal or they may enter the information manually into the portal. Establishments that do not use the template provided by FSIS to record their results would need to manually enter microbial sampling data into the portal to submit the monthly data.

Under Component One of the October 2022 draft framework, FSIS considered whether it should require poultry slaughter establishments to characterize

Salmonella as a hazard reasonably likely to occur at receiving and require that incoming flocks be tested for *Salmonella* before entering an establishment. This approach would require the flock to meet a predetermined target level for *Salmonella* at receiving.

FSIS considered the available scientific research as well as input from the NACMCF and concluded that, at this time, the research does not support the use of a threshold for test results at the receiving step to reduce or eliminate *Salmonella* from raw poultry products. In addition, FSIS received several comments from small poultry processors and producers and trade associations representing the meat and poultry industries that expressed concerns that the measures under consideration in Component One would impose an overwhelming burden on small producers and processors. The comments also stated that requiring that establishments determine that *Salmonella* is a hazard reasonably likely to occur at receiving is inconsistent with HACCP principles. While FSIS has decided at this time not to establish a regulatory requirement that establishments characterize *Salmonella* as a hazard reasonably likely to occur at receiving or that incoming flocks be tested for *Salmonella* before entering an establishment, the Agency is focusing on a non-regulatory approach for reducing the *Salmonella* load on incoming birds. The Agency intends to provide updated guidance on pre-harvest interventions and practices for preventing or reducing *Salmonella* colonization of live birds. The Agency also will continue to explore and develop strategies for industry to address *Salmonella* contamination risk at receiving.

Costs and Benefits of the Proposed Rule and Proposed Determination

FSIS estimates this proposal would have a net benefit of \$4.1 million per year, ranging from \$1.1 million to \$6.7 million, assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, as discussed below (Table 1). This proposal is estimated to cost industry \$16.4 million per year, ranging from \$3.3 to \$32.3 million. The main cost component in this proposal is the requirement that establishments subject to FSIS verification sampling for adulterants maintain control of sampled product pending test results. This cost is likely an overestimate as discussed below. Industry may also incur costs associated with HACCP plan

³ In a format that provides a digital representation of data or information that can be imported and read into a computer system for further processing.

reassessments and changes to process control requirements.

FSIS estimates this proposal would result in benefits to society of \$20.5 million per year, ranging from \$4.4

million to \$39.0 million. The majority of the benefits are derived from prevented illnesses of \$12.9 million per year, ranging from \$0.3 to \$28.7 million. FSIS also estimated avoided costs from a

reduction in the risk of outbreak-related recalls for industry. Additional industry actions in response to this proposal may lead to additional benefits.

TABLE 1—SUMMARY OF COSTS AND BENEFITS

Description	Total (million \$)		
	Low	Medium	High
Costs:			
Costs associated with the proposed rule:			
Statistical Process Control	0.04	0.04	0.04
Electronic data submission	0.18	0.18	0.18
HACCP plan reassessment	0.09	0.18	0.26
Costs associated with the proposed determination:			
Maintaining control of sampled product	2.11	14.47	29.26
Lost value to the industry	0.87	1.52	2.43
Microbiological sampling plan reassessment	0.02	0.04	0.08
Total costs	3.31	16.43	32.25
Benefits and Avoided Costs:			
Prevented illnesses from consumption of chicken products	0.09	4.35	15.11
Prevented illnesses from consumption of comminuted turkey	0.19	8.58	13.55
Prevented outbreak-related recalls	4.16	7.56	10.34
Total benefits	4.45	20.49	39.00
Net benefits	1.14	4.06	6.75

Note: All costs and benefits are annualized over 10 years at a 7 percent discount rate. Numbers in table may not sum to totals due to rounding.

Table of Contents

I. Background

A. Salmonella in Poultry and Human Illnesses

1. Salmonella Illnesses Attributed to Poultry
2. Salmonella Performance Standards for Poultry
3. Salmonella Performance Standards and Illnesses
- B. Consideration of Need for a New Framework To Control Salmonella in Poultry
1. Petitions and Initial Stakeholder Input
2. FSIS Announces New Salmonella Effort
3. Activities Initiated To Support a New Salmonella Framework
4. Initial Measures Implemented To Address Salmonella Illnesses Associated With Consumption of Poultry Products
- C. Public Meeting on Salmonella Framework Under Consideration and Public Comments
1. Public Meeting and Proposed Framework
2. Public Comments on the Proposed Framework
3. Additional Stakeholder Input
4. Overview of Modifications to the Proposed Salmonella Framework
5. Severability

II. Component Three: Proposed Final Product Standards

- A. Current Salmonella Performance Standards and Consideration of an Alternative Approach
- B. Pathogens as Adulterants in Raw and Not-Ready-To Eat Meat and Poultry Products
- C. The Adulteration Standard for Raw Poultry Products

1. Pathogen Serogroups or Types Associated With Human Illness

2. Dose Considerations
3. Severity of Illnesses
4. Consumer Cooking Practices
- E. Risk per Serving, Salmonella Levels, and Proposed Determination
1. Final Product Standards Salmonella Levels and Risk per Serving
2. Proposed Determination
- F. Proposed Policy Implementation
1. HACCP Reassessment
2. Proposed Implementation and Status of Laboratory Methods

III. Component Two: Enhanced Establishment Process Control Monitoring

- A. Background and Current Regulatory Requirements
- B. Need To Enhance Establishment Process Control Monitoring
1. NACMCF Charge and Recommendations
2. PHIS Inspection Data
3. Exploratory Sampling Program Data
4. FSIS Risk Assessments
- C. Proposals To Enhance Establishment Process Control Monitoring
1. SPC Monitoring
2. Microbial Monitoring Organism
3. Sampling Location
4. Sample Collection Monitoring Frequency
5. Corrective Actions
6. Recordkeeping Requirements

IV. Component One: Pre-Harvest Measures

- A. Scientific Support and Public Comments
- B. Possible Approaches To Control Salmonella at Pre-Harvest
1. National Poultry Improvement Program
2. Vaccination
3. Supply Chain Control Programs

4. Updated Pre-Harvest Guidance

- V. State Programs and Foreign Government Programs
- VI. Executive Orders 12866, as Amended by 14094, and 13563
- VII. Regulatory Flexibility Act Assessment
- VIII. Paperwork Reduction Act
- IX. E-Government Act
- X. Executive Order 12988, Civil Justice Reform
- XI. E.O. 13175
- XII. USDA Non-Discrimination Statement
- XIII. Environmental Impact
- XIV. Additional Public Notification

I. Background

A. Salmonella in Poultry and Human Illnesses

1. Salmonella Illnesses Attributed to Poultry

Salmonella in poultry is a significant food safety and public health concern. The Centers for Disease Control and Prevention (CDC) estimates that non-typhoidal *Salmonella* from all sources is responsible for over 1.3 million illnesses, 26,500 hospitalized, and 420 deaths each year in the United States.⁴ From this overall number, FSIS estimates that there are 125,115 chicken-associated and 42,669 turkey-associated foodborne *Salmonella* illnesses per year. These values are

⁴ Collier SA, Deng L, Adam EA, et al. Estimate of Burden and Direct Healthcare Cost of Infectious Waterborne Disease in the United States. *Emerging Infectious Diseases*. 2021;27(1):140–149. <https://doi.org/10.3201%2F010676>.

calculated as the product of the total number of CDC FoodNet cases per year (7,600),⁵ the share of these cases that are foodborne (66 percent)⁶ and of domestic origin (89 percent),⁷ and the under-diagnosis multiplier for *Salmonella* (24.3),⁸ then dividing by the FoodNet catchment area (15 percent).⁹ Finally, this number is multiplied by the portion the Interagency Food Safety Analytics Collaboration (IFSAC) estimates is attributable to chicken (17.3 percent) or turkey (5.9 percent).¹⁰ Uncertainty remains in the FSIS estimation of chicken- and turkey-associated

foodborne *Salmonella* illnesses per year. These illness estimates are subject to the same limitations encountered with other illness estimates.¹¹ Nevertheless, FSIS believes these are the best available estimates.

Salmonella illnesses associated with poultry also represent a considerable economic burden, particularly when accounting for not just the direct medical costs, but also productivity losses, lost life expectancy, chronic illness, and other associated pain and suffering. A recent study estimates that the economic costs of *Salmonella* illnesses in the United States associated with chicken is \$2.8 billion annually.¹²

2. Salmonella Performance Standards for Poultry

FSIS is responsible for verifying that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and properly labeled. In support of this mission, FSIS began its *Salmonella* verification testing program with the PR/HACCP final rule, published on July 25, 1996 (61 FR 38806). Among other things, the PR/HACCP final rule established *Salmonella* pathogen reduction performance standards for establishments that slaughter selected classes of food animals and/or that produce selected classes of raw ground products.¹³ The purpose of the

Salmonella performance standards for raw product is to allow FSIS to verify whether establishments have effective process controls to address *Salmonella*. Since publishing the PR/HACCP final rule, FSIS has updated the performance standards for poultry products through a series of **Federal Register** notices.¹⁴

FSIS has established *Salmonella* performance standards for young chicken and turkey carcasses, raw chicken parts, and comminuted chicken and turkey products. The current performance standards are expressed as a fraction of the maximum number of allowable *Salmonella*-positive results over a targeted number of samples collected and analyzed in a 52-week moving window (see Table 2). FSIS categorizes establishments based on the *Salmonella* verification sampling results and posts the categorization of all establishments subject to the performance standards on the FSIS website.¹⁵ ¹⁶ In addition, FSIS schedules follow-up verification sampling, a Public Health Risk Evaluation (PHRE),¹⁷

2001). In that case, the court enjoined FSIS from suspending inspection services against a meat grinding operation for failure to meet the *Salmonella* performance standards. Since that time, FSIS has used *Salmonella* failures as a basis to conduct an in-depth evaluation of the establishment's food safety systems, including its HACCP plan and sanitation SOPs.

¹⁴ See *Salmonella* Verification Sample Result Reporting: Agency Policy and Use in Public Health Protection (71 FR 9772, Feb 27, 2006); *New Performance Standards for Salmonella and Campylobacter in Young Chicken and Turkey Slaughter Establishments: Response to Comments and Announcement of Implementation Schedule* (76 FR 15282, Mar 21, 2011); *New Performance Standards for Salmonella and Campylobacter in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcement of Implementation Schedule* (81 FR 7285, Feb 11, 2016); *Changes to the Salmonella and Campylobacter Verification Testing Program: Revised Categorization and Follow-Up Sampling Procedures* (83 FR 56046, Nov 9, 2018).

¹⁵ *Salmonella* Categorization of Individual Establishments for Poultry Products at: <https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/salmonella-verification-testing-program-monthly>.

¹⁶ The category definitions under verification sampling are as follows:

- Category 1: Establishments that have achieved 50 percent or less of the maximum allowable percent positive during the most recently completed 52-week moving window;
- Category 2: Establishments that meet the maximum allowable percent positive but have results greater than 50 percent of the maximum allowable percent positive during the most recently completed 52-week moving window; and
- Category 3: Establishments that have exceeded the maximum allowable percent positive during the most recently completed 52-week moving window.

¹⁷ The PHRE is an analysis of establishment performance based on "For-cause" and "Routine risk-based" criteria, FSIS Directive 5100.4 Revision 2—Public Health Risk Evaluation Methodology ([usda.gov](https://www.fsis.usda.gov)).

⁵ Collins JP, Shah HJ, Weller DL, et al. Preliminary Incidence and Trends of Infections Caused by Pathogens Transmitted Commonly Through Food—Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 2016–2021. *MMWR Morb Mortal Wkly Rep* 2022;71:1260–1264. DOI: <https://doi.org/10.15585/mmwr.mm7140a2>. Note: the most recent annual FoodNet report was used for the total estimated FoodNet cases annually.

⁶ Beshearse E, Bruce BB, Nane GF, Cooke RM, Aspinall W, Hald T, et al. Attribution of Illnesses Transmitted by Food and Water to Comprehensive Transmission Pathways Using Structured Expert Judgment, United States. *Emerg Infect Dis*. 2021;27(1):182–195. <https://doi.org/10.3201/eid2701.200316>. Note: This article represented a recent appraisal of the foodborne share of all *Salmonella* illnesses.

⁷ Scallan E, Hoekstra RM, Angulo FJ, Tauxe RV, Widdowson MA, Roy SL, Jones JL, Griffin PM. Foodborne illness acquired in the United States—major pathogens. *Emerg Infect Dis*. 2011 Jan;17(1):7–15. doi: 10.3201/eid1701.p11101. PMID: 21192848; PMCID: PMC3375761. Note: This article outlines the general approach to estimating the burden of domestic foodborne illnesses. It provides an estimate for share of foodborne illnesses associated with foreign travel (11%) that was supported in the more recent Collins et al. (2022) article referenced above.

⁸ Ebel, E.D., Williams, M.S., & Schlosser, W.D. (2012). Parametric distributions of underdiagnosis parameters used to estimate annual burden of illness for five foodborne pathogens. *J Food Prot*, 75, 775–778. <https://doi.org/10.4315/0362-028X.JFP-11-345>. Note: This article estimated parametric distributions for uncertainty about the under-diagnosis multiplier based on the Scallan et al. (2011) model assumptions.

⁹ Scallan et al. (2011).

¹⁰ Interagency Food Safety Analytics Collaboration. Foodborne illness source attribution estimates for 2020 for *Salmonella*, *Escherichia coli* O157, and *Listeria monocytogenes* using multi-year outbreak surveillance data, United States. GA and DC: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Food and Drug Administration, U.S. Department of Agriculture's Food Safety and Inspection Service. 2022. Annually, IFSAC releases a report that estimates foodborne illness source attribution for major commodity groups, including *Salmonella* in poultry products. At the time this proposal was developed, the 2019 IFSAC attribution estimates were the most recent data available. IFSAC released a new annual report in November 2023, which includes attribution estimates for 2020. In the 2023 report, IFSAC estimated that 18.6 percent of *Salmonella* illnesses are attributed to chicken products and 5.5 percent to turkey products, for a total 24.1 percent attributed to poultry products. FSIS intends to incorporate the 2023 report attribution estimates if this rule becomes final.

¹¹ Illness estimates from any risk assessment model are limited by uncertainty, simply because they are models. As explained by Food and Agriculture Organization of the World Health Organization (FAO/WHO), "uncertainty is a property of the methodology and data used. Assessments with different methodologies and data will have different levels of uncertainty regarding their outputs. An understanding of uncertainty is important because it provides insight into how the lack of knowledge can affect decisions." See FAO/WHO *Microbiological Risk Assessment Guidance for Food* (MRA 36) at 206. FAO/WHO goes on to say, "It is the risk managers' role to decide if the uncertainty of a risk assessment output allows for a decision to be made or not." *Id.* FSIS fully explored uncertainty in its risk assessment models to allow risk managers to make a fully informed decision. Full details are on pages 116–128 of the chicken risk assessment and pages 94–99 of the turkey risk assessment. The code for these analyses has also been provided.

¹² Scharff R.L. Food Attribution and Economic Cost Estimates for Meat and Poultry-Related Illnesses. *Journal of Food Protection*. 2020; 83(6): 959–967.

¹³ When FSIS initially implemented the *Salmonella* performance standards, the regulations authorized FSIS to suspend inspection if an establishment failed to take the corrective actions necessary to comply with the performance standards, or if an establishment failed to meet the standards on the third consecutive series of FSIS-conducted tests for that product. However, the Agency's ability to directly enforce the pathogen reduction performance standards has been limited since 2001, after a ruling by the U.S. Court of Appeals for the Fifth Circuit in *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432 (5th Cir.

and possibly a Food Safety Assessment (FSA)¹⁸ for establishments that do not meet the pathogen reduction performance standards. If, after 90 days, an establishment has not been able to regain process control, as determined

from FSIS' follow-up sampling and from the results of the PHRE or FSA, and the establishment has not taken corrective actions, FSIS may take enforcement actions, such as by issuing a NOIE or by suspending inspection, under the

conditions and according to the procedures described in 9 CFR part 500 (81 FR 7285, 7289). FSIS does not issue an NOIE or suspend inspection based solely on the fact that an establishment did not meet a performance standard.

TABLE 2—SALMONELLA PERFORMANCE STANDARDS FOR POULTRY PRODUCTS

Product	Performance standard *	Maximum acceptable percent positive	Minimum number of samples to assess process control
Broiler Carcasses	5 of 51	9.8	11
Turkey Carcasses	4 of 56	7.1	14
Comminuted Chicken	13 of 52	25.0	10
Comminuted Turkey	7 of 52	13.5	10
Chicken Parts	8 of 52	15.4	10

* The performance standard is represented as a fraction of the maximum allowable positives over the target number of samples collected and analyzed in a 52-week window.

3. Salmonella Performance Standards and Illnesses

The current *Salmonella* performance standards are based on risk assessments¹⁹ and are designed to achieve the Healthy People targets for foodborne illness reduction. When FSIS implemented the performance standards, the Agency expected that there would be an observed reduction in *Salmonella* illnesses rates because a smaller proportion of certain raw poultry products would likely be contaminated with *Salmonella* than had been the case without standards (81 FR 7285). The results of FSIS' *Salmonella* verification sampling show that the current prevalence-based performance standards approach has been effective in reducing *Salmonella* contamination in poultry.^{20 21 22} However, these measures have yet to have an observable impact on *Salmonella* illnesses. With respect to foodborne illness reduction goals, the Healthy People 2020 objectives had aimed to reduce the annual number of foodborne illnesses caused by *Salmonella* from 15.0 per 100,000

population in 2006–2008²³. However, the CDC estimated that in 2019, Americans experienced 17.1 per 100,000 population *Salmonella* illnesses.²⁴ This represents an increase of 14 percent from the 2006–2008 baseline. As discussed below, there are likely several reasons why the reduction in *Salmonella* contamination in poultry products has not resulted in an observable impact on *Salmonella* illnesses.

With respect to *Salmonella* illnesses associated with chicken and turkey, one study found that the proportion of outbreaks associated with these commodities was essentially unchanged from 1998–2017 and that both the proportion of outbreaks and number of outbreaks associated with chicken remained essentially constant.²⁵ During that period, the per capita annual consumption for pork, beef, and turkey all declined between 9 percent and 22 percent, while annual consumption of chicken increased by 15 percent.

The overall findings of another study indicated declining trends in illness due to *Salmonella* serotypes associated with

poultry and increasing trends in illness due to *Salmonella* serotypes not associated with poultry.²⁶ However, illness attribution was not an objective of the analysis. Thus, the observed illness declines may have been caused by reduced risk in non-poultry sources that have poultry-like serotype profiles.

The Healthy People 2030 target is to reduce the *Salmonella* illness national case rate of 15.3 per 100,000 population in 2016–2018 by 25 percent, or to no more than 11.5 per 100,000 population per year.²⁷ Thus, to reach the 2030 target, illnesses must be reduced by 25 percent. Although this target is for *Salmonella* illnesses from all sources, FSIS has adopted the same target for foodborne illnesses linked to FSIS-regulated products and aims to reduce these *Salmonella* illnesses by 25 percent. To move closer to achieving this target, FSIS has determined that it will need to adopt a new approach to more effectively reduce foodborne illness associated with FSIS-regulated products, starting with poultry as one of the leading food sources.

¹⁸ The purpose of an FSA is to conduct a risk-based, targeted review of establishment food safety systems to verify that the establishment is able to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements. FSIS Directive 5100.1—Food Safety Assessment Methodology ([usda.gov](https://www.fsis.usda.gov)).

¹⁹ Ebel, E.D., Williams, M.S., Golden, N.J., Marks, H.M., 2012. Simplified framework for predicting changes in public health from performance standards applied in slaughter establishments. *Food Control* 28, 250–257; Williams, M.S., Ebel, E.D., Vose, D., 2011. Framework for microbial food-safety risk assessments amenable to Bayesian modeling. *Risk Analysis* 31, 548–565.

²⁰ Ebel E.D., Williams M.S., and Schlosser W.D. (2017). Estimating the Type II error of detecting changes in foodborne illness via public health surveillance. *Microbial Risk Analysis* 7: 1–7. <https://doi.org/10.1016/j.mran.2017.10.001>.

²¹ Ebel, ED and Williams MS (2020). Assessing the effectiveness of revised performance standards for *Salmonella* contamination of comminuted poultry. *Microbial Risk Analysis* 14:100076. <https://doi.org/10.1016/j.mran.2019.05.002>.

²² Williams MS, Ebel ED, Golden NJ, Saini G, Nyirabahiizi E, and Clinch N (2022). Assessing the effectiveness of performance standards for *Salmonella* contamination of chicken parts. *International Journal of Food Microbiology* 378: 109801. <https://doi.org/10.1016/j.ijfoodmicro.2022.109801>.

²³ HHS Office of Disease Prevention and Health Promotion archive. Healthy People 2020 at: <https://wayback.archive-it.org/5774/20220414163116/https://www.healthypeople.gov/2020/topics-objectives/topic/food-safety/objectives>.

²⁴ Tack DM, Ray L, Griffin PM, et al. Preliminary Incidence and Trends of Infections with Pathogens Transmitted Commonly Through Food—Foodborne Disease Active Surveillance Network, 10 U.S. Sites,

2016–2019, *MMWR Morb Mortal Wkly Rep* 202;69:509–514. Available at: https://www.cdc.gov/mmwr/volumes/69/wr/mm6917a1.htm#T1_down.

²⁵ Williams, M.S., & Ebel, E.D. (2022). Temporal changes in the proportion of *Salmonella* outbreaks associated with 12 food commodity groups in the United States. *Epidemiology and Infection*, 150, e126. <https://doi.org/10.1017/S0950268822001042>.

²⁶ Powell M.R. (2023). Trends in reported illnesses due to poultry-and nonpoultry associated *Salmonella* serotypes; United States 1996–2019. *Risk Analysis*. <https://doi.org/10.1111/risa.14181>.

²⁷ HHS Office of Disease Prevention and Health Promotion archive. Healthy People 2030 at: <https://health.gov/healthypeople/objectives-and-data/browse-objectives/foodborne-illness/reduce-infections-caused-Salmonella-fs-04/data?group=None&state=United+States&from=2016&to=2018&populations=&tab=data-table#data-table>.

B. Consideration of Need for a New Framework To Control Salmonella in Poultry

1. Petitions and Initial Stakeholder Input

Consumer advocacy organizations and other stakeholders have noted that the Healthy People *Salmonella* reduction targets have not been met and have submitted petitions and letters to FSIS requesting that the Agency revise its current approach for reducing *Salmonella* illnesses associated with poultry. For example, in January 2020, Marler Clark LLP submitted a petition on behalf of several individuals and consumer advocacy organizations requesting FSIS to issue an interpretive rule to declare 31 *Salmonella* serotypes that have been associated with foodborne illness outbreaks to be adulterants of all meat and poultry products.²⁸ According to the petition, such action is needed to protect the health and welfare of consumers by encouraging the meat and poultry industry to engage in more effective oversight measures and create and implement effective preventative measures.

In May 2022, FSIS denied the petition without prejudice, citing a lack of sufficient data available to support the sweeping actions requested in the petition. In the response, FSIS agreed that an updated *Salmonella* strategy is necessary to reduce *Salmonella* illnesses associated with poultry and described how FSIS was working towards gathering data and information necessary to support a revised strategy.²⁹

On January 25, 2021, the Center for Science in the Public Interest (CSPI) and other consumer advocacy organizations petitioned FSIS to establish enforceable standards targeting *Salmonella* types of greatest public health concern and all *Campylobacter*³⁰ in poultry.³¹

²⁸ Marler Clark LLP petition # 20–01 “Petition for an Interpretive Rule Declaring ‘Outbreak’ Serotypes of *Salmonella enteritica* subspecies to be Adulterants” dated January 19, 2020. Available at: <https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-Salmonella-serotypes>.

²⁹ FSIS Final Response to Petition #20–01, May 31, 2022. Available at: <https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-Salmonella-serotypes>.

³⁰ While the CSPI requested that FSIS take actions related to both *Salmonella* and *Campylobacter*, FSIS is currently focusing on re-evaluating its approach to prevent *Salmonella* illnesses associated with poultry.

³¹ CSPI petition #21–01, “Petition to Establish Enforceable Standards Targeting *Salmonella* Types of Greatest Public Health Concern while Reducing all *Salmonella* and *Campylobacter* in Poultry, and to Require Supply Chain Controls” (January 25, 2021) at: <https://www.fsis.usda.gov/policy/petitions/petition-submitted-center-science-public-interest>.

Referencing the Healthy People reduction goals, the petition asserted that FSIS’ current performance standards have not been effective in reducing *Salmonella* illnesses because they aim to reduce the prevalence of all *Salmonella* rather than prioritizing control efforts for the *Salmonella* serotypes most likely to make people sick. The petition laid out several suggestions for standards that FSIS could use to address *Salmonella* in poultry. The petition recommended that FSIS work with stakeholders and other public health agencies to establish enforceable final product standards to target *Salmonella* serotypes of greatest public health concern with an aim to eliminate these strains from poultry products over time. The petition also suggested that FSIS consider revising the current prevalence-based *Salmonella* performance standard to provide for quantitative testing and add *Salmonella* levels to the performance standards criteria to better ensure that when *Salmonella* is present on a product, it is present at low levels less likely to cause human illness. The petition asserted that FSIS is authorized to deem poultry products that contain virulent *Salmonella* strains and that contain pathogen levels above a set threshold to be adulterated under the PPIA because more virulent serotypes and certain levels of *Salmonella* are more likely to render poultry products injurious to health as defined in 21 U.S.C. 453(g)(1).

The 2021 CSPI petition also requested that FSIS initiate rulemaking to require that poultry establishments identify and control foodborne hazards within their supply chains, including *Salmonella*. The petition stated that supply chain interventions may include targeted vaccines developed for specific *Salmonella* serotypes and purchasing chicks from suppliers certified to be free of priority serotypes. The petition asserted that FSIS is authorized to require supply chain controls through the current HACCP regulations, which direct establishments to address, as appropriate, hazards both introduced in the establishment and introduced outside the establishment, including food safety hazards that occur before entry into the establishment (9 CFR 417.2). The petition also asserted that FSIS has authority to verify the effectiveness of supply chain controls under the PPIA’s antemortem inspection authority, which requires FSIS to conduct an antemortem inspection in each official establishment processing

[petitions/petition-submitted-center-science-public-interest](https://www.fsis.usda.gov/policy/petitions/petition-submitted-center-science-public-interest).

poultry or poultry products for commerce or otherwise subject to inspection under the PPIA “where and to the extent considered . . . necessary,” “[f]or the purpose of preventing the entry into or flow or movement in commerce of . . . any poultry product which is capable of use as human food and is adulterated” (21 U.S.C. 455(a)). FSIS has not yet responded to the 2021 CSPI petition but has considered the issues raised in developing this proposal.

In September 2021, FSIS received a letter from the Food Safety Coalition (FSC), a coalition of several food safety leaders, public health and consumer advocates, scientists, and members of the food industry. Like the CSPI petition, the FSC letter noted that although FSIS’ current prevalence-based pathogen reduction performance standards have led to reduced occurrence of *Salmonella* contamination in poultry products, the Healthy People 2020 goals set by the Department of Health and Human Services in 2010 for lowering *Salmonella* and *Campylobacter* illness rates were not being met. The FSC letter stated that the likely reason is that FSIS’ current *Salmonella* performance standards do not effectively target the particular types of *Salmonella* and products containing *Salmonella* levels that pose the greatest risks of illness. The letter stated that a new approach is needed to achieve the new Healthy People 2030 *Salmonella* illness rate target and presented several suggested changes to help reduce the rates of foodborne illness. The proposed changes recommended by the FSC included establishing modernized enforceable pathogen standards that “invite innovation,” as well as modernizing the HACCP framework to address risk reduction across the full production process, including defining the responsibility of poultry processors to consider pre-harvest practices and interventions in their HACCP plans.³²

2. FSIS Announces New Salmonella Effort

After considering the available data on *Salmonella* illnesses associated with poultry as well as the initial stakeholder input discussed above, on October 19, 2021, FSIS announced that it was mobilizing a stronger, and more comprehensive effort to reduce *Salmonella* illnesses associated with poultry products.³³ In the

³² Food Safety Coalition Letter, September 2, 2021. Available at: <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry>.

³³ USDA Press Release, “USDA Launches New Effort to Reduce *Salmonella* Illnesses Linked to

announcement, FSIS explained that the Agency would be initiating several key activities to gather the data and information necessary to support future action and move closer to the national target of a 25 percent reduction in *Salmonella* illnesses. The announcement also stated that FSIS intended to seek stakeholder feedback on specific *Salmonella* control and measurement strategies as well as using data to determine if there are other approaches to reduce *Salmonella*. The announcement noted that the effort would leverage USDA's strong research capabilities and highlighted that FSIS would ask the National Advisory Committee for Microbiological Criteria in Foods (NACMCF) to advise the Agency on how it can build on the latest science to improve its approach to *Salmonella* control. The announcement emphasized that FSIS would work closely with stakeholders on informing and implementing key activities of this framework.

Following this announcement, the Coalition for Poultry Safety Reform, a multistakeholder coalition that includes individuals and organizations representing consumers, victims of foodborne illness, food safety scientists, food safety officials, and members of the poultry industry, submitted a letter to the USDA Deputy Under Secretary for Food Safety in 2022 expressing support for a new effort to address *Salmonella*. The letter requested that FSIS focus its efforts on developing new regulatory standards related to *Salmonella* covering both products and supply chains and that these standards be informed by a risk assessment based on existing data.³⁴ The letter recommended that FSIS adopt enforceable product standards aimed at reducing risk of illness and develop and conduct a risk assessment to understand illness reduction benefits of various product standards.

3. Activities Initiated To Support a New *Salmonella* Framework

After FSIS announced its new initiative to reduce *Salmonella* illnesses associated with poultry products, the Agency initiated several activities designed to gather data and information to inform and support future actions related to this new effort.

Poultry" (October 19, 2021) at: <https://www.usda.gov/media/press-releases/2021/10/19/usda-launches-new-effort-reduce-salmonella-illnesses-linked-poultry>.

³⁴ Coalition for Poultry Safety Reform Letter, February 2, 2022. Available at: <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry>.

National Advisory Committee Charge. On October 20, 2021, FSIS announced a public meeting of NACMCF from November 17, 2021, to November 19, 2021, to discuss, among other things, a new charge focused on enhancing *Salmonella* control in poultry products.³⁵ Specifically, FSIS charged the NACMCF Subcommittee on Enhancing *Salmonella* Control in Poultry Products to provide guidance on the overarching risk management question: What types of microbiological criteria (e.g., *Salmonella* performance standards) might FSIS use to encourage reductions in *Salmonella* in poultry products so that they are more effective in preventing human *Salmonella* infections associated with these products?³⁶ FSIS also requested that the Subcommittee provide guidance on nine additional specific risk management questions. On April 25, 2022, NACMCF held a Subcommittee meeting for the workgroups addressing each of the questions in FSIS' charge to provide an update to the entire Subcommittee on their progress and to look at the overall timeline for completing the work of the Subcommittee.³⁷ On November 15, 2022, NACMCF held a virtual public meeting to discuss and vote on the Subcommittee's report on *Enhancing Salmonella Control in Poultry Products*, which had been posted to the FSIS website on November 1, 2022.³⁸ NACMCF adopted the final report pending finalization with consideration given to oral comments provided at the virtual public meeting and written comments submitted as directed in a **Federal Register** notice announcing the public meeting.³⁹ The comment period for the NACMCF report was scheduled to close on November 15, 2022, but was

³⁵ National Advisory Committee Meeting on Microbiological Criteria for Foods (NACMCF) Public Meeting—November 2021. Available at: <https://www.fsis.usda.gov/news-events/events-meetings/national-advisory-committee-microbiological-criteria-foods-nacmcf-2>.

³⁶ 2021–2023 National Advisory Committee Meeting on Microbiological Criteria for Foods (NACMCF); FSIS Charge: Enhancing *Salmonella* Control in Poultry Products Available at: <https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021>.

³⁷ NACMCF FSIS Charge: Enhancing *Salmonella* Control in Poultry, April 25, 2022. Available at: <https://www.fsis.usda.gov/news-events/events-meetings/national-advisory-committee-microbiological-criteria-foods-nacmcf-fsis>.

³⁸ Public Meeting; National Advisory Committee on Microbiological Criteria for Food, Nov 15, 2022. Available at: <https://www.fsis.usda.gov/news-events/events-meetings/public-meeting-national-advisory-committee-microbiological-criteria>.

³⁹ Public Meeting National Advisory Committee on Microbiological Criteria for Food (87 FR 64001). Available at: <https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-notices/public-meeting-national-advisory>.

extended to December 30, 2022, to provide 60 days for public review.⁴⁰ After considering the public comments, NACMCF finalized its report on March 13, 2023. The final report "Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products" (referred to as the 2023 NACMCF report in this document) is available to the public on the FSIS website at: <https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021>.

Pilot Projects. In December 2021, FSIS announced in its *Constituent Update* that the Agency was inviting poultry slaughter and processing establishments to submit proposals for pilot projects that will test different control strategies for *Salmonella* contamination in poultry products.⁴¹ The announcement explained that pilot projects would last for a defined period, during which establishments would experiment with new or existing pathogen control and measurement strategies and share data collected during the pilots with FSIS. The announcement included instructions on how interested establishments could submit proposals for pilots to FSIS. FSIS intended to analyze the data generated under the pilots to determine whether it supports changes to FSIS' existing *Salmonella* control strategies.

Since March 2023, FSIS has granted pilot projects to 9 establishments to examine the merits and logistics of excluding *Salmonella* poultry vaccine strains from the FSIS *Salmonella* performance categorization calculations. After evaluating the data collected under these pilots, on March 1, 2024, FSIS announced that beginning April 1, 2024, it intends to exclude current commercial vaccine subtypes confirmed in FSIS raw poultry samples from the calculation used to categorize establishments under the raw poultry *Salmonella* performance standards.⁴² This action is intended to remove barriers to the use of vaccination as an important pre-harvest intervention to

⁴⁰ FSIS Constituent Update—Nov 10, 2022: *Deadline Extended to Comment on NACMCF Document*. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-november-10-2022>.

⁴¹ FSIS Constituent Update—Dec 3, 2021: *FSIS Seeking Proposals for Pilot Projects to Control *Salmonella* in Poultry Slaughter and Processing Establishments*. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-december-3-2021>.

⁴² FSIS Constituent Update—March 1, 2024: *FSIS Intends to Exclude Vaccine Strains from the FSIS *Salmonella* Performance Categorization* at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-march-1-2024>.

control *Salmonella* in poultry. A summary report of the data from these pilots is posted on the Pilot Projects: *Salmonella* Control Strategies page of the FSIS website at: <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/pilot>.

On September 23, 2023, FSIS granted a pilot to 2 establishments to examine the merits of using preharvest results to optimize establishment interventions.⁴³ The data generated under the pilot will be shared with and analyzed by FSIS to determine whether it supports changes to FSIS' *Salmonella* control strategies.

Research and Science Roundtable. On February 15, 2022, FSIS held a research and science roundtable on *Salmonella* in poultry.⁴⁴ The intent of the roundtable was to convene research scientists to discuss the scientific support for various potential components of a revised strategy for *Salmonella* control in poultry. Among the topics discussed at the roundtable were: research on surveillance and risk assessments to evaluate the public health impact of the presence of *Salmonella* serotypes of concern and levels of contamination at production; research on *Salmonella* serotype dynamics in poultry production; research to identify pre-harvest food safety challenges and solutions; research modeling and correlation analysis work on pre-harvest in poultry; research on interventions to control *Salmonella* in preharvest and postharvest poultry production; and research in the area of microbial biomapping of indicators and pathogenic loads throughout the processing chain and using pre-harvest and post-harvest quantification data to develop SPC programs. The presentations on these topics and other materials associated with the research roundtable are available to the public on the FSIS website at: <https://www.fsis.usda.gov/news-events/events-meetings/Salmonella-poultry-research-and-science-roundtable>.

Exploratory Sampling Program and New *Salmonella* Quantification System. In April 2022, FSIS initiated an exploratory program that expanded young chicken carcass sampling at establishments subject to the young

chicken carcass performance standard.⁴⁵ The purpose of the exploratory sampling program was to generate microbial data to inform the Agency's effort to reduce *Salmonella* illnesses attributable to poultry. Under the program, in addition to the FSIS *Salmonella* verification sample already collected at post-chill, FSIS inspection program personnel (IPP) began collecting a second carcass sample at rehang from the same flock. In addition, FSIS IPP were instructed to collect the regularly scheduled National Antibiotic Resistance Monitoring System (NARMS) cecal samples from the same flock as the rehang and post-chill samples. The samples collected under the exploratory sampling program were initially analyzed for the presence of *Salmonella* and AC. FSIS IPP also completed a questionnaire at the time they collected exploratory samples to collect data on pre-harvest and slaughter interventions applied to the same flocks. A report on the exploratory sampling results is available at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

In August 2022, FSIS announced that FSIS laboratories would begin using new technology to quantify *Salmonella* in raw poultry rinses and updated the exploratory sampling program for young chickens to quantify confirmed *Salmonella* positive rehang and post-chill carcass results using the new quantification system.⁴⁶ These analyses were in addition to the whole genome sequencing (WGS) that FSIS had already been performing on confirmed *Salmonella*-positive post-chill carcass samples.

On January 30, 2023, FSIS added *Salmonella* quantification testing and AC indicator analyses to chicken part rinsates.⁴⁷ FSIS added these two analyses to comminuted chicken testing on February 27, 2023, and to comminuted turkey on April 3, 2023.

⁴⁵ FSIS Constituent Update—April 22, 2022: *FSIS Expands Salmonella Sampling for Young Chicken Carcasses*. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-april-22-2022>.

⁴⁶ FSIS Constituent Update—Aug 5, 2022: *FSIS to include Salmonella Quantification in all Poultry Rinse Samples*. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-august-5-2022-0>. FSIS Notice 44–22, *Revised Young Chicken Exploratory Sampling Program*, Aug 11, 2022.

⁴⁷ FSIS Constituent Update—Feb 3, 2023: *FSIS to Expand Salmonella Enumeration and Aerobic Count Indicator Testing to Other Poultry Products*. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-february-3-2023>. Notice 83–23, *New Sampling Instructions and Testing for Chicken Parts and NRTE Comminuted Poultry*, Feb 3, 2023. Available at: <https://www.fsis.usda.gov/policy/fsis-notice/08-23>.

Salmonella quantification is a significant step in updating the diagnostic capabilities of FSIS' food testing laboratories. The data generated from the new quantification system along with the data collected from the young chicken carcass exploratory sampling program were used to help inform the policies discussed in this document, including the quantitative microbial risk assessments to evaluate *Salmonella* in raw poultry discussed below. The data generated from the quantification system have also been added to FSIS' quarterly dataset release and are available at: <https://www.fsis.usda.gov/science-data/datasets-visualizations/laboratory-sampling-data>.

Risk Profile. In May 2022, FSIS initiated a risk profile for *Salmonella* subtypes in poultry linked to foodborne illness. FSIS developed the risk profile to provide information on whether certain serotypes or subtypes of *Salmonella* should be considered as adulterants in specific poultry products within the meaning of the PPIA (21 U.S.C. 453(g)). The risk profile involved a comprehensive systematic review of literature and supporting data designed to provide responses to the following six risk management questions:

1. What *Salmonella* serotypes or subtypes are linked to foodborne illness or outbreaks from consuming specific raw or not-ready-to-eat chicken or turkey products?

2. Are these *Salmonella* serotypes or subtypes of concern present in live chickens, live turkeys, and poultry products?

3. Can exposure to a small number of these *Salmonella* serotypes or subtypes of concern result in foodborne illness?

4. Can exposure to these *Salmonella* serotypes or subtypes of concern cause severe, debilitating health outcomes?

5. How can these *Salmonella* serotypes or subtypes of concern be differentiated from other *Salmonella* subtypes?

6. Would ordinary consumer handling or preparation practices affect exposure to *Salmonella* serotypes or subtypes of concern?

The risk profile was submitted for independent peer-review⁴⁸ and updated in response to peer review comments. The results of the risk profile and how they were used to inform specific measures proposed in this document are discussed below. The final *Risk Profile for Pathogenic Salmonella in Poultry* (referred to as the 2023 risk profile in

⁴⁸ *Peer Review Plan: Risk Profile for Salmonella Subtypes in Poultry Products Linked to Foodborne Illness* (usda.gov).

⁴³ Pilot Projects: *Salmonella* control strategies. Current *Salmonella* Pilot Participants available at: <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/pilot>.

⁴⁴ *Salmonella* in Poultry: Research and Science Roundtable. Available at: <https://www.fsis.usda.gov/news-events/events-meetings/Salmonella-poultry-research-and-science-roundtable>.

this document) is available at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

Risk Assessments FSIS Developed to Inform Rulemaking. FSIS conducted two new quantitative microbial risk assessments, one for *Salmonella* in chicken and one for *Salmonella* in turkey, to inform the Agency's new framework for reducing *Salmonella* attributed to poultry consumed in the United States. FSIS expanded on this work through a Cooperative Agreement (FSIS–02152022) with the University of Maryland's Joint Institute for Food Safety and Applied Nutrition (UMD–JIFSAN), in partnership with EpiX Analytics, to differentiate *Salmonella* serotypes by virulence using advanced bioinformatics (*i.e.*, machine learning) to evaluate genomic data.⁴⁹ The risk assessments address the following risk management questions:

1. What is the public health impact (change in illnesses, hospitalizations, and deaths) achieved by eliminating at receiving a proportion of chicken (or turkey) contaminated with specific levels of *Salmonella* and/or specific *Salmonella* subtypes?
 2. What is the public health impact (change in illnesses, hospitalizations, and deaths) achieved by eliminating final product contaminated with specific levels of *Salmonella* and/or specific *Salmonella* subtypes?
 3. What is the public health impact of monitoring/enforcing process control from rehang to post-chill? Monitoring could include analytes such as *Enterobacteriaceae* Count (EB), AC, or other indicator organisms, analysis could include presence/absence or levels and the monitoring could also include variability of actual result versus expected result, log reduction, absolute sample result, or other individual establishment specific criteria.
 4. What is the public health impact of implementing combinations of the risk management options listed above?
- The risk assessments were submitted for independent peer-review⁵⁰ and

updated in response to peer review comments. The risk assessments, and the manner in which the results were used to inform specific measures proposed in this document, are discussed below. The final *Quantitative Risk Assessment for Salmonella in Raw Chicken and Raw Chicken Products* and *Quantitative Risk Assessment for Salmonella in Raw Turkey and Raw Turkey Products* (referred to as the 2023 risk assessments in this document) are available at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

4. Initial Measures Implemented To Address Salmonella Illnesses Associated With Consumption of Poultry Products

After FSIS announced its new *Salmonella* initiative in October 2021, in addition to initiating the activities to gather data to inform and support a new *Salmonella* Framework discussed above, the Agency implemented some initial measures to support this effort.

Salmonella Key Performance Indicator. As part of USDA's strategic and performance planning process for fiscal years (FY) 2022–2026, FSIS established a new “key performance indicator” (KPI) targeted to reduce the proportion of poultry samples with *Salmonella* serotypes commonly associated with human illnesses.⁵¹ This KPI is a measure that is used to evaluate FSIS' progress towards reaching its objectives and goals identified in both Agency and USDA strategic plans and will serve as a metric for success for the USDA FY 2022–2026 Strategic Plan. FSIS analyzed historical Agency sampling data, in addition to FoodNet Fast data from the CDC, to determine the top three *Salmonella* serotypes commonly associated with human illness for this measure. The analysis found that these serotypes are Infantis, Enteritidis, and Typhimurium. FSIS will use annual targets to track progress toward reducing the proportion of poultry samples with the KPI serotypes and is seeking a 2 percent reduction each year, with the goal of achieving a 10 percent reduction by FY 2026. KPI serotypes are useful for strategic and performance planning purposes, and these may differ from the serotypes of

Salmonella in Turkey Products available at: https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS_Salmonella_Peer_Review_Plan_Turkey.pdf.

⁵¹ FY2022–2024 Food Safety Key Performance Indicator. Available at: <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-Salmonella-poultry/Salmonella-0#:~:text=FY2022–2026FoodSafetyKeyPerformanceIndicatorA,theUSDAFiscalYear28FY292022–2026StrategicPlan.>

public health significance (which will likely change over time as the serotypes commonly associated with human illnesses change).

Final Determination. On August 1, 2022, FSIS announced that it would be declaring *Salmonella* as an adulterant in breaded and stuffed not-ready-to-eat (NRTE) chicken products (also referred to as “NRTE breaded stuffed chicken products”).⁵² These products contain raw, comminuted chicken breast meat, trim, or whole chicken breast meat, but the finished product is heat-treated only to set the batter or breading on the exterior of the product, which may impart an RTE appearance.⁵³ Although the labeling of NRTE breaded stuffed chicken products has undergone significant changes over time to better inform consumers that the products are raw and to provide instructions on how to prepare them safely, these products continue to be associated with *Salmonella* illness outbreaks. Based on information from *Salmonella* illness outbreaks associated with NRTE breaded stuffed chicken products and information from research on consumer handling practices with respect to these products, FSIS concluded that labeling that informs consumers that these products are raw and how to prepare them safely fails to sufficiently protect consumers from illness.

On April 28, 2023, FSIS published a proposed determination to declare that NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 cfu per gram or higher are adulterated within the meaning of the PPIA (88 FR 26249). FSIS also proposed to carry out verification procedures, including sampling and testing of the chicken component of NRTE breaded stuffed chicken products prior to stuffing and breading, to ensure producing establishments control *Salmonella* in these products. The comment period for the proposed determination was scheduled to close on June 27, 2023, but was extended to August 11, 2023, in response to requests from members of the regulated industry.⁵⁴

⁵² *Salmonella* as an Adulterant in Breaded Stuffed Raw Chicken Products (Aug 1, 2022). Available at: <https://www.usda.gov/media/press-releases/2022/08/01/usda-announces-action-declare-Salmonella-adulterant-breaded-stuffed>.

⁵³ FSIS Directive 5300.1, Revision 1. Managing the Establishment Profile in the Public Health Information System. (usda.gov). See attachment 2 “NRTE Stuffed Chicken Products that appear RTE.”

⁵⁴ FSIS Constituent Update—July 21, 2023: *FSIS Extends Comment Period on Proposed Determination: Salmonella in Not-Ready-To-Eat Breaded Stuffed Chicken Products*. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-july-21-2023>.

⁴⁹ FSIS Constituent Update—July 1, 2022: *FSIS Announces Cooperative Agreement on Salmonella Risk Assessments*. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-july-1-2022>. *Salmonella* Risk Assessments and Risk Management Questions at: <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-Salmonella-poultry/Salmonella-1>.

⁵⁰ Peer Review Plan: Quantitative Microbial Risk Assessment of *Salmonella* in Chicken Products available at: https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS_Salmonella_Peer_Review_Plan_Chicken.pdf. Peer Review Plan: Quantitative Microbial Risk Assessment of

FSIS received 3,386 comments on the proposed determination. After careful consideration of the comments, on May 1, 2024, FSIS finalized the determination as proposed, with one change (89 FR 35033). Instead of collecting samples after the establishment has completed all processes needed to prepare the chicken component to be stuffed and breaded to produce a final NRTE breaded stuffed chicken product, as was proposed, FSIS will collect verification samples on the raw incoming chicken components. This change was intended to provide greater flexibility and reduce costs to industry.

As noted above, NRTE breaded stuffed chicken products are adulterated if they contain *Salmonella* at 1 cfu/g or higher, regardless of the *Salmonella* serotype. FSIS adopted this approach for NRTE breaded stuffed chicken products because these products present a unique public health risk. Unlike raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, NRTE breaded stuffed chicken products may have a cooked appearance, are thicker in diameter than many other poultry products, contain multiple ingredients, and are typically cooked from a frozen state. In addition, outbreak data cited in the NRTE breaded stuffed chicken proposal indicate that these products have been consistently and disproportionately associated with *Salmonella* illness outbreaks over the years. As FSIS acknowledged in the NRTE breaded stuffed chicken proposed and final determination, although not all *Salmonella* serotypes are equally likely to cause illness, all serotypes have the ability to invade, replicate, and survive in human host cells, resulting in potentially serious disease. Thus, because of the unique public health risk associated with NRTE breaded stuffed chicken products, FSIS determined that these products are adulterated if they contain any *Salmonella* stereotypes at or above 1 cfu/g.

C. Public Meeting on *Salmonella* Framework Under Consideration and Public Comments

1. Public Meeting and Proposed Framework

On October 17, 2022, FSIS published a **Federal Register** notice announcing that it was hosting a virtual public meeting on November 3, 2022, to discuss a regulatory framework that the Agency was considering for a new strategy to control *Salmonella* in poultry

products and more effectively reduce foodborne *Salmonella* infections linked to these products (87 FR 62784). In the notice, FSIS shared the key elements of the framework under consideration and stated that the Agency was soliciting comments from stakeholders on all elements of the draft framework, both at the public meeting and in written comments submitted in response to the **Federal Register** notice, before moving forward with any proposed changes to regulations or other actions. The Agency also made a document outlining the regulatory framework under consideration available to the public before the public meeting by publishing it on the FSIS website.⁵⁵

The three components under consideration in the draft framework included:

1. Requiring that incoming flocks be tested for *Salmonella* before entering an establishment;
2. Enhancing establishment process control monitoring and FSIS verification; and
3. Implementing an enforceable final product standard.

The framework under consideration also addressed cross-cutting issues associated with testing for *Salmonella*, considerations for small and VS establishments, and data sharing. FSIS specifically requested comments on factors the Agency should consider relative to the approaches outlined in each of the components, how each component can be strengthened, and where are there gaps in the framework. FSIS also requested comments on relevant scientific evidence or examples of how the components may be implemented or the impacts they may have on human *Salmonella* illnesses.

At the November 3, 2022, public meeting, stakeholders presented oral comments to FSIS panels comprised of FSIS leadership and experts on the three separate components of the framework and the cross-cutting issues. The primary purpose of the panels was to listen to stakeholder input and ask clarifying questions as needed.⁵⁶ In addition to the oral comments presented at the public meeting, FSIS also provided an opportunity for the public to submit written comments on the framework. The comment period for

submitted written comments was scheduled to close on November 16, 2022, but was extended to December 16, 2022, to allow stakeholders sufficient time to take into consideration the discussion at the November 3, 2022, public meeting.⁵⁷ A summary of the general issues raised by the public comments is discussed below.

2. Public Comments on the Proposed Framework

During the comment period for the proposed framework, FSIS received 1,034 comments. Seven hundred seventy-three comments were identical or similar comment letters from individuals in support of the proposed framework, and 75 were identical or similar comment letters from individuals opposed to the proposed framework. One consumer advocacy organization submitted a comment letter with a spreadsheet containing 4,916 names in support of the framework. Another consumer advocacy organization submitted a comment letter with a spreadsheet containing 3,487 names in support of the framework. FSIS also received 149 unique comments from individuals, most in opposition to the proposed framework. In addition to the individual comments and form letters, FSIS received approximately 35 separate comment letters from trade associations representing the meat and poultry industries, consumer advocacy organizations, animal welfare advocacy organizations, small poultry growers and processors, organizations that support independent family farmers, a large meat producer, a trade association representing the veterinary profession, a State Department of Agriculture, an organic/sustainable agriculture organization, a biotech company representative, a meat scientist, and academics. The general issues raised on each of the components under consideration in the framework and on the cross-cutting issues are described below.

Comments on Component One. Component One of the draft framework considered whether FSIS should require slaughter establishments to characterize *Salmonella* as a hazard reasonably likely to occur at receiving and require that incoming flocks be tested for *Salmonella* before entering an establishment. Under this approach, the flock would be required to meet a predetermined target for *Salmonella* at

⁵⁵ Proposed Regulatory Framework to *Salmonella* Illnesses Attributable to Poultry. Available at: <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/proposed>.

⁵⁶ A transcript of the public meeting and other related materials are available to the public on the FSIS website at: <https://www.fsis.usda.gov/news-events/events-meetings/public-meeting-reducing-salmonella-poultry>.

⁵⁷ FSIS Constituent Update—Oct 28, 2022: FSIS Extends Public Meeting and Comment Period on Proposed *Salmonella* Framework. Available at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-october-28-2022-1>.

receiving, which may be industry-wide or establishment-specific. The establishment would be required to demonstrate that its subsequent process will be effective in reducing *Salmonella* so that the product meets the final product standard under consideration in Component Three.

Comments from individuals, consumer advocacy organizations, and animal welfare advocacy organizations expressed general support for the measures under consideration in Component One. A consumer advocacy organization commented that requiring incoming flocks be tested for *Salmonella* would provide incentives for producers to adopt effective pre-harvest measures and for establishments to take action to further reduce food safety risks from flocks failing the incoming *Salmonella* target, such as slaughtering more contaminated flocks at the end of the day.

Comments from small poultry processors and producers, organizations representing small poultry producers and independent family farmers, and trade associations representing the meat and poultry industries expressed concerns that the measures under consideration in Component One would impose an overwhelming burden on small producers. An organization representing small poultry producers and several individual comments stated that requiring that flocks be tested for *Salmonella* before they enter an establishment would add delays and costs that small operators cannot afford.

Several comments, including comments from trade associations representing the meat and poultry industries and organizations that support independent family farmers, asserted that FSIS lacks legal authority to require the measures under consideration in Component One, particularly the requirements that incoming flocks be tested for *Salmonella*. The commenters stated that FSIS' authority under the PPIA begins at the official establishment and does not extend to the farm. The commenters also asserted that Component One conflicts with HACCP principles in that under HACCP, establishments, not FSIS, are responsible for making decisions on how to execute their food safety system.

Comments from trade associations representing the meat and poultry industries asserted that FSIS had presented no data to demonstrate that an incoming *Salmonella* threshold or limit is necessary for an establishment to maintain process control and sufficiently reduce *Salmonella* during processing. They also stated that FSIS did not explain how on-farm sampling

several weeks before a flock is processed correlates to actual incoming *Salmonella* loads or provide data to show that reducing incoming loads would have any public health impact. The commenters noted that many producers and processors currently employ interventions aimed at reducing *Salmonella* on farms and suggested that FSIS consider other measures to incentivize pre-harvest controls without requiring testing, such as encouraging establishments to consider *Salmonella* a hazard reasonably likely to occur and providing guidance for addressing *Salmonella* pre-harvest. Some of the commenters that opposed Component One suggested removing this component entirely.

Comments on Component Two. The measures under consideration in Component Two of the proposed framework would build on HACCP regulations, which provide a prevention-based approach to food safety. To ensure pathogen control throughout slaughter and processing operations, Component Two would modify the existing requirements for microbial organism testing for process control in 9 CFR 381.65(g) and establish additional parameters to better define the required analysis of the data. Establishments would be required to test for indicator organisms (e.g., AC or EB) at rehang and post-chill and would be required to use a standardized statistical approach to process control. FSIS would consider production volume when determining the frequency that establishments must collect samples.

FSIS received several comments in support of the measures under consideration in Component Two from consumer advocacy organizations and academia. These commenters generally agreed with the proposal but recommended that FSIS consider additional measures, such as requiring establishments to test more broadly for indicator organisms and/or requiring testing at more sampling points. These commenters also recommended that FSIS work with stakeholders to develop the SPC approach after conducting research to determine the best points predictive of end product *Salmonella* levels and tailor the SPC for differences in processors' equipment and plant layouts.

Trade associations representing the meat and poultry industries, a State Department of Agriculture, and an organic/sustainable agriculture organization expressed concerns about some of the measures under consideration in Component Two. The commenters asserted that there is a lack

of necessary data to support creating a rigid SPC framework for all establishments. An organic/sustainable agriculture organization requested that small producers be exempt from this component. A trade association representing the meat and poultry industry suggested that FSIS consider conducting verification sampling at specific locations and allow establishments to develop their own sampling plans. An association representing small and VS poultry establishments stated that the Component Two measures under consideration will be costly and will not reduce *Salmonella*.

Comments on Component Three. Component Three of the draft framework under consideration would implement an enforceable final product standard to prevent raw poultry products with certain levels and/or types of *Salmonella* contamination from entering the stream of commerce. FSIS would establish the standard by classifying certain *Salmonella* levels and/or serotypes as adulterants in raw poultry and take action against poultry products that exceed the final product standard.

Consumer advocacy organizations, coalitions promoting food safety, and individuals with expertise in food and meat science generally supported Component Three and recommended that FSIS prioritize developing and implementing Component Three. According to these commenters, it is the most critical part of the framework. These commenters recommended an enforceable approach to combatting *Salmonella*. The commenters stated that such an approach would provide much greater safety to consumers by preventing highly contaminated product from reaching store shelves and would motivate industry to adequately control *Salmonella* because of the direct financial cost of losing product that does not meet the final standard.

Some of the comments in support of Component Three requested that FSIS provide increased transparency and data regarding how the product standards under consideration would look. One consumer advocacy organization emphasized that FSIS should use scientifically sound risk assessments in determining final product standards. A consumer advocacy organization recommended establishing separate standards for different poultry products and stated that, for chicken, the standard could be based on FSIS' KPI serotypes Enteritidis, Infantis, and Typhimurium, and that for turkey, the standard could be based on serotypes Reading, Infantis, and Typhimurium. A

consumer advocacy organization stated that FSIS should set stricter standards for certain products if the risk assessment identifies higher risk poultry products and that the risk assessments would determine whether the final product standards should be based on *Salmonella* enumeration, serotypes, or a combination of both.

Comments from trade associations representing the meat and poultry industries, trade associations representing small poultry processors and family farmers, a state government entity, and both large and small businesses associated with poultry production did not support the establishment of enforceable final product standards. These comments opposed considering *Salmonella* to be an adulterant in raw poultry. Many of the commenters stated that FSIS has historically not considered *Salmonella* as an adulterant in raw poultry because: (1) *Salmonella* is not an “added substance” and (2) *Salmonella* is not present in levels that render chicken or turkey injurious to health because customary poultry cooking practices destroy *Salmonella*. The commenters stated that FSIS has not provided any new information to support a change in this interpretation. Comments from these trade associations and a state government entity also stated that FSIS’ comparison of *Salmonella* in raw poultry to *Escherichia coli* (E. coli) in non-intact beef is not relevant, given that the two are very different in how they occur in products and how they are destroyed through cooking.

On the other hand, comments from consumer advocacy organizations stated that *Salmonella* may be considered as an “added substance” because it is not found in the muscle tissue of healthy animals but rather is deposited through cross-contamination during slaughter and processing. The commenters asserted that regardless of whether FSIS considers certain *Salmonella* levels or serotypes most associated with human illness to be an “added substance,” they are adulterants because they “ordinarily render” contaminated poultry products injurious to health.

Commenters that opposed Component Three expressed concern about the delay that would result from a national verification testing program. A trade association representing the chicken industry argued that the extra time required for poultry producers to hold their product pending FSIS’ *Salmonella* testing results will significantly decrease the number of poultry products that can safely reach store shelves. An organization representing small poultry producers and processors stated that

waiting for acceptable test results would particularly affect small producers who may not have the capability to hold poultry for a long period of time.

Some commenters recommended alternatives to Component Three that the commenters believed would more effectively reduce *Salmonella* infection rates from poultry. For example, a large company that processes poultry recommended that, instead of developing new final product standards based on product adulteration, FSIS update the current performance standards to include a new metric based on a quantification target that measures beyond the prevalence of *Salmonella*, which the commenter said would work well within a current or an updated HACCP system.

Many comments opposed to Component Three asserted that the proposed measures under consideration lacked information on the data and methods that would be used to establish the final product standards. A trade association representing the chicken industry questioned whether FSIS had sufficient laboratory space needed to sample different product lots for *Salmonella* levels or serotypes. An organization representing independent family farmers recommended that, instead of establishing final product standards, FSIS should identify the *Salmonella* strains that cause most illnesses and target those strains specifically rather than providing more general product standards. The 75 similar comment letters that opposed the framework stated that FSIS should remove Component Three from the framework until the Agency provides a clear statement of the levels and/or strains of *Salmonella* that would define the final product standards.

Comments on other issues raised. In addition to comments about the above Components, there were comments raised about the framework in general. Among these comments were write-in campaigns that expressed general support for the proposed framework. A trade association representing the chicken industry argued that the proposed framework under consideration is not necessary because FSIS’ existing framework for addressing *Salmonella* control has been working. A trade association representing the poultry industry commented that there is a need for consumer research and education regarding safe handling of poultry. Some comments expressed concern that adopting the framework would lead to an increase in food waste.

Comments on data sharing. FSIS received five comments regarding the need to share data. An academic

suggested FSIS work with stakeholders to facilitate sharing of industry data that would provide additional insights into the sampling points that would be most predictive of process control. Trade associations representing the poultry industry urged FSIS to create a pathway for companies to share confidential proprietary data with the Agency and indicated it would be necessary to ensure that data is shared only with FSIS. A sustainable agriculture organization emphasized the need for an enhanced ability to share information among agencies, the academic community, and industry.

3. Additional Stakeholder Input

In addition to the November 2022 public meeting, FSIS also participated in technical meetings with representatives from the poultry industry, consumer advocacy organizations, academia, and other stakeholders to further discuss aspects of the proposed *Salmonella* framework. These technical meetings were organized and hosted by the regulated industry. The first technical meeting was held on March 21, 2023. Among the topics discussed were differences in production practices and *Salmonella* control strategies between chicken and turkeys, review of ongoing risk assessments, pre-harvest control risk management measures, creating, implementing, and reacting to statistical process control measures, and *Salmonella* quantification methods. A second technical meeting was held on April 12, 2023. Among the topics discussed at that meeting were incentivizing use of pre-harvest interventions, how statistical process control is used in the poultry industry and educational needs, and addressing lot size and microbiological independence, and a review of the key differences between beef and poultry. FSIS officials also held a virtual meeting with small and VS establishment owners in February 2023 to seek input on the *Salmonella* Framework under consideration.⁵⁸

4. Overview of Modifications to the Proposed *Salmonella* Framework

FSIS has carefully evaluated the written comments and other stakeholder input provided on the proposed *Salmonella* Framework, along with new studies and information that have become available since the Agency made the information about the framework under consideration

⁵⁸ Officials’ Calendar of Meetings (Feb 2023) at: <https://www.fsis.usda.gov/news-events/events-meetings/officials-calendar-meetings>.

available to the public in November 2022. Based on this evaluation, FSIS has decided to modify some of the measures it had been considering as part of the *Salmonella* Framework and is proposing these modified measures in this document. FSIS requests comments on all measures proposed in this document. If, after the close of the comment period, the Agency determines that some portions of the modified *Salmonella* Framework can be finalized sooner than others, FSIS will finalize those portions separately from the others so as not to delay regulatory action on this important public health initiative.

The proposed modified framework components are discussed in more detail under separate headings in this document. The headings for the proposed modified framework correspond to the component headings used for the draft framework that FSIS presented to the public, *i.e.*, Component One, Component Two, Component Three. The components are discussed in this proposal in an order that emphasizes the most significant proposed changes first. Therefore, the discussion begins with Component Three: Final Product Standards, followed by Component Two: Enhanced Establishment Process Control Monitoring, and finally Component One: Pre-Harvest Measures.

Following is a general summary of the modifications.

Component Three Modifications. Consistent with Component Three of the draft framework that was under consideration, FSIS is proposing enforceable final product standards to prevent raw poultry products with certain levels and *Salmonella* serotypes from entering commerce. Under this proposal, FSIS has tentatively determined that certain raw poultry products that contain *Salmonella* in an amount that exceeds a specified level and that contain any detectable level of certain *Salmonella* serotypes are adulterated as defined in the PPIA. The proposed final product standards are as follows:

- *Chicken carcasses and chicken parts: Salmonella* at or above 10 cfu per milliliter of rinsate collected in any sample *and* any detectable level of at least one of the *Salmonella* serotypes of public health significance (*i.e.*, Enteritidis, Typhimurium, and I 4,[5],12:i:-);

- *Comminuted chicken: Salmonella* at or above 10 cfu per gram of product collected in any sample *and* any detectable level of at least one of the *Salmonella* serotypes of public health significance (*i.e.*, Enteritidis, Typhimurium, and I 4,[5],12:i:-);

- *Comminuted turkey: Salmonella* at or above 10 cfu per gram of product collected in any sample *and* any detectable level of at least one of the *Salmonella* serotypes of public health significance (*i.e.*, Hadar, Typhimurium, and Muenchen).

FSIS is also proposing that the Agency would routinely collect samples of raw final products subject to the proposed standards and analyze them for *Salmonella* levels and serotypes to determine whether the product is adulterated.

Component Two Modifications. To ensure that poultry slaughter establishments are effectively controlling *Salmonella* throughout their operations, FSIS is proposing to revise the current regulations in 9 CFR 381.65(g) that require that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation. FSIS is proposing to revise these regulations to clarify that these procedures must include an MMP that incorporates SPC monitoring methods. These proposed amendments would also specify that the pre-chill sampling location is at rehang and specify the use of appropriate microbial organisms for monitoring process control. In addition, VS and VLV establishments operating under Traditional Inspection⁵⁹ would have to test at both rehang and post-chill, instead of at post-chill only, although some of these establishments would have the option to use laboratory services provided by FSIS to analyze their monitoring samples. FSIS has developed proposed guidance to help establishments meet the proposed sampling and analysis requirements. Under this proposal, the guidance would be considered as a “safe harbor” in that establishments that follow the guidance will have met the proposed MMP requirements in 9 CFR 381.65(g). FSIS is also proposing to amend the recordkeeping requirements in 9 CFR 381.65(h) to require that establishments submit their microbial monitoring results to the Agency electronically.

Component One Modifications. Based on the need for additional research and due to implementation challenges, FSIS has decided, at this time, not to establish a regulatory requirement that establishments characterize *Salmonella* as a hazard reasonably likely to occur at receiving or that incoming flocks be tested for *Salmonella* before entering an

establishment. FSIS, however, will focus on achieving the goal of Component One—reduce the amount and type of *Salmonella* contamination that enters the establishment—through non-regulatory strategies. These include actively encouraging the wider use of modified-live vaccines, which have been demonstrated to have a very effective role in mitigating the hazard associated with specific *Salmonella* serotypes, while reducing the entire load of similar serogroup *Salmonella* through cross-protection. FSIS is also working with the Animal and Plant Health Inspection Service (APHIS) to explore ways to expand the National Poultry Improvement Program (NPIP), which has been effective in reducing the prevalence of particular *Salmonella* serotypes.

The Agency will continue to explore and develop strategies for addressing *Salmonella* contamination risk at receiving. FSIS also intends to revise its existing compliance guideline on *Controlling Salmonella in Raw Poultry*⁶⁰ to provide effective guidance on pre-harvest interventions and practices for preventing or reducing *Salmonella* colonization of live birds.

5. Severability

While the three components in this proposal support a comprehensive approach to controlling *Salmonella* in poultry, they are each separate actions that could operate independently of each other to address *Salmonella* illnesses associated with poultry products. Therefore, the following portions of this proposal are mutually severable from each other: The proposed determination that would establish final product standards for certain raw poultry products proposed under Component Three; the proposed amendments to 9 CFR 381.65 (g) and (h) that would enhance process control monitoring in all poultry slaughter establishments under Component Two; and the proposed non-regulatory approach to address pre-harvest measures in Component One. Should FSIS finalize this proposal, if any of the above portions were to be set aside by a reviewing court, FSIS would intend for the remainder of this action to remain in effect.

These proposals are discussed in more detail below.

⁵⁹ Traditional Inspection is typically employed at smaller lower production volume establishments that eviscerate carcasses by hand (77 FR 4410).

⁶⁰ *FSIS Guideline for Controlling Salmonella in Raw Poultry* (July 2021). Available at: <https://www.fsis.usda.gov/guidelines/2021-0005>.

II. Component Three: Proposed Final Product Standards

A. Current *Salmonella* Performance Standards and Consideration of an Alternative Approach

As discussed above, although FSIS sampling data show that the occurrence of *Salmonella* in raw poultry products has decreased since FSIS implemented its prevalence-based *Salmonella* performance standards, there has not been a corresponding observed reduction in *Salmonella* illnesses in the United States. There are likely multiple reasons for the disconnect between the reduced *Salmonella* contamination in poultry products and continued illnesses. Individuals who become ill may be exposed to more virulent *Salmonella* strains or higher concentrations of *Salmonella*,⁶¹ and, as noted above, consumption of poultry has increased.⁶² Additionally, as discussed below, several consumer behavior research studies suggest that ordinary consumer cooking and preparation practices for many raw chicken and turkey products do not provide adequate assurance that these products will not be contaminated with *Salmonella* when consumed. Therefore, FSIS has decided to reconsider its current approach to *Salmonella* performance standards for poultry and has tentatively concluded that the Agency should adopt an alternative approach to more effectively reduce *Salmonella* illnesses associated with poultry products. This proposal addresses the disconnect between *Salmonella* contamination on poultry and human illnesses because it targets specific *Salmonella* serotypes more frequently associated with illness and limits the concentration of *Salmonella* permitted in certain raw poultry products.

⁶¹ FSIS Risk Profile for Pathogenic *Salmonella* in Poultry (2023); FAO/WHO (Food and Agriculture Organization/World Health Organization) "Microbiological Risk Assessment Series 3: Hazard Characterization for Pathogens in Food and Water". Geneva, Rome: World Health Organization, Food and Agricultural Organization of the United Nations; 2003; Cheng, RA, Eade CR, and Wiedmann M (2019). Embracing Diversity: Differences in Virulence Mechanisms, Disease Severity, and Host Adaptations Contribute to the Success of Nontyphoidal *Salmonella* as a Foodborne Pathogen. *Frontiers in Microbiology*, Volume 10 at: <https://doi.org/10.3389/fmicb.2019.01368>; Teunis, Peter FM (2022). Dose response for *Salmonella* Typhimurium and Enteritidis and other nontyphoid enteric salmonellae. *Epidemics* 41: 100653. <https://doi.org/10.1016/j.epidem.2022.100653>.

⁶² Williams, M.S., & Ebel, E.D. (2022). Temporal changes in the proportion of *Salmonella* outbreaks associated with 12 food commodity groups in the United States. *Epidemiology and Infection*, 150, e126. <https://doi.org/10.1017/S0950268822001042>.

FSIS' current *Salmonella* performance standards focus on reducing the prevalence of all *Salmonella* without considering differences in virulence among individual *Salmonella* serotypes, strains, and genotypes. Thus, the current standards do not focus on the types of *Salmonella* most likely to cause human illnesses. In addition, the current *Salmonella* performance standards consider only the presence or absence of *Salmonella* in the product, while the quantity of the pathogen may also have an impact on illness. Thus, the current performance standards do not distinguish between poultry products that are heavily contaminated and that contain the most virulent type of *Salmonella* from those that contain trace amounts of a *Salmonella* with types not typically associated with foodborne illnesses in the United States.

Additionally, and independently, the Agency's ability to directly enforce the pathogen reduction performance standards has been limited since 2001, after a ruling by the U.S. Court of Appeals for the Fifth Circuit in *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432 (5th Cir. 2001). In that case, the court enjoined FSIS from suspending inspection services against a meat grinding operation for failure to meet the *Salmonella* performance standards. Since that time, FSIS has used *Salmonella* performance standard failures as a basis to conduct an in-depth evaluation of the establishment's food safety systems, including its HACCP plan and sanitation SOPs. However, because *Salmonella* is not currently considered an adulterant in raw poultry, the Agency cannot withhold the mark of inspection or otherwise prevent products produced in an establishment that has failed the performance standards from entering commerce based solely on the establishment's performance standard results (75 FR 27288, 27293–4). This proposal, on the other hand, would set an enforceable final product standard that prevents raw poultry products with certain levels and types of *Salmonella* contamination, which would be classified as adulterants, from entering the stream of commerce.

When FSIS initially established the pathogen reduction *Salmonella* performance standards in 1996, the Agency noted that, except for *E. coli* O157:H7, FSIS had not taken the position that some amount of a pathogen necessarily renders a raw meat or poultry product unsafe and legally adulterated (61 FR 38806, 38835). At the time, the Agency believed that it was constrained by the lack of a scientific basis for determining the levels at which

specific pathogens do or do not present a safety hazard, and it also relied in part on the fact that proper cooking kills pathogens on raw product (60 FR 6774, 6799). Therefore, the initial pathogen reduction performance standards were based on a statistical evaluation of the prevalence of bacteria in each establishment's products, measured against the nationwide prevalence of the bacteria in the same products (61 FR 38806, 38836). The *Salmonella* performance standards were and still are not used to determine whether specific product lots are legally adulterated. However, when FSIS established the initial performance standards, the Agency made clear that "as more research is done and more data become available, and as more sophisticated techniques are developed for quantitative risk assessment for microbiological agents, it may be possible and appropriate to develop performance standards that use a different approach" (61 FR 38806, 38836).

Since FSIS implemented the *Salmonella* performance standards, the Agency has evaluated whether certain types of *Salmonella* should be considered as adulterants in raw meat and poultry in response to petitions submitted to the Agency in 2011, 2014, and 2022. For example, in response to two petitions submitted by CSPI in 2011 and 2014, FSIS evaluated whether certain antibiotic-resistant (ABR) *Salmonella* serotypes could be considered as adulterants in raw meat and raw poultry products under the Federal Meat Inspection Act (FMIA) and PPIA. The 2011 petition asked FSIS to declare four strains of ABR *Salmonella* as adulterants when found in ground meats and poultry.⁶³ FSIS denied the 2011 petition without prejudice on July 31, 2014. In its response, FSIS explained that the data available at that time "did not support giving the four strains of ABR *Salmonella* identified in the petition a different status as an adulterant in raw ground beef and raw ground poultry than *Salmonella* strains that are susceptible to antibiotics."⁶⁴ The response stated that additional data on the characteristics of ABR *Salmonella* are needed to determine whether certain strains could qualify as adulterants under the FMIA and PPIA.

⁶³ CSPI petition #11–06 (May 25, 2011), "Petition for an Interpretive Rule Declaring Specific Strains of Antibiotic Resistant *Salmonella* to be Adulterants With the Meaning of 21 U.S.C. 601(m)(1) and (2)(a) and 21 U.S.C. 453(g)(1) and (2)(a)." FSIS final response (July 31, 2014) at: <https://www.fsis.usda.gov/policy/petitions/petition-submitted-center-science-public-interest-0>.

⁶⁴ FSIS final response to petition #11–06, p. 1.

The response also noted that because the Agency's denial was without prejudice, the petitioner was not precluded from submitting a revised petition that includes additional information to support the requested action.

The CSPI 2014 petition was a refiling of the 2011 petition and asked that FSIS declare certain strains of ABR *Salmonella* as adulterants in all meat and poultry products based on evidence attained since 2011 that, according to the petition, demonstrates both ground and intact poultry products are associated with outbreaks from ABR *Salmonella*.⁶⁵ Based on the data available at the time, FSIS denied the 2014 petition without prejudice on February 7, 2018. In its response to the petition, the Agency concluded that, with respect to its status as an adulterant, "*Salmonella* does not appear to present the same issues as [*E. coli* O157:H7], regardless of whether it is resistant or susceptible to antibiotics."⁶⁶ Therefore, the Agency stated that it "had no basis to conclude that either ABR-*Salmonella* or non-ABR *Salmonella* would render injurious to health what consumers consider to be properly cooked meat or poultry."⁶⁷

As discussed above, FSIS also considered whether certain *Salmonella* serotypes should be considered as adulterants in all meat and poultry products in response to the January 2020 petition submitted by Marler Clark LLP requesting FSIS to declare 31 *Salmonella* serotypes that have been associated with foodborne illness outbreaks to be adulterants of all meat and poultry products.⁶⁸ As noted above, FSIS denied the petition without prejudice. However, in its response, the Agency explained that it believes that an updated *Salmonella* strategy is necessary to reduce *Salmonella* illnesses associated with poultry products and that FSIS had initiated several activities designed to gather data and information to inform and support future actions related to *Salmonella* in poultry. These activities were discussed

in the *Background* section of this document.

Since FSIS denied the 2020 Marler petition, many of the activities that were initiated to inform an updated *Salmonella* strategy have generated new studies and information that FSIS has determined support a revised approach on the use of standards to address *Salmonella* in final raw poultry products. For example, after FSIS issued the 2020 Marler petition denial, the Agency completed its chicken carcass exploratory sampling program, NACMCF issued its final 2023 report, FSIS completed the peer-reviewed 2023 risk profile as well as the peer-reviewed 2023 risk assessments for chicken and turkey. The Agency also held the November 3, 2022, public meeting and received written and oral stakeholder input on the proposed *Salmonella* Framework that the Agency was considering.

As part of Component Three of the draft *Salmonella* Framework, FSIS stated that it was assessing whether certain levels and/or types of *Salmonella* on raw poultry present an elevated risk of causing human illness such that they should be considered adulterants. To evaluate the status of *Salmonella* in raw poultry under the PPIA, FSIS has considered stakeholder input received in response to the draft *Salmonella* Framework together with the available scientific information on *Salmonella* in poultry, including recommendations in the 2023 NACMCF report, the findings of the 2023 risk profile, and the results of the 2023 quantitative risk assessments for *Salmonella* in chicken and turkey. Additionally, because FSIS has relied in part on ordinary consumer cooking practices to determine the status of pathogens as adulterants in raw products, the Agency also considered the available consumer behavior research to evaluate whether ordinary consumer cooking and handling practices are able to consistently mitigate the risk associated with certain raw poultry products contaminated with certain levels and/or types of *Salmonella*. Based on its evaluation of scientific evidence, the Agency has tentatively concluded that there are certain raw poultry products and *Salmonella* levels and serotype pairs that have characteristics that distinguish them from other raw products contaminated with *Salmonella*. FSIS has also tentatively determined that, based on its evaluation of available scientific evidence, *Salmonella*, when present in these specific products at the specified levels and serotypes, should be considered as an adulterant.

Accordingly, FSIS is proposing final product standards that would define whether certain raw poultry products contaminated with certain *Salmonella* levels and serotypes are adulterants as defined in the PPIA. Specifically, FSIS had tentatively determined that chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey are adulterated if they contain *Salmonella* at or above 10 cfu/per milliliter or gram (10 cfu/mL(g)) in analytical portion (*i.e.*, mL of rinsate or gram of product) and contain any detectable level of at least one of the *Salmonella* serotypes of public health significance identified for that product. The *Salmonella* serotypes of public health significance identified for chicken carcasses, chicken parts, and comminuted chicken are Enteritidis, Typhimurium, and I 4,[5],12:i:- and for comminuted turkey are Hadar, Typhimurium, and Muenchen. As discussed below, these serotypes were the three most highly virulent serotypes associated with a commodity identified in the 2023 risk assessments. The *Salmonella* serotypes of public health significance will likely change over time as the serotypes commonly associated with human illnesses change. FSIS will continue to track annual targets for reducing the proportion of poultry samples that contain *Salmonella* serotypes of public health significance, as well as data on rates for serotypes commonly associated with human illness to inform future revisions to the *Salmonella* serotypes of public health significance. FSIS would publicly announce and request comments on any changes to the serotypes of public health significance in the **Federal Register**. Additionally, should FSIS finalize the proposed final product standards, the Agency intends to further evaluate and, if necessary, refine these standards as advances in science and technology related to pathogen levels, serotypes, and virulence genes become available. As discussed above, if FSIS finalizes the proposed final product standards, the Agency intends to re-evaluate the serotypes of public health concern every 3–5 years at a minimum and whenever new information on *Salmonella* serotypes associated with human illness become available.

Under this proposed determination, chicken parts subject to the final product standards would include legs, breasts, wings, thighs, quarters, and halves. FSIS is not proposing final product standards for turkey carcasses or parts because historically there have been very few *Salmonella*-positive detections in turkey carcasses. Additionally, the Agency does not

⁶⁵ CSPI petition #14–01 (October 1, 2014), "Request for an Interpretive Rule Declaring Certain Antibiotic-Resistant Strains of *Salmonella* to be Adulterants" and FSIS final response (February 7, 2018) at: <https://www.fsis.usda.gov/federal-register/petitions/request-interpretive-rule-declaring-certain-antibiotic-resistant-strains>.

⁶⁶ FSIS final response to petition #14–06, p. 6.

⁶⁷ FSIS final response to petition #14–06, p. 7.

⁶⁸ Marler Clark LLP petition # 20–01 "Petition for an Interpretive Rule Declaring 'Outbreak' Serotypes of *Salmonella enteritica* subspecies to be Adulterants" dated January 19, 2020. Available at: <https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-Salmonella-serotypes>.

quantify *Salmonella* on turkey carcass sponge samples and has never had a *Salmonella* verification sampling program for turkey parts. Thus, it was not possible for the 2023 turkey risk assessment to assess the risk management questions for turkey parts or provide a robust assessment on final product standards for turkey carcasses that FSIS could use to inform the development of final product standards for these products.

The basis for the proposed final product standards and FSIS' proposed determination that products that contain the *Salmonella* levels and serotypes identified in the proposed final product standards are adulterated is discussed below.

B. Pathogens as Adulterants in Raw and Not-Ready-To Eat Meat and Poultry Products

Under the FMIA (21 U.S.C. 601 *et seq.*) and the PPIA (21 U.S.C. 451 *et seq.*), a meat or poultry product is adulterated if, among other circumstances, "it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such article shall not be considered adulterated . . . if the quantity of such substance in or on such article does not ordinarily render it injurious to health" (21 U.S.C. 601(m)(1); 21 U.S.C. 453(g)(1)). Meat and poultry products are also adulterated if they are "unsound, unhealthful, unwholesome, or otherwise unfit for human food" (21 U.S.C. 601(m)(3); 21 U.S.C. 453(g)(3)).

Historically, most foodborne pathogens, including *Salmonella*, have not been considered as adulterants of raw and other NRTE meat and poultry products based on the assumption that ordinary cooking is generally sufficient to destroy the pathogens.^{69 70} One exception to date is *E. coli* O157:H7 and certain non-O157 Shiga toxin-producing *Escherichia coli* (STEC) in raw, non-

intact beef products and intact cuts that are to be further processed into non-intact products before being distributed for consumption. These pathogens are considered adulterants in these specific raw products because they render "injurious to health" what many consumers believe to be properly cooked non-intact beef products.⁷¹ FSIS had also determined that when contaminated with these pathogens, raw, non-intact beef products are "unhealthful, unwholesome, and otherwise unfit for human food."⁷²

When FSIS determined that certain STEC are adulterants in non-intact raw beef products, the Agency identified characteristics associated with both the pathogen and the product that distinguish them from other raw products contaminated with other pathogens. Specially, FSIS considered that these STEC had been associated with illnesses and outbreaks, have a relatively low infectious dose, cause serious human illness, and can survive what many consumers consider to be ordinary preparation and cooking practices of non-intact beef products.

As discussed above, on May 1, 2024, FSIS published a final determination to declare that NRTE breaded stuffed chicken products that contain *Salmonella* at levels of 1 cfu/g or higher are adulterated within the meaning of the PPIA.⁷³ In that determination, FSIS stated that while certain STEC have been the only pathogens to date that are considered adulterants in a raw product, certain other pathogens may also exhibit characteristics that would meet the standard to be considered as adulterants in a specific raw product. In the proposed determination, FSIS also stated that if the Agency became aware of evidence to show that a specific pathogen and product pair presents a significant public health risk, it would consider the factors it identified to distinguish certain STEC from other pathogens as adulterants in certain raw beef products to determine the pathogen's status as an adulterant, *i.e.*, pathogen serogroups or types associated with human illnesses; pathogen infectious dose; pathogen and serious human illnesses; and traditional or ordinary cooking practices. After applying these factors to *Salmonella* in NRTE breaded stuffed chicken products, FSIS decided to declare that NRTE

breaded stuffed chicken products that contain *Salmonella* at levels of 1 cfu/g or higher are adulterated within the meaning of the PPIA.

Specifically, FSIS determined that NRTE breaded stuffed chicken products that contain *Salmonella* at 1 cfu/g or higher are adulterated under 21 U.S.C. 453 (g)(1) because, in these particular products, *Salmonella* is an added substance that may render them injurious to health (89 FR 35034–35035). FSIS also determined that *Salmonella* at 1 cfu/g in NRTE breaded stuffed chicken meets the more stringent "ordinarily injurious to health" standard for substances that are not added as provided in 21 U.S.C. 453(g)(1)) (89 FR 35035). Finally, FSIS determined that NRTE breaded stuffed chicken products contaminated with *Salmonella* at levels of 1 cfu/g or higher present a serious risk of causing *Salmonella* illnesses and that this elevated risk of illness makes them "unhealthful, unwholesome, or otherwise unfit for human food" as defined in 21 U.S.C. 453(g)(3) (89 FR 35037).

C. The Adulteration Standard for Raw Poultry Products

Consistent with its approach used to determine the status of certain STEC in certain raw beef products and to determine the status of *Salmonella* at certain levels in NRTE breaded stuffed chicken products, FSIS has evaluated the available information on *Salmonella* serotypes associated with human illnesses, the *Salmonella* infectious dose, the severity of human illnesses caused by *Salmonella*, and ordinary consumer preparation practices associated with these raw poultry products to assess the status of *Salmonella* in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. Based on this evaluation, FSIS is proposing final product standards for levels and serotypes of *Salmonella* in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. FSIS has also tentatively determined that chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain the *Salmonella* levels and serotypes identified in the final product standard are adulterated as defined in the PPIA because they contain a poisonous or deleterious substance that renders them "injurious to health" as defined in 21 U.S.C. 453(g)(1). Additionally, FSIS has tentatively determined that chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain the *Salmonella* levels and

⁶⁹ See proposed rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems," February 4, 1993 (60 FR 6774 at 6798–6799) and final rule "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems," July 25, 1996 (61 FR 38806 at 38835.) See also *Amer. Public Health Ass'n v. Butz*, 511 F.2d 331 (U.S. App. DC, 1974).

⁷⁰ When raw meat or poultry products are associated with an illness outbreak and contain pathogens that are not considered adulterants in those products, FSIS considers the product linked to the illness outbreak to be adulterated under 21 U.S.C. 601(m)(3) or 453(g)(3) because the product is ". . . unsound, unhealthful, unwholesome, or otherwise unfit for human food" (77 FR 72681, 72689 (Dec. 6, 2012)). Products that contain an adulterant are considered adulterated under 21 U.S.C. 601(m)(1) or 453(g)(1) even if they are not linked to an illness outbreak.

⁷¹ See *Texas Food Industry Association v. Espy*, 870 F. Supp. 143 (1994).

⁷² Shiga-Toxin Producing *Escherichia coli* in Certain Raw Beef Products (76 FR 58157, 58159).

⁷³ *Salmonella* in Not-Ready-To-Eat Breaded Stuffed Chicken Products; May 1, 2024 (89 FR 35033) at: https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-2022-0013F.pdf.

serotypes identified in the final product standards are adulterated as defined in 21 U.S.C. 453(g)(3) because their elevated risk of illness makes them “unhealthful, unwholesome, or otherwise unfit for human food.”⁷⁴ The basis for this tentative determination is discussed below.

1. Pathogen Serogroups or Types Associated With Human Illness

Approximately 2,500 *Salmonella* serotypes have been identified,⁷⁵ though not all serotypes have been isolated from poultry. Most human infections have been epidemiologically linked to fewer than 100 serotypes. Almost all strains of *Salmonella* are pathogenic as they can invade, replicate and survive in human host cells, resulting in potentially fatal disease,⁷⁶ though not all are equally likely to cause illness. To evaluate which *Salmonella* serotypes are most likely to be associated with human illness, FSIS considered information from the 2023 NACMCF report, the 2023 risk profile, and the 2023 risk assessments.

NACMCF report. In the 2023 NACMCF report, the committee considered how foodborne illness surveillance data on human *Salmonella* illnesses, data from foodborne outbreaks associated with *Salmonella* in poultry,

and data on *Salmonella* serotypes in poultry products can be used to identify the *Salmonella* serotypes of greatest public health concern associated with specific poultry products. The report stated that the relevant serotypes of greatest public health concern are those that are common causes of reported human illness, are present in poultry, and are transmitted through foods. The report noted that CDC surveillance provides data on the frequency of diagnosed illness caused by each serotype and that FSIS data from slaughterhouses and retail surveys can confirm the presence and frequency of serotypes in raw poultry. The report also concluded that outbreak investigations of foodborne salmonellosis can provide direct evidence that foodborne transmission of a particular serotype occurs.

The NACMCF report noted that several approaches have been used to attribute human salmonellosis to specific foods and sources. These include case-control studies, analysis of reported foodborne outbreaks, and most recently, source attribution based on WGS genotyping. The report concluded that attribution based on outbreak data and on genotype both give the greatest weight to data from the most recent years. NACMCF found that poultry is the leading source of human salmonellosis, based on both reported outbreaks and genotype-based attribution methods. The committee also stated that these data show that a small number of serotypes account for most poultry-associated salmonellosis led by Enteritidis, Typhimurium, I:4,5,12:i:-, Infantis, and Heidelberg, and even fewer serogroups: groups O:4 (formerly group B), O:7 (group C1), and O:9 (group D1).

Risk profile. In the 2023 risk profile, FSIS conducted a review of all information on *Salmonella* outbreaks reported in the CDC National Outbreak Reporting System (NORS), PubMed, and the web pages FSIS uses for maintaining records on outbreak investigations to determine which *Salmonella* serotypes or subtypes are linked to foodborne illnesses or outbreaks from consuming specific raw and NRTE chicken or turkey products. From these data sources, the risk profile identified 210 foodborne *Salmonella* outbreaks linked to poultry products between 1998 and 2020. Of these 210 foodborne *Salmonella* outbreaks, 84.8 percent (178/210) were linked to chicken products and 15.2 percent (32/210) to turkey products. Serotype information was available for 93.3 percent (196/210) of these outbreaks, including 2.4 percent (5/210) associated with multiple serotypes.

For the purposes of the risk profile, *Salmonella* subtypes associated with human illness outbreaks attributed to consuming chicken or turkey are referred to as “subtypes of concern.” The 196 outbreaks in which serotype information was available involved 32 subtypes of concern. Seventeen serotypes of concern were only linked to chicken products. One serotype of concern, Reading, was linked to a turkey product but not to chicken. There were 10 serotypes linked to both chicken and turkey products.

According to the data compiled for the risk profile, the 210 outbreaks include 7,018 illnesses, 1,202 hospitalizations, and 10 deaths attributed to poultry products. When considering outbreaks associated with either chicken or turkey products, nine serotypes accounted for 85 percent (5,794/7,018) of illnesses. Each of these subtypes caused 200 or more outbreak associated illnesses in chicken and/or turkey from 1998–2020. The top seven subtypes associated with chicken were Enteritidis, Heidelberg, Typhimurium, I 4,[5],12:i:-, Montevideo, Thompson, and Infantis. The top four subtypes associated with turkey were Enteritidis, Reading, Muenchen, and Heidelberg. The most common subtypes of concern associated with poultry products overall were Enteritidis, Heidelberg, Typhimurium, and I 4,[5],12:i:-.

Risk assessments. The chicken and turkey risk assessments leveraged FSIS’ 2023 risk profile to identify *Salmonella* serotypes in chicken and turkey linked to foodborne illness and adopted the guidance on risk assessment recommendations from the 2023 NACMCF report. FSIS developed a probabilistic risk assessment model describing current *Salmonella* contamination in raw poultry products and the potential human exposure through consumption of servings derived from these raw products. Data from FSIS microbiological baseline studies, routine PR/HACCP sampling, and exploratory sampling programs were used to describe *Salmonella* in chicken carcasses, fabricated chicken parts, and comminuted chicken and turkey products. FSIS partnered with EpiX Analytics through a Cooperative Agreement with the University of Maryland to incorporate genomics into the risk assessment models developed by FSIS. FSIS selected the grouping of serotypes into two “clusters” (i.e., “higher virulence” and “lower virulence”) based on the virulence profiles, exposure in food, and foodborne epidemiological data and EpiX Analytics then derived two virulence-adjusted *Salmonella* dose-

⁷⁴ Under 21 U.S.C. 601(m)(3) of the FMIA and 21 U.S.C. 453(g)(3) of the PPIA, a meat or poultry product is adulterated “if it consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food.” Historically, FSIS has interpreted the phrase “is for any other reason unsound, unhealthful, or otherwise unfit for human food” as providing a separate basis for adulteration than consists of “any filthy, putrid, or decomposed substance.” Thus, meat or poultry products that FSIS has determined are “otherwise unfit for human food” within the meaning of 21 U.S.C. 601(m)(3) and 21 U.S.C. 453(g)(3) do not also need to consist “in whole or in part of any filthy, putrid, or decomposed substance.” For example, when raw meat or poultry products are associated with an illness outbreak but contain pathogens that are not considered adulterants in raw products, FSIS has found products linked to the illness outbreak to be adulterated under 21 U.S.C. 601(m)(3) or 21 U.S.C. 453(g)(3) because they are “unsound, unhealthful, unwholesome or otherwise unfit for human food” (77 FR 72689). FSIS has also determined that certain materials from cattle as well as the carcasses of non-ambulatory disabled cattle are adulterated because they present a sufficient risk of exposing humans to the bovine spongiform encephalopathy agent such as to render them “unfit for human food” under 21 U.S.C. 601(m)(3) (69 FR 1862).

⁷⁵ Brenner FW, Villar RG, Angulo FJ, Tauxe R, Swaminathan B. *Salmonella* nomenclature. J Clin Microbiol. 2000 Jul;38(7):2465–7. doi: 10.1128/JCM.38.7.2465–2467.2000. PMID: 10878026; PMCID: PMC86943.

⁷⁶ Shu-Kee Eng, Priyia Pusparajah, Nurul-Syakima Ab Mutalib, Hooi-Leng Ser, Kok-Gan Chan & Learn-Han Lee (2015) *Salmonella*: A review on pathogenesis, epidemiology and antibiotic resistance, Frontiers in Life Science, 8:3, 284–293, DOI: 10.1080/21553769.2015.1051243.

response models.⁷⁷ FSIS used these dose-response models in its quantitative risk assessment models for *Salmonella* in chicken and turkey. FSIS assessed public health benefits, in terms of annual illnesses prevented, by modeling the impact of removal of lots with *Salmonella* at or above a certain level or with certain serotypes and simulated the probability of illness per serving.

The analysis in the chicken risk assessment found the probability of illness from chicken contaminated with “higher virulence” serotypes exposures is 5.66 times larger than the probability of illness from chicken contaminated with “lower virulence” serotypes. In FSIS sampling, the average annual percentage of “higher virulence” serotypes is approximately 26 percent for chicken carcasses, 32 percent for comminuted chicken product, and 35 percent for chicken parts. The chicken risk assessment identified Enteritidis, Typhimurium, I 4,[5], 12:i:-, Hadar, and Litchfield as the five most frequent “higher virulence” serotypes in chicken. The chicken risk assessment identified Kentucky, Infantis, Schwarzengrund, Heidelberg, and Thompson as the five most frequent “lower virulence” serotypes in chicken.

The analysis in the turkey risk assessment found there are 49 different serotypes in comminuted turkey products, as compared to only 19 serotypes isolated on turkey carcasses in the Agency’s pathogen reduction *Salmonella* sampling program. Reading and Hadar ranked as the top two in both carcasses and comminuted, comprising more than 30 percent of the serotype samples for each commodity. Hadar was also observed most often in the FSIS microbiological baseline studies for *Salmonella* in turkey⁷⁸ and appeared in the top ten CDC FoodNet annual summary from 2020.⁷⁹

The turkey risk assessment identified Hadar, I 4,[5], 12:i:-, Muenchen Typhimurium, and Saintpaul as the five most frequent “higher virulence” serotypes in turkey. The turkey risk assessment identified Reading, Infantis, Schwarzengrund, Uganda, and Agona as the five most frequent “lower virulence” serotypes in turkey.

The list of serotypes of public health significance is highly important for this

framework, as it determines whether products are adulterated as defined in the PPIA. FSIS recognizes that science constantly evolves and therefore our understanding of virulence and other factors will evolve over time.

The FSIS risk assessments utilized bioinformatic tools and methods for clustering *Salmonella* serotypes, and an optimized new dose-response model developed by EpiX Analytics. This model was genomically validated, and results corresponded with other standard bioinformatic techniques differentiating serotypes based on lineage features. Genomic virulence factors were used for the initial grouping of serotypes and the higher virulence serotypes of public health significance were validated by CDC illness outcome data and FSIS sampling data. FSIS did not rely solely on the genomic component of the risk assessment model to determine the list of serotypes of public health significance. FSIS developed a cohesive risk model that incorporates virulence factors, epidemiological outcomes, and frequency of exposure and conducted sensitivity and uncertainty analyses of the full model and the virulence component. FSIS requests comments on the full risk model and the uncertainty and sensitivity analyses, whether they are fit for the purpose of determining the serotypes of public health significance, and what model adjustments or other approaches FSIS should consider in the determination to adapt to evolving data, technology, and analytical methods.

FSIS recognizes that science consistently evolves, and therefore the Agency’s understanding of virulence and other factors will evolve over time. Because the scientific understanding of virulence and other relevant factors evolves, FSIS is requesting comments on whether the EpiX Analytics serotype clustering and dose-response adjustment (*i.e.*, risk multiplier) used the best available data and genetic factors relevant to *Salmonella* risk and contamination in the United States poultry population. Additionally, FSIS is requesting comment on potential improvements to the serotype clustering robustness analysis and the risk multiplier sensitivity analysis.

Final product standards serotypes of public health significance. As noted above, as part of USDA’s strategic and performance planning process for FY2022–2026, FSIS established a new KPI targeted to reduce the proportion of FSIS poultry samples with *Salmonella* serotypes commonly associated with

human illnesses.⁸⁰ The KPI serotype list was determined using summary statistics, namely comparison of historical Agency sampling data for poultry products and CDC FoodNet data to determine the *Salmonella* serotypes commonly associated with human illness. It is important to note that the KPI is used as an internal performance measure for FSIS, which is not intended to assess industry performance, and, as such, was not externally peer reviewed. FSIS’ analysis found that these serotypes are Infantis, Enteritidis, and Typhimurium. Thus, FSIS selected these serotypes as a KPI target for all raw poultry.

When developing the proposed final product standards, FSIS considered incorporating the KPI serotypes as the “serotypes of public health significance” as suggested by some of the comments on the initial draft *Salmonella* Framework. However, after evaluating the information on serotypes discussed above, FSIS concluded that, while the KPI serotypes are useful for strategic and performance planning purposes, the KPI was not a robust scientific tool by which to identify serotypes of public health concern as adulterants. Further, the KPI identified serotypes of public health concern for poultry as a whole, and not by individual product (*chicken v. turkey*). The KPI does not reflect the serotypes most commonly associated with illnesses from turkey, and the chicken risk assessment determined that Infantis is not a highly virulent serotype.

Therefore, instead of proposing serotypes of public health significance based solely on the KPI criteria, FSIS has decided that the proposed serotypes of public health significance should be based on a thorough review of multiple FSIS scientific analyses in this area, including the 2023 NACMCF report, the externally peer-reviewed 2023 risk profile, and the two externally peer-reviewed risk assessments. Based on consideration of these scientific efforts, these serotypes are Enteritidis, Typhimurium, and I 4,[5], 12:i:- for chicken carcasses, chicken parts, and comminuted chicken, and Hadar, Typhimurium, and Muenchen for comminuted turkey. FSIS has determined that these serotypes more accurately reflect serotypes most likely

⁷⁷ Full details of the EpiX Analytics methodology are provided in Appendix A of the chicken Risk Assessment in the report entitled “Using genomics to identify nontyphoidal *Salmonella* serovars of concern and estimating dose-response models amenable to risk assessments in poultry.”

⁷⁸ National Microbiological Baseline Data Collection Program: Young Turkey Survey available at: <https://www.fsis.usda.gov/node/1972>

⁷⁹ CDC FoodNet Reports available at: <https://www.cdc.gov/foodnet/reports/index.html>.

⁸⁰ FY2022–2024 Food Safety Key Performance Indicator. Available at: <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry/salmonella-0#:~:text=FY%202022-2026%20Food%20Safety%20Key%20Performance%20Indicator%20A,the%20USDA%20Fiscal%20Year%20%28FY%29%202022-2026%20Strategic%20Plan.>

to cause illnesses because they are based on the same epidemiological evidence used in the risk profile and the 2023 NACMCF report, but pivotally also include analyses conducted in the risk assessments, which includes an additional analysis of virulence factors, epidemiological outcomes, and frequency of exposure.

The 2023 NACMCF report, the 2023 risk profile, and the Agency's KPI all identify *Infantis* as among the serotypes commonly associated with poultry-related illnesses, the scientific evidence does not support that the rising trend in *Infantis* illnesses is associated with chicken consumption. The emergence of *Infantis* in FSIS chicken sampling in 2016 did not correspond to a proportional increase in human *Infantis* illnesses, which have been on the rise in the United States since 2010.⁸¹ Put another way, given the volume of chicken consumed by the American public—much of which is contaminated with *Infantis*—if it were a high-risk poultry serotype, we would predict more *Infantis* illnesses. Furthermore, the 2023 chicken risk assessment, which used published genomic methods,⁸² also determined that *Infantis* is less virulent than many other serotypes with the exception of Kentucky. Additionally, the risk profile found that *Infantis* accounted for 2 percent of outbreaks identified in the CDC NORS, while I 4,[5],12:i:- accounted for 4.1 percent of those outbreaks.

However, FSIS is aware *Salmonella* *Infantis* remains of considerable concern in terms of potential severity of illness⁸³ and antimicrobial resistance, as can be observed in its routine inclusion in national lists of top serotypes by outbreak numbers and sporadic case counts.⁸⁴ CDC estimates that the

serotypes of public health significance represent 66 percent of outbreaks and 68 percent of outbreak-associated illnesses in the past five years of outbreak data; including *Infantis* as a fourth serotype increases these figures to 75 percent and 79 percent, respectively.⁸⁵ Given the notable concern of the *Salmonella* *Infantis* REPJFX01 strain raised by the CDC and other public health experts, FSIS is requesting comment on the possible inclusion of *Infantis* as a serotype of public health significance. As discussed above, FSIS was not able to validate that chicken consumption is the major direct driver of the increased *Infantis* rates and is additionally asking for comment on scientific studies and data sources on this topic that are in line with regulatory evidence guidelines.

As research into *Salmonella* virulence factors and their gene functions continues to develop, clustering should be revisited to ensure reliability and consistency. FSIS took care to align the virulence modeling in the risk assessments with epidemiological and clinical patterns in surveillance data: however, current bioinformatics methods are based on the serotypes that have been the consistently highest illness causes (*Enteritidis* and *Typhimurium*) across time rather than the full genetic landscape of *Salmonella*. Furthermore, lower virulence serotypes can still outcompete higher virulence serotypes and pose public health risks. As noted above, the list of serotypes of public health significance is essential to this framework, as it determines whether products are adulterated as defined in the PPIA. FSIS requests comments on the initial proposed serotypes of public health significance and what scientific evidence and genetic *Salmonella* data sources beyond the most often studied serotypes should be considered, in addition to that already considered, in the identification of the most highly

System Dashboard. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC. Last accessed 06/07/2024. Available from URL: www.cdc.gov/norsdashboard/; Centers for Disease Control and Prevention (CDC). FoodNet Fast Dashboard. Atlanta, Georgia: U.S. Department of Health and Human Services, CDC. Last accessed 06/07/2024. Available from URL: <https://www.cdc.gov/foodnet/foodnet-fast.html>.

⁸⁵ These estimates are based a CDC pilot analysis of data (CDC unpublished data) presented in 2023 to the National Advisory Committee on Microbiological Criteria for Foods. See: NACMCF final report "Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products" (March 2023), available at: <https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021>.

virulent serotypes identified in the risk assessments, which includes a thorough review of multiple FSIS efforts in this area, including the 2023 NACMCF report and the externally peer reviewed 2023 risk profile.

2. Dose Considerations

As summarized in the 2023 risk profile, although *Salmonella* data are limited, international and domestic outbreak investigations associated with a variety of food products have been used to estimate the relationship between the number of organisms consumed and the probability of illness. These estimates, and more broadly the emergence of dose-response modeling and quantitative risk assessment over the past 25 years, are all based on the concept that a single bacterium is all that is necessary to cause infection and/or illness, that is to say the single-hit model.⁸⁶ FSIS' evaluation and summarization of dose-response models, as well as analysis of outbreak data where estimates for the number of organisms consumed were available, demonstrate that the scientific consensus is that exposure to a small number of *Salmonella* organisms can result in foodborne illness.

In a study published in 2010 (the Teunis 2010 study), and included in the 2023 risk profile, using a dose-response model approach utilizing outbreak data, and accounting for variation among outbreaks represented by the data, the *Salmonella* median illness dose was 36 cfus (with 95 percent prediction interval of 0.69–1.26×10⁷ cfu).⁸⁷ The median illness dose refers to the dose at which 50 percent of individuals in an exposed population will experience symptomatic illness. The median illness dose and its prediction interval reflect variability among outbreak strains and exposed populations and uncertainty about the dose-response relationship. Thus, it serves as a useful metric for comparing the pathogenicity of different serotypes. Additionally, the World Health Organization Food and Agriculture Organization of the United Nations developed a dose-response approach for risk assessments for *Salmonella*.⁸⁸ Also

⁸⁶ Teunis, P.F., & Havelaar, A.H. (2000). The Beta Poisson dose-response model is not a single-hit model. Risk analysis: an official publication of the Society for Risk Analysis, 20(4), 513–520. <https://doi.org/10.1111/0272-4332.204048>.

⁸⁷ Teunis P.F., et al., Dose-response modeling of *Salmonella* using outbreak data. *Int J Food Microbiol*, 2010. 144(2): p. 243–9; <https://doi.org/10.1016/j.jfoodmicro.2010.09.026>.

⁸⁸ World Health Organization, Risk assessment of *Salmonella* in eggs and broiler chickens, March 25, 2002. Available at: <https://www.who.int/publications/i/item/9291562293>.

⁸¹ NACMCF final report "Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products" (March 2023).

⁸² Fenske GJ, Pouzou JG, Pouillot R, Taylor DD, Costard S, Zagmutt FJ. The genomic and epidemiological virulence patterns of *Salmonella enterica* serovars in the United States. *PLoS One*. 2023 Dec 5;18(12):e0294624. doi: 10.1371/journal.pone.0294624. PMID: 38051743; PMCID: PMC10697515.

⁸³ FSIS is aware only of results on *Infantis* severity of illness that reinforce it is not a high risk serotype: Brown AC, Chen JC, Watkins LK, et al. CTX-M-65 Extended-Spectrum β -Lactamase-Producing *Salmonella enterica* Serotype *Infantis*, United States. *Emerging Infectious Diseases*. 2018;24(12):2284–2291. doi:10.3201/eid2412.180500.

⁸⁴ Centers for Disease Control and Prevention (CDC). BEAM (Bacteria, Enterics, Amoeba, and Mycotics) Dashboard. Atlanta, Georgia: U.S. Department of Health and Human Services. www.cdc.gov/nceizid/dfwed/BEAM-dashboard.html. Accessed 06/07/2024; Centers for Disease Control and Prevention (CDC). National Outbreak Reporting

using outbreaks, the model estimated a 13 percent chance of becoming ill if ingesting an average dose of 100 organisms. Even at the level of 1 organism ingested, there was still a non-zero chance of illness (0.25 percent).

A study published after the 2023 FSIS risk profile was peer-reviewed revisited the 2010 Teunis study discussed above.⁸⁹ Using outbreak serotype data, and accounting for variation among outbreaks within a particular serotype, the median *Salmonella* dose predicted to result in 50 percent of exposed individuals becoming ill (IID₅₀) was 3,360 cfu (95 percent range: 18–3.2×10⁹), 1,500 cfu (38–8.8×10⁷), and 1 cfu (0.69–1.0×10⁶) for Enteritidis, Typhimurium and Infantis, respectively. For the same study, the median *Salmonella* dose predicted to result in 1 percent of exposed individuals becoming ill (IID₀₁) was 0.6 cfu (95 percent range: 0.24–1.9), 9.9 cfu (0.32–57), and 0.07 cfu (0.01–2.0×10⁴) for Enteritidis, Typhimurium and Infantis, respectively. These results describe that individuals exposed to small doses of *Salmonella* can experience symptomatic illness. Other *Salmonella* serotypes were also found to cause illness at small doses including Heidelberg (IID₅₀=323 cfu and IID₀₁=1 cfu) and Schwarzengrund (IID₅₀=0.8 cfu and IID₀₁=0.04 cfu).

Furthermore, the 2023 FSIS risk assessments developed two virulence-adjusted dose-response models (one for low virulence *Salmonella* serotypes, and another for high virulence *Salmonella* serotypes), which utilize the work described in the 2023 FSIS risk profile to poultry specific serotypes. The high virulence dose-response model (which includes the serotypes of public health significance) was estimated using outbreak data and employed a beta-Poisson model of infection for a given dose as outlined in the 2023 risk profile. Risk multipliers, derived from epidemiological outbreak data attributed to poultry sources, with consideration of prevalence in animal sources from FSIS poultry sampling programs, were then used to scale the relative risk of illness from exposures to each cluster. The probability of illness from consuming chicken containing high virulence *Salmonella* serotypes exposures is 5.66 times greater than the probability of illness from exposure to chicken products containing low virulence *Salmonella* serotypes. The dose-response findings of the 2023 risk

assessment rely on the single-hit model, and the virulence adjusted dose-response models estimate of a 1 in 100 probability of illness at 1 cfu of high virulence *Salmonella* per serving and a 0.2 in 100 probability of illnesses at 1 cfu of low virulence *Salmonella* per serving. While the median illness is not attained by the low virulence *Salmonella* dose response model, the median illness dose described by the dose-response model for serotypes of public health significance is approximately 2000 cfu.

As summarized in the 2023 risk profile, five *Salmonella* foodborne outbreaks have shown that *Salmonella* can cause illness from exposure of 10 or fewer organisms per person.⁹⁰ Additionally, several outbreaks from a range of *Salmonella* serotypes in various food products have shown that exposure from 11 to 420 organisms per person can result in illness.⁹¹ Thus, in

these published studies, illnesses resulted from doses ranging from 1 to 420 *Salmonella* organisms per person.

The 2023 risk profile identified 32 *Salmonella* serotypes of concern linked to foodborne *Salmonella* outbreaks from chicken and turkey products. These identified serotypes of concern informed all subsequent risk management questions, including whether exposure to a small number of these serotypes result in foodborne illness. Because the *Salmonella* serotypes of public health significance identified in the final product standards are among the 32 *Salmonella* serotypes of concern identified in the risk profile and risk assessments, it is reasonable to conclude that the serotypes of public health significance in the final product standards all cause illness at a relatively low dose.

3. Severity of Illnesses

The 2023 risk profile found that exposure to the profile's *Salmonella* subtypes of concern, which include the final product standards serotypes of public health significance, can cause severe or debilitating human health outcomes. Although the symptoms of *Salmonella* infections are typically not reported to be as severe as some of those associated with STEC, *Salmonella* can cause bloody diarrhea, fever, abdominal cramps, nausea, and vomiting. In some instances, *Salmonella* enters the blood stream and makes its way to other areas of the body including, but not limited to, the heart, lung, bone, joints and the central nervous system.⁹² This can result in severe illness requiring hospitalizations and even death, especially in vulnerable populations, such as very young, elderly, and immunocompromised individuals. Even when *Salmonella* is no longer detectable in the body, prior *Salmonella* illness has also been associated with an increased risk in colon cancer.⁹³ Also, the illness can cause debilitating, long-lasting conditions including inflammatory bowel disease, irritable bowel syndrome and reactive arthritis.

to select controls. *Aust NZ J Public Health*, 1998. 22(5): p. 536–9; Tamber, S., E. Swist, and D. Oudit, Physicochemical and bacteriological characteristics of organic sprouted chia and flax seed powders implicated in a foodborne Salmonellosis outbreak. *Journal of Food Protection*, 2016. 79(5): p. 703–709.

⁹² Batz, M.B., et al., Long-Term consequences of foodborne illness. *Infect Dis Clin North Am*, Sept 2013. 28(3) p. 599–661; Hohmann, E.L., Nontyphoidal Salmonellosis, *Clin Infect Dis*, Sept 2001. 32 p. 263–269; Heymann, D. Salmonellosis. *Control of Communicable Disease Manual*, 2021.

⁹³ Mughini-Gras, L. et al. Increased colon cancer risk after severe *Salmonella* infection. *PLoS ONE*, 2018. 13(1): p. 1–19, <https://doi.org/10.1371/journal.pone.0189721>.

⁹⁰ Killalea, D., et al., International Epidemiological and Microbiological Study of Outbreak of *Salmonella* Agona Infection from a Ready to Eat Savoury Snack—I: England and Wales and the United States. 1996, British Medical Journal Publishing Group.; Shohat, T., et al., International Epidemiological and Microbiological Study of Outbreak of *Salmonella* Agona Infection from a Ready to Eat Savoury Snack—II: Israel. *BMJ*, 1996. 313(7065): p. 1107–1109.; D'aoust, J.Y. and J.Y.D. Aoust, Infective Dose of *Salmonella* Typhimurium in Cheddar Cheese. *American Journal of Epidemiology*, 1985. 122(4): p. 717–720.; D'aoust, J.Y., D.W. Warburton, and A.M. Sewell, *Salmonella* Typhimurium Phage-Type 10 from Cheddar Cheese Implicated in a Major Canadian Foodborne Outbreak. *Journal of Food Protection*, 1985. 48(12): p. 1062–1066.; Kapperud, G., et al., Outbreak of *Salmonella* Typhimurium Infection Traced to Contaminated Chocolate and Caused by a Strain Lacking the 60-Megadalton Virulence Plasmid. *J Clin Microbiol*, 1990. 28(12): p. 2597–601.; Hockin, J.C. et al., An International Outbreak of *Salmonella* Nima from Imported Chocolate. *J Food Prot*, 1989. 52(1): p. 51–54.; Lehmacher, A., Bockemuhl, J., and Aleksic, S. Nationwide outbreak of human salmonellosis in Germany due to contaminated paprika and paprika-powdered potato chips. 1995. *Epidemiol Infect*. 115: p. 501–11.

⁹¹ Kasuga F. et al., Archiving of food samples from restaurants and caterers—Quantitative profiling of outbreaks of foodborne *Salmonella* in Japan. *Journal of Food Protection*, 2004. 67: p. 2024–2032; Blaser, M.J., and Newman, L.S. A review of human salmonellosis: I. Infective dose. *Rev Infect Dis.*, 1982.4: p.1096–106; Abe, K., N. et al., Prolonged incubation period of Salmonellosis associated with low bacterial doses. *Journal of food protection*, 2004. 67: p. 2735–2740; Hara-Kudo, Y. and K. Takatori, Contamination level and ingestion dose of foodborne pathogens associated with infections. *Epidemiology and Infection*, 2011. 139: p. 1505–1510; Hennessy T.W., et al., A national outbreak of *Salmonella* enteritidis infections from ice cream. *N Engl J Med*, 1996. 334(20): p. 1281–6; Hedberg C.W., et al., A multistate outbreak of *Salmonella* javiana and *Salmonella* oranienburg infections due to consumption of contaminated cheese. *JAMA*, 1992. 268(22): p. 3203–7; Todd, E.C., et al., Outbreaks where food workers have been implicated in the spread of foodborne disease. Part 4. Infective doses and pathogen carriage. *J Food Prot*, 2004. 71: p. 2339–73; Scheil W., et al., A South Australian Mbandaka outbreak investigation using a database

⁸⁹ Teunis P.F.M. Dose response for *Salmonella* Typhimurium and Enteritidis and other nontyphoid enteric salmonellae. *Epidemics* 41 (2022) 100653; <https://doi.org/10.1016/j.epidem.2022.100653>.

Furthermore, a study that allows for a comparison of case-fatality proportions of both *Salmonella* and STEC O157 demonstrates a higher frequency of deaths among *Salmonella* cases than among STEC O157 cases.⁹⁴ The estimated annual domestic foodborne illnesses reported in the study were 1,027,561 and 63,153 for *Salmonella* and STEC O157, respectively. Annual deaths from domestic foodborne illnesses are 378 and 20 for *Salmonella* and STEC O157, respectively. Therefore, *Salmonella* deaths occur at a frequency of 4 per 10,000 illnesses, while STEC O157 deaths occur at a frequency of 3 per 10,000 illnesses.

4. Consumer Cooking Practices

As noted above, until recently, with the publication of the proposed determination on *Salmonella* in NRTE breaded stuffed chicken products, FSIS historically has not taken the position that certain *Salmonella* levels or serotypes render raw poultry products adulterated as defined in the PPIA. This position was based in part on the fact that proper cooking kills pathogens on raw product. However, as discussed below, several consumer behavior research studies suggest that ordinary consumer cooking and preparation practices for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey do not provide adequate assurance that these products will not be contaminated when consumed.

Consumer behavior research. FSIS recommends cooking poultry products until the center of the thickest part of the meat reaches a minimum internal temperature of 165 °F measured by using a thermometer to eliminate the presence of *Salmonella* and other foodborne pathogens.⁹⁵ However, although using a thermometer is the only reliable way to ensure that poultry is properly cooked, studies show that many consumers do not ordinarily use a thermometer to determine whether whole chicken, chicken parts, comminuted chicken, and comminuted turkey have reached an internal temperature sufficient to destroy *Salmonella*. Studies also show that many consumers that do use a thermometer do not always do so correctly.

In a study published in 2017, a web-enabled panel survey of U.S. adult grocery shoppers (n = 1,504) was

conducted to describe consumers' handling and preparation practices for raw poultry.⁹⁶ The purpose of the study was to characterize consumer food thermometer use and barriers to use. The study found that of the 62 percent of the survey respondents who reported owning a food thermometer, thermometer usage was highest among those cooking whole turkeys (73.2 percent). Fewer respondents reported using a thermometer when cooking whole chickens (56.7 percent), chicken breasts or other parts (26.3%), and meatloaf or a similar dish containing ground chicken or turkey (22.8 percent). Reported thermometer use was lowest among respondents cooking patties made with ground chicken or turkey (11.7 percent).

Participants who reported owning a food thermometer identified various reasons for not using a thermometer the last time they cooked poultry at home. For all cuts of poultry, the most common reason reported for not using a thermometer was use of another method to determine that the product was properly cooked (49.8 to 61.5 percent of respondents). The next most common reason selected was that the respondent never thought to use a thermometer (27 to 37.6 percent of respondents), which the researcher concluded suggests that these respondents do not consider it very important to use a food thermometer.

Of the respondents that reported using another method instead of a food thermometer, most reported that they determined that poultry is properly cooked by using visual cues, i.e., color, juice clarity, and cleanliness of probing utensil. Of the 61.5 percent of the respondents that reported using another method to determine that a whole turkey or chicken is properly cooked, 42.2 percent cut the food to check that it was no longer pink, 42.2 percent relied on cooking time, and 41 percent checked that the juices ran clear. Of the 56.1 percent of the respondents that reported using another method to determine that chicken and turkey parts were properly cooked, 67.6 percent cut the food to check that it was no longer pink, 46.2 percent relied on cooking time and 40 percent checked that the juices ran clear. And of the 49 percent of the respondents that reported using another method to determine whether ground chicken or turkey was properly cooked, 61.5 percent inserted a knife,

toothpick, or other utensil to see if it came out clean, 55.4 percent relied on cooking time, and 21.0 percent cut the food to check that it was no longer pink.

In an observational study published in 2016, 101 participants were observed as they prepared poultry and egg items to determine whether they followed food safety guidelines.⁹⁷ The poultry items prepared for the study were a baked whole chicken breast and a pan-fried ground turkey patty. The study found that thermometer use for all products was low. Only 37 percent of participants used a thermometer to determine that a chicken breast was properly cooked, and only 22 percent used a thermometer to determine that a turkey patty was properly cooked. For the chicken breast, the most common method used to determine doneness was cutting into the chicken (50 percent), followed by color (33 percent) and thermometer use (33 percent). For the turkey patty, the most common indicator used was color (39 percent), followed by cutting into it (30 percent), using a thermometer (22 percent), and looking at the juices (18 percent). The study also found that the participants who used a food thermometer often would use other methods, such as cutting into them or observing the juices, to determine if the poultry items were properly cooked.

The study also highlighted the importance of correctly using a thermometer to determine that poultry is properly cooked. Of the study participants who used a thermometer, 36 percent did not use it correctly in the chicken breast, the turkey patty, or both. The study also found that there was no statistical difference between a participant who did and did not use a thermometer in achieving an end point temperature of at least 165 °F in both the chicken breast and the turkey patty. Seventy-eight percent of participants that used a thermometer to cook the chicken breast reached a final internal temperature above 165 °F, compared to 75 percent for those who did not use a thermometer. Seventy-seven percent of participants who used a thermometer to cook a turkey patty reached a final internal temperature of at least 165 °F, compared to 66 percent of participants who did not use a thermometer.

⁹⁴ Scallan, et al., 2011.

⁹⁵ FSIS Safe Minimum Internal Temperature Chart. 2020; Available at: <https://www.fsis.usda.gov/food-safety/safe-food-handling-and-preparation/food-safety-basics/safe-temperature-chart>.

⁹⁶ KM Kosa, et al. (2017). Barriers to Using a Food Thermometer When Cooking Poultry at Home: Results from a National Survey. Food Protection Trends, 37/2, 116–125, available at: <https://www.foodprotection.org/files/food-protection-trends/mar-apr-17-kosa.pdf>.

⁹⁷ Maughan, et al. (2016). Food Handling Behaviors Observed in Consumers When Cooking Poultry and Eggs. Journal of Food Protection, 79:6, 970–977, available at: <https://www.sciencedirect.com/science/article/pii/S0362028X22080814?via%3Dihub>.

In another observational study published in 2014,⁹⁸ 120 volunteers were observed as they prepared chicken and salad in their homes. The study participants chose the manner of chicken preparation. Three volunteers prepared whole chicken, and all others prepared chicken parts. The study found that the most common method of determining whether the chicken was properly cooked was appearance. In response to a questionnaire administered after meal preparation, the study participants stated that to determine whether chicken was properly cooked, they looked for white colored meat, absence of blood or pink spots, and firm meat. The study found that 40 percent of the chicken that the participants considered to be properly cooked registered a temperature below 165 °F.

In this study, fewer than 5 percent of the participants voluntarily used a thermometer to record chicken temperature during meal preparation. When asked by the researcher if they wanted to check the cooked chicken's temperature, 34 percent of the participants checked the internal temperature using either their own thermometer or the thermometer provided by the researcher. When chicken temperature was taken, the internal temperature of 60 percent of the cooked chicken registered 165 °F or above. However, 39 percent of households stopped cooking even though the internal temperature of the poultry registered below 165 °F.

A 2020 study used a randomized experimental design and direct observation of meal preparation to test the effectiveness of a USDA food safety video intervention for consumer thermometer use.⁹⁹ The study was conducted in test kitchen facilities in which cameras recorded participants' meal preparation from beginning to end. A total of 383 people participated in the study, 201 in the control group (the group that did not watch the food safety video) and 182 in the treatment group. Before preparing the meal, the treatment group watched a 3-minute USDA food safety video on the importance of using

a food thermometer. Participants in the control and treatment groups were observed while cooking turkey burgers and preparing a salad to determine whether the participants used a thermometer to determine whether the turkey patties were properly cooked. Following meal preparation, all participants responded to a post observation interview about food handling behaviors.

Sixty-one percent of the control group participants and 63 percent of the treatment group participants reported owning a food thermometer, which is consistent with the percentage of the respondents that reported owning a food thermometer in the 2017 study discussed above (62 percent). During the meal preparation session, the control group used a thermometer to determine whether the turkey patties were properly cooked 34 percent of the time, while the treatment group used a thermometer 75 percent of the time. The control participants were also less likely to insert the thermometer into the side of the patty (23 percent), the recommended practice, than the treatment participants (52 percent). Of the participants that used a thermometer and for whom temperature data were available, the turkey patties were observed to reach an internal temperature of 165 °F 54 percent of the time for the control group and 73 percent of the time for the treatment group. Thus, while both the control and treatment groups were likely to own a food thermometer, the control group was much less likely to use a food thermometer, correctly place a thermometer, and cook patties to a safe internal temperature than the treatment group.

The study also addressed whether the participants used methods other than a thermometer to determine whether the turkey patty was properly cooked. The study found that 45 percent of all participants used a method other than a thermometer to determine that the turkey patty was done cooking. Among participants who did not use the thermometer and for whom usable data were available, 46 percent of control group participants and 29 percent of the treatment group participants relied on the firmness or texture of the patty to determine that it was properly cooked, and 4 percent in the control group and 16 percent in the treatment group relied on patty color. Twenty-five percent of control group and 42 percent of treatment group were observed using both firmness and color of the patty.

Thus, consumer research shows that, rather than using a thermometer to check the internal temperature of whole

chicken, chicken parts, comminuted chicken products, and comminuted turkey products, many consumers ordinarily rely on visual and textural cues to determine that these products are properly cooked. However, because these subjective cues have not been correlated with safe internal cooking temperature, they are unreliable for gauging whether poultry products have reached an internal temperature sufficient to destroy *Salmonella* that may be present.¹⁰⁰ As noted above, a 2014 observational study found that 40 percent of the chicken that participants considered to be properly cooked based on subjective cues registered a temperature below 165 °F. The 2017 survey study discussed above also cited a published summary of food safety literature that concluded that 70 percent of chicken pieces visually judged by consumers as "done" had not reached a safe internal temperature.¹⁰¹ A European study that assessed the effect of household cooking methods on the presence and numbers of *Salmonella* Typhimurium in different types of raw poultry products found that improper cooking produced inadequate heat treatments that did not fully eliminate *Salmonella* from the products even when the initial contamination levels were as low as 10 cfu/g.¹⁰² Thus, based on its review of the available consumer research, FSIS has concluded that many consumers do not cook chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey thoroughly and therefore, ordinary consumer cooking practices associated with these products fail to provide adequate assurance that the products will not be contaminated when consumed.

Cross-Contamination. In addition to consumer behavior research that found that many consumers ordinarily rely on visual and textural cues to determine that raw chicken and turkey products are properly cooked, recent studies also found that there are other ordinary consumer practices that create conditions for *Salmonella* exposure from raw poultry regardless of whether the products are properly cooked. Consumer hand washing practices are

⁹⁸ Bruhn, C.M. (2014). Chicken preparation in the home: An observational study. *Food Protection Trends*, 34(5):318–330. Available at: <https://www.proquest.com/trade-journals/chicken-preparation-home-observational-study/docview/164078777/se-2>.

⁹⁹ Duong M, Shumaker ET, Cates SC, Shelley L, Goodson L, Bernstein C, Lavallee A, Kirchner M, Goulter R, Jaykus LA, Chapman B (2020). An Observational Study of Thermometer Use by Consumers When Preparing Ground Turkey Patties. *J Food Prot.* 83(7):1167–1174. Available at: <https://www.sciencedirect.com/science/article/pii/S0362028X2210339X>.

¹⁰⁰ M. Duong et al. (2020).

¹⁰¹ Kosa, et al. (2017) citing CJ Byrd-Bredbenner et al. (2013.) Food safety in home kitchens: a synthesis of the literature. *Int. J. Environ Res Publ Hlth* 10:4060–4085.

¹⁰² Roccato A, Uyttendaele M, Cibin V, Barrucci F, Cappa V, Zavagnin P, Longo A, Ricci A (2015). Survival of *Salmonella* Typhimurium in poultry-based meat preparations during grilling, frying and baking. *Int J Food Microbiol* 197:1–8. Available at: <https://www.sciencedirect.com/science/article/pii/S0168160514006011/via%3Dihub>.

one example of this cross-contamination concern.

A 2015 observational study of consumers handling raw poultry as part of an at-home meal preparation event found that hands were washed 12 percent of the time after handling raw poultry.¹⁰³ Of note, 100 percent of the same study group responded on a pre-observation questionnaire that they washed their hands before and after handling raw poultry. Further, a 2016 observational study found that, during the preparation and cooking process, 40 percent of participants correctly washed their hands after handling raw whole chicken carcasses, and 46 percent correctly washed their hands after handling the raw ground turkey product.¹⁰⁴

Research shows that washing poultry can spread bacteria to kitchen surfaces and other foods.¹⁰⁵ Studies also show that washing or rinsing raw poultry is a pervasive consumer preparation practice that raises cross-contamination concerns. For example, a 2019 survey of food handling practices indicated that a lack of adherence to the recommended practice to not wash or rinse raw

poultry may have widespread impact on two age groups more susceptible to contracting foodborne illness—young children and older adults.¹⁰⁶ The Web-based survey found that only 39 percent of parents of young children (aged 5 years or younger) and only 31 percent of older adults (aged 60 years or older) reported not rinsing or washing raw poultry. Further, in a 2014 study on observed consumer handling behavior, 120 participants were asked to prepare in their home kitchen a chicken product and a salad. Before the observation, the participants were asked to select and purchase the ingredients, including a raw chicken carcass or part. The study found that 45 percent of the participants washed the raw chicken at the start of preparation.¹⁰⁷

Additional research indicates that food handling education on the recommendation to not wash or rinse raw poultry may have limited impact on consumer behavior. In 2016, a four-week intervention survey study exposed participants to an educational pilot program developed to raise awareness and influence consumers to not wash raw poultry.¹⁰⁸ The results indicated

that, while the program improved both knowledge and behavior of participants toward not washing raw poultry, the majority of consumers that viewed and understood the material still reported washing or rinsing raw poultry after the intervention program concluded.¹⁰⁹ These studies indicate that cross-contamination events are common during poultry handling in home kitchens, and that consumers' knowledge of proper food handling is often not correlated to safe handling behaviors.

E. Risk per Serving, Salmonella Levels, and Proposed Determination

1. Final Product Standards Salmonella Level and Risk per Serving

Salmonella contamination and levels. The 2023 risk assessments include analyses of FSIS testing of chicken and turkey products that show that the proportion of raw chicken carcasses, chicken parts, comminuted chicken and comminuted turkey products contaminated with *Salmonella* is very low and that the levels are very low for contaminated products (Table 3).

TABLE 3—ESTIMATED AMOUNT OF TEST POSITIVE SAMPLES PER SALMONELLA THRESHOLD

	Chicken carcasses (%)	Chicken parts (%)	Comminuted chicken (%)	Comminuted turkey (%)
Tests <i>Salmonella</i> Negative	96.92	93.31	72.90	84.26
Tests <i>Salmonella</i> Positive	3.08	6.69	27.10	15.74
≥1 cfu/mL or /g	9	2	11	12
≥10 cfu/mL or /g	1	0.07	3	4
≥100 cfu/mL or /g	0.10	<0.01	1	1

Approximately 97 percent of chicken carcasses and 93 percent of chicken parts test negative for *Salmonella* (i.e., results are below the 0.03 cfu/mL limit of detection (LOD)). Approximately 73 percent of comminuted chicken and 84 percent of comminuted turkey test results are below the 0.003 cfu/g LOD. Of the 3 percent of chicken carcasses that test positive for *Salmonella* at the end of production, only 1 percent have

Salmonella levels at or above 10 cfu/mL, and 0.10 percent have *Salmonella* levels at or above 100 cfu/mL. Of the chicken parts that test positive for *Salmonella*, only 0.07 percent have levels at or above 10 cfu/mL, and less than 0.01 percent were found to have levels at or above 100 cfu/mL. Of the 27 percent of comminuted chicken products that test positive for *Salmonella*, only 3 percent have levels

at or above 10 cfu/g, and 1 percent have levels at or above 100 cfu/g. Finally, of the 16 percent of comminuted turkey products that test positive for *Salmonella*, only 4 percent have levels at or above 10 cfu/g, and 1 percent have levels at or above 100 cfu/g. Thus, given that the majority of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey have *Salmonella* at levels below 0.03 cfu/

¹⁰³ E Mazengia, et al. (2015). Direct Observational Study of the Risk of Cross-Contamination during Raw Poultry Handling: Practices in Private Homes. Food Protection Trends, 35/1, 8–23. Available at: <https://www.foodprotection.org/files/food-protection-trends/JAN-FEB-15-mazengia.pdf>.

¹⁰⁴ Maughan, et al. (2016). Food Handling Behaviors Observed in Consumers When Cooking Poultry and Eggs. Journal of Food Protection, 79/6, 970–977. Available at: <https://www.sciencedirect.com/science/article/pii/S0362028X22080814?via%3Dihub>. For the purposes of the study, proper hand washing was defined as washing hands with soap for a minimum of 20 seconds immediately after touching the raw product and without touching anything else.

¹⁰⁵ Food Safety Consumer Research Project: Meal Preparation Experiment Related to Poultry Washing Final Report (August 20, 2019). Available at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-02/FSCRP_Year%2B2_Final_Aug2019.pdf.

¹⁰⁶ Kosa, KM, et al. (2019). Older Adults and Parents of Young Children Have Different Handling Practices for Raw Poultry. Journal of Food Protection, 82(2), 200–206, available at: <https://pubmed.ncbi.nlm.nih.gov/30673351/>.

¹⁰⁷ Bruhn, C.M. (2014). Chicken Preparation in the Home: An Observational Study. Food Protection Trends, 34/5, 318–330, available at: <https://www.proquest.com/trade-journals/chicken-preparation-home-observational-study/docview/164078777/se-2>.

¹⁰⁸ Henley, S., et al. (2016). Don't Wash Your Chicken!: A Food Safety Education Campaign to Address a Common Food Mishandling Practice. Food Protection Trends, 36/1, 43–53, available at: <https://www.foodprotection.org/files/food-protection-trends/jan-feb-16-henley.pdf>.

¹⁰⁹ Twenty-five percent of consumers in the intervention group reported not washing whole raw poultry, compared to 20.1 percent of consumers in the control group. Sixteen-point-three percent of consumers in the intervention group reported not washing small cuts of raw poultry, compared to 9.8 percent of consumers in the control group.

mL(g), FSIS testing data shows that *Salmonella* levels at or above 10 cfu/mL(g) represent comparatively higher levels of contamination that are infrequently identified in these raw poultry products.

Risk per Serving. The risk assessments also quantify and compare the probability of illness associated with chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey contaminated with *Salmonella* levels at or above 10 cfu/mL(g) with the average level of contamination for these raw products. The risk assessments used two dose-response models to provide a description of risk of illness per serving for *Salmonella* from chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products, when combined with an attenuation distribution. This attenuation

distribution describes the variety of activities that occur between FSIS sampling a final product lot and a consumer ingesting a serving from that lot. These activities include product mixing, transportation, and cooking—all of which can result in both *Salmonella* growth and die off.

A summary of probability of illness per serving for the main scenarios that were considered in the risk assessments is provided in Table 4. The average *Salmonella* level for product lots that test at or above each threshold level are provided, along with the average dose consumed, *i.e.*, the level after attenuation, and likelihood that consumers are exposed to such servings.

The model-derived baseline probability of illness for chicken carcasses is 0.2 illnesses per 100,000 servings, for chicken parts is 0.3

illnesses per 100,000 servings, and 2.5 illnesses per 100,000 servings for comminuted chicken, and 2.5 illnesses per 100,000 servings for comminuted turkey. Comparison of the threshold probability of illness to the baseline quantifies how much higher than average the risk per serving is for each scenario.

Table 4—Average characteristics (level, dose, and probability of illness by serocluster) of failing lots for *Salmonella* threshold level scenarios in FSIS-sampled products under consideration and the overall likelihood of consumer exposure. The serotypes of public health significance (Enteritidis, Typhimurium, and I 4,[5],12:i:- for chicken products and Hadar, Typhimurium and Muenchen for Comminuted turkey) are among the higher virulence Serotype Cluster

Salmonella THRESHOLD LEVEL SCENARIOS UNDER CONSIDERATION

[cfu/mL or g]

Measurement	Product type	0.003	0.033	1	10	100
Average level for failing lots (cfu/mL(g)).	Chicken Carcasses	0.48	1.65	16	97	682
	Chicken Parts	0.08	0.30	4	33	281
	Comminuted Chicken	17	37	163	582	2,572
	Comminuted Turkey	163	348	1,373	4,249	15,479
Average dose consumed for average failing lot (cfu/serving).	Chicken Carcasses	0.08	0.26	3	15	108
	Chicken Parts	0.01	0.05	0.67	5	45
	Comminuted Chicken	3	6	26	92	408
	Comminuted Turkey	26	55	218	673	2,453
Probability of illness per 100,000 servings *, high virulence.	Chicken Carcasses	23	54	224	612	1,598
	Chicken Parts	6	16	100	340	1,050
	Comminuted Chicken	235	363	800	1,486	2,849
	Comminuted Turkey	801	1,166	2,184	3,490	5,660
OR						
Probability of illness per 100,000 servings *, low virulence.	Chicken Carcasses	4	9	42	119	329
	Chicken Parts	1	3	18	64	211
	Comminuted Chicken	44	69	158	305	611
	Comminuted Turkey	158	235	460	761	1,287
Likelihood of consumer exposure to raw product at or above initial level.	Chicken Carcasses	11%	3%	0.27%	0.03%	<0.01%
	Chicken Parts	31%	7%	0.17%	<0.01%	<0.01%
	Comminuted Chicken	27%	13%	3%	0.79%	0.17%
	Comminuted Turkey	16%	7%	2%	0.60%	0.16%

* Given average initial level multiplied by attenuation distribution.

As illustrated in Table 4, the risk assessments found that the probability of illness for servings of raw chicken carcasses that are contaminated with *Salmonella* levels at or above 10 cfu/mL and contain a serotype of public health significance is 612 illnesses per 100,000 servings of raw chicken carcasses, while the average probability of illness is 0.3 illnesses per 100,000 servings; the great majority of which have levels far below 10 cfu/mL. Therefore, servings from production lots of raw chicken carcasses

that test positive for *Salmonella* at levels of 10 cfu/mL or greater with a serotype of public health significance are 2,000-fold (*i.e.*, ~ 612/0.3) more likely to cause illness than the average across all chicken carcass servings. Thus, while there is a relatively low probability that individuals will be exposed to carcasses that contain *Salmonella* at 10 cfu/mL, if exposed, there is a much higher probability of illness, *i.e.*, 2,000-fold, when compared

to exposure to the majority of servings from chicken carcasses.

For raw chicken parts, the risk assessment found that chicken parts servings that are contaminated with *Salmonella* levels at or above 10 cfu/mL at the end of production and contain a serotype of public health significance have a probability of illness of 340 illnesses per 100,000 servings, while the average probability of illness is 0.3 per 100,000 servings for all servings; the great majority of which have levels

much below 10 cfu/mL. Therefore, servings from production lots of raw chicken parts that test positive for *Salmonella* at levels at or above 10 cfu/mL with a serotype of public health significance are 1,100-fold (*i.e.*, ~340/0.3) more likely to cause illness than the average across all chicken parts servings. Thus, while there is a relatively low probability that consumers will be exposed to chicken parts that contain *Salmonella* at 10 cfu/mL, if exposed, there is a much higher probability of illness, *i.e.*, 1,100-fold, when compared to exposure to the majority of servings from raw chicken parts.

For raw comminuted chicken servings, the risk assessments found that products that are contaminated with at least 10 cfu/g of *Salmonella* at the end of production and contain a serotype of public health significance have a 1,500 per 100,000 servings probability of illness, while average probability of illness is 2.5 per 100,000 servings for all servings; the majority of which have levels below 10 cfu/g. Therefore, servings from production lots of comminuted chicken that test positive for *Salmonella* at or above 10 cfu/g with a serotype of public health significance are 590-fold (*i.e.*, ~1,500/2.5) more likely to cause illness than the average across all comminuted chicken servings. Thus, while there is a relatively low probably that consumers will be

exposed to comminuted chicken that contains *Salmonella* at 10 cfu/g, if exposed, there is a much higher probability of illness, *i.e.*, 590-fold, when compared to the majority of servings of comminuted chicken.

For raw comminuted turkey servings, the risk assessments found that products that are contaminated with at least 10 cfu/g of *Salmonella* at the end of production and contain a serotype of public health significance have a 3,500 per 100,000 servings probability of illness, while the average probability of illness is 2.5 per 100,000 servings across all servings; the majority of which have levels below 10 cfu/g. Therefore, servings from production lots of comminuted turkey that test positive for *Salmonella* at or above 10 cfu/g with a serotype of public health significance are 1,400-fold (*i.e.*, ~3,500/2.5) more likely to cause illness than the average across all comminuted turkey servings. Thus, while there is a relatively low probability that consumers will be exposed to comminuted turkey that contains *Salmonella* at 10 cfu/g, if exposed, there is a much higher probability of illness, *i.e.*, 1,400-fold, when compared to the majority of servings of comminuted turkey.

Illnesses prevented. The risk assessments also predicted the total number of illnesses prevented annually for chicken carcasses, parts, and comminuted chicken and turkey for

different *Salmonella* threshold levels—0.03 cfu/mL(g), 1 cfu/mL(g), 10 cfu/mL(g), and 100 cfu/mL(g) (Table 5). Uncertainty analyses were also run for the main scenarios under consideration. A threshold set at the *Salmonella* detection level for comminuted chicken and turkey (0.003 cfu/g) was not as effective as the higher threshold levels in Table 5 below. Therefore, an analysis evaluating the uncertainty around the predicted public health impact for a threshold of 0.003 cfu/g *Salmonella* in comminuted poultry was not evaluated in the risk assessments.

The resulting overlapping 95 percent credible intervals around the estimated number of illnesses prevented suggest that there is little meaningful difference in effectiveness between the threshold standards with respect to annual illnesses prevented. However, as discussed above, when compared with the majority of servings, chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain *Salmonella* at 10 cfu/mL(g) or higher present a much higher probability of illness. Thus, based on the elevated probability of illness associated with raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey associated with *Salmonella* levels at or above 10 cfu/mL(g), FSIS is proposing 10 cfu/mL(g) as the *Salmonella* level for the proposed final product standards.

TABLE 5—ANNUAL ILLNESSES PREVENTED, MOST LIKELY
[95% Credible Interval]

Threshold level	Chicken carcasses	Chicken parts	Comminuted chicken	Comminuted turkey
0.03 cfu/mL(g)	4600 (2000, 7100)	7900 (3300, 12700)	1500 (800, 2200)	2500 (700, 4900)
1 cfu/mL(g)	2400 (700, 5000)	1400 (400, 3600)	1400 (600, 2100)	2300 (600, 4800)
10 cfu/mL(g)	1000 (200, 3100)	200 (40, 700)	1000 (400, 1900)	2000 (500, 4300)
100 cfu/mL(g)	200 (0, 1500)	20 (0, 100)	600 (200, 1500)	1400 (200, 3500)

2. Proposed Determination

After careful consideration of the information presented above, FSIS has concluded that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey contaminated with *Salmonella* at or above 10 cfu/mL(g) and a serotype of public health significance present an unacceptable risk of illness based on their risk per serving. As discussed above, the 2023 risk assessments for chicken found that production lots of raw chicken carcasses and raw chicken parts contaminated with these *Salmonella* levels and serotypes are at least 1,000 times more likely than average to cause illness across all chicken parts and carcass

servings, and that servings from production lots of comminuted chicken and turkey contaminated with *Salmonella* at these levels and serotypes are at least 590 times more likely than average to cause illness across all comminuted chicken and turkey servings.

Additionally, *Salmonella* has been associated with severe and debilitating human illness and available data suggest that the *Salmonella* infectious dose for the serotypes of public health concern is relatively low. Information from consumer behavior research shows that, rather than using a food thermometer to check the internal temperature of whole chicken, chicken parts, comminuted chicken products,

and comminuted turkey products, many consumers ordinarily rely on visual and textural cues to determine that these products are properly cooked. Consumer research also shows that chicken that consumers considered to be properly cooked based on these subjective cues often had not reached an internal temperature sufficient to destroy *Salmonella* that may be present, and one study found that for certain poultry products, that application of inadequate heat treatments from improper cooking was unable to assure complete elimination of *Salmonella* even with a low initial contamination level of 10 cfu/g. Information from consumer behavior research also shows

that ordinary consumer handling associated with chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey creates conditions for *Salmonella* exposure from raw poultry through cross contamination.

Thus, because *Salmonella* can survive what many consumers consider to be ordinary cooking and handling practices for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, and because the 2023 risk assessments found that servings of these products that test positive for *Salmonella* at levels at or above 10 cfu/mL(g) and a serotype of public health significance are much more likely to cause illness when compared to the majority of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey servings, FSIS has tentatively determined that, when contaminated with *Salmonella* at these levels and serotypes, these products are adulterated as defined in the PPIA. Specifically, FSIS has tentatively concluded that these products are adulterated as defined in 21 U.S.C. 453(g)(1) because their elevated risk of illness renders them “injurious to health.” FSIS has also tentatively concluded that they are adulterated as defined in 21 U.S.C. 453(g)(3) because their elevated risk of illness makes them “unsound, unhealthful, unwholesome, or otherwise unfit for human food.”

The adulteration definition in 21 U.S.C. 453(g)(1) includes two separate standards for determining whether a product is adulterated. Under 21 U.S.C. 453(g)(1), if a substance is an “added substance” the product is adulterated if the substance “may render” the product injurious to health. If the substance is not added, the product is adulterated “if the quantity of such substance in or on” the product “ordinarily” renders it injurious to health.

As noted above, in response to the draft October 2022 *Salmonella* Framework, FSIS received comments on whether *Salmonella* should be considered as an “added substance” in raw poultry. Comments from consumer advocacy organizations asserted that *Salmonella* should be considered as an “added substance” because it is not normally present in the muscle tissue of healthy birds. The comments stated that while *Salmonella* is present in the gastrointestinal tract of live birds, it is an “added substance” in poultry products because it only makes its way onto to poultry muscle tissue through contamination that occurs during slaughter and processing, specifically during defeathering and evisceration. To support this position, the commenters

referenced case law that provides that where some portion of toxic substance present in a food has been introduced by human intervention, the entirety of that substance present in the food will be treated as an “added substance”.¹¹⁰

Comments from trade associations representing the meat and poultry industries asserted that *Salmonella* is not an “added substance” because it exists naturally in and on the live birds. The comments stated that *Salmonella* can exist in a chicken’s skin, muscle tissue, and gut. A trade association representing the chicken industry cited references that, according to the comment, show that researchers have identified *Salmonella* in chicken neck skin, on the outer layer of skin, on feather follicles, connective tissue, and in drumstick muscle. The commenter also stated that literature shows correlations between *Salmonella* loads on the farm and in birds and at various processing steps, reinforcing that *Salmonella* enters the process via the chickens themselves. A comment from a trade association representing the meat and poultry industry stated that *Salmonella* can exist on the exterior of the animal, harbor in feather follicles, and travel from the gastrointestinal tract of poultry to the bloodstream, theoretically providing a pathway for *Salmonella* to be distributed throughout the bird.

In addition, the comments stated that the case law provides that to be “added,” a substance must not otherwise be present in the food and must be artificially introduced by a person.¹¹¹ According to the chicken industry trade association, the fact that *Salmonella* may be present in greater expected concentrations in some parts of a chicken than others does not make it an “added substance” in poultry muscle because, as with any microbe, naturally-occurring *Salmonella* can be spread through cross-contact during processing.

FSIS has traditionally viewed *Salmonella* as “naturally occurring” in food animals.¹¹² FSIS has previously rejected broad requests for it to declare that *Salmonella* is considered an

“added substance” in all products,¹¹³ however, FSIS has not previously determined whether certain circumstances, considering what current scientific data indicates about *Salmonella*’s spread to or within products, may render *Salmonella* an “added substance” in the raw products covered by this proposed framework. Before taking a position on whether there are any circumstances in which *Salmonella* can be considered an “added substance” in raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, FSIS has decided to request additional comments on both the legal and factual aspects of this issue.

As noted above, under 21 U.S.C. 453(g)(1), there are two definitions for adulteration, depending on whether a substance in a poultry product is “added” or “not added.” However, the PPIA does not define the circumstances in which a substance in a poultry product is “added” within the meaning of the statute. Prior court decisions that address whether *Salmonella* is an adulterant in raw meat or poultry products have never directly considered whether and under what circumstances *Salmonella* may be considered an “added substance” under the PPIA.¹¹⁴

As noted above, some of the comments on the October 2022 draft *Salmonella* Framework asserted that *Salmonella* should be considered as an “added substance” in raw poultry based on the holding in *U.S. v. Anderson Seafoods*. The *Anderson Seafoods* case involved toxic levels of mercury in swordfish. The issue before the court was whether all mercury found in the swordfish should be considered as an “added substance” under the adulteration provisions of the FFDCA¹¹⁵ when some mercury in swordfish occurs naturally and some is the result of man-made pollution. The court held that “where some portion of a toxin present in a food has been introduced by man, the entirety of that substance present in the food will be

¹¹³ See FSIS Final Response to Marler Clark petition.

¹¹⁴ See *American Public Health Association (APHA) v. Butz*, 511 F. 2d 331 (D.C. Cir. 1974); *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38 (D.C. Cir. 1982); *Supreme Beef Processors, Inc. v. USDA*, 275 F.3d 432 (5th Cir. 2001).

¹¹⁵ The adulteration definition in the FFDCA at issue in *Anderson Seafoods* is, in relevant parts, identical to the definition in the PPIA and provides that “A food shall be deemed to be adulterated (a)(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health” (21 U.S.C. s 342(a)(1)).

¹¹⁰ See *United States v. Anderson Seafoods, Inc.*, 622 F.2d 157 (5th Cir. 1980); *Continental Seafoods, Inc. v. Schweiker*, 674 F.2d 38 (D.C. Cir. 1982).

¹¹¹ These commenters cite *United States v. Coca Cola*, 241 U.S. 265 (1915) and *United States v. Anderson Seafoods, Inc.* 622 F.2d 157, 160 (5th Cir. 1980).

¹¹² See FSIS Final Response to Marler Clark LLP petition # 20–01 “Petition for an Interpretive Rule Declaring ‘Outbreak’ Serotypes of *Salmonella enteritica* subspecies to be Adulterants” Available at: <https://www.fsis.usda.gov/policy/petitions/petition-interpretive-rule-related-certain-Salmonella-serotypes>.

treated as an added substance” as defined in the statute.¹¹⁶ Based on this holding, some comments asserted that *Salmonella* should be considered as an “added substance” in raw poultry because poultry muscle does not normally contain *Salmonella*, and *Salmonella* only makes its way onto to poultry muscle tissue through contamination that occurs during slaughter and processing.

As noted by the comments, *Salmonella* is present in the gastrointestinal tract of live birds, and there is evidence that extraintestinal *Salmonella* exist in poultry skin, livers, bones, and bone marrow before processing.¹¹⁷ Most *Salmonella* contamination on carcasses is believed to result from leakage of ingesta during crop removal and from feces during evisceration, as well as aerosolization during picking.^{118 119} After poultry carcasses are scalded, the carcasses travel through a series of defeathering machines where their feathers are removed using mechanical pickers with rubber “fingers.” During the picking process, these rubber fingers not only can massage *Salmonella*-contaminated water remaining from the scald into the carcass but can also inadvertently press on the abdomen of the carcass, pushing out fecal matter and ingesta, resulting in transfer of *Salmonella* to the carcass skin or to the machinery.¹²⁰ The 2023 risk profile identified studies that show that *Salmonella* can persist on processing equipment after cleaning and sanitation,¹²¹ which increases the potential for cross-contamination.

Another step in the process in which *Salmonella* may be spread to or increased in poultry carcasses is evisceration. During evisceration, *Salmonella* that is present in the gastrointestinal tract may be transferred to the skin and other carcass surfaces due to rupture of the viscera when the carcass is opened.¹²² Additionally, the 2023 risk profile found that although used as a control step, immersion chilling may be an opportunity for cross-contamination of broiler carcasses. For example, in one study, a lower incidence of *Salmonella* in air-chilled broilers compared to immersion-chilled broilers (18.7 percent to 24.7 percent positive carcasses) suggests that cross-contamination may be more prevalent for immersion-chilled broilers.¹²³

In addition to processes that can contribute to *Salmonella* contamination on poultry carcasses during slaughter and processing, further processing of carcasses into other commodities may also add *Salmonella* to or increase *Salmonella* in finished poultry parts, such as wings, breasts, and thighs. FSIS sampling data show that further processed chicken parts have a higher incidence of *Salmonella* compared to carcasses.¹²⁴ This difference is likely because of cross contamination between positive and negative parts and carcasses during further processing.^{125 126} Further processing presents various opportunities in which

Salmonella that is present in certain parts of the bird may be added to interior edible muscle where *Salmonella* is not ordinarily found. For example, *Salmonella* can be found in feather follicles in the skin.^{127 128} When the skin is cut, *Salmonella* can be exposed and spread during processing to previously uncontaminated product and/or increased in product with low levels of contamination.¹²⁹ In addition, *Salmonella*-negative raw poultry parts and comminuted poultry may become cross-contaminated by contact with *Salmonella*-contaminated equipment or when they are commingled with *Salmonella*-positive products, such as when they are collected in combo bins for further processing.^{130 131}

Comminuted products are those that are ground, mechanically separated, or hand- or mechanically deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size. Because of the nature of comminuted processes, *Salmonella* contamination in chicken skin and bone can spread throughout an entire batch or lot through cross-contamination. FSIS sampling data show that ground and other raw comminuted chicken products that were produced using either bone-in or skin-on source materials were more likely to be contaminated with *Salmonella* than those fabricated from deboned, skinless source materials.¹³² *Salmonella*-contaminated equipment used to produce comminuted poultry may also contribute to *Salmonella* contamination in these products.

FSIS requests comments on whether the available science supports that some *Salmonella* in a raw poultry product is “naturally occurring” and some is “added.” FSIS also requests comments on whether, under the reasoning of *Anderson Seafoods* or another rationale, the Agency has authority to regulate *Salmonella* as an “added substance” if it can demonstrate that some *Salmonella* can be artificially

¹¹⁶ *Anderson Seafoods*, 622 F.2d at 161.

¹¹⁷ Rimet, C.S., et al. (2019). *Salmonella* Harborage Sites in Infected Poultry That May Contribute to Contamination of Ground Meat. *Frontiers in Sustainable Food Systems* 3(2). see also Jones-Ibarra, A.M., et al. (2019). *Salmonella* recovery from chicken bone marrow and cecal counts differ by pathogen challenge method. *Poult Sci* 98(9): 4104–4112. see also Cox, N.A., et al. (2007). Recovery of *Campylobacter* and *Salmonella* Serovars from the Spleen, Liver and Gallbladder, and Ceca of Six- and Eight-Week-Old Commercial Broilers. *Journal of Applied Poultry Research* 16(4): 477–480.

¹¹⁸ National Advisory Committee on Microbiological Criteria for Foods. (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *J Food Prot.* 82(4):645–668.

¹¹⁹ Singh M and Thippareddi H (2020). *Managing Microbial Food Safety Risks in Poultry Processing*. White Paper for 3M Food Safety at: <https://berstlerllc.com/wp-content/uploads/2023/03/3M-Food-Safety-Poultry-Segment-Whitepaper.pdf>.

¹²⁰ Singh 2020.

¹²¹ Obe, T., et al., *Prevalence of Salmonella Enterica on Poultry Processing Equipment after Completion of Sanitization Procedures*. *Poultry Science*, 2020. 99(9): p. 4539–4548. Veluz, G.A., S. Pitchiah, and C.Z. Alvarado, *Attachment of Salmonella Serovars and Listeria Monocytogenes to*

Stainless Steel and Plastic Conveyor Belts. *Poultry Science*, 2012. 91(8): p. 2004–2010. Rothrock, M.J., Jr., et al., *The Characterization of Salmonella Enterica Serotypes Isolated from the Scalding Tank Water of a Commercial Poultry Processing Plant: Recovery of a Multidrug-Resistant Heidelberg Strain*. *Poultry Science*, 2015. 94(3): p. 467–472. Bailey, J.S., et al., *Sources and Movement of Salmonella through Integrated Poultry Operations: A Multistate Epidemiological Investigation*. *Journal of Food Protection*, 2001. 64(11): p. 1690–7.

¹²² Singh (2020); National Advisory Committee on Microbiological Criteria for Foods. (2019). Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry. *J Food Prot.* 82(4):645–668.

¹²³ Smith, D.P., J.A. Cason, and M.E. Berrang, *Effect of Fecal Contamination and Cross Contamination on Numbers of Coliform, Escherichia coli, Campylobacter, and Salmonella on Immersion-Chilled Broiler Carcasses*. *Journal of Food Protection*, 2005. 68(7): p. 1340–1345.

¹²⁴ Sampling Results for FSIS-Regulated Products. Available at: <https://www.fsis.usda.gov/science-data/sampling-program/sampling-results-fsis-regulated-products>.

¹²⁵ FSIS Guidance for Controlling *Salmonella* in Poultry (June 2021) p. 59. Available at: https://www.fsis.usda.gov/sites/default/files/media_file/2021-07/FSIS-GD-2021-0005.pdf.

¹²⁶ Codex Guideline for the Control of *Campylobacter* and *Salmonella* in Chicken Meat at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXG%2B78-2011%252FCXG_078e.pdf.

¹²⁷ Kim J-W and Slavik MF. 1996. Cetylpyridinium Chloride (CPC) treatment on poultry skin to reduce attached *Salmonella*. *J. Food Prot.* 59: 322–326.

¹²⁸ Wu D, Alali WQ, Harrison MA, and Hofacre CL. 2014. Prevalence of *Salmonella* in neck skin and bone of chickens. *J Food Prot.* 77(7): 1193–1197.

¹²⁹ FSIS Guidance for Controlling *Salmonella* in Poultry (June 2021) pp. 59–60.

¹³⁰ FSIS Guidance for Controlling *Salmonella* in Poultry (June 2021) pp. 59.

¹³¹ Codex Guideline for the Control of *Campylobacter* and *Salmonella* in Chicken Meat.

¹³² FSIS Guidance for Controlling *Salmonella* in Poultry (June 2021) pp. 65–66, Table 4 FSIS exploratory sampling test results, raw comminuted chicken by source material composition (6/1/13–6/30/15, 2,688 samples).

introduced into raw poultry products through processing procedures and other actions attributable to man.

As discussed above, consumer behavior research shows that *Salmonella* can survive what many consumers consider to be ordinary cooking and handling practices for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. In addition, the 2023 risk assessments, which modeled a broad distribution of consumer cooking behavior, found that servings of these products that test positive for *Salmonella* at levels at or above 10 cfu/mL(g) and a serotype of public health significance are much more likely to cause illness when compared to the majority of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey servings. Thus, regardless of whether *Salmonella* is considered as an “added substance,” FSIS tentatively determines through this proposal that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain *Salmonella* levels at or above 10 cfu/mL(g) and a serotype of public health significance are adulterated under 21 U.S.C. 453(g)(1) because when contaminated with these levels and serotypes of *Salmonella*, the high likelihood that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey will result in illnesses when compared to the average serving of these products “ordinarily” renders them injurious to health. Additionally, through this proposal, FSIS tentatively determines that raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey contaminated with *Salmonella* levels and serotypes in the proposed final product standards are adulterated as defined in 21 U.S.C. 453(g)(3) because their elevated risk of illness makes them “unsound, unhealthful, unwholesome, or otherwise unfit for human food.” This tentative determination does not depend on the status of *Salmonella* as an “added substance.”

FSIS requests comments on its proposed determination that, when contaminated with *Salmonella* at the levels and serotypes provided in the final products standards, chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey are adulterated as defined in 21 U.S.C. 453(g)(1) and (3) and whether there are alternative bases for determining adulteration for these poultry products.

F. Proposed Policy Implementation

1. HACCP Reassessment

The HACCP system regulations require that every establishment reassess the adequacy of its HACCP plan at least annually and whenever any changes occur that could affect the underlying hazard analysis or alter the HACCP plan (9 CFR 417.4(a)(3)). If finalized, FSIS’ proposed determination that chicken carcasses, chicken parts, comminuted chicken and comminuted turkey that contain *Salmonella* levels of 10 cfu/mL(g) or higher and any detectable levels of a serotype of public health significance are adulterated would be such a change. Thus, if FSIS finalizes this proposed determination, all establishments that produce chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey as final products that will enter commerce would need to reassess their HACCP plans. Establishments that make changes to their production process because of their reassessment would also need to re-validate their HACCP plans. FSIS would issue instructions to IPP in establishments that produce these final products to verify that these establishments have completed their reassessment before the effective date of any final determination resulting from this proposal.

2. Proposed Implementation and Status of Laboratory Methods

Products subject to verification sampling. Should FSIS finalize these proposed standards, the Agency intends to conduct a routine sampling and verification testing program for *Salmonella* in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey in which the Agency would collect samples of raw final products and analyze them for *Salmonella* levels and serotypes to determine whether the final product is adulterated. FSIS would collect the verification samples after the establishment has completed all validated antimicrobial interventions. Under the proposed *Salmonella* verification testing program, FSIS intends to only collect and analyze samples of the final poultry products produced by an establishment, *i.e.*, chicken carcasses to be shipped in commerce as whole chickens, chicken parts to be shipped in commerce as chicken parts, comminuted chicken to be shipped in commerce as comminuted chicken products, and comminuted turkey to be shipped in commerce as comminuted turkey products. Thus, under this proposal, if a chicken slaughter establishment uses carcasses

processed in the establishment to produce other final products, such as chicken parts or comminuted chicken, FSIS would not collect whole carcass samples as part of the proposed verification sampling program. Likewise, chicken parts produced by an establishment that are intended for use in another final product produced by the establishment, such as comminuted chicken, would not be subject to FSIS verification sampling. FSIS also does not intend to collect samples of mechanically separated chicken or mechanically separated turkey under the proposed verification sampling program. However, final comminuted chicken and turkey products that contain mechanically separated chicken or turkey would be eligible for verification sampling.

The final product samples collected under the proposed verification sampling plan would be determined on an establishment basis. Thus, all raw final products produced by an establishment that are not intended to be further processed into a RTE product would be subject to verification sampling regardless of where the product is shipped. For example, FSIS would consider whole carcasses or parts to be final products subject to verification sampling if the establishment that produced the carcasses or parts ships them to another establishment for further processing into a raw parts or comminuted product. FSIS would not, however, collect verification samples from raw whole carcasses, parts, or comminuted products that are shipped to another establishment for cooking or to be further processed into a ready-to-eat product. If off-site interventions, such as high-pressure processing or irradiation, are applied to prevent or control *Salmonella*, FSIS would sample the product after the off-site intervention is applied.

Additionally, should FSIS finalize these proposed final product standards, the Agency intends to conduct testing for *Salmonella* of imported raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products in accordance with FSIS’ import reinspection procedures.¹³³ Poultry imports represent a small fraction of the U.S. domestic poultry supply, accounting for less than 0.5

¹³³ FSIS Directive 9900.2, Import Reinspection of Meat, Poultry and Egg Products (Rev. 2)(Oct 12 2021). Available at: <https://www.fsis.usda.gov/policy/fsis-directives/9900.2>.

FSIS Directive 9900.6, Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products (Nov 3, 2015). Available at: <https://www.fsis.usda.gov/policy/fsis-directives/9900.6>.

percent in 2021. Currently, FSIS samples and tests imported chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey for the presence of *Salmonella*. According to data from PHIS, in 2021, FSIS collected and analyzed about 850 samples of imported chicken and turkey products, which represented about 15.8 million pounds of product. These samples were mainly from chicken parts and carcasses, as imports of comminuted chicken and turkey are relatively low. While data on the volume of imported product with results at or above 10 cfu/mL(g) are not available, FSIS estimates this would be a relatively low volume of product.

Sample analysis. The detection and isolation methodology for *Salmonella* is described in MLG chapter 4.14, of the FSIS Microbiology Laboratory Guidebook.¹³⁴ Based on current FSIS methodologies, when sampling the chicken carcasses and parts under this proposed determination, FSIS would collect a rinsate sample from the establishment to analyze 30 mL per test for *Salmonella*. When sampling comminuted chicken or comminuted turkey, the Agency would collect 1 pound of the product from the establishment to analyze 325 g per test for *Salmonella*. Samples would be initially screened, post-enrichment, for the presence or absence of *Salmonella*. Samples that screen negative would be reported as “negative.” For samples that screen positive, FSIS would use selective and differential culture-based media and proteomics testing to confirm. In parallel, all screen positives will be analyzed for levels and targeted rapid serotype screening. A sample is considered confirmed positive for *Salmonella* after completion of confirmatory tests. Any chicken carcass, chicken parts, comminuted chicken, or comminuted turkey final product sample “confirmed positive” with *Salmonella* levels of 10 cfu/mL(g) or higher and screened positive for a serotype of public health significance would not be allowed to enter commerce. Any chicken carcass, chicken parts, comminuted chicken, or comminuted turkey final product sample that contains *Salmonella* levels of 10 cfu/mL(g) or higher and a serotype of public health significance would be considered adulterated.

Based on current testing methodologies, FSIS estimates that *Salmonella* screening results and quantification results would routinely

be available 2 days after a sample is taken. For samples above the quantification threshold, an additional 3 days may be necessary for a confirmed positive or negative result. Currently, the routine procedure is to use WGS to determine *Salmonella* isolate sequence, serotypes, and antimicrobial resistance (AMR) profile, which require at least 14 days for result reporting. FSIS could use a non-routine molecular serotyping methodology to determine the serotype in a more time sensitive manner such that results would be available by *Salmonella* confirmation, 5 days after sample collection, if not sooner.

FSIS is proposing the combined quantification and serotype final product standards recognizing current efforts underway by ARS and private sector laboratories to develop rapid, reliable, *Salmonella* quantification and serotyping technologies. FSIS is actively working to explore technologies that may have the capability of WGS in determining serotype and reduce the current timeframe. All timeframes and methods are likely to change as FSIS continuously incorporates new laboratory technologies into its sampling verification program. Any final verification sampling plan resulting from this proposal would use testing methods that are validated and fit for purpose.

FSIS requests comments on available technologies and methods for of quantification and serotyping. If FSIS finalizes this proposed sampling plan, data gathered from the sampling plan would enable the Agency to gauge more precisely the hazard posed by certain *Salmonella* levels and serotypes in chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. FSIS intends to further evaluate and, if necessary, refine the proposed status of *Salmonella* as an adulterant in these raw poultry products as advances in science and technology related to pathogen levels, serotypes, and virulence genes become available.

Sampled Lot. When FSIS tests a product sample for adulterants, the Agency withholds its determination as to whether product is not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received (77 FR 73401). Under this policy, establishments and importers of record at official import inspection establishments must maintain control of products tested for adulterants to ensure that the products do not enter commerce while waiting for receipt of the test results. Thus, if FSIS finalizes its proposed routine *Salmonella* verification testing program for chicken

carcasses, chicken parts, comminuted chicken, and comminuted turkey, establishments that produce these raw products and official import inspection establishments where these raw products are reinspected would need to control and maintain the integrity of the sampled lot pending the availability of test results.

Under any final verification sampling plan, FSIS IPP would give establishments and official import inspection establishments advance notice before IPP collect a product sample for *Salmonella* to give these entities enough time to control the sampled lot without altering the process that the sample represents. The sampled lot is the product represented by the sample collected and analyzed by FSIS. Establishments are responsible for providing a supportable basis for defining the sample lot. For sampling purposes, product lots should be defined such that they are microbiologically independent. Microbiological independence is documented by separation, e.g., physical, temporal, or by sanitation intervention, that clearly delineates the end of one production lot and the beginning of the next. The microbiological results from one test are independent of prior or later lots. In other words, if a product sample tests positive for *Salmonella* at a level of 10 cfu/mL(g) or higher and contains a detectable level of at least one serotype of public health significance, products from other production lots should not be implicated, provided the establishment can support that the lots remain microbiologically independent.

Generally, FSIS recommends that establishments develop and implement in-plant sampling plans that define production lots or sub-lots that are microbiologically independent of other production lots or sub-lots. Production lots that are so identified may bear distinctive markings on the shipping cartons. FSIS has issued guidance to help establishments and official import inspection establishments comply with the Agency’s policy that does not allow product that FSIS has tested for adulterants to enter commerce until test results become available.¹³⁵ In addition to providing guidance on adequate control measures that establishments and official import inspection establishments can implement for products tested for adulterants, the document also includes guidance on

¹³⁴ FSIS Microbiology Laboratory Guidebook available at: <https://www.fsis.usda.gov/news-events/publications/microbiology-laboratory-guidebook>.

¹³⁵ FSIS Compliance Guideline: Controlling Meat and Poultry Product Pending FSIS Test Results (2013) at: <https://www.fsis.usda.gov/guidelines/2013-0003>.

how to define a product lot in order to determine the amount of product that must be controlled pending test results. If FSIS finalizes the proposed new standards for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey, FSIS would consider updating the guidance to cover *Salmonella* sampling of these raw poultry products.

As discussed above, establishments would be required to control the raw poultry products sampled by FSIS pending the test results. If test results detect *Salmonella* at a level of 10 cfu/mL(g) or higher and at least one *Salmonella* serotype of public health significance, FSIS would consider products represented by the sampled lots to be adulterated and would issue an NR. Additionally, all products in the lot represented by the sample would be prohibited from entering commerce. If any product from the lot represented by the product samples has entered commerce, FSIS would request that the producing establishment recall the implicated products. Depending on the circumstances, in addition to issuing an NR, FSIS could take other appropriate enforcement action as authorized in 9 CFR part 500 because the establishment would have produced and shipped adulterated product. Such actions may include immediately suspending inspection or issuing an NOIE.

For imported products tested at port of entry, if the product tests positive for *Salmonella* at 10 cfu/mL(g) or higher and any detectable level of a *Salmonella* serotype of public health significance and has not been held at the official import inspection establishment or at an off-site premises under adequate controls, FSIS would request that the importer of record recall the product. If the product has been held, the product will be refused entry. Product lots subsequently presented for import inspection from the same foreign country and establishment would be held at the official import inspection establishment pending results in accordance with FSIS' import reinspection procedures.¹³⁶ The FSIS Office of International Coordination would notify the program officials of the affected exporting country when a positive result is reported, so that they can determine whether the producing establishment has exported any other product from the same production lot to the United States. If the foreign establishment has properly defined the

product lot on the basis of specific control factors, and accurately tracked the containerization of product produced under those controls, the establishment can reduce the likelihood that adulterated product will enter commerce and can more easily recover product if a sample is positive for *Salmonella* levels and serotypes that would render the product adulterated.

Proposed implementation. To mitigate the impact of regulatory changes on small and VS establishments, FSIS has typically used a phased approach for implementation to provide additional time for small and VS establishments to adjust their operations to comply with any new regulatory requirements. FSIS defines large, small, and VS establishments based on the number of establishment employees and, for VS establishments, annual sales.¹³⁷

Should FSIS finalize the proposed final product standards, the Agency intends to use a phased approach to initiate verification sampling in establishments that produce raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. However, instead of implementing the Agency's verification sampling program based on the current large, small, and VS establishment size definitions, FSIS has tentatively decided to establish implementation dates based on annual number of birds slaughtered or, for establishments that do not conduct slaughter operations, production volume. The current small establishment size definition was established in the HACCP final rule and corresponded to the Small Business Administration's size standards for business entities at that time (61 FR 38819). However, because FSIS has applied these standards to individual establishments rather than business entities, establishments classified as "small" may have up to 500 employees. Thus, FSIS believes that a phased implementation based on production volume would be a more effective approach to mitigate the impact of this proposed determination on low and VLV establishments than the current establishment size definitions.

As FSIS implements the final product standards verification sampling program, the Agency has tentatively decided to phase out all current *Salmonella* performance standards for poultry. Thus, when the proposed final product verification sampling program

is fully implemented, FSIS would no longer use *Salmonella* sampling results to categorize poultry establishments and would no longer publish these establishments' performance standards categories on the FSIS website. FSIS evaluates and revises its sampling and testing programs each year. Any final verification sampling program resulting from this proposal would be sufficient to verify that establishments are meeting the final product standards.

The proposed production volume categories and proposed verification sampling implementation schedule are as follows.

TABLE 6—PROPOSED IMPLEMENTATION DATES

Establishment volume category	Implementation date
High	1 year after publication.
Medium	2 years after publication.
Low	3 years after publication.
Very Low	3 years after publication.

TABLE 7—PROPOSED VOLUME CATEGORIES CHICKEN PARTS

Volume category	Definition (annual production pounds)
High	Over 70,000,000.
Medium	Between 1,000,000 and 70,000,000.
Low	Less than 1,000,000.

TABLE 8—PROPOSED VOLUME CATEGORIES CHICKEN CARCASSES

Establishment volume category	Definition (birds slaughtered per year)
High	Over 10 million.
Medium	Between 1.1 and 10 million.
Low	Between 440,001 and < 1.1 million.
Very Low	No more than 440,000.

TABLE 9—PROPOSED VOLUME CATEGORIES COMMUNUTED CHICKEN AND TURKEY

Volume category	Definition (daily production pounds)
High	Over 250,000.
Medium	Between 6,001 and 250,000.
Low	No more than 6,000.

FSIS requests comments on this proposed implementation approach and on the proposed establishment production volume categories. FSIS also requests comments on whether the Agency should phase out the current performance standards as the Agency implements the final product standards or if the Agency should retain the current performance standards and later determine if these standards are still

¹³⁶ FSIS Directive 9900.8, Meat, Poultry, and Egg Products Refused Entry into the United States (Dec. 1 2020). Available at: <https://www.fsis.usda.gov/policy/fsis-directives/9900.8>.

¹³⁷ Large establishments are establishments with 500 or more employees, small establishments are establishments with 10 or more employees but fewer than 500, and very small establishments are establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

needed when evaluating the effectiveness of the proposed final product standards.

FSIS also requests comments on whether the Agency should consider an alternative implementation approach that would focus its final product verification sampling on establishments that have a demonstrated lack of process control. Under such an approach, FSIS would establish a microbial process control standard based on a threshold or some other parameter and require that establishments conduct sampling at a frequency sufficient to demonstrate that they are meeting the process control standard. Establishments whose results exceed the process control standard would be required to conduct intensified sampling, including environmental sampling and sampling at multiple points in the process, to determine if the initial results were an outlier or if there are problems with the establishment's production process. If an establishment's intensified sampling results show that it is meeting the process control standard, the establishment would return to the standard sampling protocol. If the establishment continues to exceed the process control standard, it would be required to take corrective actions and continue to conduct intensified sampling. If the establishment exceeds the process control standard again, FSIS would collect and analyze final product samples for *Salmonella* levels and serotypes because, at this point, the establishment would have a record that demonstrates that there are problems with its production process. The establishment would be required to control product represented by the sampled lot pending FSIS' test results. Product that tests positive for *Salmonella* at or above 10 cfu/mL(g) and a *Salmonella* serotype of public health significance would be considered unfit for human food and would be prohibited from entering commerce. If the establishment released the product into commerce, the product would be subject to recall.

III. Component Two: Enhanced Establishment Process Control Monitoring

A. Background and Current Regulatory Requirements

Process control monitoring, in the context of poultry slaughter, consists of the programs and procedures an establishment implements to ensure its processes are operating as intended in preventing contamination (including contamination with enteric pathogens and fecal material) of poultry carcasses

and parts throughout the slaughter and dressing process and to ensure that the resulting products meet applicable regulatory standards or definitions (79 FR 49565, 49602). Establishments must demonstrate that their process is in control by implementing verification procedures, collecting data, and developing and maintaining accurate records to demonstrate that their processes and procedures are performing as intended and as required (9 CFR 381.65(g) and (h) and 9 CFR part 417). An effective process control system entails an establishment responding effectively to re-establish control when its ongoing verification activities show that its processes are not producing the expected results. Effective process control monitoring procedures should lead to lower rates of pathogen contamination because establishments will discover deficiencies in processing sooner and more reliably than would be the case without effective process control monitoring procedures.

Contamination of poultry carcasses and parts by enteric pathogens and fecal material (e.g., *Salmonella* and *Campylobacter*) are hazards reasonably likely to occur in poultry slaughter establishments unless addressed in a sanitation SOP or other prerequisite program (79 FR 49565, 49613). To ensure that establishments that slaughter poultry implement appropriate measures to prevent carcasses from becoming contaminated with pathogens, and that both FSIS and establishments have the documentation to verify the effectiveness of these measures on an on-going basis, current regulations require, among other things, that all establishments that slaughter poultry other than ratites develop, implement, and maintain written procedures to prevent contamination of poultry carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing operation (9 CFR 381.65(g)). Establishments are required to incorporate their process control procedures into their HACCP plan, sanitation SOPs, or other prerequisite programs (collectively, "the HACCP system") and maintain daily records sufficient to document the implementation and monitoring of these procedures (9 CFR 381.65(g) and (h)).

Microbiological test results that represent levels of microbiological contamination at key steps in the slaughter process are necessary for establishments to provide comprehensive, objective evidence that they are effectively maintaining process control to prevent carcasses from

becoming contaminated before and after they enter the chiller (79 FR 49565, 49602). At present, establishments conduct pre-chill testing to monitor how well an establishment is minimizing contamination on live birds coming to slaughter and on carcasses throughout the slaughter and dressing process, and post-chill testing to monitor how well an establishment is minimizing contamination during chilling and the overall effectiveness of any antimicrobial interventions that were applied (79 FR 49565, 49566). FSIS also collects a verification sample at the post-chill location and tests for *Salmonella* and *Campylobacter*. In 2012, FSIS considered requiring a third establishment sampling location at rehang (i.e., after picking and prior to evisceration) to monitor the incoming load of pathogens but concluded that it was unnecessary to impose the additional costs on industry (77 FR 4407, 4428).

Regulations at 9 CFR 381.65 (h) and 9 CFR 417.5 (a)(1) require establishments to document their procedures and results in records subject to Agency verification. At a minimum, these procedures must include sampling and analysis for microbial organisms at the pre- and post-chill location to monitor for process control, with an exception for VS and VLV establishments operating under the Traditional Inspection System (9 CFR 381.65 (g)(1)).¹³⁸ In 2014, FSIS stated that because these establishments are typically less automated and run slower line speeds than larger establishments operating under other inspection systems, they may require less complicated measures for maintaining and monitoring process control on an ongoing basis (79 FR 49565, 49603). Therefore, at present, they are required to collect and analyze samples for microbial organisms only at the post-chill location.

In addition to prescribing the sampling locations for monitoring process control, the regulations specify a minimum sampling frequency to ensure establishments can detect changes in processing or inconsistencies

¹³⁸ Very small establishments are establishments with fewer than 10 employees or annual sales of less than \$2.5 million dollars (9 CFR 381.65(g)(1)(i)). Very low volume establishments annually slaughter no more than 440,000 chickens, 60,000 turkeys, 60,000 ducks, 60,000 geese, 60,000 guineas, or 60,000 squab (9 CFR 381.65(g)(1)(ii)). Traditional Inspection must be used for turkeys when neither the New Turkey Inspection System (NTI) nor the New Poultry Inspection System (NPIS) is used. For other classes of poultry, Traditional Inspection must be used when SIS, NELs, and the NPIS are not used (9 CFR 381.76(b)(1)(v)).

that may occur (79 FR 49565, 49604). At a minimum, for chickens, establishments are required to collect a pair of pre-and post-chill samples once per 22,000 processed carcasses, but at a minimum of once each week of operation, and for turkeys, ducks, geese, guineas, and squab, establishments are required to collect a pair of samples once per 3,000 processed carcasses but a minimum of once each week of operation (9 CFR 381.65(g)(2)(i)). To minimize the sampling costs to the lower volume establishments, VLV establishments must minimally collect and analyze samples at least once during each week of operation starting June 1 of every year. If, after consecutively collecting 13 weekly samples, an establishment can demonstrate that it is effectively maintaining process control, it may modify its sampling plan (9 CFR 381.65(g)(2)(ii)). All establishments are required to conduct testing at a frequency sufficient to detect a loss of process control soon after it occurs so that they can take the necessary corrective actions to prevent further product contamination (79 FR 49565, 49605). Therefore, regardless of the prescribed minimum sampling frequency, the establishment must sample at a frequency that is adequate to monitor their ability to maintain process control for enteric pathogens and fecal contamination (9 CFR 381.65(g)(2)(iii)).

When FSIS updated its poultry inspection regulations in 2014 (79 FR 49565), it referenced data from FSIS' 2007–2008 Young Chicken Baseline survey (hereinafter, the “baseline survey”), which found levels of detectable generic *E. coli* (GEC) on post-chill carcasses well below the performance criteria in the existing regulations.¹³⁹ The baseline survey found that over 60 percent of samples had non-detectable levels of GEC. Among 12 establishments from which 10 or more samples were analyzed, none had detectable levels of GEC. On the other hand, FSIS analyzed 22 samples from each of 2 of these establishments and found that all 44 samples had detectable AC measurements. FSIS also concluded that AC levels at rehang were more highly correlated with *Salmonella* than GEC levels which suggested that AC measurements might provide a better measure of process control.¹⁴⁰

¹³⁹ FSIS (2007). Young Chicken Survey (baseline) June 2007–June 2008. https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Baseline_Data_Young_Chicken_2007-2008.pdf.

¹⁴⁰ Williams, M.S., et al. (2015). “Industry-level changes in microbial contamination on market hog and broiler chicken carcasses between two locations

Despite the baseline survey findings, FSIS did not require that establishments use a specific microbial organism to monitor process control when it updated its regulations in 2014. Thus, at present, establishments decide which microbiological organisms will best help them to monitor the effectiveness of their process control procedures and may develop sampling plans to test carcasses for enteric pathogens, such as *Salmonella*, or another appropriate indicator organism. Because establishments must incorporate their microbiological sampling plan into their HACCP system, they are required to provide scientific or technical documentation to support the judgements made in designing their sampling plans, as required by 9 CFR 381.65 (h) and HACCP regulation 9 CFR 417.4(a).

B. Need To Enhance Establishment Process Control Monitoring

Based on NACMCF recommendations, an analysis of PHIS inspection results, sampling data, and the findings of the 2023 risk assessments, FSIS has determined that there is a need to enhance establishment process control monitoring. These recommendations and findings are discussed below and collectively support FSIS' conclusion that regulatory revision will improve establishments' ability to monitor microbiological process control; demonstrate the effectiveness of their measures to prevent carcasses from becoming contaminated; and ensure that both FSIS and establishments have the documentation necessary to verify the effectiveness of these measures on an on-going basis. These recommendations and findings have also prompted FSIS to evaluate the need for additional resources, services, and guidance to help establishments develop microbiological process control monitoring programs and comply with FSIS requirements.

1. NACMCF Charge and Recommendations

According to NACMCF, process control can be defined as maintaining the output of a process within a desired range based on stability and capability to meet specifications.¹⁴¹ Process

in the slaughter process.” *Food Control* 51: 361–370.

¹⁴¹ Note that a process can be stable and not capable of meeting specifications, or an unstable process may produce product that meets specifications. NACMCF (2015). “Regarding Microbiological Criteria as Indicators of Process Control or Insanitary Conditions, available at https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/NACMCF-Report-Process-Control-061015.pdf.

control is accomplished through six steps: (1) The output must be monitored and quantified with appropriate sampling and testing; (2) There must be predefined limits and targets traceable to acceptable specifications and the history of the process; (3) The monitoring results must be compared to the relevant process control limits; (4) There must be a predetermined plan of action (such as a corrective action plan) based on the size and frequency of deviation from relevant limits; (5) The proper action must be decided upon based on the observed deviation; and (6) the proper action must be promptly taken to adjust the process.¹⁴²

In 2015, NACMCF provided microbiological limits for food categories that reflect process control and sanitary manufacturing conditions. These limits can help FSIS-regulated establishments develop systems for measuring SPC. SPC is an approach that uses statistical methods to monitor and control a process. A process is under statistical control when the output varies as expected within a statistical range. Process variability is caused by chance or assignable causes. Assignable causes can be linked to improperly adjusted or controlled machines, operator errors, or defective raw material. A process that is operating with assignable causes is out-of-control.¹⁴³ Process capability is defined as the degree by which SPC limits fall within specifications. If the process exceeds an upper or a lower specification limit, the product does not meet the specification even if it is operating without assignable causes and is in control. Process capability is traditionally measured using a process capability index (Cp). For example, USDA's Agricultural Marketing Service uses Cp to monitor process control of fat content meeting allowable upper and specification lower limits and a one-side calculated process capability to monitor process control of microbial detection levels meeting upper allowable limits in raw beef finished products as part of the National School Lunch Program.¹⁴⁴

Using microbiological testing to monitor SPC presents some challenges. Some testing may result in a discrete (presence/absence or binary) result or a continuous measure such as a plate

¹⁴² NACMCF (2018). “Response to Questions Posed by the Department of Defense Regarding Microbiological Criteria as Indicators of Process Control or Insanitary Conditions.” *J Food Prot* 83(1): 115–141.

¹⁴³ Montgomery, D.C. (2013). Introduction to Statistical Quality Control 7th edition, chapter 5.

¹⁴⁴ AMS National School Lunch Program, information available at: <https://www.fns.usda.gov/nslp>.

count. Binary results and plate counts are typically modeled using a binomial or Poisson probability distributions, and their log-transformed values usually follow a lognormal distribution from which the statistical mean and variance may be calculated and used for SPC analyses that assume a normal probability distribution. Count data may include zero results, either due to the absence of the organism, or presence at levels below or above the test's limits of quantitation (LOQ). The later result is referred to as a censored value. Data with censored results exceeding the number of zeros expected by the Poisson distribution may consist of a heterogeneous mixture in which the organism is completely absent from some portion of the product and present in another portion. Such results may follow a zero-inflated Poisson distribution. A variety of methods have been proposed to fit censored data to a probability distribution. The choice of method depends on the number of samples and the proportion with enumerated samples. A distribution function cannot be reliably fitted to a dataset where fewer than 20 percent of samples are enumerated,¹⁴⁵ which is an important consideration for using count data. Other considerations for SPC include sampling frequency and lot definition. With respect to frequency, counts are more robust than binary results, and indicators of process control are best obtained with higher frequency sampling. NACMCF recommended sampling frequency be capable of detecting the presence of expected assignable causes within the first 10 percent of their persistence time since disruptions occur for a finite period and not much is learned if the disruption is not detected or detected too late for corrective action. Product lot definition has implications both for determining the acceptability of a lot and for monitoring SPC. In general, the defined product lot should be produced under reasonably constant conditions so that a lot is a homogeneous volume of contemporaneous production for calculating the mean level and variability. For poultry slaughter and dressing, a homogeneous volume of contemporaneous production means that each lot should represent a cohort (flock) of birds raised, transported, slaughtered and processed over the same period and locations. Production lots with equivalent means may have

different variabilities and therefore, SPC methods should evaluate variance both within and between production lots.

When a microbiological sampling program is properly designed and implemented, it can provide valuable information about an establishment's process control. A well-designed microbiological sampling program should clearly define the intended use of the testing program, organisms of concern that will be the target of testing, sampling units (flocks, houses at preharvest, carcasses or parts at post-harvest), sampling scheme, microbiologically independent lotting practices, sampling locations, procedures for sample collection and for maintaining sample integrity, testing method, method for evaluating test results, and actions taken based on test results.¹⁴⁶ Results charting is typically used to identify trends and for identifying exceptions to process control that could be due to assignable causes. For low frequency binary results, NACMCF recommended a g-chart based on mean time between events. For higher frequency binary results, a p-chart based on proportions is recommended, and for counts, mean and range charts can be used.

In 2019, NACMCF concluded that most carcass contamination results from leakage of ingesta during crop removal, from feces during evisceration, as well as aerosolization during picking.¹⁴⁷ The committee also advised, to best assess controls, each establishment should look at the whole food safety system from breeder farm through processing, so it is not overwhelmed by the incoming load. Evaluating the prevalence and concentration of *Salmonella* on carcasses and parts throughout the production process unique to each facility can help to identify pathogen reduction at each step in the process.

In its October 2021 charge to the NACMCF Subcommittee on Enhancing *Salmonella* Control in Poultry Products, FSIS noted there is a documented correlation between a reduction in the quantity of AC between carcasses and finished products and the occurrence of *Salmonella* in finished products for beef, pork, and poultry. The Agency specifically requested that the Subcommittee provide guidance on how this information might be used to set

microbiological criteria to assess process (pathogen) control in poultry.¹⁴⁸

In response to FSIS' request for guidance on setting microbiological criteria to assess process control in poultry, the 2023 NACMCF report discussed process control as a method of determining trends over time and how it is useful to determine the sources of variation within a process. It noted that "indicator organisms such as *Enterobacteriaceae* (EB) or [AC] have been used by the industry as gauges of process control and to measure the microbial reduction from carcasses at slaughter to post-chill." The report stated that "studies show conflicting and apparent weak correlation between indicators and either the presence or level of *Salmonella* post carcass wash." The report also stated that, in addition to published studies, "unpublished data provided by the poultry industry and university researchers suggests that indicator bacteria have very limited predictive value for the prevalence of *Salmonella*."

Although the report found that the available data show that in many cases there may not be a strong statistical correlation between the presence or amount of an indicator and the presence or amount of *Salmonella* at specific points during processing or in finished poultry products, the report concluded that, "... a change in [AC] from an early sampling point on the slaughter line to a final sampling point on the processing line, as well as absolute levels at the final point, may provide useful information about the effectiveness of the process in maintaining hygienic conditions." Therefore, the report concluded, "[AC] may be useful to indicate process control even though it is not a true indication of the presence, level, or virulence of *Salmonella*."

2. PHIS Inspection Data

The purpose of 9 CFR 381.65(g) and (h) is to ensure that establishments implement appropriate measures to prevent carcasses from becoming contaminated throughout the slaughter and dressing operation. Establishments must design and implement a program that uses microbiological sampling and analysis to monitor their ability to maintain process control and produces the documentation needed for FSIS and the establishment to continuously verify the effectiveness of these measures on an on-going basis, *i.e.*, an MMP. Establishments must provide scientific and technical support to justify the design of their MMPs.

¹⁴⁵ Williams, M.S., et al. (2013). "Sample size guidelines for fitting a lognormal probability distribution to censored most probable number data with a Markov chain Monte Carlo method." *International Journal of Food Microbiology* 165(2): 89–96.

¹⁴⁶ NACMCF (2019). "Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry." *Journal of Food Protection* 82(4): 645–668.

¹⁴⁷ NACMCF (2019). "Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry." *Journal of Food Protection* 82(4): 645–668.

¹⁴⁸ 2021–2023 NACMCF report: Question 5.

As discussed, SPC monitoring evaluates microbial data against predefined quantitative and qualitative specifications. SPC monitoring results that do not fall within the predefined specifications with assignable causes indicate a process is not capable or in control. An effective MMP must, therefore, define and support the quantitative and qualitative microbial monitoring criteria an establishment will use to gauge whether its process is in control and the corrective actions it will take when its microbial monitoring results are not within its predefined parameters. Specifically, the establishment MMP must incorporate three criteria—target change, quantitative consistency, and qualitative consistency standards. “Target change” refers to the expected change in quantified levels of microbial contamination detected between two monitoring points that supports the procedures’ ability to control contamination as required in 9 CFR 381.65(g) and as expected by the establishment. “Quantitative consistency” is measured by how close individual sampling results are to defined target change parameters and how much variation is expected amongst the results over time. “Qualitative consistency” is measured by assessing whether MMP process control findings are consistent with other process control monitoring results representing the same procedures (e.g., fecal zero tolerance monitoring). Consistency can also be qualitatively assessed as whether the MMP process control determination is consistent with the process control determination for the HACCP system overall, i.e., if all HACCP monitoring intended to assess process control draws the same conclusion. An effective MMP also defines how an establishment will respond when performance is not as expected, such as the corrective actions it will take.

A recent analysis of PHIS inspection data identified issues with the design and implementation of establishment MMPs, including how establishments respond to MMP results.¹⁴⁹ FSIS analyses of the PHIS inspection verification data from February 17, 2015, through December 31, 2022, found that MMP noncompliance with 9 CFR

381.65(g) was most often associated with sampling frequency and the monitoring of results to ensure frequency compliance (49 percent). Specifically, NRs showed establishments did not plan or adjust their sampling plan minimum frequencies in accordance with the actual slaughter volume; failed to collect samples at the frequency planned, at the minimum frequency required, or to collect additional samples when collected samples could not be analyzed. These noncompliance issues indicate that establishments are not assessing or adjusting the sampling frequency procedures in their MMPs as necessary due to their failure to identify and document the absence of expected monitoring results. These noncompliance issues also show that establishments often fail to provide adequate justification for not evaluating and updating the sampling frequency procedures in their MMPs in response to monitoring results, IPP observations, or other relevant information indicating that their current sampling frequency is not adequate to monitor process control.

NRs also indicated establishments failed to identify monitoring criteria, monitoring deviations, or documented trends or—when identified—failed to perform any root cause assessment for the deviation or perform corrective actions (31 percent). Further, NRs show that establishments failed to implement their sample collection or laboratory analysis methods as written (12 percent). These findings indicate establishments are not adequately considering or utilizing the MMP monitoring of process control in their overall consideration of whether the procedures incorporated into the HACCP system are performing as expected and the HACCP system is overall controlling the hazard to the acceptable level as intended.

3. Exploratory Sampling Program Data

As noted above, from April to November 2022, FSIS implemented an exploratory sampling program¹⁵⁰ to generate microbial data to inform the Agency’s effort to reduce *Salmonella* illnesses attributable to poultry. Under the program, rehang and post-chill rinsate samples were tested for *Salmonella*, AC, and EC, and beginning August 11, 2022, for *Salmonella* levels using a quantitative method adopted by FSIS laboratories.

Overall, FSIS analyzed 4,654 paired samples collected from 204 of the 272 establishments that slaughtered young

chicken in Calendar Year 2022. Testing results indicated that 2,910 rehang and 232 post-chill samples were positive for *Salmonella*. Of these, 1,460 rehang and 121 post-chill samples were analyzed with the *Salmonella* quantitative method, and the results indicated that approximately 90 percent of rehang and 86 percent of post-chill samples were below the lower LOQ.¹⁵¹ Further, out of the 4,654 paired samples, tests detected AC in 4,592 and EB in 4,580 of both the rehang and post-chill location samples. Of the pairs that detected the AC or EB at both locations, 69.2 percent of the pairs yielded a quantified value at both rehang and post-chill for AC; whereas only 15.9 percent yielded a quantified value for EB.¹⁵²

Of the 3,177 paired samples with quantified levels of AC, 98.7 percent demonstrated a reduction in AC from rehang to post-chill; while only 1.29 percent of paired samples demonstrated an increase in AC.¹⁵³ Among the 180 establishments with 12 or more analyzed paired samples,¹⁵⁴ all 180 establishments had greater than 20 percent of samples with AC detectable above the lower LOQ at post-chill, and 25 percent had greater than 20 percent of samples with EB above the lower LOQ. *Salmonella* percent positive was reduced from rehang to post-chill by an average of 56.6 percent and AC quantified level was reduced an average of 2.93 log₁₀ cfu/mL (74 percent reduction).

Based on these findings, FSIS concluded that microbial monitoring of EB or *Salmonella* is unlikely to yield the reliable quantified results necessary for an individual establishment to support SPC monitoring. There has been an observable decline in post-chill levels of organisms detected since the 2007–2008

¹⁵¹ The lower LoQ for the *Salmonella*, AC, and EC tests utilized by FSIS laboratories was 10 cfu/mL.

¹⁵² Comparatively, FSIS’s 2007–2008 baseline survey did not assess results as true pairs or when both rehang and post-chill yielded quantifiable results. This prior survey reported the 3,275 analyzed pairs had levels significantly lower at post-chill and quantifiable AC and EC was detected in 97.1 percent and 57.4 percent of post-chill samples, respectively. The average rehang and post-chill AC values reported 4.51 log AC and 2.43 Log AC and EC as 3.28 Log EC and 1.57 Log EC, respectively (average change 2.08 Log AC and 1.71 Log EC). <https://www.fsis.usda.gov/node/1973>.

¹⁵³ Because a distribution function cannot be reliably fitted to a dataset where fewer than 20 percent of the samples are above the LOQ, FSIS has only summarized results for quantitative AC, not *Salmonella* or EC. See Helsel, D. R. (2005). “Nondetects and Data Analysis: Statistics for Censored Environmental Data.”

¹⁵⁴ FSIS had estimated at least 12 pairs would be necessary over the study period to evaluate an individual establishment’s indicator organism performance and 180 of the 204-establishment sampled had at least 12 pairs analyzed.

¹⁴⁹ 7096 noncompliance records (NRs) citing 381.65(g) were issued between 2/17/2015 and 12/31/2022; 8 had incomplete descriptions and were not further analyzed. Each of the 7088 NRs were read by OFO analysts to determine if the microbial monitoring program was reviewed as part of the verification and if the establishment microbial monitoring program was documented to be the cause of observed noncompliance.

¹⁵⁰ FSIS Notice 44–22Revised Young Chicken Carcass Exploratory Sampling Program.

Young Chicken Baseline Survey. The current data shows that AC is more likely to yield reliably detectable quantified microbial results compared to either EB or *Salmonella* for most establishments. Additionally, given all establishments sampled consistently demonstrated a qualitative decrease in levels of organisms detected between rehang and post-chill, FSIS has determined that assessing the quantified level of decrease achieved is more informative of individual establishment process control changes and trends than the qualitative criteria of whether a decrease occurred.

4. FSIS Risk Assessments

The 2023 risk assessments for *Salmonella* in chicken and turkey evaluated, among other things, the public health impact of monitoring and enforcing process control from rehang to post-chill.¹⁵⁵ For all young chicken establishments sampled during the 2022 exploratory sampling program, FSIS measured an average of 4.40 and 1.39 log AC per mL at rehang and post-chill locations, respectively, *i.e.*, an average reduction of 3.01 log AC per mL. Comparatively, the 2007–2008 baseline survey measured an average of 4.50 and 2.46 log AC per mL at rehang and post-chill locations, respectively, *i.e.*, an average log reduction of 2.04 log AC per mL. These data show that between 2008 and 2022, there were no decreases in incoming AC loads on chicken carcasses; however, during that time, establishments achieved an additional 1 log reduction in AC levels after slaughter and processing. Based on this current study it is reasonable to expect reductions of 3 logs in *Salmonella* between rehang and post-chill. The risk assessment found weak correlations between post-chill *Salmonella* prevalence and AC, either based on the AC reduction between rehang and post-chill, or the fraction of post-chill samples where AC is not observed. Ultimately, FSIS' recent chicken risk assessment concluded that a hypothetical AC reduction standard could achieve a 25 percent reduction in *Salmonella* illnesses attributed to chicken only if microbiological criteria based on 2.5–3.0 log reduction or no AC tests exceed 10 cfu/mL at the post-chill location. The risk assessment concluded that AC is only moderately correlated with the occurrence of *Salmonella* and thus an AC based standard would

perform less well than a *Salmonella* standard.

In addition to identifying a decrease in the average level of log AC detected at post-chill between the 2007–2008 baseline survey and 2022 exploratory sampling program from 2.46 to 1.39 log AC per mL, respectively, the 2023 chicken risk assessment identified a decrease in the proportion of young chicken carcass post-chill AC results above the limit of detection (LOD), from 97.1 percent at baseline to 70.0 percent currently. EB followed a similar trend with 57.4 percent during the prior baseline to just 16.1 percent above the LOD currently.

The 2023 turkey risk assessment reported that the correlation between AC or EB and *Salmonella* prevalence is weak, and it was not possible to fully assess the public health impact of monitoring and enforcing process control from rehang to post-chill.

C. Proposals To Enhance Establishment Process Control Monitoring

FSIS is proposing to amend 9 CFR 381.65(g) and (h) to establish new requirements pertaining to how establishments monitor and document whether their processes for preventing microbial contamination throughout the slaughter and dressing operation are in control. The goal of the proposed amendments is to clarify existing regulatory requirements related to process control monitoring and recordkeeping in 9 CFR 381.65(g) and (h) and to better define requirements with respect to the type of microbial data that should be collected, how the data should be analyzed, the level of acceptable process control deviations, and how establishments should respond to process control deviations. The clarifications are also intended to promote the collection of more standardized data by establishments to facilitate data quality. If this proposed rule is finalized, FSIS intends to update relevant guidance to help establishments comply with new requirements.

1. SPC Monitoring

This proposed rule revises 9 CFR 381.65(g) to require establishments to incorporate SPC monitoring principles into their MMPs. As discussed, SPC monitoring uses statistical methods to compare quantitative results against predefined benchmarks and, thereby, determine whether a process is operating within expected parameters.¹⁵⁶

The proposed revisions to 9 CFR 381.65(g) would therefore require establishments to use only validated microbial sampling and laboratory analysis procedures, generate and record statistically meaningful microbial monitoring data, set benchmarks by which to evaluate microbial monitoring data, and to otherwise define the statistical methods the establishment will use to evaluate the recorded data against the predefined limits. The MMP design should also be consistent with other process control monitoring procedures and the establishment's HACCP system. For example, if an establishment assesses process control independently by evisceration line for visible fecal contamination, the establishment's MMP for process control of procedures to prevent fecal contamination should also be separated by evisceration line.

Statistical Methods. There must be scientific and technical support to justify the design of a MMP, including the statistical methods an establishment will use. Specifically, the MMP must include documentation and data demonstrating the initial scientific basis, validation, and ongoing verification of the statistical methods, including whether the quantified monitoring data generated by the establishment's process is normally or not normally distributed and whether the statistical method is appropriate. In instances where the minimum sampling frequency requirements of 9 CFR 381.85(g)(2) do not generate "statistically robust" results, an establishment must either increase its sampling frequency to generate robust results or provide support to demonstrate that the minimum frequency of collection is, nonetheless, adequate to demonstrate whether its particular process is in control.

FSIS has developed a Lower Capability Process Index (CPL) Statistical Measurement Model (SMM) which fits parameters for normally distributed data. The CPL–SMM is available for review and comment on the FSIS website.¹⁵⁷ Under this proposal, the CPL–SMM would be considered a "safe harbor," in that establishments that incorporate the CPL–SMM into their MMPs would not be required to provide FSIS with

¹⁵⁵ The risk assessments analyzed data from the 2022 Exploratory Project, 2007–2008 Young Chicken Baseline Survey, and the 2008–2009 Turkey Baseline Survey.

¹⁵⁶ NACMCF (2015). "Regarding Microbiological Criteria as Indicators of Process Control or

Insanitary Conditions, available at https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/NACMCF-Report-Process-Control-061015.pdf.

¹⁵⁷ Statistical Process Control Monitoring Method Assessment and the FSIS Proposed Lower Capability Process Index (CPL) Statistical Measurement Model (SMM) available at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

additional scientific or technical information to support their chosen statistical methods.¹⁵⁸ Should FSIS finalize this proposal, the Agency would make available on its website an electronic file for download (*i.e.*, a spreadsheet) programmed to calculate the change achieved, CPL, and chart results as the establishment inputs each sampling result as it is received from the laboratory. FSIS will provide relevant instructions for adopting the “safe harbor” method in a future guidance document. An example of the electronic file that FSIS intends to provide is available for viewing and public comment at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

FSIS requests comments on its proposed CPL–SMM and the related electronic file. FSIS also requests input on any other statistical monitoring methods that FSIS should recognize as satisfying the requirements of 9 CFR 381.65(g) without further scientific support, including but not limited to methods for normally and non-normally distributed results, use with specific indicator organisms, and various analyzed results sample sizes. FSIS requests that commenters include the appropriate data necessary to support any proposed alternatives as these data may not have been available to FSIS at the time of this rulemaking.

Target Change and Quantitative Consistency Criteria. To effectively incorporate SPC monitoring into an MMP, establishments must define and support target change and quantitative consistency microbial monitoring criteria. “Target change,” in the context of microbial process control monitoring, is the expected change in quantified levels of microbial contamination detected between two sampling locations that supports a procedure’s ability to control contamination as minimally required in 9 CFR 381.65(g) and as expected by the establishment. For an MMP, target change parameters must be appropriate for the microbial monitoring organism an establishment uses to monitor process control. At a minimum, establishment MMPs must define the minimum target change expected (lower specification limit). The minimal level target change approach sets a benchmark from which establishments can evaluate trends in

microbial contamination during slaughter and dressing with other trends in slaughter performance data such as pathogen, feces and ingesta, and sanitary operations monitoring findings. Establishment MMPs may also define a maximum target change expected (upper specification limit).

AC and EB are routinely utilized to monitor poultry slaughter process control and are frequently reported in logarithmic format (log).¹⁵⁹ FSIS’ review of current scientific support indicates that, when monitoring indicator organisms reported in log, establishments should strive for a minimum target change value of 1 log reduction and that a change between 0 and 1 log is not reliably detected in normally distributed data, particularly at the statistical power associated with the single pair minimum sampling frequencies prescribed in 9 CFR 381.65(g)(2).¹⁶⁰ The 2023 risk assessment also identified a moderate correlation with the detection of post-chill *Salmonella* when at least a 3 log AC change was observed.¹⁶¹ Moreover, FSIS’ exploratory sampling program observed an average 2.93 log AC reduction in establishments with at least 12 carcass pairs analyzed.

Based on these findings, the Agency would consider an establishment’s target change criteria to meet the requirements in 9 CFR 381.65(g) when its MMP sets an expected reduction of at least 1.0 log in detected microbial levels between sampling locations.¹⁶² Establishments may, of course, set more stringent target change criteria in their MMP than the minimum 1.0 log reduction without providing additional support to FSIS. MMPs that define an expected target change value of less than 1.0 log must include

comprehensive scientific support to demonstrate that its target change criteria reflect a statistically reliable value for measuring process control and why its expected target change is less than changes identified in national baseline data (*e.g.*, 2 log or 3 log as above). Establishments that conduct microbial sampling and testing in more than two locations in the slaughter process may define different quantified values to be achieved between the various points but, minimally, the target change value for monitoring between each pair of points should meet the minimum requirement as appropriate for the microbial monitoring organism being monitored. Similarly, establishments monitoring more than one shift, evisceration line, or species/subclass of poultry may elect to define different quantified target change values expected providing they meet the same minimum requirements. In any event, establishments must use scientifically validated mathematical methods to calculate the change in levels detected between sampling locations. FSIS would consider a simple subtraction method (*e.g.*, Sampling Point-A log value—Sampling Point-B log value) to be scientifically valid.

MMPs must also define quantitative consistency criteria. As discussed, SPC monitoring includes assessing the variation of results as each result is reported and over time to identify and detect when procedures may not be functioning as intended to prevent the enteric pathogen and fecal contamination from being introduced at one or more points in the process. In statistical applications, 99 percent of results fall within 6 standard deviations of the mean, or 3 standard deviations on either side of the mean. For an MMP monitoring whether the minimum target change expected is met (lower specification), the detected change between the two points monitored is within 3 standard deviations less than the average change detected for all samples in the monitoring period.

The establishment MMP must define and support the acceptable quantitative consistency (statistical variation) expected among the changes detected over time. The quantitative consistency expected must not exceed 3 standard deviations lower than the mean and for the establishment to conclude microbial contamination variability was controlled (one-side for lower specification). That is, FSIS recognizes the MMP defined quantified value is minimally supported when the sample result is no more than 3 standard deviations below the mean. As with target change criteria, establishments are

¹⁵⁸ Establishments are to be aware that the proposed CPL–SMM reflects the *minimum* frequency prescribed in 9 CFR 381.65(g)(2), and the establishment may need to increase the frequency of collection to meet compliance with the requirement the frequency is adequate to monitor their ability maintain process control as required under 9 CFR 381.65(g)(2)(iii).

¹⁵⁹ Microbial organism levels are frequently transformed to base 10 logarithmic format (log) for statistical assessment unless the conversion would result in log “0” censored data result.

¹⁶⁰ De Villena, J.F., et al. (2022). “Bio-Mapping Indicators and Pathogen Loads in a Commercial Broiler Processing Facility Operating with High and Low Antimicrobial Intervention Levels.” *Foods* 11(6): 775. Cano, C., et al. (2021). “Application of Peroxyacetic Acid for Decontamination of Raw Poultry Products and Comparison to Other Commonly Used Chemical Antimicrobial Interventions: A Review.” *J Food Prot* 84(10): 1772–1783. Brashears, M.M. and B.D. Chaves (2017). “The diversity of beef safety: A global reason to strengthen our current systems.” *Meat Sci* 132: 59–71.

¹⁶¹ Quantitative Microbial Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

¹⁶² FSIS notes that all sample results in the exploratory CPL–SMM modeling datasets had AC reductions greater than 1 log (97.5 percent) and mean log AC reductions across the exploratory sampling period were greater than 1 for 98.7 percent of establishments.

encouraged to define quantitative consistency criteria at each point monitored and may also set quantitative consistency criteria specific to shift, line, or specific/subclass of poultry slaughtered, provided the consistency variation target limit meets the minimum requirements discussed herein. Establishment MMP monitoring criteria decisions for target change and quantitative consistency expected, and the actual values observed during monitoring, must also consider and support the establishment's MMP organism, location, and frequency decision rationale. Establishments must assess their results as ongoing validation data to maintain support for all MMP requirements.

Monitoring Period. As discussed, SPC involves an assessment of trends measured over time. As such, an establishment's MMP must define the period over which trends will be assessed, *i.e.*, the "monitoring period." FSIS' assessment of exploratory sampling program and *Salmonella* Initiative Program¹⁶³ data found that the sample collection frequency impacts

the monitoring period required to generate a statistically robust sample size and how quickly the entire sample size is replaced with new results, *i.e.*, the "sample size turnover." Based on the assessment of these available data, FSIS has identified the monitoring periods necessary for establishments to adequately assess trends over time. Establishments that incorporate these monitoring periods into their MMPs would not be required to provide the Agency with additional scientific or technical support.

As shown in Table 10 below, FSIS recommends that establishment MMPs define the monitoring periods as follows by the minimum monitoring frequency (paired carcass collection) prescribed in 9 CFR 381.65(g): (1) Poultry establishments collecting samples at a frequency of once per 22,000 (chicken) or 3,000 (other species) head slaughtered, respectively, or greater, are to designate a monitoring period of 140 samples or 52 weeks, whichever is shortest; (2) any poultry establishments collecting at a weekly frequency are to designate a monitoring period of the 52

most current weeks; (3) and VLV poultry establishments collecting 13 samples annually are to designate their monitoring period as all of the samples available in the most recent 52 weeks or all the samples in the current period of operations if slaughter of the predominant species is seasonal and not continuous. All poultry slaughter establishments are required to assess for trends during their designated monitoring period, as well as compare the monitoring periods for the current 52 weeks against the prior 52 weeks. Further, those establishments that collect less than weekly are to also compare trends going back an additional 52 weeks (*i.e.*, compare the current 52 weeks against the prior 104 weeks). All poultry slaughter establishments must also identify the sample size turnover rate based on their intended frequency of collection and provide scientific support for how the establishment will consider the turnover in their assessment of process control trends over time.

TABLE 10—MONITORING PERIOD BY MINIMUM FREQUENCY RECOGNIZED BY FSIS WITHOUT FURTHER SUPPORT

Poultry species	Minimum monitoring frequency	Minimum monitoring period	Minimum trend over time period
Chicken	≥1 per 22,000 head	Period necessary to obtain 140 samples or 52 weeks, whichever is shorter.	Prior 52 weeks.
Turkey, Goose, Guinea, Duck, Squab	≥1 per 3,000 head.		
Any Poultry Species	Weekly	52 weeks.	
Any Poultry Species	13 per year	All samples in 52 weeks or the period of operations for year if seasonal operations.	Prior 104 weeks.

2. Microbial Monitoring Organism

FSIS is proposing to amend 9 CFR 381.65(g) to establish new criteria that an establishment must meet to demonstrate that its selection of microbial organism is fit for purpose. Specifically, FSIS is proposing that establishments analyze for microbial organisms that are quantifiably detectable in the establishment's slaughter process and that will generate microbial monitoring data that is adequate to monitor their ability to maintain process control for enteric pathogens. Under this proposal, the establishment's measured results at each sample location must yield statistically reliable quantified value results.

The Agency recognizes that in order to successfully analyze quantified data, at least 20 percent or more of the sample size results must be quantified;

otherwise, the data will be skewed, *i.e.*, shifted above or below the true value.¹⁶⁴ Thus, to comply with the proposed revisions to 9 CFR 381.65(g), establishments would have to demonstrate and continuously validate that their chosen microbial monitoring organism generates a quantified value in at least 20 percent of the results reported at each monitored location. Results that are reported "above the limit of quantification" or "below the limit of quantification" or "0" when log transformed would not be considered as quantified results, nor would samples with results not analyzed by the establishment. The establishment would also have to demonstrate and continuously validate that for each sample monitoring location, the microbial organism can be quantified across the upper and lower levels that

actually occur in the establishment's individual process.

The Agency would consider the use of AC to monitor process control to meet the proposed criteria discussed above. FSIS has evaluated the available published studies and data at the time of rulemaking and concluded that AC are the microbial organisms most likely to result in quantified results that are reliably detectable at rehang and post-chill. Available paired microbial data representing pathogens like *Salmonella* and indicator organisms other than AC do not meet the 20 percent minimum quantified detection recommended. Establishments that choose to use other indicator organisms like EB, total coliforms, or GEC to assess the minimum target level of change, equal to or greater than 1 log₁₀, must support the estimated change in a statistically appropriate manner.

¹⁶³ FSIS Salmonella Initiative Program, details available at <https://www.fsis.usda.gov/science-data/>

[data-sets-visualizations/microbiology/microbiological-testing-program-rte-meat-and](https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/microbiological-testing-program-rte-meat-and).

¹⁶⁴ Helsel, D.R. (2005). "Nondetects and Data Analysis: Statistics for Censored Environmental Data."

Regardless of the microbial monitoring organism chosen, the proposed revisions would require establishments to demonstrate that their chosen sample collection method is appropriate for the product sampled, the microbial organism monitored, and the laboratory method used to analyze the samples. Moreover, the proposed revision would require establishments' microbial sampling results to be generated by validated laboratory analyses and methods. Current HACCP regulations also require ongoing verification of the establishment's microbial monitoring procedures including the methods and equipment used (9 CFR 417.4).

Establishments that adhere to the Agency's carcass rinse and sponge sample collection method¹⁶⁵ would not be required to provide additional support to justify their chosen method of organism collection. Further, establishments that document sample analyses by International Standards Organization (ISO) or USDA's Accredited Laboratory Program (ALP) accredited laboratories would not be required to provide the Agency with additional support to justify their use of laboratory analyses and methods. Nonetheless, all establishments would be required to demonstrate and continuously validate that their MMPs analysis method can detect the selected microbial monitoring organism at the levels intended, expected, and occurring at the monitored points in the process. FSIS requests comments on whether FSIS should require establishments to use ISO accredited or USDA ALP accredited laboratories to analyze their microbial monitoring samples.

In lieu of requiring the VS or VLV establishments that slaughter the predominate species of poultry under Traditional Inspection to utilize their own resources to meet compliance with the proposed revisions to 9 CFR 381.65(g), FSIS is proposing that such establishments have access to laboratory services provided by FSIS at no monetary cost for sample supplies, analyses, or shipment. Eligible establishments would be required to agree to terms of participation that would be publicly announced following the publication of any final rule resulting from this proposal. These terms would limit the use of laboratory microbial analyses service to eligible establishments that sample for AC, given more than 75 percent of the post-

chill carcass samples analyzed as part of the recent FSIS exploratory sampling assessment were below the FSIS lower limit of detection for EB and nearly 85 percent of the enumerated post-chill *Salmonella* were below the level of quantification.¹⁶⁶ The terms would also address laboratory service logistics such as establishment sample collection and shipment methods, collection and shipment dates to assure laboratory analysis capacity, reporting of establishment results through PHIS and LIMS-Direct email, and that the establishment agree to incorporate the FSIS CPL–SMM into its MMP exactly as described in the *Statistical Process Control Monitoring Method Assessment and the FSIS Proposed Lower Capability Process Index (CPL) Statistical Measurement Model (SMM)* at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

3. Sampling Location

FSIS is proposing to revise the sampling location regulations at 9 CFR 381.65(g)(1) to require that establishments, at a minimum, collect and analyze samples for microbial organisms at the rehang and post-chill points in the process, as opposed to the pre-chill and post-chill locations. FSIS has determined that sampling at the rehang point in the process, *i.e.*, after picking and prior to evisceration, is likely to be more effective for monitoring process control, given the introduction of carcass contamination tends to occur at slaughter process steps at or just prior to the rehang location and evisceration¹⁶⁷ and pre-chill sampling often takes place after evisceration and some antimicrobial interventions have already occurred.¹⁶⁸ The FSIS 2023 chicken risk assessment and FSIS assessment of exploratory sampling program data reported that there has been an increase in the log AC reduction achieved between rehang and post-chill influenced mostly because the levels of indicator organisms detected post-chill have declined since the prior 2007–2008 baseline study. FSIS has observed that pre-chill samples collected after evisceration and after most interventions, and prior to the

chiller, typically have lower levels of organisms detected than rehang samples collected prior to evisceration and fewer intervention steps.

Under this proposal, establishments would be required to identify and provide supporting rationale for the exact point where they intend to collect their rehang sample. Establishments would be permitted to collect a pre-chill sample at a location other than rehang if they provide supporting data to demonstrate that the alternative location is at least as effective as rehang sampling for monitoring their ability to maintain process control. However, one benefit of rehang sampling is that it allows establishments to assess the level of microbial contamination early in the slaughter process and, thereby, better understand the level of enteric pathogen hazard associated with flocks at receiving. Also, according to NACMCF, monitoring change in AC “from an early sampling point on the slaughter line to the final sampling point on the processing line . . . may provide useful information about the effectiveness of the process in maintaining hygiene conditions.”¹⁶⁹ Moreover, continuing to monitor at pre-chill, which tends to occur after establishments apply antimicrobial interventions, would make it more difficult for establishments to justify how the microbial monitoring data they generate validates that their established target change and quantitative consistency parameters are adequate to monitor process control. Thus, ideally, the exact point of an establishment's rehang sampling should be immediately after the early slaughter processing steps that are mostly likely to introduce microbial contamination and before the establishment's use of antimicrobial interventions. Establishments slaughtering poultry predominantly under religious exemptions that result in feet on, uneviscerated carcasses, or otherwise are slaughtered at post-picking but prior to the evisceration rehang step are to collect samples at the point in the process that results in the greatest source of introduction of enteric pathogen and fecal contamination.

Finally, FSIS' proposed amendments to 9 CFR 381.65(g)(1) would require VS and VLV establishments operating under Traditional Inspection to—like all other establishments—collect and analyze microbial samples at rehang and

¹⁶⁶ Quantitative Microbial Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

¹⁶⁷ NACMCF (2019). “Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry.” *Journal of Food Protection* 82(4): 645–668.

¹⁶⁸ Exploratory Project questionnaire responses indicate that 51 percent of the establishments applied one or more interventions prior to rehang, whereas all but one establishment applied one or more interventions after rehang.

¹⁶⁵ FSIS Directive 10,250.1, *Salmonella* and *Campylobacter* Verification Program for Raw Poultry Products, <https://www.fsis.usda.gov/policy/fsis-directives/10250.1>.

¹⁶⁹ 2021–2023 National Advisory Committee Meeting on Microbiological Criteria for Foods (NACMCF); FSIS Charge: Enhancing *Salmonella* Control in Poultry Products Available at: <https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021>.

post-chill locations. These establishments are currently required to collect microbial samples at the post-chill point only. To offset the economic impact of this amendment, these establishments would be eligible to have access to laboratory services provided by FSIS at no cost as described and discussed above. The FSIS 2023 risk assessment and the Agency's assessment of the exploratory sampling program data both recognized that greater levels of detected microbial organisms were more likely to be observed in the smaller size and volume establishments than the larger establishments, although microbial levels detected at post-chill were overall lower than previously observed during the 2007–2008 baseline study. FSIS has concluded that post-chill samples representing only the end of the slaughter process does not provide the same level of MMP adequacy to monitor process control throughout the slaughter and dressing process as minimum two-point sampling. Microbial monitoring at both rehang and post-chill will help VS and VLV establishments operating under Traditional Inspection to assess levels of microbial contamination at a point closer to the start of the slaughter process and the effect that their anti-microbial intervention steps have in reducing such contamination.

4. Sample Collection Monitoring Frequency

As discussed, a recent FSIS review of PHIS inspection data found that MMP noncompliance issues were frequently associated with sampling frequency and that the noncompliant establishments were most often those that produced lower volumes of product. FSIS is proposing, therefore, to amend 9 CFR 381.65(g) to make it easier for establishments to understand and comply with minimum sampling frequency requirements. First, FSIS is proposing to update the sampling

frequency regulations for VLV establishments, which currently require that such establishments collect and analyze 13 weekly samples starting on June 1 of each year. FSIS has concluded that the current requirement would not generate statistically robust process control monitoring data regardless of if the results are collected over 13 consecutive weeks or at other intervals throughout the year. FSIS has also concluded that the June 1 requirement makes it difficult for VLV establishments to demonstrate that their MMP is adequate to monitor process control without collecting additional samples at other times of the year, such as during the establishment's greatest seasonal production or the slaughter of poultry from growers associated with greater risks of increased microbial carcass contamination. As such, FSIS is proposing to revise 9 CFR 381.65(g)(2)(ii) to remove the June 1 requirement and otherwise give VLV establishments the flexibility to collect their 13 weekly samples in accordance with their slaughter operations throughout the year. The MMP decision making rationale for all establishments, regardless of annual slaughter volume, must support how the establishment will determine when the monitoring will be performed and how the specific carcass will be selected for sampling.

Second, to help all establishments better understand their minimum sampling frequency requirements and develop their sampling frequency procedures, FSIS is proposing to tie sampling frequency requirements to annual slaughter volumes, as opposed to weekly slaughter volumes. As discussed, FSIS review of NRs found that many establishments have trouble planning or adjusting their sampling frequency regime to comply with current regulations given actual weekly slaughter volumes tends to fluctuate irregularly. Moreover, FSIS reviewed

current sampling frequency requirements relative to annual slaughter volumes and determined that they require many lower volume establishments to collect samples at a greater rate than larger establishments.¹⁷⁰ The proposed revisions, which are outlined in Table 11 and Table 12 below, would simplify proposed slaughter volume criteria cut points for VLV, low volume, and medium to high volume establishments and make it easier for establishments to adapt to fluctuating conditions. Specifically, FSIS is proposing that medium to large volume establishments slaughtering as their predominant species *more than* 1,100,000 chickens or 156,000 other poultry species annually be required to collect at a minimum frequency of one paired sample every 22,000 or 3,000 head slaughtered, respectively.¹⁷¹ Further, FSIS is proposing that LV establishments that slaughter as their predominant species between 440,001 to 1,100,000 chickens or 60,001 to 156,000 other poultry species annually be required to collect a minimum of one paired sample a week, regardless of weekly fluctuations in their actual slaughter volume. Lastly, FSIS is proposing that VLV establishments be required to collect a minimum of 13 weekly paired samples per year. Those VLV establishments that plan to operate less than 13 weeks per year may collect their 13 annual samples on a less than weekly basis, assuming they can demonstrate that their sample frequency is effectively monitoring that they are maintaining process control throughout the year and during any periods of slaughter operations. Regardless of these *minimum* required frequencies, FSIS regulations would continue to mandate that all establishments collect samples at a frequency that is adequate for the establishment to monitor process control.

TABLE 11—PROPOSED REVISIONS TO 9 CFR 381.65(g)(2) MINIMUM SAMPLING FREQUENCY: CHICKEN

Predominant poultry species slaughtered	Establishment volume sizes	Annual slaughter head volume	Minimum frequency of paired collection
Chicken	Very Low Volume	1–440,000	13 Weekly Pairs per Year.
Chicken	Low Volume	440,001–1,100,000	Weekly.
Chicken	Medium and High Volume	≥1,100,000	1 per 22,000.

¹⁷⁰ E.g., under current regulations, non-VLV establishments that slaughter less than 22,000 chickens per week (*i.e.*, between 440,001 to 1,144,000 head annually) are required to collect at least 1 sample weekly, resulting in a collection range of 1 sample per every 8,461 to 22,000 chickens (*i.e.*, a midpoint rate of 1 sample per every

15,231 head). This is a greater sampling rate than those larger volume establishments collecting a minimum of only one sample every 22,000 head.

¹⁷¹ Under current regulations, these establishments collect 1 sample for every 22,000 chickens or 3000 other poultry species slaughtered.

This is an annualized slaughter volume of 1,140,000 head of chicken or 156,000 other species. To simplify proposed slaughter volume criteria cut points, FSIS rounded 1,144,000 to the 1,100,000 identified in Table 11; an annual slaughter of 1,100,000 averages 21,153 head per week.

TABLE 12—PROPOSED REVISIONS TO 9 CFR 381.65(g)(2) MINIMUM SAMPLING FREQUENCY: TURKEY, GEESE, GUINEA, DUCK, SQUAB

Predominant poultry species slaughtered	Establishment volume sizes	Annual slaughter head volume	Minimum frequency of paired collection
Turkey, geese, guineas, Ducks, Squab	Medium and High Volume	≥156,000	1 per 3,000.
Turkey, Geese, Guinea, Ducks, Squab	Low Volume	60,001–156,000	Weekly.
Turkey, Geese, Guinea, Ducks, Squab	Very Low Volume	1–60,000	13 Weekly Pairs per Year.

5. Corrective Actions

FSIS is proposing to amend 9 CFR 381.65(g) to further clarify that MMP monitoring results and documented corrective actions must be part of the pre-shipment review process required under 9 CFR 417.5(c). Current regulations at 9 CFR 381.65(g) require establishments to incorporate microbial monitoring procedures into their HACCP systems. Under 9 CFR 417, HACCP records must be maintained and continuously evaluated as part of the establishment’s validation, ongoing verification, and reassessment process. Moreover, HACCP regulations at 9 CFR 417.3 and 417.5 specifically require establishments to identify, in writing, the corrective actions that they will take when a HACCP system procedure may have failed. This failure may be observed by either the establishment or FSIS and may include failure to implement or maintain a procedure, evidence that the outcome of a procedure was ineffective, or when monitoring identifies the defined allowable limits have not been met.

FSIS is proposing to revise the regulations to ensure that establishments comply with these corrective action provisions as they apply to the establishment’s MMP. Specifically, FSIS is proposing to amend 9 CFR 381.65(g) to require establishments to, at a minimum, implement written corrective actions, including a root cause assessment, when microbial monitoring results deviate from predefined target change, quantitative consistency, or other criteria defined in the MMP.

FSIS is also proposing that establishments’ MMPs define the corrective actions the establishment intends to take when its MMP results do not align with other process control monitoring conclusions or when its MMP results do not support the conclusion that its HACCP system is controlling hazards as intended. FSIS recognizes a qualitative analysis of MMP results is necessary, given that a process can be stable and not capable of meeting quantitative specifications or unstable yet produce product that meets

quantitative specifications.¹⁷² Thus, establishments will need to continually consider their MMP results in conjunction with all other process control monitoring efforts to qualitatively assess the overall ability of their procedures to maintain process control and function as intended. Establishments are to investigate and implement corrective actions when their MMP monitoring results do not align with the other process control monitoring conclusions. FSIS expects establishments to consider their MMP results as part of their total HACCP system validation and ongoing verification in the assessment of whether the procedures as required by 9 CFR 381.65(g) are controlling the biological hazard (enteric pathogens) as intended by the establishment’s HACCP system. A slaughter establishment’s HACCP system should clearly identify what process control procedures are monitored by the MMP, any other process control monitoring results reflecting the same procedures, a lot of products represented by this process control monitoring, and any other procedures intended to control the same hazard as the procedures required by 9 CFR 381.65(g). Establishment documented corrective actions to observed MMP deviations must demonstrate the establishment assessed the root cause of any deviation in target change, quantitative consistency, and qualitative consistency as described above.

6. Recordkeeping Requirements

FSIS is proposing to add a new paragraph (2) to 381.65(h) that would require establishments to electronically submit a copy of their microbial monitoring results to FSIS on a monthly basis. As part of the publication of any final requirements, FSIS would provide a template to each establishment for submitting monthly results. While FSIS inspectors would continue to review process control sampling data in

establishments, the proposed change would allow FSIS headquarters personnel to evaluate national trends to determine the efficacy of the revised process control requirements in reducing final product contamination and to inform FSIS’ decision-making concerning agency verification sampling.

As part of the *Salmonella* Framework effort, FSIS met with internal FSIS, industry, and other government official stakeholders to explore potential improvements to FSIS receipt of third-party data. FSIS, academic, and industry stakeholders expressed concern around the lack of options for nationally represented industry microbial data. FSIS has determined it could update its information technology systems to provide for both individual result and bulk result data uploads by third parties. FSIS would publish guidance regarding the electronic submission of data alongside any final rule resulting from this proposal. FSIS is developing a web portal that will allow external partners to securely upload their sampling information and submit the data to FSIS electronically in a machine-readable format. The proposed fields that would be uploaded into the portal are: a sample identification number, the establishment number, date, time, slaughter line number, location of sample collection (e.g., rehang, post-chill), poultry species sampled, sample type (e.g., rinsate, sponge), analyte (e.g., AC, EB), analyte units (e.g., cfu/mL), quantified analyte result, and text analyte result (e.g., <Lower LOD, >Upper LOD). FSIS is seeking comments on the proposed data fields requested. Establishments would have the option of entering the information directly into the system or utilizing the FSIS provided spreadsheet file discussed above as a template to bulk upload the information. FSIS anticipates that most establishments would use the FSIS provided template as the HACCP MMP monitoring record to avoid duplication of monitoring results.

FSIS is also seeking comment on specific data use opportunities which could be pursued that would support FSIS investing additional resources into the technology systems necessary to

¹⁷² NACMCF (2015). “Regarding Microbiological Criteria as Indicators of Process Control or Insanitary Conditions, available at https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/NACMCF-Report-Process-Control-061015.pdf.

blind the proprietary MMP result record copies for research, industry, academic, or other pursuits.

IV. Component One: Pre-Harvest Measures

A. Scientific Support and Public Comments

Under Component One of the October 2022 draft framework, FSIS indicated that it was considering whether it should require poultry slaughter establishments to characterize *Salmonella* as a hazard reasonably likely to occur at receiving and require that incoming flocks be tested for *Salmonella* before entering an establishment. This component is grounded in the strong scientific support for use of pre-harvest interventions and management practices, in particular that removing flocks of highly *Salmonella*-contaminated birds from the slaughter process would result in less human exposure to *Salmonella*.

The results of the 2023 risk assessments underscore the potential public health benefit of requiring pre-harvest interventions and management practices to reduce *Salmonella* contamination on poultry. Within the risk assessments, risk management options for controlling *Salmonella* at the receiving step focused on chicken and turkey slaughter establishments and sample results at the rehang location as a proxy for sampling live birds at or before the receiving step.¹⁷³ The 2023 risk assessments estimated the impact of eliminating certain serotypes. Two options were modeled: in the first, rehang results were considered as a verification of pre-harvest *Salmonella* control strategies. More effective strategies mean lower rates of certain serotypes at rehang. For the second option, rehang testing results would be used to take actions, such as diverting positive flocks with higher virulence serotypes to a safe end point (e.g., cook product from those flocks).

If rehang testing is considered as a verification of pre-harvest strategies, between 27,000 and 55,000 annual salmonellosis cases could be avoided if flocks that have higher virulence serotypes were not being processed for food. Alternatively, if rehang testing is used to identify and divert contaminated carcasses, about 36,000

cases could be avoided. However, to achieve these outcomes, flocks with a higher virulence serotype would be diverted to a safe end point (e.g., for cooking at an official establishment), resulting in the diversion of 46,000 flocks. Further, the rehang step takes place during processing. Requiring processors to react to testing—with results not available to at least two days—is not feasible. Currently, FSIS analyzes about 10,000 young chicken carcasses from rinsates collected at the post-chill location annually. By comparison, there are approximately 9.384 billion carcasses that are processed each year at approximately two hundred slaughter establishments. Therefore, currently, FSIS analyzes about one out of every million young chicken carcasses processed annually.

Testing results at or before the receiving step may have a substantial public health impact. However, the requirements associated with the first option (verification of pre-harvest *Salmonella* control strategies) would require substantial industry resources, and there is no guarantee that the poultry industry would implement such *Salmonella* control strategies, since the first option would not penalize establishments for having highly virulent serotypes at the rehang step. The second option (divert flocks that test positive to a safe endpoint) would require the same resources as the first option. However, FSIS is not proposing such a diversion requirement at this time.

FSIS does not have a routine sampling program at the rehang location, but the Agency evaluated such a program as part of the 2022 young chicken exploratory sampling program discussed above. Among 180 establishments sampled twelve or more times at the rehang location, *Salmonella* positive rates for young chicken carcasses ranged from 0 to 100 percent, and the 95 percent confidence interval ranged from 54.9 to 69.0 percent. Variability at the rehang location was also observed with AC and EB. Among 180 establishments with at least twelve analyzed sample pairs, the ACs average at the rehang location was 4.40 log cfu per mL (95 percent confidence 4.34 to 4.46 log cfu per mL) and EB average was 3.00 log cfu per mL (95 percent confidence 2.94 to 3.06 log CFU per mL).

Two recent NACMCF reports, one published in March 2019 and the March 2023 NACMCF Final Report, support the important role pre-harvest measures play in controlling *Salmonella* in poultry.

2019 NACMCF Report. At a March 2017 NACMCF meeting, FSIS asked the

committee to address the issue of how to reduce the prevalence of *Salmonella* on poultry throughout the farm-to-table continuum.¹⁷⁴ In March 2019, the committee's final report addressing the Agency's questions was published in the Journal of Food Protection.¹⁷⁵ Questions two, three, and six related to pre-harvest measures to control *Salmonella* in poultry. Question two asked where *Salmonella* resides inside and on the surface of poultry and how those populations of bacteria contribute to food contamination. The committee responded that most carcass contamination is believed to result from leakage of ingesta during crop removal and from feces during evisceration, as well as aerosolization during picking. In addition, *Salmonella* may be present in feather follicles and on the surface of broilers when they enter the slaughter establishment. Several preslaughter strategies to reduce the burden of *Salmonella* in flocks entering slaughter establishments have been shown to be effective, and data demonstrating a correlation between flock status of *Salmonella* and pre- and post-chill contamination have been reported. Control measures for *Salmonella* in poultry can be classified as those that target (i) exposure and colonization within an individual animal, (ii) transmission between parent flocks and progeny, and (iii) transmission between birds within a flock. The committee also noted that *Salmonella* vaccination is one breeder-level pre-harvest intervention that contributes to an overall reduction and/or elimination of specific *Salmonella* serotypes. The committee stated that the most effective vaccination strategy is to focus on vaccination of breeder flocks and reduce vertical transmission of *Salmonella*.

Question three asked whether removing flocks of highly *Salmonella*-contaminated birds entering the slaughter establishment can reduce foodborne illnesses in humans. The committee responded that it is logical to expect that removing flocks of highly *Salmonella*-contaminated birds from the slaughter process would result in less human exposure to that source of *Salmonella*, potentially resulting in reduced foodborne illness in humans.

¹⁷⁴ 2015–2017 NACMCF Charge, *Salmonella* Control Strategies in Poultry, available at: <https://www.fsis.usda.gov/news-events/publications/2015-2017-national-advisory-committee-microbiological-criteria-foods>.

¹⁷⁵ Response to Questions Posed by the Food Safety and Inspection Service Regarding *Salmonella* Control Strategies in Poultry (March 26, 2019), Journal of Food Safety, available at: <https://www.fsis.usda.gov/news-events/publications/2015-2017-national-advisory-committee-microbiological-criteria-foods>.

¹⁷³ For chicken FSIS used rehang sample data collected during the FSIS young chicken carcass exploratory sampling program (April to November 2022). For turkey, FSIS modeled *Salmonella* at receiving using rehang sampling data from the 2008–2009 FSIS Young Turkey Carcass baseline study due to the absence of other data for the turkey industry.

However, there was no consensus within the committee regarding the predictive ability of farm sampling and subsequent *Salmonella* contamination on neck skin at the end of processing. Given uncertainty about the impact of removing flocks of highly *Salmonella*-contaminated birds from slaughter, the committee recommended that process controls be validated to address a worst-case scenario for contamination of incoming birds and be continually operating at that level to address the potential risk from highly contaminated birds. The committee concluded that rather than establishing lot- or flock-specific thresholds, *Salmonella* management programs should be based on historical trend analyses of specific farms and transportation supplying birds to the slaughter process. Sampling birds immediately before entering the slaughter process would be ideal, but detection technology did not currently exist to provide the rapid detection needed for this scenario. Historical data might be used to build statistical models to predict the potential for elevated levels of *Salmonella* from a particular farm. In addition, monitoring of external factors, such as weather or seasonality, may help indicate the possibility of a higher-than-normal contamination level. Historical knowledge of process controls and facility capability can be used by a processor to determine whether process controls should be reassessed and validated to address predicted risks.

Question six asked the committee to identify the top three focus points, control measures, or best practices that would be compatible with industry-wide practices and could be addressed or implemented to achieve the highest rate of reductions of *Salmonella* product contamination and foodborne illness. The committee's response included the statement that prevention or elimination of *Salmonella* colonization, should be effective for reducing *Salmonella* in final product and contributing to public health improvements.

2023 NACMCF Report. In the 2023 NACMCF report, the committee addressed issues related to pre-harvest measures to control *Salmonella* in poultry.¹⁷⁶ For question two of the NACMCF charges, FSIS asked the committee what types of microbiological criteria could be established to encourage control of *Salmonella* at pre-harvest, and what

industry data would provide evidence of control. As part of its response, the committee noted that vaccination programs have been incorporated on U.S. farms. The committee described such vaccination programs as an effective management practice for controlling *Salmonella* at pre-harvest and noted that vaccines are likely the only serotype-specific intervention strategies.

Together, the 2019 and 2023 NACMCF report responses related to pre-harvest measures support the use of these measures to control *Salmonella* in poultry. In the 2019 report, the committee concluded that preslaughter strategies to reduce the burden of *Salmonella* in flocks entering slaughter establishments are effective, and that data show a correlation between flock status of *Salmonella* and pre- and post-chill contamination. The 2019 report also indicated that it is probable that removing flocks of highly *Salmonella*-contaminated birds from the slaughter process would result in less human exposure to that source of *Salmonella*, potentially resulting in reduced foodborne illness in humans. In the 2023 report, the committee recommended that the Agency target for consideration conditions in houses, transport crates, and holding areas that harbor and transmit *Salmonella* by universal implementation of known and validated mitigation strategies. Of note, both final reports indicated uncertainty regarding whether current testing technology and data are available to design and broadly implement effective threshold requirements for segregating *Salmonella*-contaminated flocks at receiving.

As discussed above, FSIS received comments on Component One of the October 2022 draft *Salmonella* Framework that raised concerns related to costs, testing technology, and implementation challenges. Several comments from small poultry processors and producers and trade associations representing the meat and poultry industries that expressed concerns that the measures under consideration in Component One would impose an overwhelming burden on small producers and processors.

In light of these comments, FSIS has decided at this time not to establish a regulatory requirement that establishments characterize *Salmonella* as a hazard reasonably likely to occur at receiving or that incoming flocks be tested for *Salmonella* before entering an establishment. FSIS will actively seek evidence and best practices from the poultry industry. The Agency will revisit its strategy for using testing

(including quantitation and deep serotyping) to minimize the risk of cross-contamination at processing when logistical challenges have been addressed and testing becomes more timely and affordable.

FSIS has decided, instead, for the time being, to focus on non-regulatory approaches to controlling *Salmonella* at preharvest and reducing the *Salmonella* load on birds at receiving. FSIS not proposing to enforce measures under Component One at this time. If the Agency decides to make any of the approaches discussed below mandatory, it will do so through future rulemaking.

B. Possible Approaches To Control Salmonella at Pre-Harvest

1. National Poultry Improvement Program

FSIS will explore whether existing or new certification programs under the National Poultry Improvement Program ("NPIP" or the "Plan") could serve to verify and document producers' actions (such as use of *Salmonella* vaccines) to control *Salmonella*, including serotypes of public health significance.

Administered by APHIS, NPIP is a cooperative industry, state, and federal program initially established to improve poultry and poultry products and prevent and control poultry diseases.¹⁷⁷ The Plan identifies States, flocks, hatcheries, dealers, and slaughter plants that meet certain disease control standards specified in the Plan's various programs. NPIP regulations in 9 CFR parts 145 and 146 contain requirements that must be observed by participating flocks, including testing and biosecurity measures. These measures are updated over time as the science and technology evolve and improve. Affiliated flock-owners participate in the Plan through an agreement with a participating hatchery. Participating hatcheries must be maintained in sanitary condition as outlined in the NPIP Program Standards and the U.S. Code of Federal Regulations and are subject to third party audit by an official state agency at least once every two years or a sufficient frequency to ensure compliance. NPIP programs are available for multiplier and primary breeding flocks for meat-type chicken and products (9 CFR part 145 subparts C and H), and turkey breeding flocks and products (9 CFR part 145 subpart D). These programs include biosecurity measures and may include testing for *Salmonella* or *Salmonella* serotype Enteritidis. The

¹⁷⁶ NACMCF final report "Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products" (March 13, 2023), available at: <https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021>.

¹⁷⁷ USDA Animal and Plant Health and Inspection Service (APHIS) National Poultry Improvement Plan information available at: <https://www.poultryimprovement.org/default.cfm>.

Plan's "U.S. *Salmonella* Monitored Program" is intended for primary breeders of meat type chickens to reduce the incidence of *Salmonella* organisms in hatching eggs and chicks through an effective and practical sanitation program at the breeder farm and in the hatchery. The Plan's "U.S. S. Enteritidis Clean Program" is intended for primary or multiplier breeders of meat-type chickens wishing to assure their customers that the chicks produced are certified free of *Salmonella* Enteritidis.

2. Vaccination

FSIS will more actively encourage the development, licensure, and use of poultry vaccines against *Salmonella* serotypes of public health concern, particularly live attenuated vaccines, and will provide sampling data and technical support, as appropriate, to industry and regulatory bodies to advance these goals.

Salmonella vaccination is one tool in a multifaceted approach to overall *Salmonella* reduction and/or elimination of specific *Salmonella* serotypes. Vaccines reduce the susceptibility of individual birds to *Salmonella* infection, transmission among breeding flocks, cross-contamination during meat bird production, contamination of poultry house environments, and transmission to subsequent flocks. Live attenuated vaccines are derived from a specific strain of a target organism (i.e., *Salmonella* Typhimurium), subunit vaccines containing protein or nucleic acid from the target organism, and autogenous inactivated vaccines against a cocktail of strains found in a local area. Vaccines may provide cross protection across serotypes. For example, the availability of a commercial live attenuated vaccine created from *Salmonella* Typhimurium corresponded to a profound decline in the incidence of both Typhimurium and a related serotype Heidelberg illnesses.¹⁷⁸ Attenuated strains can be designed to expose common antigens, therefore inducing cross-protective immunity against diverse *Salmonella* serotypes.¹⁷⁹ Although vaccines can be

protective and limit horizontal transmission of infection within broiler flocks, they must be given multiple times to all birds in each flock and, therefore, present logistical and cost challenges that must be overcome.

FSIS will continue to collect data on the impact of vaccine use on FSIS verification testing through pilot projects. As noted above, since March 2023, FSIS has granted pilot projects to 9 establishments to examine the merits and logistics of excluding *Salmonella* poultry vaccine strains from the FSIS *Salmonella* performance categorization calculation. Modified live *Salmonella* vaccines are used to reduce *Salmonella* colonization in poultry. These vaccine strains are not foodborne pathogens, making them a valuable pre-harvest tool for controlling wild-type *Salmonella*. FSIS is able to identify vaccine strains isolated from raw poultry products through the use of whole genome sequencing.

FSIS examined *Salmonella* detection and serotype data from flocks vaccinated with a modified live *Salmonella* vaccine at pre- and post-intervention points in the participating slaughter establishments. These data show that vaccine strains can occasionally be found in raw poultry products even when the vaccine is used as directed on the label. After reviewing the data, FSIS concluded that its policy to count such strains as a positive result in performance categorization may discourage use of vaccination as a tool to control *Salmonella*. Therefore, on March 1, 2024, FSIS announced that beginning April 1, 2024, it intends to exclude current commercial vaccine subtypes confirmed in FSIS raw poultry samples from the calculation used to categorize establishments under the raw poultry *Salmonella* performance standards.¹⁸⁰ This action is intended to remove barriers to the use of vaccination as an important pre-harvest intervention to control *Salmonella* in poultry. A summary report of the data from these pilots is posted on the Pilot Projects: *Salmonella* Control Strategies page of the FSIS website at: <https://www.fsis.usda.gov/inspection/inspection-programs/inspection-poultry-products/reducing-salmonella-poultry-pilot>.

Salmonella typhimurium vaccine in preventing colonization and invasion of laying hens by *Salmonella* typhimurium and *Salmonella* enteritidis." Avian Dis 41(4): 783–791.

¹⁸⁰ FSIS Constituent Update—March 1, 2024: FSIS Intends to Exclude Vaccine Strains from the FSIS *Salmonella* Performance Categorization at: <https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-march-1-2024>.

3. Supply Chain Control Programs

Establishments operating under HACCP regulations (9 CFR part 417) must perform a hazard analysis to identify food safety hazards that can occur before, during, and after entry into the establishment and to identify the preventive measures the establishment can apply to control those hazards. Establishments that identify hazards that occur before entry face the challenge of providing assurance that preventive measures are effectively applied. FSIS-inspected establishments operating under HACCP must document, validate, and verify the effectiveness of their hazard control(s). While not required to do so, establishments slaughtering poultry that have identified *Salmonella* as a hazard during the breeder and multiplier and production stages are encouraged by FSIS to use supply chain programs¹⁸¹ to verify the effectiveness of their supplier's interventions, and the Agency will ramp up its efforts to assist any establishment that wants to implement a supply chain program.

4. Updated Pre-Harvest Guidance

FSIS intends to revise its existing guideline on *Controlling Salmonella in Raw Poultry*¹⁸² to provide updated guidance on pre-harvest interventions and management practices for preventing and reducing *Salmonella* colonization in live birds. FSIS remains committed to identifying and developing strategies for addressing *Salmonella* contamination in the pre-harvest environment. Additionally, the Agency is working with the USDA's Agricultural Research Service (ARS) on a literature review of *Salmonella* presence in poultry at pre-harvest.

V. State Programs and Foreign Government Programs

States that have their own poultry inspection programs for poultry

¹⁸¹ One example of a supply chain program is a process verified program (PVP) administered by USDA's Agricultural Marketing Service (AMS). A PVP may include one or more agricultural processes or portions of processes where self-described process points are supported by a documented management system, and independently verified by a qualified AMS auditor. One PVP available to the poultry industry is the Quality System Assessment (QSA). The QSA provides companies that supply agricultural products and services the opportunity to assure customers of their ability to provide consistent quality products or services. It is limited to programs or portions of programs where specified product requirements are supported by a documented quality management system. USDA AMS Process Verified Program information available at: <https://www.ams.usda.gov/services/auditing/process-verified-programs>.

¹⁸² FSIS Guideline for Controlling *Salmonella* in Raw Poultry (June 2021), available at: <https://www.fsis.usda.gov/guidelines/2021-0005>.

¹⁷⁸ NACMCF Report: "Response to Questions Posed by the Food Safety and Inspection Service: Enhancing *Salmonella* Control in Poultry Products" (Mar 2023). Available at: <https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf/2021>.

¹⁷⁹ Aehle, S. and R. Curtiss (2017). Chapter 14—Current and Future Perspectives on Development of *Salmonella* Vaccine Technologies. Producing Safe Eggs. S. C. Ricke and R. K. Gast. San Diego, Academic Press: 281–299; Hassan, J. O. and R. Curtiss III (1997). "Efficacy of a live avirulent

products produced and transported solely within the State are required to have mandatory ante-mortem and post-mortem inspection, reinspection, and sanitation requirements that are at least equal to those in the PPIA (21 U.S.C. 454(a)(1)). Therefore, if FSIS finalizes this proposed rule and determination, these States would need to develop sampling procedures and testing methods to detect *Salmonella* at or above 10 cfu/mL(g) in an analytical portion and *Salmonella* serotypes of public health significance identified for raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products that are at least as sensitive as FSIS' procedures and testing methods for *Salmonella*. Additionally, these States would need to implement requirements for poultry slaughter establishments to develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation that are at least equal to FSIS' proposed revisions to the poultry regulations. FSIS will coordinate closely with States that maintain federally supported poultry inspection programs to ensure that this *Salmonella* Framework for raw poultry products is implemented in all intrastate establishments.

Foreign countries that are eligible to export poultry products to the United States must apply inspection, sanitary, and other standards that are equivalent to those that FSIS applies to those products (21 U.S.C. 466). Thus, in evaluating a foreign country's poultry inspection system to determine the country's eligibility to export products to the United States, FSIS will consider whether the sampling procedures and testing methods that the country implements for detection of *Salmonella* at or above 10 cfu/mL(g) in an analytical portion and *Salmonella* serotypes of public health significance identified for raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products are equivalent to FSIS' sampling procedures and testing methods. Additionally, FSIS will also evaluate whether the country's requirements for slaughter establishments to develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation are equivalent to FSIS' proposed revisions to the poultry regulations. FSIS will continue to use the existing equivalence process to ensure that foreign countries implement requirements, sampling procedures and testing methods

equivalent to FSIS' proposed revisions to the poultry regulations and the sampling procedures and testing methods for *Salmonella* in raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products. FSIS intends to provide countries that export poultry products to the United States 3 years after publication of the final rule to submit adequate documentation to support that their poultry inspection system is equivalent to FSIS' inspection system. Thus, exporting countries would have a 3-year transition period in which they could continue to export poultry products to the United States while they implement measures to ensure that their poultry inspection system is equivalent to the U.S. system. FSIS would likely begin testing imported raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products to verify products are not adulterated one year after the final publication. FSIS will provide additional details on these issues in any final rule and determination resulting from this proposal.

VI. Executive Orders 12866, as Amended by 14094, and 13563

Executive Orders (E.O.) 12866, as amended by 14094, and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule and proposed determination have been designated a "significant" regulatory action by the Office of Information and Regulatory Affairs under section 3(f) of E.O. 12866. Accordingly, the proposed rule and proposed determination have been reviewed by the Office of Management and Budget under E.O. 12866.

Regulatory Impact Analysis

FSIS is proposing to clarify certain process control requirements for poultry slaughter establishments and establish final product standards for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. This proposal is aimed at reducing *Salmonella* illnesses in the U.S. population.

FSIS is proposing to clarify current requirements for monitoring compliance with 9 CFR 381.65(g) for poultry

slaughter establishments and to require poultry slaughter establishments to submit process control monitoring data electronically to FSIS. These establishments are currently required to monitor their processes to ensure they comply with FSIS regulations. FSIS is clarifying that MMPs need to be statistically based and is requiring that establishments collect samples specifically at rehang, or an alternative location if they submit and maintain supporting documentation. The proposed clarifications are estimated to have minimal economic impact on most establishments, while the potential effects on VLV and VS establishments operating under Traditional Inspection, as described in this analysis, would be potentially mitigated by the use of laboratory services provided by FSIS.

FSIS is also proposing to implement new standards for chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey as final products that would enter commerce. Product subject to these standards, as described in the foregoing, would be subject to FSIS routine sampling and verification testing for *Salmonella*. Establishments subject to FSIS verification sampling would be required to maintain control of sampled product pending test results. Product lots that do not meet the standards would be considered adulterated and would be diverted from commerce. Establishments could divert adulterated product to be fully cooked at a federal establishment and then sent into commerce.

Finally, FSIS is encouraging establishments to consider including pre-harvest measures in their HACCP systems to address the hazard of *Salmonella* contamination prior to slaughter. The Agency is not requiring that establishments adopt pre-harvest measures; thus, any potential costs or benefits associated with those measures are especially challenging to analyze, and we request comment on relevant data and analytic methods of analysis.

Need for the Rule

This regulatory action is necessary because while the results of FSIS' *Salmonella* verification sampling show that the current prevalence-based performance standards approach has been effective in reducing the proportion of poultry products contaminated with *Salmonella*, these measures have yet to have an observable impact on overall human *Salmonella* illness rates (see the *Salmonella Performance Standards and Illnesses* section for more details). An estimated 23 percent of *Salmonella* illnesses are

attributed to poultry—17 percent to chicken products and 6 percent to turkey products—making poultry one of the leading sources of foodborne *Salmonella* illnesses in the United States.¹⁸³ Thus, a reduction in *Salmonella* illnesses associated with poultry consumption would be expected to have an impact on overall *Salmonella* illnesses. A 2015 analysis found that poultry consumption was more likely than any other animal protein to lead to *Salmonella* illnesses.¹⁸⁴ Additionally, a 2021 study observed that *Salmonella* outbreaks related to consumption of single ingredient poultry products were disproportionately higher than the estimated level of consumption of single ingredient poultry products.¹⁸⁵

As part of this proposal for *Salmonella* in poultry, FSIS is proposing to clarify existing regulatory requirements related to process control monitoring and recordkeeping in 9 CFR 381.65(g) and (h) to better ensure that poultry slaughter establishments are effectively controlling *Salmonella* throughout their slaughter and dressing operations. FSIS is also proposing to declare that raw chicken carcasses,

parts, and comminuted chicken and turkey that contain *Salmonella* at or above 10 cfu/mL(g) and a serotype of public health significance are adulterated because the 2023 risk assessments found that servings contaminated with these *Salmonella* levels and serotypes are much more likely to cause illness than the majority of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey servings (see the *Risk per Serving, Salmonella Levels, and Proposed Determination* section for more details). The 2023 risk assessments estimate that diverting products that contain these *Salmonella* levels and serotypes from commerce would prevent annual foodborne illnesses from *Salmonella* linked to poultry.¹⁸⁶ Moreover, the FSIS risk profile indicates that for certain *Salmonella* serotypes often linked to poultry products a small amount of *Salmonella* bacteria can cause illness.¹⁸⁷ It also noted that these serotypes caused hospitalization more frequently and led to invasive disease and death as well as debilitating human health outcomes.

FSIS is taking this regulatory action to protect public health and reduce the number of *Salmonella* illnesses linked to poultry products. If this proposal is finalized, it would protect consumers from consuming products that have a higher probability of illness and would incentivize producers implement food safety measures that would minimize the risk of *Salmonella* illnesses.

Baseline for Evaluation of Costs and Benefits

Poultry consumption has grown 13 percent over the past 10 years, with broiler meat accounting for 83 percent of the total consumption, while turkey accounts for about 16 percent. Poultry—mainly chicken—is the main source of animal protein across demographic groups and is consumed both at home and away from home.¹⁸⁸ Poultry

products are available in multiple formulations, ranging from raw whole birds and parts to fully cooked, ready-to-eat products. In the United States, chicken breasts, legs, and wings are the most consumed chicken products.¹⁸⁹ Turkey consumption, in contrast, is mainly as whole turkey, deli meat, ground turkey, or turkey bacon. Ground turkey consumption has increased substantially in the last decade, mainly as consumers opt for this product as a substitute for ground beef.¹⁹⁰

On average, U.S. poultry establishments slaughtered 9.5 billion birds annually between 2017 and 2021, which is approximately 49.4 billion pounds of poultry. Broiler and turkey meat accounted for 87 and 12 percent of this production, respectively.¹⁹¹ The U.S. poultry supply is mainly comprised of domestically grown and processed poultry as imports represent a very small fraction of the total supply.¹⁹² Federally inspected establishments produce the vast majority of U.S. commercial poultry supply.¹⁹³ Most federally inspected establishments that produce a high volume of product solely produce chicken or turkey products. Some establishments also slaughter other classes of poultry, such as duck and geese. While there are establishments that slaughter multiple species, they tend to produce a low volume of product.

Demand and Diet Quality,” by Diansheng Dong and Hayden Stewart, April 4, 2022, <https://www.ers.usda.gov/amber-waves/2022/april/racial-and-ethnic-diversification-will-likely-shape-u-s-food-demand-and-diet-quality/>.

¹⁸⁹ USDA, Economic Research Service (ERS), “Chicken leads U.S. per person availability of meat over last decade,” March 1, 2023, <https://www.ers.usda.gov/data-products/chart-gallery/gallery/chart-detail/?chartId=105929>.

¹⁹⁰ National Turkey Federation, “Turkey by the Numbers,” accessed June 20, 2021, <https://www.eatturkey.org/turkeystats/>; Agricultural Marketing Resource Center, “Turkey Profile,” January 2022, <https://www.agmrc.org/commodities-products/livestock-dairy-poultry/poultry/turkey-profile>.

¹⁹¹ Other types of poultry (e.g., duck) account for the remaining 1 percent.

¹⁹² Imports of poultry products into the United States represented less than 0.5 percent of total U.S. poultry consumption in 2021. The United States is a net exporter of poultry to the world and is the second largest exporter globally, with exports representing about 16 percent of the total domestic production in 2021. USDA, Foreign Agricultural Service, “Production, Supply and Distribution database,” accessed May 11, 2023.

¹⁹³ USDA, National Agricultural Statistics Service, Surveys: Poultry Slaughter, October 19, 2020, https://www.nass.usda.gov/Surveys/Guide_to_NASS_Surveys/Poultry_Slaughter/index.php.

¹⁸³ The Interagency Food Safety Analytics Collaboration (IFSAC), “Foodborne illness source attribution estimates for 2019 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter* using multi-year outbreak surveillance data, United States,” October 2021, <https://www.cdc.gov/ifsac/php/annual-reports/index.html>. Annually, IFSAC releases a report that estimates foodborne illness source attribution for major commodity groups, including *Salmonella* in poultry products. At the time this proposal was developed, the 2019 IFSAC attribution estimates were the most recent data available. IFSAC released a new annual report in November 2023, which includes attribution estimates for 2020. In the 2023 report, IFSAC estimated that 18.6 percent of *Salmonella* illnesses are attributed to chicken products and 5.5 percent to turkey products, for a total 24.1 percent attributed to poultry products. FSIS intends to incorporate the 2023 report attribution estimates if this proposal is finalized. IFSAC, “Foodborne illness source attribution estimates for *Salmonella*, *Escherichia coli* O157, and *Listeria monocytogenes*—United States 2021,” November 2023, <https://www.cdc.gov/ifsac/php/annual-reports/index.html>.

¹⁸⁴ The analysis estimated that the risk of getting sick from *Salmonella* from one serving of poultry products was 94, 97, and 87 percent larger than that for a serving of pork, beef, and lamb products, respectively. Hsi, D.J., Ebel, E.D., Williams, M.S., Golden, N.J. and Schlosser, W.D., 2015. Comparing foodborne illness risks among meat commodities in the United States, *Food Control*, 54, pp.353–359. <https://doi.org/10.1016/j.foodcont.2015.02.018>.

¹⁸⁵ The analysis observed that while chicken and turkey consumption represent roughly 0.6 and 0.2 percent of the U.S. daily diet, the share of outbreaks linked to these products is significantly higher: 2.1 and 1.5 percent, respectively. These estimates are for chicken and turkey consumed as single-ingredient foods. Richardson, L.C., Cole D., Hoekstra, R.M., Rajasingham, A., Johnson, S.D., Bruce, B.B., 2021. Foods Implicated in U.S. Outbreaks Differ from the Types Most Commonly Consumed. *Journal of Food Protection*, 84(5), pp.869–875. <https://doi.org/10.4315/JFP-20-293>.

¹⁸⁶ USDA, FSIS, “Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,” January 2023; USDA, FSIS, “Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,” January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

¹⁸⁷ USDA, FSIS, “Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,” February 28, 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

¹⁸⁸ There is variability in poultry consumption among demographic groups. For example, poultry consumption is higher among the non-Hispanic Black population, followed by Hispanics and non-Hispanic Asians. Poultry also represents a substantial source of protein for children, with chicken being the main source of animal protein among them. USDA, ERS, “Racial and Ethnic Diversification Will Likely Shape U.S. Food

Establishments Subject to the Current Salmonella Performance Standards and Proposed Final Product Standards

FSIS used 2021 Public Health Information System (PHIS) data to identify establishments under the current *Salmonella* performance standards that produce chicken carcasses, chicken parts, comminuted

chicken, and comminuted turkey, as well as their production volumes.¹⁹⁴

Chicken Carcasses

In 2021, there were a total of 188 establishments under FSIS verification sampling for chicken carcasses that slaughtered over 8.3 billion chickens. FSIS classified these establishments into

one of four volume categories (Table 13). Of these, 142 establishments were high-volume establishments, 9 were medium-volume, 4 were low-volume, and 33 were VLV chicken slaughter establishments. The 142 high-volume establishments accounted for over 99.5 percent of the total head count slaughtered in 2021.

TABLE 13—CHICKEN CARCASSES: ESTABLISHMENTS UNDER FSIS PERFORMANCE STANDARDS [2021]

Establishment volume category	Definition (birds)	Number of establishments	Annual production (million birds)	Share of production (%)
High	10 million or more	142	8,270	99.52
Medium	More than 1.1 million and less than 10 million.	9	33	0.40
Low	More than 440,001 and less than 1.1 million.	4	2	0.03
Very Low ¹	No more than 440,000	33	4	0.05
Total		188	8,309	

¹ Very low-volume establishments are defined in 9 CFR 381.65g(1)(i).
Note: Numbers in table may not sum to totals due to rounding.

Chicken Parts

In 2021, there were 490 establishments under FSIS verification sampling that produced chicken legs, breasts, wings, halves, and/or quarters (Table 14). Of these, 484 establishments were subject to FSIS performance standards sampling for chicken legs, breasts, and wings. The proposal would apply to establishments that produce chicken legs, breasts, wings, thighs, halves, and quarters. In 2021, most of the establishments producing chicken halves and quarters also produced legs,

breasts, and wings. FSIS sampling at these establishments would be adjusted to incorporate chicken halves and quarters samples, while maintaining the current sampling frequency. In 2021, six establishments produced chicken halves and quarters, but did not produce legs, breasts, or wings. These six establishments are currently sampled as part of FSIS’ exploratory sampling program for chicken halves and quarters.

FSIS estimates that these establishments produced over 31.2 billion pounds of chicken parts in 2021.

FSIS classified these establishments according to the volume categories the Agency used in the 2016 cost-benefit analysis in support of FSIS “Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards.”¹⁹⁵ In 2021, 154 of these establishments were high-volume, 209 were medium-volume, and 127 were low-volume establishments (Table 14). The 154 high-volume establishments accounted for roughly 90 percent of the production volume of chicken parts in 2021.

TABLE 14—CHICKEN PARTS: ESTABLISHMENTS UNDER FSIS PERFORMANCE STANDARDS (2021)

Establishment volume category	Definition (annual production pounds)	Number of establishments	Annual production (million pounds)	Share of production (%)
High	70 million or more	154	28,113	90.1
Medium	More than 1 million and less than 70 million.	209	3,055	9.8
Low	1 million or less	127	40	0.1
Total		490	31,208	

Note: Numbers in table may not sum to totals due to rounding.

Comminuted Chicken

In 2021, there were 74 establishments under FSIS verification sampling for

comminuted chicken (Table 15). FSIS estimates that these establishments produced about 2.3 billion pounds of comminuted chicken in 2021. Using the

categories in the 2016 cost-benefit analysis, the Agency classified 35 establishments as medium-volume and 39 establishments as low-volume. The

¹⁹⁴ USDA, FSIS, Public Health Information System database, accessed January 2, 2023 and April 5, 2023. Certain establishments are currently excluded from *Salmonella* verification testing. 81 FR 7288. FSIS adjusted the estimates for chicken

parts, comminuted chicken, and comminuted turkey to match slaughter totals in the analysis period.

¹⁹⁵ USDA, FSIS, “Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance

Standards,” Final Cost-Benefit Analysis, February 11, 2016, https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.

35 medium-volume establishments
accounted for 97.2 percent of total

production of comminuted chicken in
2021.

TABLE 15—COMMINUTED CHICKEN: ESTABLISHMENTS UNDER FSIS PERFORMANCE STANDARDS (2021)

Establishment volume category	Definition (daily production pounds)	Number of establishments	Annual production (million pounds)	Share of production (%)
High	250,000 or more	0	0	0.0
Medium	More than 6,000 and less than 250,000	35	2,193	97.2
Low	Less than 6,000	39	63	2.8
Total		74	2,256	

Note: Numbers in table may not sum to totals due to rounding.

Comminuted Turkey

In 2021, there were 48 establishments under FSIS verification sampling for comminuted turkey (Table 16). FSIS estimates that these establishments produced about 1.7 billion pounds of

comminuted turkey in 2021. Using the categories in the 2016 cost-benefit analysis, the Agency classified 5 establishments as high-volume, 25 establishments as medium-volume, and 18 as low-volume establishments. The 5 high-volume establishments accounted

for 54.2 percent of the total production in 2021, while medium-volume establishments accounted for 45.3 percent, and low-volume establishments accounted for less than 1 percent of the total.

TABLE 16—COMMINUTED TURKEY: ESTABLISHMENTS UNDER FSIS PERFORMANCE STANDARDS (2021)

Establishment volume category	Definition (daily production pounds)	Number of establishments	Annual production (million pounds)	Share of production (%)
High	250,000 or more	5	917	54.2
Medium	More than 6,001 and less than 250,000	25	766	45.3
Low	Less than 6,000	18	8	0.5
Total		48	1,691	

Note: Numbers in table may not sum to totals due to rounding.

Salmonella on Poultry Products

Salmonella is a foodborne pathogen commonly attributed to consumption of contaminated products that can lead to serious illness and death. In the United States, it is estimated to cause over 1.35 million illnesses annually, including 26,500 hospitalizations and 420 deaths.¹⁹⁶ *Salmonella* is estimated to be the leading pathogen in terms of total cost of illnesses in the United States,

with about 24 percent of the total cost.¹⁹⁷ A 2020 study estimated that the economic costs of *Salmonella* illnesses associated with chicken is \$2.8 billion annually.¹⁹⁸ A 2021 Interagency Food Safety Analytics Collaboration report attributed roughly 23 percent of the total annual *Salmonella* illnesses to consumption of poultry products, mainly chicken (17 percent) and turkey (6 percent).¹⁹⁹ *Salmonella* outbreaks

linked to poultry products have continued to occur over the last two decades. From 1998 to 2020, FSIS identified 210 foodborne *Salmonella* outbreaks linked to chicken or turkey (Figure 1).²⁰⁰ Generally, chicken products were implicated in 84.8 percent (178 out of 210) of the outbreaks and turkey products were implicated in 15.2 percent (32 out of 210) of the outbreaks.²⁰¹

¹⁹⁶ CDC, “*Salmonella*,” November 10, 2022. <https://www.cdc.gov/salmonella/index.html>; USDA, FSIS, “Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry,” February 28, 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

¹⁹⁷ USDA, ERS, “Cost Estimates of Foodborne Illnesses,” Total cost of foodborne illness estimates for 15 leading foodborne pathogens dataset, March 10, 2021, <https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx>.

¹⁹⁸ USDA, FSIS, “USDA Releases Proposed Regulatory Framework to Reduce *Salmonella* Infections Linked to Poultry Products,” October 14, 2022, <https://www.fsis.usda.gov/news-events/news-press-releases/usda-releases-proposed-regulatory->

[framework-reduce-salmonella](https://www.fsis.usda.gov/news-events/news-press-releases/usda-releases-proposed-regulatory-framework-reduce-salmonella). A cost of illness model that replaces the productivity loss estimates with a pain, suffering, and functional disability measure based on monetized quality-adjusted life year estimates indicates that the estimated annual cost of *Salmonella* illness was around \$11.4 billion (ranging from \$2.5 to \$29.1 billion) in 2010 dollars. Scharff, R.L., 2012. Economic burden from health losses due to foodborne illness in the United States. *Journal of food protection*, 75(1), pp.123–131, DOI: 10.4315/0362-028X.JFP-11-058.

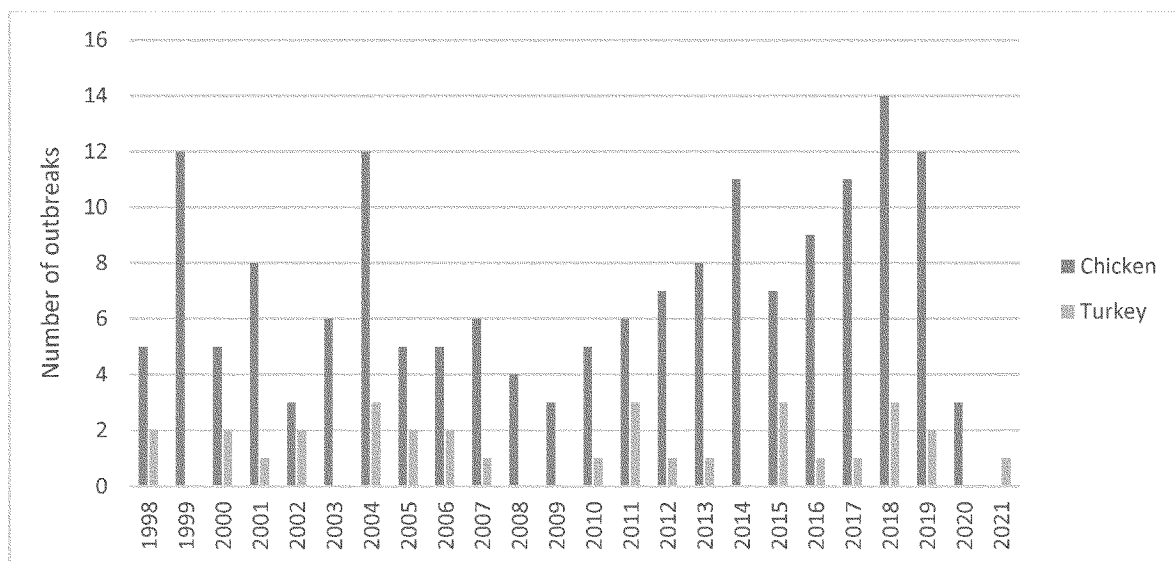
¹⁹⁹ The Interagency Food Safety Analytics Collaboration, “Foodborne illness source attribution estimates for 2019 for *Salmonella*, *Escherichia coli* O157, *Listeria monocytogenes*, and *Campylobacter*

using multi-year outbreak surveillance data, United States,” October 2021, <https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2019-report-TriAgency-508.pdf>.

²⁰⁰ Chicken was considered the source of contamination on the outbreak linked to stuffed chicken products.

²⁰¹ CDC, National Outbreak Reporting System (NORS), NORS Dashboard, accessed April 2023, <https://wwwn.cdc.gov/norsdashboard/>; USDA, FSIS, “Outbreak Investigations: Response May 10, 2023 <https://www.fsis.usda.gov/food-safety/foodborne-illness-and-disease/outbreaks/outbreak-investigations-response>.

Figure 1. Outbreaks with chicken and turkey as contaminated single ingredient from 1998 to 2020



In 2023, FSIS developed a risk profile that details current knowledge on *Salmonella* to inform Agency efforts. The risk profile identified 28 *Salmonella* serotypes (out of around 2,500 serotypes) and four serogroups which were attributed to human salmonellosis from consuming chicken and turkey products. The FSIS risk profile indicated that for at least some subtypes of concern a small amount (i.e., low dose of *Salmonella* bacteria), can cause illness. The FSIS risk profile noted that certain serotypes caused hospitalization more frequently and also led to invasive disease and death. Some subtypes have also been found to cause debilitating human health outcomes. Among these outcomes are cancer, inflammatory bowel disease, irritable bowel syndrome, and reactive arthritis. The overall hospitalization rate for all *Salmonella* is about 2 percent and the fatality rate is about 0.04 percent. However, the hospitalization rate for these serotypes is nearly 23 percent and the fatality rate is about 0.5 percent.²⁰²

Salmonella is the main pathogen resulting in foodborne illness-related deaths and hospitalizations, as well as loss of quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs). The CDC estimates that *Salmonella* accounts for about 11 percent of total cases of domestically

acquired foodborne illness.²⁰³ However, it disproportionately accounts for about 44 percent of deaths associated with domestic bacterial foodborne illness from major pathogens and 28 percent of the hospitalizations. It has also been estimated to lead to the highest amount of QALYs lost among 14 domestic foodborne bacterial, viral, and parasitic pathogens. *Salmonella* is also estimated to contribute to 32,900 lost DALYs, or about 30 percent of lost DALYs from seven leading foodborne pathogens.²⁰⁴

Potential Costs and Benefits of the Proposed Rule and Proposed Determination

FSIS estimates that this proposal would result in a reduction in *Salmonella* illnesses among consumers. Furthermore, for producers, the reduction in the risk of illness, and hence outbreaks, would result in a lower risk of having to recall product. Producers would, as a result avoid the costs associated with that reduction. While producers would respond to this proposal in a way that makes economic sense to them, FSIS estimated the quantified cost associated with this proposal as explained in more detail below.

This proposal would also benefit industry as FSIS would clarify process control requirements for poultry

slaughter establishments, which would likely contribute to a reduction in *Salmonella* contamination. Further, the Agency would incentivize innovation and the adoption of safer scientific methods in poultry production.

In the following sections, this analysis presents potential costs and benefits generated over a range of assumptions that could accrue as a result of FSIS' action, if this rule is finalized. To implement this proposal, FSIS would adopt an implementation schedule that would allow medium-, low-, and very low-volume establishments additional flexibility. Specifically, medium-volume establishments would have two years after the proposal is finalized to comply with the proposed requirements, while low- and very low-volume establishments would have three years. High-volume establishments would be required to comply with these proposed requirements one year after this rule is finalized. The Agency incorporated this implementation schedule into the annualization of costs and benefits estimates in this analysis, which are presented after the one-time and recurring cost estimates for each requirement. FSIS annualized costs and benefits using a 7 percent discount rate over a period of 10 years. FSIS applied the share of production for each establishment category to derive the lost value and prevented illness estimates that correspond with the implementation schedule. FSIS is seeking comment on these assumptions.

²⁰² USDA, FSIS, "Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry," February 28, 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²⁰³ CDC, "Burden of Foodborne Illness: Findings," November 5, 2018, <https://www.cdc.gov/foodborneburden/2011-foodborne-estimates.html>.

²⁰⁴ USDA, FSIS, "Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry," February 28, 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

Potential Costs of the Proposed Rule and Proposed Determination

Costs Associated With the Proposed Rule

Statistical Process Control Costs

FSIS currently requires poultry slaughter establishments to develop, implement, and maintain written procedures to prevent contamination by enteric pathogens and fecal contamination throughout the entire slaughter operation and incorporate these procedures into their HACCP systems (9 CFR 381.65(g)). At a minimum, these procedures must include sampling and analysis for microbial organisms at pre-and post-chill to monitor their ability to maintain process control, with some exceptions for VS and VLV establishments operating under Traditional Inspection. The proposal specifies that establishments must collect the pre-chill sample at rehang (post-picking and pre-visceration) and clarifies that its microbial organism monitoring practices must result in data suitable for monitoring process control. While many establishments already meet the proposed specifications, some establishments may change where they collect the pre-chill sample or change the microbial organism they test for. However, establishments may continue their current sampling location and microbial organism monitoring practices, or adopt an alternative location and organism, if they submit and maintain supporting documentation. The Agency is also

providing guidance for establishments to develop their MMPs. FSIS assumes that most establishments would meet the proposed MMP requirements without having to make any changes that would result in costs, while some establishments would have to make minor changes in response to this proposal at de minimis costs. The Agency is seeking comments on these assumptions.

FSIS regulations currently require that VLV establishments collect process control monitoring samples minimally once per week for a minimum of 13 consecutive weeks per year, beginning the first week of June.²⁰⁵ FSIS is proposing to eliminate the requirement that VLV establishments begin sample collection the first week in June, which would allow establishments to begin collecting samples throughout the year. FSIS estimates there is no cost associated with this revised requirement, while establishments may benefit from this flexibility.

FSIS estimates that 90 VLV and 2 VS poultry slaughter establishments operating under Traditional Inspection would likely need to make changes in response to the proposed process control requirements.²⁰⁶ FSIS is proposing to revise 9 CFR 381.65g(1) such that all poultry slaughter establishments would be required to collect samples at the rehang and post-chill locations. Very small and VLV establishments operating under Traditional Inspection are currently required to collect samples only at post-chill. FSIS currently requires that VLV

establishments minimally collect 13 weekly samples per year to monitor process control. If this rule is finalized, these establishments would be required to collect and analyze 13 additional samples per year. The number of additional samples for VS establishments operating under Traditional Inspection that are not VLV establishments depends on their production volume. FSIS assumed that these VS establishments currently collect 52 samples per year and, consequently, would collect an additional 52 samples per year. FSIS is seeking comment on these assumptions.

FSIS would reduce the burden this proposed increase in sampling places on VLV and VS establishments operating under Traditional Inspection by making laboratory services available to these establishments. Use of the laboratories provided by FSIS would enable these establishments to comply with the proposed minimum requirements for MMPs. Should these establishments elect not to use the laboratory services provided by FSIS, the Agency estimated the combined cost for these establishments to meet the proposed increase in sampling would be \$48,412 annually (Table 17). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for these establishments to meet the proposed increase in sampling would be \$35,950. This analysis assumed samples collected at these establishments are analyzed for AC, at a cost of \$38 per sample.

TABLE 17—STATISTICAL PROCESS CONTROL COSTS

Establishments type	Number of establishments (2021)	Testing cost (\$)
Very low-volume under Traditional Inspection	90	44,460
Very small under Traditional Inspection	2	3,952
Total	92	48,412
Annualized ¹		35,950

¹ Costs annualized at a discount rate of 7% over 10 years.
* **Note:** Numbers in table may not sum to totals due to rounding.

Electronic Data Submission

FSIS would require poultry slaughter establishments subject to 9 CFR 381.65(g) and (h) to electronically submit data generated as part of their process control monitoring. FSIS estimates that high- and medium-

volume establishments already compile process control data electronically due to the large volume of their operations and the frequency of their sample collection and analysis. To mitigate the impact on low- and VLV establishments, should this rule become final, the Agency would develop and publish a

template these establishments could use to record and submit their monthly results.

In 2021, there were 298 establishments that would have been subject to this change, of which 175 were high-volume, 15 medium-, 14 low-, and 94 very low-volume.²⁰⁷

²⁰⁵ 9 CFR 381.65(g)(2)(ii).
²⁰⁶ Very low-volume establishments are those that slaughter less than 440,000 chickens or 60,000 of any other poultry class annually. Very small

establishments are those with less than 10 employees or under \$2.5 million in annual sales. 9 CFR 381.65g(1)(i) and 9 CFR 381.65g(1)(ii).

²⁰⁷ The 94 VLV establishments include the 90 establishments operating under Traditional Inspection, as well as four establishments not under Traditional Inspection.

Establishments that elect to use laboratory services provided by FSIS for their process control samples would meet this requirement and not incur additional costs. This analysis assumed that none of the eligible establishments would choose to use laboratories provided by FSIS and the Agency estimated the costs associated with this requirement for all eligible establishments. Consequently, there is a

tendency toward overstatement in the cost to regulated establishments associated with this proposal.

FSIS assumed it would take a quality control (QC) manager 30 minutes (0.5 hours) once a month to submit these data. FSIS estimates that the average wage for a QC manager is \$113.24, which includes an average hourly wage of \$56.62 multiplied by a benefits and overhead factor of two.²⁰⁸ Under these

assumptions, the combined cost to industry is \$202,473 (0.5 hours × 12 months × 298 establishments × \$113.24) per year (Table 18), including \$118,902 for high-volume establishments, \$10,192 for medium-volume, \$9,512 for low-volume, and \$63,867 for VLV. Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for electronic data submissions is \$182,228.

TABLE 18—ELECTRONIC DATA SUBMISSION COSTS

Establishment volume category	Cost (\$)			
	Chicken	Turkey	All other classes	Total
High	97,839	19,024	2,038	118,902
Medium	8,153	679	1,359	10,192
Low	7,474	679	1,359	9,512
Very Low	55,714	7,474	679	63,867
Total	169,181	27,857	5,436	202,473
Annualized ¹				182,228

¹ Costs annualized at a discount rate of 7% over 10 years.

Note: Numbers in table may not sum to totals due to rounding.

HACCP Plan Reassessment Costs ²⁰⁹

The Agency assumed that every poultry slaughter establishment would reassess their HACCP plans and incur associated costs. This likely overestimates costs because not every establishment would reassess their HACCP plans. For chicken slaughter establishments that produce chicken carcasses subject to these proposed final product standards and are also subject to the proposed process control requirements, FSIS assumed they would only reassess their slaughter HACCP plan once. However, for establishments that produce multiple products subject to these final product standards, FSIS assumed they would reassess their HACCP plans for each of the products they produce that are affected by the

proposed changes. However, establishments that have to reassess HACCP plans for multiple products would likely experience some economies of scope. Furthermore, establishments could coordinate reassessing their HACCP plans in response to this proposal with currently required annual reassessments.

FSIS estimates that the total cost to industry from reassessing HACCP plans as a result of this proposal is \$1.39 million, ranging from \$0.70 to \$2.09 million (Table 19). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for HACCP plan reassessment is \$0.18 million, ranging from \$0.09 million to \$0.26 million. High- and medium-volume establishments need an average of 60

hours (ranging from 30 to 90), while low and VLV establishments need an average of 30 hours (ranging from 15 to 45) to reassess a HACCP plan, according to the 2015 “Costs of Food Safety Investments” report. This report estimated costs for large and small establishments. FSIS assumed the large category would correspond with high- and medium-volume establishments, while the small category would correspond with low- and very low-volume establishments. FSIS used data from the U.S. Bureau of Labor Statistics to update the hourly wage for estimating these labor costs. Specifically, FSIS used the 2021 hourly wage for a production worker of \$30.78, which includes an average hourly wage of \$15.39 multiplied by a benefits and overhead factor of two.

TABLE 19—HACCP PLAN REASSESSMENT COSTS

Establishment volume category	Number of establishments	Cost (million \$)		
		Low	Mid	High
High	333	0.31	0.61	0.92
Medium	279	0.26	0.52	0.77
Low	193	0.09	0.18	0.27
Very Low	91	0.04	0.08	0.13
Total		0.70	1.39	2.09
Annualized ¹		0.09	0.18	0.26

¹ Costs are annualized at a 7 percent discount rate over 10 years.

²⁰⁸ Mean hourly wage estimate of \$56.62 obtained from the Bureau of Labor Statistics, May 2021 National Industry Specific Occupational Employment and Wage Estimates for 11–3051

Management Occupations. <https://www.bls.gov/oes/2021/may/oes113051.htm>.

²⁰⁹ Note: For simplicity, this section includes HACCP reassessment costs associated with the

proposed rule and proposed determination, as some establishments subject to the proposed rule are also subject to the proposed determination.

Note: Number of establishments is not additive as some establishments produce multiple products. Numbers in table may not sum to totals due to rounding.

Validation of HACCP Plans

If an establishment makes changes to their HACCP plan, they would also have to validate it, incurring associated costs. However, the Agency assumed few establishments would make changes to their MMPs and only those that make changes would need to validate their HACCP plans. Additionally, the Agency assumed that many establishments have already implemented *Salmonella* controls in response to the 2016 FSIS performance standards and will not need to make changes to their HACCP plan. The 2015 “Costs of Food Safety Interventions” report indicates that high- and medium-volume establishments would need an average of 320 labor hours, while low- or very low-volume establishments would need an average of 400 hours to validate a HACCP plan. The estimated cost for HACCP plan validation is \$25,894 for a high or medium-volume establishment, on average, and for a low- or very low-volume establishment it is \$32,368. FSIS used the 2021 hourly wage for a food scientist of \$80.92, which includes an average hourly wage of \$40.46 multiplied by a benefits and overhead factor of two, for this estimate.²¹⁰ FSIS did not include a total industry HACCP validation cost because FSIS does not have data on the number of establishments that will make changes to their plans in response to this proposal. FSIS is requesting comments to address this data gap.

Costs Associated With the Proposed Determination

Maintaining Control of Sampled Product Costs

FSIS is proposing that chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey with *Salmonella* levels at or above 10 cfu/mL(g) and one of the *Salmonella* serotypes of public health significance intended for consumption as final products would be adulterated. As proposed, FSIS inspected establishments would be required to maintain control of product sampled as part of FSIS verification sampling for adulterants. Any chicken carcass, parts, comminuted chicken, or comminuted turkey final products testing positive for *Salmonella* levels at 10 cfu/mL(g) or

higher would not be allowed to enter commerce until the *Salmonella* serotype result is reported and no serotypes of public health significance are detected.

If this proposal is finalized, establishments would be required to prevent product sampled as part of FSIS verification sampling from entering commerce until a negative test result or one above the 10 cfu/mL(g) level but not containing a serotype of public health significance is received. FSIS does not require establishments to hold product at their physical location; thus, product can be stored off-site at an establishment's storage facility, or another private or public storage facility, pending test results. Product subject to FSIS verification sampling can also be diverted and processed into a product that is not subject to these final product standards (*i.e.*, fully cooked products) instead of being sent to cold storage.

FSIS anticipates that the Agency would provide establishments with final adulteration results five days after the sample is collected.²¹¹ Results on a product's level of *Salmonella* would require industry to hold sampled lots for two days and results on the presence of a serotype of public health significance would take an additional three days. The Agency assumed that establishments would maintain control of product until final adulteration results are available. Establishments would be able to move product with test results at levels below 10 cfu/mL(g) into commerce, which would necessitate product to be under establishment's control for up to two days. The Agency assumed that establishments would decide to divert adulterated product after results on its adulteration status are available. This cost is described in the *Lost value to the industry costs* section.

To estimate the industry cost for holding product pending test results, FSIS used 2021 data from PHIS. FSIS assumed that establishments subject to these final product standards would maintain control of each sampled lot pending FSIS verification sampling results. Regulated establishments define their production lots according to their specific conditions and FSIS allows establishments to adjust their lot sizes if

they provide scientific justification for defining lots.²¹² Thus, FSIS used Agency data to approximate the amount of product subject to verification sampling. For chicken carcasses, the estimated lot size is 46,000 birds for high- and medium-volume establishments and 1,800 birds for low- and very low-volume establishments.²¹³ For establishments producing chicken parts, comminuted chicken, and comminuted turkey, the estimated lot sizes are (1) one hour, (2) one shift, and (3) one day of production. These estimated lot sizes, respectively, represent the low, medium, and high scenarios used for estimating the cost of maintaining control of product pending test results for chicken parts, comminuted chicken, and comminuted turkey in this analysis. FSIS is seeking comment on these assumptions.

Since FSIS is proposing to sample these products at the same rate as the current performance standards, the Agency used the number of samples collected in 2021 at establishments that would be subject to this proposal and the estimated lot sizes to approximate the volume of product that would be subject to the Agency's verification sampling program.²¹⁴

FSIS used the per pound cost of cold storage as estimated in the 2015 “Costs of Food Safety Investments” report to monetize the cost to industry from holding product due to this proposal.²¹⁵

²¹² 77 FR 73401.

²¹³ Establishments that slaughter less than 1 million birds per year had flock sizes ranging from 100 to 3,500 birds. FSIS used the average, or 1,800 birds, to approximate the total sampled production at these establishments.

²¹⁴ FSIS collects up to five continuous samples per month at establishments producing young chicken and turkey carcasses, and raw chicken parts, comminuted chicken and turkey products. USDA, FSIS, “*Salmonella* Verification Testing Program Monthly Posting,” April 20, 2023, <https://www.fsis.usda.gov/science-data/data-sets-visualizations/microbiology/Salmonella-verification-testing-program-monthly>.

²¹⁵ For cold storage, the report assumes that the cost of creating and maintaining onsite storage would be equivalent to third-party, offsite cold storage. The establishment needs to ensure that the offsite cold storage facility is certified for food-grade products by USDA. Incoming product will already be cooled, so the storage facility would only need to maintain the product temperature. FSIS assumed product would be refrigerated. RTI Costs of Food Safety Investments. September 2015. Contract No. AG-3A94-B-13-0003 Order No. AG-3A94-K-14-0056. Revised Final Report. Prepared by Catherine L. Viator, Mary K. Muth, Jenna E. Brophy. RTI International. RTI Project Number 0214016.003.000.001. The full report is available here: https://www.fsis.usda.gov/sites/default/files/media_file/documents/Costs_of_Food_Safety_Investments_FGIS-2022-0013.pdf.

²¹⁰ BLS, May 2021 National Industry-Specific Occupational Employment and Wage Estimates for 19-1012 Food Scientists and Technologists, accessed April 13, 2023, <https://www.bls.gov/oes/2021/may/oes191012.htm>.

²¹¹ While the Agency currently uses whole genome sequencing to determine the presence of *Salmonella* serotypes on product sampled by FSIS, the Agency would adopt an alternative approach that would lead to results on the presence of *Salmonella* serotypes in one to three days after screening.

FSIS updated this estimate to 2021 dollars by applying the growth in the “Moving, storage, freight expense” consumer price index.²¹⁶ The resulting cost of cold storage estimate, on a per pound, per day basis is \$0.0023 in 2021 dollars. Establishments may already store product in their facilities or in an off-site location for a certain amount of time. However, the Agency assumed that all costs of storing product for the sampled lots are due to this proposal. FSIS is seeking comments on cold storage costs and availability at

inspected establishments or off-site facilities.

Chicken Carcasses

FSIS estimated that in 2021 establishments subject to the performance standards produced 33.2 billion pounds of chicken carcasses.²¹⁷ The Agency estimated that about 11 percent of chicken carcasses are consumed as whole birds and, thus, final products subject to the proposal.²¹⁸ To account for uncertainty in this estimate, the Agency used 6, 11, and 16

percent as the low, medium, and high estimates of the volume of chicken carcasses subject to the proposal. FSIS estimated that in 2021 a total of 162.9 million pounds, ranging from 88.9 to 237.0 million, would have been sampled as part of these final product standards (Table 20).²¹⁹ There is likely a tendency toward overstatement in this estimate of the volume of product subject to FSIS verification sampling as lot sizes vary by establishments and lot sizes may be smaller than the sizes FSIS assumed for this analysis.

TABLE 20—CHICKEN CARCASSES: ESTIMATED SAMPLED VOLUME BY ESTABLISHMENT VOLUME CATEGORY [2021]

Establishment volume category	Number of establishments	Estimated sampled volume (million pounds)		
		Low	Medium	High
High	142	86.8	159.1	231.4
Medium	9	1.8	3.4	4.9
Low	4	0.04	0.1	0.1
Very Low	33	0.2	0.4	0.6
Total	188	88.9	162.9	237.0

Note: Numbers in table may not sum to totals due to rounding.

This analysis assumed establishments would maintain control of sampled product until results on the level of *Salmonella* are available, which is expected to take two days. FSIS assumes establishments would move into commerce product with test results below 10 cfu/mL(g) and would hold product at or above that level for an additional three days. FSIS estimated

that 654,123 pounds of chicken carcasses would have test results at or above 10 cfu/mL, which would be held until results on the presence of a serotype of public health significance were available. FSIS estimated the total cost to industry of holding all sampled chicken carcasses pending test results at \$0.75 million annually [(162.9 million × \$0.0023 × 2) + (654,123 × \$0.0023 × 3)],

ranging from \$0.41 to \$1.09 million (Table 21). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for holding chicken carcasses pending test results is \$0.75 million, ranging from \$0.41 million to \$1.09 million.

TABLE 21—CHICKEN CARCASSES: MAINTAINING CONTROL OF SAMPLED PRODUCT COSTS

Category	Estimated cost (million \$)		
	Low	Medium	High
High	0.40	0.73	1.07
Medium	0.01	0.02	0.02
Low	0.0002	0.0003	0.0005
Very low	0.0011	0.0020	0.0029
Total	0.41	0.75	1.09
Annualized ¹	0.41	0.75	1.09

¹ Costs are annualized at a 7 percent discount rate over 10 years.

Note: Numbers in table may not sum to totals due to rounding.

²¹⁶ Bureau of Labor Statistics (BLS), Consumer Price Index (CPI), “Moving, storage, freight expense in U.S. city average, all urban consumers, not seasonally adjusted,” (Series ID CUUR0000SEHP03), accessed February 14, 2023. This CPI grew 37.5 percent from 2015 to 2021.

²¹⁷ (8.3 billion birds × 4 pounds). Dressed weights for chickens vary. For broilers, which is the main class of poultry slaughtered at FSIS inspected establishments, the 2023 chicken Risk Assessment used an average carcass weight was 4 pounds.

²¹⁸ USDA, FSIS, “Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,” January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

Estimates from the National Chicken Council indicate that about 9 percent of broilers, the main chicken subclass produced in the United States, were marketed as whole birds in 2021. National Chicken Council (NCC), “How Broilers are Marketed,” accessed May 11, 2023, <https://www.nationalchickencouncil.org/statistic/how-broilers-are-marketed/>.

²¹⁹ This is the sum of the estimated sampled volume for all establishment categories. For each category, this volume is calculated as: number of establishments × average number of samples × lot size converted to pounds × estimated share of production intended as final product. For example, the medium estimate for high-volume establishments is 142 × 55 × (46,000 × 4) × 0.10. Calculations might not sum to totals due to rounding.

Chicken Parts

FSIS estimated that in 2021 establishments subject to the performance standards processed 31.2 billion pounds of chicken parts.²²⁰ Raw chicken parts processed at FSIS regulated establishments can be sent into commerce as final products or further processed into a variety of

preparations, including cooked products (e.g., fully cooked chicken breasts). As such, FSIS assumed that 80, 85, or 90 percent of the estimated production of chicken parts would be raw final product subject to this proposal. FSIS is seeking comments on this assumption. FSIS estimated that 2.6 billion pounds of chicken parts, ranging from 308

million to 5.5 billion, would have been sampled as part of these final product standards (Table 22).²²¹ There is likely a tendency toward overstatement in this estimate of the volume of product subject to FSIS verification sampling as lot sizes vary by establishments and lot sizes may be smaller than the sizes FSIS assumed for this analysis.

TABLE 22—CHICKEN PARTS: ESTIMATED SAMPLED VOLUME BY ESTABLISHMENT VOLUME CATEGORY
[2021]

Category	Number of establishments	Estimated sampled volume (million pounds)		
		Low	Medium	High
High	154	286	2,433	5,153
Medium	209	21	181	325
Low	127	0	3	5
Total	490	308	2,617	5,483

Note: Numbers in table may not sum to totals due to rounding.

This analysis assumed establishments would maintain control of sampled product until results on the level of *Salmonella* are available, which is expected to take two days. FSIS assumed establishments would move product with test results below 10 cfu/mL(g) into commerce and would hold for an additional three days product with results at or above that level. FSIS

estimated that about 246,949 pounds of chicken parts would have test results at or above 10 cfu/mL(g), which would be held until results on the presence of a serotype of public health significance were available. FSIS estimated the cost to industry of holding all sampled chicken parts pending test results at \$12.0 million annually [(2.6 billion × \$0.0023 × 2) + (246,949 × \$0.0023 × 3)],

ranging from \$1.4 to \$25.1 million (Table 22). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for holding chicken parts pending test results is \$11.88 million, ranging from \$1.4 million to \$24.9 million.

TABLE 23—CHICKEN PARTS: MAINTAINING CONTROL OF SAMPLED PRODUCT COSTS

Category	Cost (million \$)		
	Low	Medium	High
High	1.31	11.15	23.62
Medium	0.10	0.83	1.49
Low	0.00	0.02	0.02
Total	1.41	12.00	25.13
Annualized ¹	1.40	11.88	24.93

¹ Costs are annualized at a 7 percent discount rate over 10 years.

Note: Numbers in table may not sum to totals due to rounding.

Comminuted Chicken

FSIS estimated that in 2021 establishments subject to the performance standards processed 2.3 billion pounds of comminuted chicken. Raw comminuted chicken processed at FSIS regulated establishments can be sent into commerce as final products or further processed into a variety of

preparations, including cooked products (e.g., fully cooked chicken nuggets). As such, FSIS assumed that 80, 85, or 90 percent of the estimated production of comminuted chicken would be raw final product subject to this proposal. FSIS is seeking comments on this assumption. FSIS estimated that 264.19 million pounds, ranging from 26.1 to 427.65 million pounds of comminuted chicken,

would have been sampled as part of these final product standards (Table 24).²²² There is likely a tendency toward overstatement in this estimate of the volume of product subject to FSIS verification sampling as lot sizes vary by establishments and lot sizes may be smaller than the sizes FSIS assumed for this analysis.

²²⁰ The 2023 chicken risk assessment estimated that, of the total chicken slaughtered volume, about 83 percent is consumed as chicken parts. In 2021, total chicken slaughter volume was an estimated 37 billion pounds, 31.2 billion of which are estimated to be processed into chicken parts.

²²¹ FSIS calculated these estimates using average daily production volume and total number of samples in 2021 for each of the establishments producing chicken parts assuming lot sizes of one hour, one shift, and one day of production. FSIS multiplied this result by the share production

intended as final product to obtain the low, medium, and high estimates.

²²² FSIS calculated these estimates using average daily production volume and total production days in 2021 for each of the establishments producing comminuted chicken and multiplying by the share production intended as final product.

TABLE 24—COMMINUTED CHICKEN: ESTIMATED SAMPLED VOLUME BY ESTABLISHMENT VOLUME CATEGORY
[2021]

Category	Number of establishments	Estimated sampled volume (million pounds)		
		Low	Medium	High
High	0	0	0	0
Medium	35	25.12	254.59	415.22
Low	39	1.02	9.59	12.43
Total	74	26.14	264.19	427.65

Note: Numbers in table may not sum to totals due to rounding.

This analysis assumed establishments would maintain control of this product until results on the level of *Salmonella* are available, which is expected to take two days. FSIS assumed establishments would move product with test results below 10 cfu/mL(g) into commerce and would hold for an additional three days products with results at or above that level. FSIS estimated that about 5.0

million pounds of comminuted chicken would have test results at or above 10 cfu/mL(g), which would be held until results on the presence of a serotype of public health significance were available. FSIS estimated the cost to industry of holding all sampled comminuted chicken pending test results at \$1.3 million annually (264.2 million × \$0.0023 × 2) + (5.0 million ×

\$0.0023 × 3)], ranging from \$0.2 to \$2.0 million (Table 25). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for holding comminuted chicken products pending test results is \$1.1 million, ranging from \$0.1 million to \$1.7 million.

TABLE 25—COMMUNUTED CHICKEN: MAINTAINING CONTROL OF SAMPLED PRODUCT COSTS

Category	Cost (million \$)		
	Low	Medium	High
High	0	0	0
Medium	0.15	1.20	1.94
Low	0.006	0.04	0.06
Total	0.15	1.25	1.99
Annualized ¹	0.13	1.07	1.72

¹ Costs are annualized at a 7 percent discount rate over 10 years.

Note: Numbers in table may not sum to totals due to rounding.

Comminuted Turkey

FSIS estimated that in 2021 establishments subject to the performance standards processed 1.7 billion pounds of comminuted turkey. Raw comminuted turkey processed at FSIS regulated establishments can be sent into commerce as final products or further processed into preparations

including cooked products (e.g., fully cooked sausages). As such, FSIS assumed that 80, 85, or 90 percent of the estimated production of comminuted turkey would be raw final product subject to this proposal. FSIS is seeking comments on this assumption. FSIS estimates that 156.7 million pounds, ranging from 18.4 to 330.4 million,

would have been sampled as part of these final product standards (Table 26).²²³ There is likely a tendency toward overstatement in this estimate of the volume of product subject to FSIS verification sampling as lot sizes vary by establishments and lot sizes may be smaller than the sizes FSIS assumed for this analysis.

TABLE 26—COMMUNUTED TURKEY: ESTIMATED SAMPLED VOLUME BY ESTABLISHMENT VOLUME CATEGORY
[2021]

Category	Number of establishments	Estimated sampled volume (million pounds)		
		Low	Medium	High
High	5	11.49	97.71	206.91
Medium	25	6.90	58.63	122.86
Low	18	0.04	0.36	0.65
Total	48	18.43	156.69	330.42

Note: Numbers in table may not sum to totals due to rounding.

²²³ FSIS calculated these estimates using average daily production volume and total production days

in 2021 for each of the establishments producing

comminuted turkey and multiplying by the share production intended as final product.

This analysis assumed establishments would maintain control of this product until results on the level of *Salmonella* are available, which is expected to take two days. FSIS assumed establishments would move product with test results below 10 cfu/mL(g) into commerce and would hold for an additional three days product with results at or above that level. FSIS estimated that about 2.3

million pounds of comminuted turkey would have test results at or above 10 cfu/mL, which would be held until results on the presence of a serotype of public health significance were available. FSIS estimated the cost to industry of holding all sampled comminuted turkey pending test results at \$0.7 million annually [(156.7 million × \$0.0023 × 2) + (2.3 million × \$0.0023

× 3)], ranging from \$0.1 to \$1.5 million (Table 27). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for holding comminuted turkey products pending test results is \$0.70 million, ranging from \$0.09 million to \$1.45 million.

TABLE 27—COMMUNUTED TURKEY: MAINTAINING CONTROL OF SAMPLED PRODUCT COSTS

Category	Cost (million \$)		
	Low	Medium	High
High	0.06	0.45	0.96
Medium	0.04	0.28	0.57
Low	0.0003	0.0017	0.0031
Total	0.10	0.73	1.53
Annualized ¹	0.09	0.70	1.45

¹ Costs are annualized at a 7 percent discount rate over 10 years.

Note: Numbers in table may not sum to totals due to rounding.

Import Establishments Costs

FSIS conducts sampling activities at official import inspection establishments to verify that a foreign country's poultry inspection system is equivalent to the U.S. poultry inspection system. If this rule is finalized, FSIS would adapt its current *Salmonella* sampling program for imported chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. Import establishments would be required to maintain control of sampled product pending test results to verify that these products are not adulterated. Similar to domestic producers, FSIS assumed that official import inspection establishments would maintain control of sampled imported product lots for two days until results on the level of *Salmonella* are available. Sampled product with results below 10 CFU/mL(g) could be moved into commerce. If test results show *Salmonella* at or above 10 CFU/mL(g), FSIS assumed establishments would maintain control of these product lots for an additional one to three days, until the presence or absence of a serotype of public health significance is confirmed. Adulterated product would be diverted from U.S. commerce.

FSIS estimates the cost to import establishments for maintaining control of imported product subject to FSIS verification sampling for *Salmonella*, as described in this proposal, would be minimal. Poultry imports represent a small fraction of the U.S. domestic poultry supply, accounting for less than

0.5 percent in 2021.²²⁴ In that year, only three countries exported raw chicken and turkey products to the United States: Canada, Chile, and Mexico.²²⁵ Canada was the sole exporter of whole chicken carcasses, accounting for about 14 million pounds of chicken. Chile, in

²²⁴ USDA, Foreign Agricultural Service, "Production, Supply and Distribution database," accessed May 11, 2023. Although U.S. import data does not directly correspond with the final product categories in this proposal, FSIS used available trade data to identify Harmonized Tariff Schedule (HTS) codes that would approximate imports of chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. FSIS estimates that imports of chicken carcasses to the United States reached 13.7 million pounds in 2021 (HTS 0207.11 and 0207.12, Whole young chickens and Whole frozen chickens, respectively), while imports of chicken parts and comminuted chicken were 164 million pounds (HTS 0207.13 and 0207.14, Meat and edible offal of chickens, fresh or chilled and frozen, respectively). FSIS assumed that imports under HTS 0207.26 and 0207.27 (Meat and edible offal of turkeys, fresh or chilled and frozen, respectively) approximate imports of comminuted turkey, although this is likely an overestimate as this HTS code also includes turkey parts. Imports under HTS 0207.26 and 0207.27, combined, reached 74.3 million pounds in 2022. Imports under these HTS codes represent 0.5 percent of U.S. production of chicken carcasses, 0.04 percent of U.S. production of chicken parts and comminuted chicken, and 4 percent of imports of comminuted turkey. U.S. International Trade Commission DataWeb/U.S. Department of Commerce, accessed June 28, 2023.

²²⁵ Three countries are eligible to export raw chicken and turkey products to the United States—Canada, Chile, and Poland,—while Mexico is eligible to export only processed poultry products slaughtered under Federal inspection in the United States or in a country eligible to export slaughtered poultry to the United States. USDA, FSIS, "Eligible Foreign Establishments," July 14, 2023, <https://www.fsis.usda.gov/inspection/import-export/import-export-library/eligible-foreign-establishments>.

turn, was the main exporter of chicken parts (132 million pounds).²²⁶

Currently, FSIS samples and tests imported chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey for the presence of *Salmonella*. According to data from PHIS, in 2021, FSIS collected and analyzed about 850 samples of imported chicken and turkey products, which represented about 15.8 million pounds of product. These samples were mainly from chicken parts and carcasses, as imports of comminuted chicken and turkey are relatively low.

FSIS estimated the cost for these import establishments assuming that establishments would maintain control pending test results of all sampled product identified in 2021 data, which is likely an overestimate. The estimated cost for import establishments is \$0.07 million per year (15.8 million pounds × 2 days × \$0.0023). While data on the volume imported of product with results at or above 10 cfu/mL(g) are not available, FSIS estimates this would be a relatively low volume of product. In 2021, about 17 percent of imported poultry samples were positive for the presence of *Salmonella*, representing about 2.6 million pounds of product. This is likely a high estimate as countries would be required to implement measures to maintain equivalence with the U.S. poultry inspection system if this rule is finalized.

²²⁶ U.S. International Trade Commission DataWeb/U.S. Department of Commerce accessed June 28, 2023.

Total Costs to Industry From Maintaining Control of Sampled Product

FSIS estimated that the total cost to industry from complying with FSIS verification sampling requirements in this proposal is \$14.47 million annually, ranging from \$2.11 to \$29.26 million (Table 28), assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate. As previously described,

establishments are required to maintain control pending test results for product subject to FSIS verification sampling for adulterants. FSIS estimated that an average of 3.2 billion pounds of product per year would be subject to FSIS verification sampling. FSIS allows establishments to move product to an alternate location pending test results for an adulterant as long as they maintain control of the sampled product. Producers can also elect to divert sampled product into a product

that is not subject to these standards (*i.e.*, fully cooked products), rather than maintaining control of it pending test results. Moreover, FSIS allows establishments to produce smaller representative product lots for FSIS verification sampling if they demonstrate that the lot presented is microbiologically independent from other production lots.²²⁷ Thus, the cost for holding product pending test results is likely an overestimate. FSIS is seeking comments on these assumptions.

TABLE 28—SUMMARY OF COSTS TO INDUSTRY FROM MAINTAINING CONTROL OF SAMPLED PRODUCT

Product	Number of establishments ¹	Cost (million \$) ²		
		Low	Medium	High
Chicken carcasses	188	0.41	0.75	1.09
Chicken parts	490	1.40	11.88	24.93
Comminuted chicken	74	0.13	1.07	1.72
Subtotal for chicken products	752	1.94	13.71	27.74
Comminuted turkey	48	0.09	0.69	1.45
Import establishments	12	0.07	0.07	0.07
Total		2.11	14.47	29.26

¹ Establishments may produce more than one of the products subject to these final product standards.
² Costs are annualized at a 7 percent discount rate over 10 years.
Note: Numbers in table may not sum to totals due to rounding.

Lost Value to the Industry Costs

FSIS estimated the cost to industry from lost value resulting from diverting adulterated product subject to these final product standards. FSIS assumed that establishments would divert product after receiving final results showing a level of *Salmonella* at or above 10 cfu/mL(g) and the presence of a serotype of public health significance.

As previously mentioned, FSIS laboratories would provide results on the level of *Salmonella* to establishments within two days from sample collection and results on the presence of a serotype of public health significance three days after initial results.

The 2023 risk assessments estimated that approximately 0.2 million pounds of chicken carcasses, 0.07 million

pounds of chicken parts, 1.6 million pounds of comminuted chicken, and 0.6 million pounds of comminuted turkey per year would have *Salmonella* levels at or above 10 cfu/mL(g) and would contain a serotype of public health significance (Table 29). This represents less than 0.1 percent of estimated production for each of the product categories.

TABLE 29—TOTAL PRODUCTION, VOLUME OVER 10 cfu/mL(g) AND CONTAINING A SEROTYPE OF PUBLIC HEALTH SIGNIFICANCE, AND SHARE OF PRODUCTION BY PRODUCT

Product	Total production (million pounds)	Volume over 10 cfu/mL(g) and containing a serotype of public health significance (million pounds)	Share of production (%)
Chicken carcasses	33,238	0.2	0.000005
Chicken parts	31,208	0.07	0.000002
Comminuted chicken	2,256	1.6	0.000691
Comminuted turkey	1,691	0.6	0.000336

Note: Numbers in table may not sum to totals due to rounding.

To estimate the cost to industry of this lost value as a result of this proposal, FSIS applied the per pound retail price of select poultry products to the estimated volume of lost product. FSIS used data from 2017 to 2021 and used a range in these prices to account for variability and uncertainty: the lowest

retail price in the five-year period as the minimum, the highest as the maximum, and the five-year average as the medium estimate. For chicken carcasses, FSIS used the retail price for whole fresh chicken while for chicken parts the Agency used the retail price for chicken breasts (Table 30). Because data for the

five-year period for comminuted or ground chicken were not readily available, FSIS used the retail price for chicken legs as a proxy. For comminuted turkey, FSIS used data for whole frozen turkeys as data for the five-year period for comminuted or ground turkey were not available.

227 77 FR 73402.

TABLE 30—RETAIL PRICES FOR SELECT COMMODITIES

Product	Price source	Price per pound (\$)		
		Low	Medium	High
Chicken carcasses	Whole fresh chicken ^a	1.36	1.51	1.75
Chicken parts	Chicken breasts ^b	2.90	3.19	3.72
Comminuted chicken	Chicken legs ^c	1.32	1.50	1.73
Comminuted turkey	Whole frozen turkey ^d	0.80	0.99	1.23

^a U.S. Bureau of Labor Statistics (BLS), Chicken, fresh, whole, per lb. (453.6 gm) in U.S. city average, average price, not seasonally adjusted [APU0000706111], accessed July 6, 2023, https://data.bls.gov/timeseries/APU0000706111?amp%253bdata_tool=XGtable&output_view=data&include_graphs=true.

^b BLS, Chicken breast, boneless, per lb. (453.6 gm) [APU0000FF1101], accessed July 6, 2023; https://data.bls.gov/timeseries/APU0000FF1101?amp%253bdata_tool=XGtable&output_view=data&include_graphs=true.

^c BLS, Chicken legs, bone-in, per lb. (453.6 gm) in U.S. city average, average price, not seasonally adjusted [APU0000706212], accessed July 6, 2023, https://data.bls.gov/timeseries/APU0000706212?amp%253bdata_tool=XGtable&output_view=data&include_graphs=true.

^d USDA, Economic Research Service, Turkey Sector: Background & Statistics: Price Statistics, April 18, 2023, <https://www.ers.usda.gov/news-room/trending-topics/turkey-sector-background-statistics>.

Previous FSIS analyses assumed that diverted product would lose 66 percent of its value.²²⁸ As product under these final product standards are raw materials that can be diverted to a variety of fully cooked preparations, the Agency used a range to estimate the cost

of lost value to the industry. Specifically, FSIS used 34, 50, and 66 percent as the low, medium, and high estimates. FSIS estimated that the cost to industry from diverting product is \$1.7 million annually, with a range of \$1.0 to \$2.6 million (Table 31).

Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for lost value of products subject to this proposal is \$1.5 million, ranging from \$0.9 million to \$2.4 million.

TABLE 31—LOST VALUE TO THE INDUSTRY COSTS, MILLION \$

Product	Low	Medium	High
Chicken carcasses	0.1	0.1	0.2
Chicken parts	0.1	0.1	0.2
Comminuted chicken	0.7	1.2	1.8
Comminuted turkey	0.2	0.3	0.5
Total	1.0	1.7	2.6
Annualized ¹	0.9	1.5	2.4

¹ Costs are annualized at a 7 percent discount rate over 10 years.

Note: Numbers in table may not sum to totals due to rounding.

Microbiological Sampling Plan Reassessment Costs

Establishments subject to these proposed final product standards may incur costs associated with reassessing their sampling plans. Current performance standards focus on the presence or absence of *Salmonella* in certain poultry products. However, the proposed standards would make product adulterated if it contains *Salmonella* at or above 10 cfu/mL(g) and has at least one of the serotypes of public health significance. To estimate a cost associated with this requirement, FSIS assumed a portion of establishments would reassess their microbiological sampling plans. Consistent with the estimates in the

previous cost-benefit analysis for the 2016 performance standards, FSIS estimated the cost of reassessing a sampling plan for 30, 40, and 50 percent of the establishments subject to this proposal.²²⁹ FSIS included all volume categories in these estimates. However, as previously noted in the cost-benefit analysis for the 2016 performance standards, FSIS does not expect low and VLV establishments to have an internal sampling plan.²³⁰ FSIS assumed that these establishments would opt to not incur the expense of developing a sampling plan as sampling does not directly contribute to pathogen reduction. The Agency is seeking comments on this assumption.

FSIS estimated that the total cost to industry from reassessing their sampling plans is \$0.3 million, ranging from \$0.1 to \$0.6 million (Table 32). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the cost for microbiological sampling plan reassessment is \$0.04 million, ranging from \$0.02 million to \$0.08 million. High- and medium-volume establishments need an average of 40 hours (ranging from 20 to 60), while low- and very low-volume establishments need an average of 20 hours (ranging from 10 to 30) to reassess a sampling plan, according to the 2017 *Costs of Food Safety Investments in the Meat and Poultry Slaughter*

²²⁸ USDA, FSIS, "Cost-Benefit Analysis for FSIS's Implementation of Its Non-O157 STEC Testing on Beef Manufacturing Trimmings and Expansion of Its Testing to Ground Beef and Ground Beef Components Other Than Beef Manufacturing Trimmings," June 2020, https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/FSIS-Non-O157-STE-Testing-CBA-June-2020.pdf; USDA, FSIS, "Salmonella in Certain Not-Ready-To-Eat

Breaded Stuffed Chicken Products," Preliminary Cost-Benefit Analysis, April 2023, https://www.fsis.usda.gov/sites/default/files/media_file/documents/NRTE_Stuffed_Chicken_CBA_FSIS-2022-0013.pdf.

²²⁹ USDA, FSIS, Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards, Final Cost-Benefit Analysis, February 11, 2016, https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.

[file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf](https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf).

²³⁰ USDA, FSIS, Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards, Final Cost-Benefit Analysis, February 11, 2016, https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.

*Industries.*²³¹ This publication estimated costs for large and small establishments. FSIS assumed the large category would correspond with high- and medium-volume establishments, while the small category would

correspond with low- and very low-volume establishments. FSIS used data from the U.S. Bureau of Labor Statistics to update the hourly wage for estimating these labor costs. Specifically, FSIS used the 2021 hourly wage for a

production worker of \$30.78, which includes an average hourly wage of \$15.39 multiplied by a benefits and overhead factor of two.

TABLE 32—MICROBIOLOGICAL SAMPLING PLAN REASSESSMENT COSTS

Establishment volume category	Number of establishments	Cost (thousand \$)		
		Low	Medium	High
High	302	0.06	0.15	0.28
Medium	276	0.05	0.14	0.25
Low	190	0.02	0.05	0.08
Very Low	91	0.003	0.007	0.014
Total		0.13	0.34	0.63
Annualized ¹		0.02	0.04	0.08

¹ Costs are annualized at a 7 percent discount rate over 10 years.
Note: Numbers in table may not sum to totals due to rounding.

Validation of Microbiological Sampling Plans

If an establishment makes changes to their microbiological sampling plans in response to this proposal, they would incur costs associated with validating these changes. The 2015 “Costs of Food Safety Interventions” report indicates that high- and medium-volume establishments would need an average of 960 labor hours for validation of a microbiological sampling plan and 1,200 labor hours for low- and very low-volume establishments. On a per plan basis, the cost for validation of a microbiological sampling plan for a high- or medium-volume establishment is \$77,683, on average, while for low- or very low-volume establishments, the average cost is \$97,104. FSIS used the 2021 hourly wage for a food scientist of \$80.92, which includes an average hourly wage of \$40.46 multiplied by a benefits and overhead factor of 2.²³² FSIS did not include an estimate of total industry validation costs for microbiological sampling plans because FSIS does not have data on the number of establishments that would make changes to their plans in response to this proposal. FSIS is requesting comments to address this data gap.

Corrective Actions

FSIS would require establishments that do not meet the final product standards to take corrective actions. These corrective actions would be aimed at removing adulterated product from market and making changes to prevent production of adulterated product in the future. Interventions available to the poultry industry include antimicrobial agents, new equipment, and employee practices. FSIS does not have information on the types or frequency of corrective actions establishments may take in response to not meeting the final products standards, and the Agency is seeking comments on the potential costs associated with these.

Summary of Costs to Industry From This Proposed Rule and Proposed Determination

FSIS estimated the main cost to industry to comply with this proposal is \$16.4 million annually, with a range of \$3.3 to \$32.3 million (Table 33), assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate. The principal component of this cost is the requirement that establishments must maintain control of product subject to FSIS verification sampling for adulterants pending test results. The

cost estimate associated with this requirement is likely an overestimate as it is possible that establishments’ current practices and procedures would allow them to maintain control of a lower volume of product. Additionally, all timeframes and methods for *Salmonella* testing are likely to change as FSIS continuously incorporates new laboratory technologies into its sampling verification program. FSIS is seeking comment on these estimates. FSIS estimated that the total costs to establishments from reassessing HACCP and microbiological sampling plans, combined, is \$0.22 million (\$0.18 + \$0.04 million). The estimated cost associated with the proposed statistical process control requirements is \$0.04 million, which is likely an overestimate as certain establishments would be able to mitigate the cost by using laboratory services provided by FSIS, as previously described. To varying degrees, industry may also incur other costs associated with their individual responses to this proposal. The Agency estimated that this total cost represents less than 1 percent of the total industry’s revenue in 2021. In 2021, the estimated total sales value for broilers and turkeys, on a live basis, was \$37.4 billion, with a five-year average between 2017 and 2021 of \$33.5 billion.²³³ This value increased to \$57.5 billion in 2022. For the poultry processing industry, the

²³¹ Viator CL, Muth MK, Brophy JE, Noyes G. Costs of Food Safety Investments in the Meat and Poultry Slaughter Industries. J Food Sci. 2017 Feb;82(2):260–269. doi: 10.1111/1750–3841.13597. Epub 2017 Jan 24. PMID: 28117890. FSIS derived the labor hours from the total costs presented on table 5 and the wage rate for production occupations on table 2. BLS, May 2021 National Industry-Specific Occupational Employment and Wage Estimates for 19–1012 Food Scientists and

Technologists, accessed April 13, 2023, <https://www.bls.gov/oes/current/oes191012.htm>.
²³² Viator CL, Muth MK, Brophy JE, Noyes G. Costs of Food Safety Investments in the Meat and Poultry Slaughter Industries. J Food Sci. 2017 Feb;82(2):260–269. doi: 10.1111/1750–3841.13597. Epub 2017 Jan 24. PMID: 28117890. FSIS derived the labor hours from the total costs presented on table 5 and the wage rate for production occupations on table 2. BLS, May 2021 National Industry-Specific Occupational Employment and

Wage Estimates for 19–1012 Food Scientists and Technologists, accessed April 13, 2023, <https://www.bls.gov/oes/current/oes191012.htm>.
²³³ USDA, ERS, “Poultry Sector at a Glance” June 1, 2023, <https://www.ers.usda.gov/topics/animal-products/poultry-eggs/sector-at-a-glance/>; USDA, National Agricultural Statistics Service, “Poultry—Production and Value: 2022 Summary,” April 2023, <https://downloads.usda.library.cornell.edu/usda-esmis/files/m039k491c/wm119387d/5138kw352/plva0423.pdf>.

total 2021 revenue was \$77 billion, according to U.S. Census data.²³⁴

TABLE 33—SUMMARY OF INDUSTRY COSTS

Cost descriptions	Cost (million \$)		
	Low	Medium	High
Costs associated with the proposed rule:			
Statistical process control	0.04	0.04	0.04
Electronic data submission	0.18	0.18	0.18
HACCP plan reassessment	0.09	0.18	0.26
Costs associated with the proposed determination:			
Maintaining control of sampled product	2.11	14.47	29.26
Lost value to the industry	0.87	1.52	2.43
Microbiological sampling plan reassessment	0.02	0.04	0.08
Total ¹	3.31	16.43	32.25

¹ Costs are annualized at a 7 percent discount rate over 10 years.

Note: Numbers in table may not sum to totals due to rounding.

FSIS estimates industry would incur annual costs in response to this rule.

Table 34 includes the expected undiscounted annual costs of this

proposal assuming the implementation schedule over a 10-year period.

TABLE 34—SUMMARY OF ANNUAL COSTS OVER 10 YEARS

Year	Low	Medium	High
1	2,342,792	13,490,291	27,612,367
2	3,330,215	16,984,639	33,483,179
3	3,250,382	16,788,952	33,160,044
4	3,099,498	16,471,425	32,667,872
5	3,099,498	16,469,009	32,667,872
6	3,099,498	16,466,751	32,667,872
7	3,099,498	16,464,641	32,667,872
8	3,099,498	16,462,668	32,667,872
9	3,099,498	16,460,825	32,667,872
10	3,099,498	16,459,102	32,667,872

Costs to FSIS

FSIS does not anticipate the proposal, including using laboratory services provided by FSIS for analyzing process control samples for VS and VLV establishments under Traditional Inspection, as well as conducting verification sampling for the final product standards, will increase Agency costs. The Agency would adapt its current sampling for *Salmonella* on poultry products to conduct verification sampling for the new final product standards and would be able to shift existing resources as necessary to implement this proposal if finalized. FSIS currently enumerates samples collected as part of FSIS verification sampling for *Salmonella*. Consequently, if this proposal is finalized, the only

additional cost to FSIS would be to incorporate serotype testing on *Salmonella* positive samples. The Agency estimates analyzing these tests would require 520 labor hours, or \$0.03 million, per year to analyze results, with additional hours, including data management, procurement, result review and authorization, as needed.²³⁵

Costs related to follow-up sampling and conducting FSAs are not expected to increase. The Agency would conduct follow up sampling and a PHRE for any establishments that does not meet the final product standards. FSIS would use the results of the PHRE to determine the need for an FSA. FSIS currently conducts follow up sampling and PHREs on establishments that do not meet the current *Salmonella* performance standards. For instance, in

2022, FSIS conducted 30 FSAs at category three establishments. The Agency estimated that the average cost to conduct a for-cause FSA in 2016 was about \$4,800, which, inflated to 2021 dollars, is about \$5,400 per FSA.²³⁶

Potential Benefits and Avoided Costs From the Proposed Rule and Proposed Determination

Prevented Salmonella Illnesses

FSIS is proposing to declare *Salmonella* at or above 10 cfu/mL(g) and containing a serotype of public health significance an adulterant on chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey as final products that would enter commerce. The 2023 risk assessments provide a range of data on the public health impacts achieved by reducing

²³⁴ Sales, value of shipments, or revenue for the Poultry processing industry, as defined in the North American Industry Classification System code 311615. U.S. Census Bureau, Annual Survey of Manufacturers: Summary Statistics for Industry Groups and Industries in the U.S.: 2018–2021 (NAICS 311615), accessed on April 11, 2023.

²³⁵ FSIS used the 2024 base salary of a GS–12 step 1 full time employee of \$35.67 per hour and included the Civilian Position Full Fringe Benefit Cost Factor of 36.25 percent. Executive Office of The President, Office of Management and Budget, Circular No. A–76 (Revised), May 29, 2003, https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A76/a76_incl_tech_correction.pdf.

²³⁶ Based on the FSIS Office of the Chief Financial Officer (OCFO) preliminary analysis of the average cost per FSA under the new FSA methodology, FY 2016. The costs were inflated, by using the 2021 BLS Consumer Price Index (CPI) All items in U.S. city average, all urban consumers, not seasonally adjusted (CUUR0000SA0, CUUS0000SA0 Not Seasonally Adjusted).

final product contaminated with *Salmonella*, as well as the higher risk per serving associated with product that would be declared adulterated by the proposal. FSIS used this range of data to estimate the potential public health benefits of this proposal. FSIS also used findings from the FSIS risk profile to create these estimates, including information regarding the higher virulence of certain *Salmonella* serotypes, as well as the potential debilitating human health outcomes from *Salmonella* infection (e.g., reactive arthritis), which are not included in the cost of illness estimates.

The 2023 risk assessments estimated the number of illnesses that could be prevented if product lots with results at or above 10 cfu/mL(g) of *Salmonella* are diverted from commerce as part of FSIS verification sampling programs. For chicken carcasses, the 2023 chicken risk assessment estimated that 1,000 illnesses could be prevented, while for chicken parts and comminuted chicken it estimated 200 and 1,000 illnesses, respectively. The 2023 chicken risk assessment assessed the effect of a carcass final product standard on all chicken associated illnesses, including those from parts and comminuted product consumption, but could not assess the effect of carcasses and secondary products standards sequentially. As such, the 2023 chicken risk assessment estimates for chicken products are not additive.²³⁷ For comminuted turkey, the 2023 turkey risk assessment estimated that 2,100 illnesses could be prevented.²³⁸ This analysis presents three illustrative scenarios based on these results.

FSIS estimated that if this proposal becomes final, the number of illnesses prevented may range from 765 to 4,300 cases per year (Table 34).²³⁹ These estimates are based on the best data currently available.

For the low estimate, the Agency used sampling data and results from the 2023 risk assessments to estimate the number of prevented illnesses from the final

products standards. FSIS sampling data show that the serotypes of public health significance identified in this proposal are present in 24 percent of the chicken carcass samples and 25 percent of the comminuted turkey samples.²⁴⁰ The Agency applied the share of samples with at least one serotype of public health significance to the estimated number of prevented illnesses from diverting chicken carcasses and comminuted turkey with results at or above 10 cfu/mL(g). Thus, for the low estimate in this analysis, the Agency estimated that the final product standards would prevent a total of 765 *Salmonella* illnesses, 240 from chicken carcasses and 525 from comminuted turkey. Research indicates that chicken carcass samples often contain multiple *Salmonella* serotypes.²⁴¹ For example, it is likely that a sample from a chicken carcass could test positive for *Salmonella* Kentucky and also contain *Salmonella* Enteritidis, which is a serotype of public health significance, but *Salmonella* Enteritidis was not captured by FSIS testing on that sample. At present there is no rapid way to screen for multiple *Salmonella* serotypes at one time. Moreover, the 2023 chicken risk assessment estimated that diverting from commerce chicken carcasses containing serotypes in the higher virulence cluster would result in 1,800 prevented illnesses, which is higher than the estimated number of illnesses prevented from diverting carcasses with *Salmonella* at or above 10 cfu/mL (1,000 illnesses).²⁴² Additionally, FSIS data show that serotypes of public health significance have been detected at higher rates in chicken parts and comminuted chicken

products.²⁴³ Further, the serotypes of public health significance have been identified in over 50 percent of the outbreaks associated with chicken products between 2012 and 2021. FSIS is seeking comments on these assumptions and estimates. While the estimates in the 2023 risk assessments refer to *Salmonella* levels and serotypes separately, the data indicate that the number of illnesses prevented by the final product standards in this proposal is higher than the low estimate included in this analysis.

For the medium estimate, FSIS used the 2023 risk assessments results of illnesses prevented from diverting chicken carcasses (1,000 illnesses) and comminuted turkey (2,100 illnesses) with *Salmonella* levels at or above 10 cfu/mL(g). This estimate accounts for some of the uncertainty around potential health benefits from this proposal. The Agency used this because as discussed above, products with *Salmonella* at or above 10 cfu/mL(g) have a higher risk per serving than other products and would be more likely to cause illness. Specifically, the 2023 chicken risk assessment noted that the probability of illness for a serving that tests at or above 10 cfu/mL(g) and has a serotype of public health significance is 2,000-fold higher than the average across all servings for carcass lots, 1,100-fold higher than the average serving for chicken parts, and 590-fold higher than the average serving for comminuted chicken products. In contrast, the probability of illness per serving for lots with *Salmonella* at 0.03 cfu/mL(g), which is the current screening limit of detection for carcasses and parts is at least 14-fold higher than for average lots. The probability of illness per serving for comminuted chicken lots with *Salmonella* at 0.03 cfu/mL(g), which is the current screening limit of detection, is at least 160-fold higher than for average lots. Research shows that it is likely that the share of product samples with serotypes of public health significance is higher than current estimates indicate, and this share varies between product subject to this proposal (24 percent for chicken

²⁴⁰ FSIS used only the prevented illness estimates for chicken carcasses as the 2023 chicken risk assessment could not assess the effect of carcasses and secondary products standards sequentially. USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products," January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²⁴¹ USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products," January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>; Obe, T., Sicheloff, A.T., Crowe, M.G., Scott, H.M., & Shariat, N.W. (2023). Combined Quantification and Deep Serotyping for *Salmonella* Risk Profiling in Broiler Flocks. *Applied and Environmental Microbiology*, 89(4), e02035–02022. <https://doi.org/10.1128/aem.02035-22>; Thompson, C.P., Doak, A.N., Amirani, N., Schroeder, E.A., Wright, J., Kariyawasam, S., Lamendella, R., & Shariat, N.W. (2018). High-Resolution Identification of Multiple *Salmonella* Serovars in a Single Sample by Using CRISPR-SeroSeq. *Applied and Environmental Microbiology*, 84(21), e01859–18.

²⁴² These estimates are not available for chicken parts, comminuted chicken, or comminuted turkey products.

²⁴³ The serotypes of public health significance have been identified in FSIS sampling programs for poultry products at varying rates between 2016 and 2021: 24 percent of chicken carcass samples, 33 percent of chicken parts samples, 29 percent of comminuted chicken samples, and 25 percent of comminuted turkey samples. USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products," January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>; USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products," January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²³⁷ USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products," January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²³⁸ USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products," January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²³⁹ FSIS used these estimates for calculating the monetary benefits associated with this proposal given the higher risk per serving and probability of illness associated with serotypes of public health significance. Thus, while the amount of product with results at or above 10 cfu/mL(g) that is diverted is higher, the number of prevented illnesses is potentially a representative scenario of the total benefits associated with this rule.

carcasses, 33 percent for chicken parts, 29 percent for comminuted chicken, and 25 percent for comminuted turkey). Furthermore, industry may react to this proposal in a variety of ways. For example, while the assumptions in the cost estimates reflect the requirement of maintaining control of product until adulteration results are available, some establishments may opt to divert chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products with test results at or above 10 cfu/mL(g) instead of waiting until results on the adulteration status of the product is available. For these reasons, FSIS estimates that the number of prevented illnesses from diverting chicken carcasses at or above 10 cfu/mL better approximates a portion of the illnesses not included in the low estimate as the Agency estimates that diverting these products from commerce would lead to a greater reduction in

illnesses. Additionally, this proposal clarifies process control requirements, and encourages establishments to adopt pre-harvest measures, which may have compounding effects on reducing cross-contamination and may prevent a higher number of illnesses each year.

For the high estimate, FSIS used the combined estimated number of prevented illnesses from diverting chicken carcasses (1,000 illnesses), chicken parts (200 illnesses), comminuted chicken (1,000 illnesses), and comminuted turkey (2,100 illnesses) product from the 2023 risk assessments. As noted above, the prevented illness estimates in the 2023 risk assessments reflect a standard at the 10 cfu/mL(g) level for these products. While these estimates do not reflect the final products standards in this proposal, FSIS is including these as a high estimate for the reasons outlined above. For the low and medium

estimates, FSIS used only the prevented illness estimates for chicken carcasses as the 2023 chicken risk assessment could not assess the effect of carcasses and secondary products (parts and comminuted chicken) standards sequentially, as mentioned above. In contrast, for the high estimate, FSIS used the sum of all three estimates (chicken carcasses, chicken parts, and comminuted chicken) to illustrate a potential number of illnesses prevented from implementing this proposed policy, including the potential compounding benefits across product types and the upper limit of direct and indirect (*i.e.*, benefits from actions industry voluntarily takes in response to this proposal) health benefits. The Agency used the same estimate for comminuted turkey for the medium and high estimates. FSIS is seeking comments on these estimates.

TABLE 34—ESTIMATED NUMBER OF ILLNESSES PREVENTED BY PRODUCT

Product	Prevented illnesses		
	Low	Medium	High
Chicken products:	240	1,000	2,200
Chicken carcasses	240	1,000	1,000
Chicken parts			200
Comminuted chicken			1,000
Comminuted turkey	525	2,100	2,100
Total	765	3,100	4,300

Public health benefits, including in the form of prevented illnesses, are difficult to monetize as a market for these does not exist. Typically, economic analyses use alternative methods for these non-market measures that approximate the value of these benefits. To monetize the estimated direct public health impact of this proposal, and consistent with other Agency regulatory impact analyses,²⁴⁴ FSIS applied the estimated cost of a *Salmonella* illness to the estimated number of prevented illnesses. FSIS used the “Cost Estimates of Foodborne Illnesses” developed by the U.S.

Department of Agriculture, Economic Research Service to do so.²⁴⁵ These estimates incorporate associated expenditures on medical care, lost wages due to productivity loss, and estimates of willingness to pay (WTP) to reduce mortality.²⁴⁶ This WTP measure is estimated in the form of the value of a statistical life. The average per case cost for *Salmonella* in 2021 dollars was \$4,351, with a lower bound estimate of \$387 and a higher bound estimate of \$6,873. The variability in the cost estimate is driven by variations in the number of fatalities, which are zero at

the low estimate and 378 at the high estimate.

FSIS estimated the total benefits from prevented illness for this proposal at \$13.49 million [(1,000 prevented illnesses from chicken products + 2,100 prevented illnesses from comminuted turkey products] × \$4,351), with a range from \$0.3 million to \$29.55 million (Table 35). Assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate, the benefits associated with the estimated prevented illnesses are \$12.92 million, ranging from \$0.28 million to \$28.66 million.

²⁴⁴ USDA, FSIS, “*Salmonella* in Certain Not-Ready-To-Eat Breaded Stuffed Chicken Products,” Preliminary Cost-Benefit Analysis, April 2023, https://www.fsis.usda.gov/sites/default/files/media_file/documents/NRTE_Stuffed_Chicken_CBA_Fsis-2022-0013.pdf. USDA, FSIS, “Proposed Performance Standards for *Salmonella* in Raw Comminuted Pork and Intact or Non-Intact Pork Cuts,” Preliminary Cost-Benefit Analysis, February

16, 2022, https://www.fsis.usda.gov/sites/default/files/media_file/2022-02/Pork-Salmonella-Performance-Standards-Cost-Benefit-Analysis.pdf; USDA, FSIS, Chicken Parts and Not-Ready-To-Eat Comminuted Poultry Performance Standards, Final Cost-Benefit Analysis, February 11, 2016, https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.

²⁴⁵ USDA, ERS, “Cost Estimates of Foodborne Illnesses,” Cost of foodborne illness estimates for *Salmonella* (non-typhoidal) dataset, January 29, 2021 <https://www.ers.usda.gov/data-products/cost-estimates-of-foodborne-illnesses.aspx>.

²⁴⁶ This is incorporated through value of a statistical life estimates that are applied to mortality associated with each pathogen for which estimates were developed.

TABLE 35—ESTIMATED BENEFITS FROM PREVENTED ILLNESSES FOR EACH PRODUCT GROUP

Product group	Benefits (million \$)		
	Low	Medium	High
Chicken products	0.09	4.35	15.12
Comminuted turkey	0.20	9.14	14.43
Total	0.30	13.49	29.55
Annualized ¹	0.28	12.92	28.66

¹ Costs are annualized at a 7 percent discount rate over 10 years.
Note: Numbers in table may not sum to totals due to rounding.

The cost estimate of foodborne illness for *Salmonella* cases is likely an underestimate of the total economic burden of foodborne illness. Specifically, cost of illness estimates account for major costs of medical treatment, time lost to illness, and individuals' WTP to reduce risk of death but these do not include other components of individual's WTP (to reduce illness, pain and suffering or costs associated with potential severe, debilitating human health outcomes).²⁴⁷ According to the FSIS Risk Profile, *Salmonella* subtypes of concern can cause severe human health outcomes, including acute gastroenteritis, bacteremia (bacteria in the blood), and focal infections. *Salmonella* infections can also lead to debilitating human health outcomes in a subset of patients, which includes reactive arthritis, cancer, inflammatory bowel disease, and irritable bowel syndrome, which are not included in these estimates. The FSIS Risk Profile notes that 5.8 percent of *Salmonella* cases develop reactive arthritis, and about 66 percent had persistent symptoms five years after becoming infected with *Salmonella*. Additionally, about 3.3 percent of cases developed irritable bowel syndrome. *Salmonella* infection can also increase the risk of colon cancer.²⁴⁸

Salmonella infections can result in a variety of outcomes and for some serotypes a small number of bacteria can cause illness.²⁴⁹ The 2023 risk assessments estimated a higher proportion of deaths among the serotypes identified as higher virulence, including some identified by FSIS as part of this proposal. For all *Salmonella*,

the domestic foodborne hospitalization rate is about 2 percent, and the fatality rate is about 0.04 percent. In contrast, the FSIS risk profile noted that, for a subset of *Salmonella* serotypes, the hospitalization rate was 22.8 percent, and the fatality rate was 0.5 percent.²⁵⁰ *Salmonella* illnesses disproportionately impact children under five years old and adults over 65, who experience higher rates of illnesses and death.²⁵¹ The FSIS risk profile notes that children under 1 year of age are particularly susceptible to invasive disease and infants have a higher likelihood of bacteremia resulting from *Salmonella* illness compared with adults.

Costs Avoided From Prevented Outbreak-Related Recalls

FSIS estimates that this proposal would result in prevented outbreak-related recalls. Specifically, by diverting adulterated products entering commerce, should this rule become final, official establishments would likely have a reduction in the risk of recalls due to *Salmonella* illness outbreaks. FSIS assumed that, if finalized, this proposal would prevent one to three recalls over a 10-year period, as described below.

Recalls are companies' actions to remove product that may be adulterated or misbranded from commerce.²⁵² Companies recall products due to a variety of reasons, including due to illness outbreaks. For instance, between 2012 and 2021 there were 7 recalls due to *Salmonella* outbreaks linked to various poultry products.²⁵³ In that

same period, there were 100 outbreaks linked to *Salmonella* in poultry products.²⁵⁴ While not all outbreaks lead to product recalls, poultry establishments face the risk of recalling product that may result in human illnesses. As previously mentioned, product that would be adulterated under this proposal (*i.e.*, with *Salmonella* levels at or above 10 cfu/mL(g) and containing a serotype of public health significance) have a higher risk per serving and hence a higher probability of resulting in illnesses.

Poultry establishments have economic incentives to prevent recalls, which are costly to industry and have spillover effects beyond the product lot that is subject to it. Recalls have a direct cost for establishments in the form of lost profits, product retrieval and disposal costs, business interruptions, and customer reimbursement, among others. Additional indirect costs are also part of the economic impact of a food recall, including external costs to distributors, wholesalers, and retailers, among others, which have been estimated to be 51, 6, and 5 percent of the total cost of a recall for manufacturers, wholesalers, and retailers, respectively.²⁵⁵ These include lost sales as consumers purchase alternative brands or products, potential litigation and liability risk, and brand damage affecting non-recalled product of the same brand. The exact cost of a recall varies depending on factors such as company size, product volume, and geographic distribution of the recalled product, among others. For publicly traded companies, recalls could reduce the

²⁴⁷ Hoffmann, Sandra, Bryan Macculloch, and Michael Batz. Economic Burden of Major Foodborne Illnesses Acquired in the United States, EIB-140, U.S. Department of Agriculture, Economic Research Service, May 2015, p.3–5.

²⁴⁸ USDA, FSIS, "Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry," February 28, 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²⁴⁹ USDA, FSIS, "Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry," February 28, 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²⁵⁰ USDA, FSIS, "Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry," February 28, 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²⁵¹ CDC, FoodNet Fast, Pathogen Surveillance, October 8, 2022, <https://wwwn.cdc.gov/foodnetfast/>.

²⁵² USDA, FSIS, "Managing Adulterated or Misbranded Meat, Poultry, and Egg Products—Revision 8," December 19, 2023, <https://www.fsis.usda.gov/policy/fsis-directives/8080.1>.

²⁵³ This excludes recalls associated with raw stuffed and breaded chicken products. USDA, FSIS, "Recalls and Public Health Alerts," accessed July 10, 2023, <https://www.fsis.usda.gov/recalls>.

²⁵⁴ USDA, FSIS, "Risk Profile for Pathogenic *Salmonella* Subtypes in Poultry," February 28, 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²⁵⁵ U.S. Department of Health and Human Services, Food and Drug Administration (FDA), "Requirement for Additional Traceability Records for Certain Foods Final Regulatory Impact Analysis" November 21, 2022, <https://www.fda.gov/media/163155/download?attachment>; FDA, "Requirements for Tobacco Product Manufacturing Practice (Proposed Rule) Preliminary Regulatory Impact Analysis," March 10, 2023, <https://www.fda.gov/media/166055/download?attachment>.

stock market prices of the implicated companies and could lead them to bankruptcy and business closure. Recalls also negatively impact consumers by creating anxiety and time-consuming inconveniences, which includes looking for recall information, checking the products purchased, and returning or disposing of products identified by the recalls.

Individual establishments may not currently effectively control for *Salmonella* to further reduce their risk due to the perceived low risk of a recall. For instance, the 7 recalls between 2014 and 2021 were linked to different establishments. Further, an individual establishment may experience pressure to underinvest in food safety measures given uncertainty over how much other establishments may invest in food safety measures and a need to maintain cost competitiveness. Since consumers are unable to distinguish between products in the marketplace that have higher probabilities of resulting in *Salmonella* illness and those with lower probabilities, both types of products are sold at the same price point. Under such market conditions, establishments are disincentivized from investing in food safety measures and controlling for *Salmonella*. This results in an increased risk of *Salmonella* illnesses, and, in consequence, an increased risk of outbreaks and outbreak-related recalls for establishments.

If this proposal is finalized, establishments producing chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey products would have the same incentives for controlling for *Salmonella*. Consequently, establishments producing these products would have a lower risk of recalls due to *Salmonella* illnesses and outbreaks. Establishments that invest in food safety controls would benefit from having a clear standard where product that would be adulterated would be diverted from commerce. Diverting adulterated product from commerce would equally reduce the probability of recalls for all FSIS regulated establishments, serving as insurance against this risk. While this would

benefit establishments of all sizes, the benefit may be more pronounced for low and very low volume establishments, for which the burden of a recall may be higher. As the proposal would reduce the probability that all regulated establishments incur costs associated with product recalls, the Agency is approximating this quantitative benefit by estimating the avoided cost of outbreak-related recalls. (See discussion above, about recalls leading to external costs, including to wholesalers and distributors.)

FSIS estimated that one outbreak-related recall may cost the U.S. poultry industry about \$31.3 million in 2021 dollars.²⁵⁶ While the cost of a recall varies depending on multiple factors, recalls due to illness outbreaks (class I) are a significant event for producers and are likely more costly than other types of recalls.²⁵⁷ The 2023 risk assessments estimated that annually roughly 8 lots of chicken carcasses (0.7), chicken parts (0.2), comminuted chicken (5), and comminuted turkey (2) would be diverted as a result of this proposal.²⁵⁸ This equals roughly 80 lots of adulterated products diverted in 10 years. FSIS estimates it is likely that at least a portion of these diverted lots would have otherwise led to outbreaks and, consequently, recalls. As mentioned above, data indicate that industry has conducted recalls for about 7 percent of the outbreaks in the last 10 years (7 recalls in 100 outbreaks). Considering these products have a higher probability of resulting in illnesses and could have led to *Salmonella* outbreaks, if 7 percent of them led to recalls, this would have resulted in 5.6 recalls over 10 years. To illustrate the avoided cost from a reduction in the risk of outbreak-related recalls, FSIS assumed that this proposal would prevent two recalls (medium estimate), with a range of one (low estimate) to three (high estimate) recalls in a 10-year period. This is roughly 2.5 percent of the diverted lots, ranging from 1.3 percent to 3.8 percent. The estimated benefits from preventing recalls as part of this proposal is \$7.6 million, ranging from \$4.2 million to

\$10.3 million, annualized over 10 years at a 7 percent discount rate.

Summary of Costs and Benefits

FSIS estimated this proposal would have a net benefit of \$4.1 million per year, ranging from \$1.1 million to \$6.7 million, assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate (Table 35).

This proposal is estimated to cost industry \$16.4 million per year, ranging from \$3.3 to \$32.3 million, assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate. The majority of this cost, \$14.5 million, ranging from \$2.1 million to \$29.3 million, is associated with requiring establishments to maintain control of sampled product pending test results, followed by industry cost due to lost product value of \$1.5 million, ranging from \$0.9 million to \$2.4 million. Industry may also incur costs associated with HACCP and microbiological sampling plan reassessments and changes to MMPs for process control. To varying degrees, industry may also incur other costs associated with their individual responses to this proposal.

In terms of benefits, this proposal is estimated to result in benefits to society of \$20.5 million per year, ranging from \$4.4 million to \$39.0 million (Table 36), assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate. The majority of the benefits are derived from prevented illnesses of \$12.9 million per year, ranging from \$0.3 to \$28.7 million. Additional benefits from this proposal include the reduction in the risk of outbreak-related recalls for products subject to these final product standards, which represent an estimated \$7.6 million in benefits to industry, ranging from \$4.2 million to \$10.3 million. Moreover, industry might take additional actions in response to this proposal, which may lead to additional benefits. For example, producers may adopt testing programs, process control measures, or pre-harvest measures that may result in additional benefits from this proposal.

²⁵⁶ This estimate is derived from a report by the Consumers Brands Association that surveyed 36 food, beverage, and consumer products companies that have faced a recall in the previous five years to derive these estimates. Based on the report, FSIS estimated the cost of an outbreak related recall at \$25.8 million in 2011 dollars. The Agency adjusted this estimate for inflation using the consumer price index. Consumers Brands Association, "Capturing Recall Costs: Measuring and Recovering the Losses," 2011, https://globalfoodsafetyresource.com/wp-content/uploads/2014/08/www.gmaonline.org_file-manager_images_

[gmapublications.Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf](https://www.gmapublications.Capturing_Recall_Costs_GMA_Whitepaper_FINAL.pdf); BLS, Consumer Price Index, All items in U.S. city average, all urban consumers, not seasonally adjusted (CUUR0000SA0, CUUS0000SA0 Not Seasonally Adjusted).

²⁵⁷ FSIS uses a classification system for recalls. Class I recalls are a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. Class II recalls are those with a remote probability that the product will cause adverse health consequences, while Class III

recalls are situations where the product will not cause adverse health consequences. USDA, FSIS, "Managing Adulterated or Misbranded Meat, Poultry, and Egg Products—Revision 8," December 19, 2023, <https://www.fsis.usda.gov/policy/fsis-directives/8080.1>.

²⁵⁸ USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products," January 2023; USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products," January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

TABLE 36—SUMMARY OF COSTS AND BENEFITS

Description	Total (million \$)		
	Low	Medium	High
Costs			
Costs associated with the proposed rule:			
Statistical Process Control	0.04	0.04	0.04
Electronic data submission	0.18	0.18	0.18
HACCP plan reassessment	0.09	0.18	0.26
Costs associated with the proposed determination:			
Maintaining control of sampled product	2.11	14.47	29.26
Lost value to the industry	0.87	1.52	2.43
Microbiological sampling plan reassessment	0.02	0.04	0.08
Total costs	3.31	16.43	32.25
Benefits			
Prevented illnesses from adulterated chicken products	0.09	4.35	15.11
Prevented illnesses from adulterated comminuted turkey	0.19	8.58	13.55
Avoided cost from prevented outbreak-related recalls	4.16	7.56	10.34
Total benefits	4.45	20.49	39.00
Net benefits	1.14	4.06	6.75

Note: All costs and benefits are annualized over 10 years at a 7 percent discount rate. Numbers in table may not sum to totals due to rounding.

This regulatory impact analysis provides potential cost and benefits scenarios. As discussed in the *Potential benefits and avoided costs from the proposed rule and proposed determination* section, establishments may elect to divert product before final adulteration results are available to them. To also illustrate this possibility, FSIS estimated the potential costs associated with establishments diverting product with test results at or above 10 cfu/mL(g) before a serotype of public health significance is detected. This would likely increase industry cost by \$3.6 million, ranging from \$2.1 million to \$5.7 million. This range is associated with changes to the cost of maintaining control of sampled product, which would decrease, while the lost value to industry from diverting product would likely increase. While FSIS did not incorporate these into the main scenarios presented in this regulatory impact analysis, the net benefit from industry diverting product that tests at or above 10 cfu would be \$0.5 million, ranging from a net cost of \$0.9 million to a net benefit of \$1.0 million and keeping all other assumptions constant.²⁵⁹

FSIS compared the respective low, medium, and high costs and benefits estimates as the Agency's primary estimates to summarize the potential economic outcomes of this proposal. However, each of the cost scenarios in this analysis could result in any of the benefit scenarios also previously discussed. As such, when considering a wider range for these scenarios, FSIS estimated this proposal would have a net benefit of \$4.1 million per year, ranging from –\$31.9 million to \$35.7 million, assuming the proposed implementation schedule and annualizing over 10 years at a 7 percent discount rate.

Alternative Regulatory Approaches

FSIS considered the following five alternatives in the analysis for this proposal (Table 37). To evaluate potential alternatives, FSIS first analyzed the costs and benefits associated with taking no regulatory action, which is discussed under Alternative 1 and represents the baseline for this analysis. Alternative 2 discusses the proposal. For Alternative 3, which is a more stringent regulatory scenario, FSIS estimated the costs and benefits associated with declaring

adulterated chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey with levels of *Salmonella* at or above 1 cfu/mL(g) and containing a serotype of public health significance. Alternative 4 represents a more lenient regulatory scenario by estimating costs and benefits associated with declaring these products adulterated with *Salmonella* levels at or above 100 cfu/mL(g) and containing a serotype of public health significance. Finally, Alternative 5 represents the most stringent scenario considered and estimates the benefits and costs associated with declaring chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey with *Salmonella* at or above 1 cfu/mL(g) adulterated regardless of serotype. For each alternative, the Agency assumed that all other costs, specifically those associated with process control requirements (collecting an additional sample and electronic data submission), as well as HACCP and microbiological sampling plan reassessments, would remain equal. Similarly, the Agency assumed that the benefits from preventing outbreak-related recalls would be the same for each alternative.

²⁵⁹ In this scenario, the low bound in the net benefits estimate reflects the adjustment in illnesses made in the Expected benefits section to account for

the share of product that is likely to be at or above 10 cfu/mL(g) and contain a serotype of public

health significance. Hence, the net cost would be lower than \$0.9 million.

TABLE 37—REGULATORY ALTERNATIVES

Alternative ¹	Costs (medium estimate)	Benefits (medium estimate) ²	Net (medium estimate)
1: No regulatory action (Baseline)	Continued illnesses and deaths associated with <i>Salmonella</i> from these products.	No new costs to industry	n/a.
2: The proposed rule and proposed determination.	\$16.43 million compared to the baseline ..	\$20.49 million from prevented <i>Salmonella</i> illnesses and outbreak-related recalls.	\$4.06 million.
3: The proposed rule and proposed determination with a lower level for adulterated product (1 cfu/mL(g) and serotypes of public health significance).	\$29.52 million compared to the baseline ..	\$19.65 million from prevented <i>Salmonella</i> illnesses and outbreak-related recalls.	(\$9.88) million.
4: The proposed rule and proposed determination with a higher level for adulterated product (100 cfu/mL(g) and serotypes of public health significance).	\$15.34 million compared to the baseline ..	\$8.85 million in the form of prevented <i>Salmonella</i> illnesses and outbreak-related recalls.	(\$6.59 million).
5: The proposed rule and proposed determination with a lower contamination level for adulterated product of 1 cfu/mL(g) <i>Salmonella</i> regardless of serotype.	\$49.96 million compared to the baseline ..	\$34.50 million from prevented <i>Salmonella</i> illnesses and outbreak-related recalls.	(\$15.45 million).

¹ Costs and benefits are annualized at a 7 percent discount rate over 10 years.

² Alternatives 2–5 have additional potential benefits from reduced risk of outbreak-related recalls and increased consumer trust.

Note: Numbers in table may not sum to totals due to rounding.

Alternative 1: No regulatory action (Baseline).

FSIS considered keeping the current performance standards for *Salmonella* in poultry products and taking no regulatory action. This alternative would prevent society from realizing benefits in the form of prevented illnesses due to *Salmonella* contamination. While this alternative would not impose costs on industry from maintaining control of sampled product or lost value due to diverted product, the Agency would fail to address the increased probability of illness resulting from chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain *Salmonella* at or above 10 cfu/mL(g) and a serotype of public health significance. FSIS would also fail to clarify process control requirements for poultry slaughter establishments. Therefore, the Agency rejects this alternative.

Alternative 2: The proposed rule and proposed determination.

Under this proposal, chicken carcasses and parts and comminuted chicken and turkey products which are final products that will enter commerce that test at or above 10 cfu/mL(g) and contain a *Salmonella* serotype of public health significance would be adulterated. FSIS would also clarify process control requirements for poultry slaughter establishments, require that VLV and VS establishments operating under Traditional Inspection collect and analyze an additional sample for process control monitoring, and require all establishments electronically submit process control data. Society would

benefit from this proposal as FSIS estimated that between 765 and 4,300 *Salmonella* illnesses could be prevented each year. This represents between 0.5 and 3 percent of the total number of *Salmonella* illnesses attributed to products subject to this proposal.²⁶⁰ Additionally, industry would benefit from a reduced risk of outbreak-related recalls. This is the Agency's preferred alternative.

Alternative 3: The proposed rule and proposed determination with a lower contamination level for adulterated product of 1 cfu/mL(g) and serotypes of public health significance.

Alternative 3 would consider product under this proposal to be adulterated if it contains 1 cfu/mL(g) and a *Salmonella* serotype of public health significance. This alternative results in higher costs for industry to comply with the proposal, resulting from the increased volume of lost product that is diverted (\$14.48 million, ranging from \$8.29 million to \$21.08 million). Alternative 3 also presents higher benefits from prevented *Salmonella* illnesses, which range from 1,214 to 7,750. This represents between 0.8 and 5.4 percent of the total number of

Salmonella illnesses attributed to products subject to this proposal.²⁶¹ However, the net benefits from this alternative (benefits minus costs) are negative for all scenarios. Therefore, the Agency rejects this alternative.

Alternative 4: The proposed rule and proposed determination with a higher contamination level for adulterated product of 100 cfu/mL(g) and serotypes of public health significance.

Alternative 4 would consider product under this proposal to be adulterated if it contains 100 cfu/mL(g) and a *Salmonella* serotype of public health significance. This alternative results in lower costs for industry to comply with the proposal, as a lower volume of product would have initial results at or above 100 cfu/mL(g) and would result in a lower lost value for the industry (\$0.62 million, ranging from \$0.35 million to \$3.16 million). Alternative 4 also presents fewer prevented *Salmonella* illnesses, which range from 384 to 2,220. This represents between 0.3 and 1.5 percent of the total number of *Salmonella* illnesses attributed to products subject to this proposal.²⁶² The

²⁶¹ According to the 2023 risk assessments, there are 125,000 and 18,000 *Salmonella* illnesses attributed to products subject to this proposed rule each year. USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products," January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>; USDA, FSIS, "Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products," January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²⁶² According to the 2023 risk assessments, there are 125,000 and 18,000 *Salmonella* illnesses

Continued

net benefits from this alternative (benefits minus costs) are negative at the medium, and high estimates. Therefore, the Agency rejects this alternative.

Alternative 5. The proposed rule and proposed determination with a lower contamination level for adulterated product of 1 cfu/mL(g) Salmonella regardless of serotype.

Alternative 5 would consider product under this proposal to be adulterated if it contains 1 cfu/mL(g) *Salmonella*, regardless of the presence of *Salmonella* serotype. This alternative results in higher costs for industry to comply with the proposal, as a higher volume of product would be adulterated with results at or above 1 cfu/mL(g). The lost value to industry would increase to \$48.0 million (ranging from \$27.4 million to \$72.0 million), which is the highest in comparison to the other alternatives. Alternative 5 also presents higher benefits from prevented *Salmonella* illnesses, which range from 5,000 to 7,750. This represents between 3.5 and 5.4 percent of the total number of *Salmonella* illnesses attributed to products subject to this proposal.²⁶³ However, this alternative results in the lowest net benefits (benefits minus costs) and all scenarios result in net costs. Therefore, the Agency rejects this alternative.

VII. Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule and proposed

determination, if finalized, would not have a significant economic impact on a substantial number of small entities in the U.S., as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Establishments subject to this proposal are classified in the 311615 Poultry Processing sector of the North American Industry Classification System (NAICS). The U.S. Small Business Administration (SBA) size standard for small businesses in this section is 1,250 employees.²⁶⁴ This NAICS sector includes establishments “primarily engaged in (1) slaughtering poultry and small game and/or (2) preparing processed poultry and small game meat and meat byproducts.” As a result, the sector includes establishments that produce products beyond the scope of this proposal, including further processing of poultry products. FSIS has typically classified establishments in three size categories based on employment counts and annual sales: large establishments have over 500 employees, small establishments have between 10 and 499 employees, and very small establishments have less than 10 employees or less than \$2.5 million in annual sales.²⁶⁵ These categories, however, do not necessarily capture the variability in production volumes between regulated establishments. For this reason, FSIS classified establishments based on production volumes of the products subject to this proposal.

FSIS established volume categories for this proposal based on Agency data

on establishments’ production volumes and the 2016 cost-benefit analysis in support of the FSIS “Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards,” as shown in tables 38 and 39.²⁶⁶ Furthermore, FSIS uses production volumes for allocating samples to be collected at regulated establishments, therefore these volume categories more closely capture the estimated impact of this proposal. This proposal is estimated to impact a total of 284 establishments classified as low- and very low-volume establishments. FSIS considers these volume categories to be small entities.

Final Product Standards

The volume categories for establishments subject to the proposed final product standards are summarized in Table 38. Of these, 37 establishments produced chicken carcasses, 127 produced chicken parts, 39 produced comminuted chicken, and 18 produced comminuted turkey products that would be subject to the final product standards. This represents roughly 27.6 percent of the establishments impacted by this proposal.²⁶⁷ Low- and very low-volume establishments, combined, accounted for 0.08 percent of the total chicken carcasses produced in 2021. In that same year, low-volume establishments represented 0.1, 2.8, and 0.5 percent of the total production of chicken parts, comminuted chicken, and comminuted turkey, respectively.²⁶⁸

TABLE 38—VOLUME CATEGORIES FOR ESTABLISHMENTS SUBJECT TO THE FINAL PRODUCTS STANDARDS

Establishment volume category	Chicken carcasses (birds slaughtered annually)	Chicken parts (annual production pounds)	Comminuted chicken (daily production pounds)	Comminuted turkey (daily production pounds)
High	10 million or more	70 million or more	250,000 or more	250,000 or more.
Medium	More than 1.1 million and less than 10 million.	More than 1 million and less than 70 million.	More than 6,000 and less than 250,000.	More than 6,000 and less than 250,000.
Low	More than 440,001 and less than 1.1 million.	1 million or less	Less than 6,000	Less than 6,000.
Very Low ¹	No more than 440,000	n/a	n/a	n/a.

¹ Very low-volume establishments are defined in 9 CFR 381.65g(1)(i).

attributed to products subject to this proposed rule each year. USDA, FSIS, “Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,” January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>; USDA, FSIS, “Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,” January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²⁶³ According to the 2023 risk assessments, there are 125,000 and 18,000 *Salmonella* illnesses attributed to products subject to this proposed rule each year. USDA, FSIS, “Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Chicken and Raw Chicken Products,” January

2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>; USDA, FSIS, “Quantitative Microbiological Risk Assessment for *Salmonella* in Raw Turkey and Raw Turkey Products,” January 2023 at: <https://www.regulations.gov/docket/FSIS-2023-0028>.

²⁶⁴ U.S. Census Bureau, “North American Industry Classification System—2022 NAICS Definition: 311615 Poultry Processing January 3, 2024, <https://www.census.gov/naics/?input=311615&year=2022&details=311615>; SBA, Table of size standards, October 25, 2023, https://www.sba.gov/sites/default/files/2023-06/Table%20of%20Size%20Standards_Effective%20March%2017%2C%202023%20%282%29.pdf.

²⁶⁵ 61 FR 38806.

²⁶⁶ USDA, FSIS, Chicken Parts and Not Ready-To-Eat Comminuted Poultry Performance Standards, Final Cost-Benefit Analysis, February 11, 2016, https://www.fsis.usda.gov/sites/default/files/media_file/documents/FRN-related-CBA-Salmonella-Campy-2014-0023-022016.pdf.

²⁶⁷ Some establishments may produce more than one product subject to these final product standards. For these estimates, FSIS counted establishments separately for each product subject to the final product standards, therefore, establishments may be counted more than once.

²⁶⁸ Note that there is no very low-volume category for chicken parts, comminuted chicken, and comminuted turkey.

As a result of the proposal, based on the assumptions and estimates described in the *Regulatory Impact Analysis* section, FSIS estimates that the medium per establishment cost for low-volume establishments that produce chicken carcasses is \$1,260 per year. For very low-volume establishments in this product group, the medium per establishment cost would be \$1,067, if the proposal is finalized. For low-volume establishments that produce chicken parts, comminuted chicken, and comminuted turkey, the estimated medium per establishment cost is \$1,305, \$3,152, and \$1,296 per year, respectively.

FSIS used the per pound retail prices described in the *Lost value to the industry costs* section to estimate the average revenue for low- and very low-volume establishments from producing chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey. FSIS estimates the cost associated with this proposal represents about 0.04 percent of the chicken carcass revenue for low-volume establishments and 0.15 percent for very low-volume establishments.²⁶⁹ For low-volume establishments producing chicken parts, the estimated cost of the proposal represents about 0.1 percent of the estimated revenue.²⁷⁰ This estimated cost represents 0.9 and 0.4 percent of the estimated revenue for low-volume establishments that

produce comminuted chicken and comminuted turkey, respectively.²⁷¹

FSIS also expects the cost burden of this proposal on low- and very low-volume establishments to be limited due to several factors:

(1) FSIS estimates that the total cost for low- and very low-volume establishments for complying with this proposal is small. As proposed, final product standards account for the largest proportion of estimated costs, which are estimated to cost these establishments \$1,569, on average, per establishment per year. This cost will vary depending on an establishment's production level.

(2) The cost estimates presented as part of this analysis are based on FSIS' estimated lot size. FSIS allows establishments to produce smaller representative batches of product for sampling.²⁷² Consequently, low- and very low-volume establishments can reduce costs by reducing their lot size when FSIS collects a sample.

(3) FSIS is also adopting an implementation schedule that allows low- and very low-volume establishments additional flexibility to adjust to the new regulations. Low- and very low-volume establishments would have three years to comply with this proposal after it is finalized.

Process Control Requirements

The volume categories for establishments subject to the statistical

process control requirements are summarized in Table 39. Of the 284 small entities impacted by this proposal, 108 are poultry slaughter establishments subject to the statistical process control requirements, or about 36.2 percent of all poultry slaughter establishments. This proposal requires that very low-volume and very small establishments operating under Traditional Inspection collect an additional sample for monitoring process control, as explained in the *Statistical Process Control costs* section. This requirement is estimated to impact 92 establishments that are considered to be small entities by FSIS. The rule also requires all poultry slaughter establishments to electronically submit to FSIS data generated as part of their process control monitoring. This requirement is estimated to impact 108 establishments that are considered to be small entities by FSIS. In 2021, there were 93 low and very low-volume chicken slaughter establishments, 12 turkey slaughter, 1 duck slaughter, 1 goose slaughter, and 1 squab slaughter establishments.²⁷³ In that year, low and very low volume establishments accounted for 0.2 percent of chicken slaughter, 0.1 percent of turkey slaughter, and 0.01 percent of duck slaughter. For goose slaughter, one establishment accounted for about 98 percent of total slaughter in 2021, while one low volume establishment accounted for 16 percent of squab slaughter in that year.

TABLE 39—VOLUME CATEGORIES FOR ESTABLISHMENTS SUBJECT TO THE STATISTICAL PROCESS CONTROL REQUIREMENTS

Chicken	All other poultry classes
More than 10 million	More than 1 million.
Between 1.1 million and 10 million	Between 156 thousand and 1 million.
Between 440 thousand and 1.1 million	Between 60 thousand and 156 thousand.
Less than 440 thousand	Less than 60 thousand.

FSIS estimated process control requirements would cost \$2,129 per establishment per year. As these establishments produce a wide variety of products, including multiple poultry classes, FSIS is unable to estimate the share this cost represents of establishments' total revenue. However, FSIS production data show that 79 establishments (73 percent) slaughter more than one class of poultry. Additionally, 36 establishments (about

33 percent) produce other nonpoultry FSIS inspected products. Nonpoultry products represent 54 percent, on average, of these establishments' total production by volume. However, to mitigate the impact and costs of this requirement, the Agency is proposing to make laboratory services available to analyze process control samples instead of the establishment using establishment resources or commercial laboratories. In addition, FSIS is

providing a template for establishments to use when submitting data to the Agency. Consequently, these costs could be mitigated and represents potential cost savings for these establishments.

VIII. Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), FSIS has reviewed the proposed rule. All establishments that slaughter poultry are currently required to

²⁶⁹ FSIS estimated the average chicken carcass revenue for low-volume establishments at \$3.2 million, while for very low-volume establishments this revenue was \$0.7 million in 2021.

²⁷⁰ FSIS estimated the average chicken parts revenue for low-volume establishments at \$1.2 million.

²⁷¹ FSIS estimated the average comminuted chicken revenue for low-volume establishments at \$0.35 million, while for low-volume establishments

producing comminuted turkey, this estimate is \$0.32 million.

²⁷² 77 FR 73402.

²⁷³ For establishments that slaughter multiple species, process control requirements apply to the most predominant species slaughtered annually.

monitor their ability to maintain process control through microbial testing and recordkeeping under the currently approved information collection, 0583–0156, *Modernization of Poultry Slaughter Inspection*. FSIS is proposing to revise this collection to require that establishments submit their microbial sampling results to FSIS electronically on a monthly basis. FSIS is also proposing to require that all establishments, including VS and VLV establishments operating under Traditional Inspection to test at 2 points (rehang and post-chill) instead of only post-chill. VS and VLV establishments operating under Traditional Inspection would have the option to use laboratory resources provided by FSIS to analyze their monitoring samples for them, but they would still be required to have their results recorded and submitted to FSIS electronically.

Should FSIS finalize this proposal, the Agency would provide a template

that establishments could use to record and submit their monthly results. FSIS is developing a web portal that will allow external partners to securely upload sampling information and submit it to FSIS in a machine- readable format. The proposed fields that would be uploaded into the portal are: a sample identification number, the establishment number, date, time, slaughter line number, location of sample collection (e.g., rehang, post-chill), poultry species sampled, sample type (e.g., rinsate, sponge), analyte (e.g., AC, EB), analyte units (e.g., cfu/mL), quantified analyte result, and text analyte result (e.g., <Lower LOD, >Upper LOD). Establishments that use the spreadsheet template to record the microbial monitoring results may upload their completed spreadsheet into the web portal to submit their monthly microbial data to FSIS or they may enter the information manually into the portal. Establishments that do not use

the spread sheet provided by FSIS as a template to record their results would need to manually enter their microbial sampling data into the portal to submit their monthly data.

FSIS is revising this information collection to add 1,788 total burden hours due to the proposed new requirements. The burden estimate has also been updated to reflect the current number of poultry slaughter establishment respondents, which has increased from 289 to 298 since the initial information collection approval. FSIS requests comments on the proposed data fields and on the proposed electronic data submission process.

FSIS estimates that a total of 298 establishments would conduct microbial testing and enter 6–12 associated data points into the spread sheet, or directly into the portal, 12 times annually for a total of 1,788 hours.

MICROBIAL TESTING, RECORDING, AND ELECTRONIC SUBMISSION
[9 CFR 381.65(g) and (h)]

	Number of respondents	Number of responses per respondent	Total annual responses	Time for response in mins.	Total annual time in hours
Total	298	1	12	30	1,788

Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; (202) 937–4272. Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS’ functions, including whether the information will have practical utility; (b) the accuracy of FSIS’ estimate of the burden of the proposed collection of information, including the validity of the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253

IX. E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

X. Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this proposed rule: (1) All State and local laws and regulations that are inconsistent with this proposed rule will be preempted; (2) no retroactive effect will be given to this proposed rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this proposed rule.

XI. E.O. 13175

E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that

have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes. FSIS has assessed the impact of this proposed rule on Indian tribes and determined that this proposed rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

XII. USDA Non-Discrimination Statement

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status,

income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident. Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (e.g., Braille, large print, audiotope, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720-2600 (voice and TTY); or the Federal Relay Service at (800) 877-8339. To file a program discrimination complaint, a complainant should complete a Form, AD-3027, USDA Program Discrimination Complaint Form, which can be obtained online at <https://www.usda.gov/forms/electronic-forms>, from any USDA office, by calling (866) 632-9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights about the nature and date of an alleged civil rights violation. The completed AD-3027 form or letter must be submitted to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250-9410; (2) Fax: (833) 256-1665 or (202) 690-7442; or (3) Email: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

XIII. Environmental Impact

Each USDA agency is required to comply with 7 CFR part 1b of the Departmental regulations, which supplements the National Environmental Policy Act regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4(b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4(b)(6)). This proposed rule would establish final product standards for certain raw poultry products. Under this

proposal, raw chicken carcasses, chicken parts, comminuted chicken, and comminuted turkey that contain *Salmonella* levels and serotypes in the proposed final product standards would be adulterated. This proposed rule would also revise the regulations that require that all poultry slaughter establishments develop, implement, and maintain written procedures to prevent contamination by enteric pathogens throughout the entire slaughter and dressing operation to clarify that these procedures must include a MMP that incorporates SPC monitoring methods and to require all establishments to conduct testing at rehang and post chill. FSIS has determined that this proposed rule would not create any extraordinary circumstances that would result in this normally excluded action having a significant individual or cumulative effect on the human environment. Therefore, this action is appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4(b)(6) of the U.S. Department of Agriculture regulations.

XIV. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: <https://www.fsis.usda.gov/federal-register>. FSIS will also announce and provide a link through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Constituent Update is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <https://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 381

Meat inspection, Poultry and poultry products.

For the reasons set forth in the preamble, FSIS proposes to amend 9 CFR part 381 as follows:

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 1. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 138f, 1633; 21 U.S.C. 451–472; 7 CFR 2.7, 2.18, 2.53.

■ 2. Amend § 381.65 by revising paragraphs (g) and (h) to read as follows:

§ 381.65 Operations and procedures, generally.

* * * * *

(g) *Procedures for controlling contamination throughout the slaughter and dressing operation.* Official poultry slaughter establishments must develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal contamination throughout the entire slaughter and dressing operation. Establishments must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs. At a minimum, these procedures must establish a microbial monitoring program that includes sampling and analysis of microbial organisms in accordance with the requirements in paragraphs(g)(1)-(5) of this section to monitor an establishment's ability to maintain process control.

(1) *Sampling locations.* Establishments must collect and analyze samples for microbial organisms at the rehang and post-chill points in the process.

(i) The establishment's microbial monitoring program must identify and provide supporting rationale for the specific point in the process where rehang and post-chill samples will be collected.

(ii) An establishment may collect samples at a location other than rehang if the establishment provides supporting data to demonstrate that the alternate location is at least as effective as rehang sampling for monitoring the establishment's ability to maintain process control.

(2) *Sampling frequency.*

(i) Except as provided in paragraph (g)(2)(ii) of this section, all official poultry establishments must collect and analyze paired monitoring samples at the following rates. Establishments that slaughter multiple species may conduct sampling on the type of poultry slaughtered in the greatest number.

(A) Chickens

Predominant poultry species slaughtered	Establishment volume sizes	Annual slaughter head volume	Minimum frequency of paired collection
Chicken	Very Low Volume	1–440,000	13 Weekly Pairs per Year.
Chicken	Low Volume	440,001–1,100,000	Weekly.
Chicken	Medium and High Volume	≥1,100,000	1 per 22,000.

(B) Turkeys, ducks, geese, guineas and squabs

Predominant poultry species slaughtered	Establishment volume sizes	Annual slaughter head volume	Minimum frequency of paired collection
Turkey, Geese, Guinea, Ducks, Squab	Very Low Volume	1–60,000	13 Weekly Pairs per Year.
Turkey, Geese, Guinea, Ducks, Squab	Low Volume	60,001–156,000	Weekly.
Turkey, Geese, Guineas, Ducks Squab	Medium and High Volume	≥156,000	1 per 3,000.

(ii) Very low volume establishments as defined in paragraphs (g)(2)(i)(A) and (B) of this section that plan to operate less than 13 weeks per year may collect and analyze 13 samples less than weekly if the establishment can demonstrate that it is effectively maintaining process control throughout the year and during any periods of slaughter operations.

(iii) Establishments must sample at a frequency that is adequate to monitor their ability to maintain process control for enteric pathogens.

(iv) Establishments must maintain accurate records of all test results and retain these records as provided in paragraph(h) of this section.

(3) *Microbial Organism and Methods.* Establishments must analyze monitoring samples for microbial organisms that are quantifiably detectable in their slaughter process and that will generate microbial monitoring data that is adequate to monitor their ability to maintain process control for enteric pathogens.

(i) The establishment’s measured results at each sample location must yield statistically reliable quantified value results

(ii) The establishments’ sample collection method must be appropriate

for the product sampled, the microbial organism monitored, and the laboratory method used to analyze the samples.

(iii) The establishment’s microbial sampling results must be generated by validated laboratory analyses and methods.

(4) *Microbial Monitoring Criteria.* The establishment must use appropriate statistical methods to compare microbial monitoring data against predefined quantitative limits adequate to gauge its ability to maintain process control. At a minimum, the microbial monitoring program must identify and support limits for:

(i) The minimal expected change in microbial levels measured between sampling locations; and

(ii) The expected consistency of the levels of change detected over a specified monitoring period.

(5) *Corrective Actions.* The establishment must implement written corrective actions, including a root cause assessment, at a minimum when:

(i) The microbial monitoring results deviate from predefined quantitative limits;

(ii) The microbial monitoring results are not consistent with the other process

control monitoring results for the same procedures; or

(iii) The microbial monitoring results are not consistent with the process control determination made for the entire slaughter HACCP system.

(h) *Recordkeeping requirements.* Official poultry slaughter establishments must maintain daily records sufficient to document the implementation and monitoring of the procedures required under paragraph (g) of this section. Records required by this section may be maintained on computers if the establishment implements appropriate controls to ensure the integrity of the electronic data. Records required by this section must be maintained for at least one year and must be accessible to FSIS.

(1) Official poultry slaughter establishments must submit their microbial sampling results to FSIS electronically on a monthly basis.

(2) [reserved]

Done in Washington, DC.

Paul Kiecker,
Administrator.
[FR Doc. 2024–16963 Filed 8–6–24; 8:45 am]
BILLING CODE 3410-DM-P



FEDERAL REGISTER

Vol. 89

Wednesday,

No. 152

August 7, 2024

Part V

Department of the Treasury

Internal Revenue Service

26 CFR Parts 1 and 301

Rules Regarding Dual Consolidated Losses and the Treatment of Certain
Disregarded Payments; Proposed Rule

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Parts 1 and 301****[REG-105128-23]****RIN 1545-BQ72****Rules Regarding Dual Consolidated Losses and the Treatment of Certain Disregarded Payments****AGENCY:** Internal Revenue Service (IRS), Treasury.**ACTION:** Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that address certain issues arising under the dual consolidated loss rules, including the effect of intercompany transactions and items arising from stock ownership in calculating a dual consolidated loss. The proposed regulations also address the application of the dual consolidated loss rules to certain foreign taxes that are intended to ensure that multinational enterprises pay a minimum level of tax, including exceptions to the application of the dual consolidated loss rules with respect to such foreign taxes. Finally, the proposed regulations include rules regarding certain disregarded payments that give rise to losses for foreign tax purposes.

DATES: Written or electronic comments and requests for a public hearing must be received by October 7, 2024.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically via the Federal eRulemaking Portal at <https://www.regulations.gov> (indicate IRS and REG-105128-23) by following the online instructions for submitting comments. Requests for a public hearing must be submitted as prescribed in the “Comments and Requests for a Public Hearing” section. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comments submitted to the IRS’s public docket. Send paper submissions to: CC:PA:01:PR (REG-105128-23), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations generally, Andrew L. Wigmore at (202) 317-5443; concerning the proposed regulations regarding intercompany transactions, Julie Wang at (202) 317-6975; concerning submissions of comments or requests for a public

hearing, Publications and Regulations Section at (202) 317-6901 (not toll-free numbers) or by email at publichearings@irs.gov (preferred).

SUPPLEMENTARY INFORMATION:**Background***I. The Dual Consolidated Loss Rules**A. In General*

Section 1503(d) was enacted in response to concerns that taxpayers were isolating expenses in dual resident corporations to enable two profitable companies, subject to tax in two different jurisdictions, to use the dual resident corporation’s losses. *See* S. Rep. No. 99-313, 99th Cong., 2nd Sess., at 419-421 (1986). Section 1503(d) and the regulations thereunder are intended to prevent this result and to neutralize other types of “double-deduction outcomes,” that is, where the same economic loss could be used to offset or reduce both income subject to U.S. tax (but not a foreign jurisdiction’s tax) and income subject to the foreign jurisdiction’s tax (but not U.S. tax). *See id.* and TD 9315 (72 FR 12902).

Section 1503(d)(1) generally provides that a dual consolidated loss of a domestic corporation cannot reduce the taxable income of a domestic affiliate (a “domestic use”). *See also* §§ 1.1503(d)-2 and 1.1503(d)-4(b). Except as provided in regulations under section 1503(d)(2)(B), section 1503(d)(2)(A) defines a dual consolidated loss as any net operating loss of a domestic corporation which is subject to an income tax of a foreign country without regard to whether such income is from sources in or outside of such foreign country, or is subject to such a tax on a residence basis. Section 1503(d)(3) provides regulatory authority to treat any loss of a separate unit of a domestic corporation as a dual consolidated loss.¹ Accordingly, § 1.1503(d)-1(b)(5) defines a dual consolidated loss as a net operating loss of a dual resident corporation or the net loss of a domestic corporation attributable to a separate unit.

A dual resident corporation is generally defined as a domestic corporation that is subject to an income tax of a foreign country on its worldwide income or on a residence basis. *See* § 1.1503(d)-1(b)(2)(i). A separate unit is generally defined as either a foreign branch (defined in

§ 1.1503(d)-1(b)) or an interest in a hybrid entity² that is carried on or owned, as applicable, directly or indirectly, by a domestic corporation (a “domestic owner” of the separate unit). *See* § 1.1503(d)-1(b)(4)(i). An affiliated dual resident corporation and an affiliated domestic owner are defined as a dual resident corporation and a domestic owner, respectively, that is a member of a consolidated group. *See* § 1.1503(d)-1(b)(10).

Pursuant to section 1503(d)(2)(B), the dual consolidated loss regulations provide certain exceptions to the general prohibition against the domestic use of a dual consolidated loss. For example, the domestic use limitation does not apply if, pursuant to a “domestic use election,” the taxpayer certifies that there has not been and will not be a “foreign use” of the dual consolidated loss during a certification period.³ *See* § 1.1503(d)-6(d). If a foreign use or other triggering event occurs during the certification period, the dual consolidated loss must be recaptured, and an interest charge is imposed on the recaptured amount. *See* § 1.1503(d)-6(e)(1). In general, a foreign use occurs when any portion of the dual consolidated loss is made available under the income tax laws of a foreign country to offset or reduce, directly or indirectly, the income of a foreign corporation or the direct or indirect owner of a hybrid entity that is not a separate unit. *See* § 1.1503(d)-3(a)(1). Other triggering events include certain transfers of the interests in or assets of a separate unit, as well as the failure to satisfy various certification requirements. *See* § 1.1503(d)-6(e).

B. Computing Income or Dual Consolidated Loss

In general, the income or dual consolidated loss of a dual resident corporation for a taxable year is computed based on the dual resident corporation’s items of income, gain, deduction, and loss for the taxable year. *See* § 1.1503(d)-5(b)(1). Similarly, the income or dual consolidated loss of a separate unit is generally computed as if the separate unit were a domestic corporation and based solely on the items of income, gain, deduction, and

² Hybrid entity means an entity that is not taxable as an association for U.S. tax purposes but is subject to an income tax of a foreign country as a corporation (or otherwise at the entity level) either on its worldwide income or on a residence basis. § 1.1503(d)-1(b)(3).

³ Section 1.1503(d)-6(b) (involving certain elective agreements between the United States and a foreign country) and § 1.1503(d)-6(c) (if it can be demonstrated that there is no possibility of a foreign use) also provide exceptions to the prohibition on domestic use.

¹ Although the term “separate unit” is not defined in the statute, the legislative history to section 1503(d)(3) provides one example: a foreign branch the losses of which are, under foreign law, able to offset income of an affiliated foreign corporation. *See* H.R. Rep. No. 100-795, 100th Cong., 2d Sess., at 292-93 (1988).

loss of the domestic owner of the separate unit that are attributable to the separate unit. *See* § 1.1503(d)–5(c)(1). If the dual resident corporation or domestic owner is a member of a consolidated group, then the computations are made in accordance with rules under section 1502 regarding the computation of consolidated taxable income. *See* § 1.1503(d)–5(b)(1) and (c)(1).

The income or dual consolidated loss of a dual resident corporation or separate unit does not, however, include items attributable to an interest in a “transparent entity.” *See* § 1.1503(d)–5(b)(2)(iii), (c)(1)(i) and (iii). A transparent entity is an entity that (i) is not taxable as an association for U.S. tax purposes, (ii) is not subject to income tax in a foreign country as a corporation either on its worldwide income or on a residence basis, and (iii) is not a pass-through entity under the laws of the foreign country under which the relevant separate unit or dual resident corporation is subject to tax. *See* § 1.1503(d)–1(b)(16)(i). A domestic limited liability company that, for U.S. tax purposes, is either disregarded as an entity separate from its owner or classified as a partnership is an example of a business entity that may be a transparent entity if the foreign jurisdiction does not view it as a pass-through entity. Because it is unlikely that items attributable to an interest in a transparent entity are taken into account by the jurisdiction in which the dual resident corporation or separate unit is subject to tax, such items should not affect the calculation or use of a dual consolidated loss. *See* TD 9315 (72 FR 12902, 12904–05).

For purposes of attributing items to a separate unit, only items of the domestic owner of the separate unit that are regarded for U.S. tax purposes are taken into account. *See* § 1.1503(d)–5(c)(1)(ii). Thus, items related to disregarded transactions—irrespective of whether such items are regarded and taken into account for foreign tax or accounting purposes—are not taken into account for purposes of determining the amount of income or dual consolidated loss of the separate unit. *See id.*; *see also* §§ 1.1503(d)–7(c)(6)(iii), 1.1503(d)–7(c)(23), and 1.1503(d)–7(c)(24) for examples illustrating this treatment for various types of disregarded payments.

In the case of a foreign branch separate unit (as defined in § 1.1503(d)–1(b)(4)(i)(A)), items of the domestic owner generally are attributable to the separate unit based on rules under section 864 and § 1.882–5 (by treating the domestic owner as a foreign corporation and the foreign branch

separate unit as a trade or business within the United States). *See* § 1.1503(d)–5(c)(2).

In the case of a hybrid entity separate unit (as defined in § 1.1503(d)–1(b)(4)(i)(B)), items of a domestic owner generally are attributable to the separate unit to the extent they are reflected on the books and records of the hybrid entity. *See* § 1.1503(d)–5(c)(3)(i). These items reflected on the books and records must, however, be adjusted to conform to U.S. tax principles. *Id.*

Pursuant to a special rule, any amount included in income of a domestic owner arising from the ownership of stock in a foreign corporation through a separate unit (for example, a subpart F inclusion) is attributable to the separate unit if an actual dividend from such foreign corporation would have been so attributed. *See* § 1.1503(d)–5(c)(4)(iv); *see also* § 1.1503(d)–7(c)(24) for an example illustrating the application of § 1.1503(d)–5(c)(4)(iv).

In general, these rules are intended to attribute items existing for U.S. tax purposes to a separate unit to the extent that it is likely that the relevant foreign country would take into account the item (assuming the item is recognized) for tax purposes, with such approach serving as a proxy for determining whether a double-deduction outcome could result. *See* TD 9315 (72 FR 12902, 12908).

C. Made Available Standard and All or Nothing Principle

A foreign use may occur if any portion of a dual consolidated loss is made available to offset income, even if there are no items of income to actually offset in that taxable year. *See* § 1.1503(d)–3(b). This “made available” standard was adopted because of the administrative complexity that would result from having a foreign use occur only when the dual consolidated loss actually offsets income. *See* REG–102144–04 (70 FR 29868, 29872–73). For example, if a portion of a dual consolidated loss is made available to be used by another person, and that person already has a loss before accounting for the dual consolidated loss, then a portion of the dual consolidated loss could become part of a loss carryover, which could be available to be carried forward or carried back to offset income in different taxable years. Departing from the made available standard would require that the portion of the loss carryforward or carryback that was taken into account in computing the dual consolidated loss be identified and tracked, which would require detailed ordering rules for determining when such losses were used and an

understanding of the timing and base differences between the United States and the foreign jurisdiction. *See id.*

In general, any amount of the dual consolidated loss being put to a foreign use would cause the entire amount of the dual consolidated loss to be recaptured and reported as income. *See* § 1.1503(d)–6(e)(1). This “all or nothing” principle was adopted because, like the made available standard, departing from it would have led to significant administrative complexity and the need for detailed ordering rules. *See* TD 9315 (72 FR 12902, 12910–11). For example, to depart from this standard and determine the amount of recapture on actual foreign use, taxpayers and the IRS would need to undertake a complex analysis of foreign law and distinguish a permanent (or base) difference from a timing difference, to ensure that the portion of the dual consolidated loss that is not recaptured will not be available for a foreign use at some point in the future. *See id.*

D. Mirror Legislation Rule

A foreign use of a dual consolidated loss may also be deemed to occur pursuant to the “mirror legislation” rule if the foreign income tax laws would deny any opportunity for the foreign use of the dual consolidated loss in the year in which the dual consolidated loss is incurred (assuming the foreign country recognized the loss in the same year), provided that the foreign use of the loss is denied under such laws for any of the following reasons: (i) the dual resident corporation or separate unit that incurred the loss is subject to income taxation by another country (for example, the United States) on its worldwide income or on a residence basis; (ii) the loss may be available to offset income (other than income of the dual resident corporation or separate unit) under the laws of another country (for example, the United States); or (iii) the deductibility of any portion of a deduction or loss taken into account in computing the dual consolidated loss depends on whether such amount is deductible under the laws of another country (for example, the United States). *See* § 1.1503(d)–3(e). Thus, in order for the rule to apply, two requirements must be satisfied: the income tax laws of the foreign country must deny any opportunity for a foreign use, and the reason for such denial must be described in one of the three enumerated paragraphs in § 1.1503(d)–3(e)(1). In other words, being described in one of the three enumerated paragraphs alone does not cause a foreign law to be treated as mirror

legislation (if, for example, the dual consolidated loss could nevertheless be put to a foreign use).

The mirror legislation rule is intended to prevent foreign jurisdictions from enacting legislation that gives taxpayers no choice but to use a dual consolidated loss to offset an affiliate's income in the United States. *See* REG-102144-04 (70 FR 29868, 29873-74). A lack of choice is contrary to the approach in the dual consolidated loss rules providing taxpayers the option of putting a dual consolidated loss to either a domestic use or a foreign use (but not both). *See id.*

E. Foreign Income Tax

Section 1503(d)(2)(A) defines a dual consolidated loss as any net operating loss of a domestic corporation which is subject to an income tax of a foreign country on its income without regard to whether such income is from sources in or outside of such foreign country, or is subject to such a tax on a residence basis. The exception to the definition of a dual consolidated loss under section 1503(d)(2)(B) similarly references "foreign income tax law." The legislative history to section 1503(d) references foreign taxes on income without further discussion of the characteristics of a foreign income tax. *See, for example*, S. Rep. No. 99-313, 99th Cong., 2nd Sess., at 419-421 (1986). Similarly, the regulations only reference a foreign income tax when setting forth many dual consolidated loss rules. *See, for example*, §§ 1.1503(d)-(1)(b)(2) (dual resident corporation definition), 1.1503(d)-(1)(b)(3) (hybrid entity definition), 1.1503(d)-(1)(b)(16) (transparent entity definition) and 1.1503(d)-(3)(a)(1) (foreign use definition). Thus, the dual consolidated loss rules neither define the term "income tax" nor describe the characteristics that distinguish an income tax from another type of tax.

II. The Intercompany Transaction Regulations and the Matching Rule

The regulations under § 1.1502-13 (the "intercompany transaction regulations") provide rules for taking into account items of income, gain, deduction, and loss of consolidated group members from intercompany transactions (as defined in § 1.1502-13(b)(1)(i)). Their purpose is to provide rules to clearly reflect the taxable income (and tax liability) of the group as a whole by preventing intercompany transactions from creating, accelerating, avoiding, or deferring consolidated taxable income (or consolidated tax liability). This is accomplished by treating the selling member ("S") and

the buying member ("B") as separate entities for some purposes, but as divisions of a single corporation for other purposes. S's income, gain, deduction, or loss arising from an intercompany transaction is an intercompany item, and B's income, gain, deduction, or loss arising from an intercompany transaction, or from property acquired in an intercompany transaction, is the corresponding item. The amount and location of S's intercompany items and B's corresponding items are determined on a separate entity basis ("separate entity treatment"). The timing, character, source, and other attributes of the intercompany items and corresponding items, although initially determined on a separate entity basis, generally are redetermined under the intercompany transaction regulations to produce the effect of transactions between divisions of a single corporation ("single entity treatment").

One of the principal rules within the intercompany transaction regulations that implements single entity treatment is the matching rule of § 1.1502-13(c). Section 1.1502-13(c)(1) requires the attributes of the intercompany and corresponding items to be redetermined to the extent necessary to achieve the same overall effect as if the members were divisions of a single corporation.

Under the matching rule, although treated as divisions of a single corporation, S and B are treated as engaging in their actual transaction and owning any actual property involved in the transaction (rather than treating the transaction as not occurring). Accordingly, under § 1.1502-13(c), the existence of the intercompany transaction and the intercompany items generally is not disregarded. Although treated in the same manner as divisions of a single corporation, S and B are treated as having any special status that they have under the Code or regulations.

Section 1.1502-13(c)(4) provides rules for allocating and redetermining attributes under the matching rule. To the extent that B's corresponding item matches S's intercompany item in amount, the attributes of B's corresponding item generally will control S's offsetting intercompany item. The symmetry that is ordinarily required under the matching rule by conforming the source, character, and other attributes of one member's items to the other member's items is expressly overridden when either S or B has a "special status." Section 1.1502-13(c)(5) provides that, when the attributes otherwise determined under § 1.1502-13(c)(1)(i) for a member's item are permitted or not permitted under the

Code or regulations because of a member's special status, the attributes required by the Code or regulations apply to that member's items, but not to the items of another member. The special status rule lists examples of members with special status, including banks, life insurance companies, and a member carrying forward a loss subject to limitation under the separate return limitation year ("SRLY") rules.

III. Sections 301.7701-1 Through 301.7701-3—Classification of Business Entities

Sections 301.7701-1 through 301.7701-3 classify a business entity with two or more members as either a corporation or a partnership, and a business entity with a single owner as either a corporation or disregarded as an entity separate from its owner ("disregarded entity"). Certain business entities with a single owner are classified as disregarded entities by default or through an election. *See* § 301.7701-3(a) through (c).

IV. Pillar Two

A. GloBE Model Rules

On December 20, 2021, the OECD/G20 Inclusive Framework on BEPS published model rules (the "GloBE Model Rules")⁴ to assist in the implementation of a reform to the international tax system. *See* OECD/G20, Tax Challenges Arising from the Digitalisation of the Economy Global Anti-Base Erosion Model Rules (Pillar Two). The GloBE Model Rules create a coordinated system of minimum taxation intended to ensure that certain large Multinational Enterprise Groups ("MNE Groups") pay a minimum level of tax based on the income, adjusted for certain items, arising in each of the jurisdictions where they operate.⁵

Under the GloBE Model Rules, an in-scope MNE Group must compute the GloBE Income or Loss of each of its Constituent Entities.⁶ The computation of GloBE Income or Loss generally begins with the net income or loss of a Constituent Entity determined using the accounting standard used in preparing the Consolidated Financial Statements and without any consolidation

⁴ As the context requires, references to the GloBE Model Rules include references to a foreign jurisdiction's legislation implementing the GloBE Model Rules.

⁵ Capitalized terms used in this part IV of the Background section and parts I.D of the Explanation of Provisions section of this preamble, but not defined herein, have the meanings ascribed to such terms under the GloBE Model Rules.

⁶ Constituent Entities include legal persons (other than a natural person), arrangements that prepare separate financial accounts (such as a partnership or trust), or a Permanent Establishment.

adjustments that would eliminate income or expense attributable to intra-group transactions. To reflect GloBE policy outcomes, this amount is then adjusted for specific items to determine the Constituent Entity's GloBE Income or Loss.⁷

The MNE Group must then calculate its Effective Tax Rate ("ETR") for each jurisdiction in which it operates. The ETR of a jurisdiction equals (i) the sum of Adjusted Covered Taxes of each Constituent Entity located in the jurisdiction, divided by (ii) the Net GloBE Income of the jurisdiction for the Fiscal Year. The Net GloBE Income of the jurisdiction is determined by aggregating the GloBE Income or Loss of all Constituent Entities of the MNE Group located in the same jurisdiction.⁸ This "jurisdictional blending" is mandatory and is intended to avoid distortions arising from tax consolidation and similar regimes and shifting income and taxes between Constituent Entities located in the same jurisdiction. *See* OECD (2024), *Tax Challenges Arising from the Digitalisation of the Economy—Consolidated Commentary to the Global Anti-Base Erosion Model Rules* (2023); *Inclusive Framework on BEPS, OECD Base Erosion and Profit Shifting Project*, April 2024, OECD Publishing, Paris ("GloBE Model Rules Consolidated Commentary"), Article 5.1.1, Paragraph 4. If the ETR in that jurisdiction would be below the 15% Minimum Rate, a top-up tax may be imposed and collected under a Qualified Domestic Minimum Top-up Tax ("QDMTT"), an IIR (the income inclusion rule), or a UTPR (commonly referred to as the undertaxed profits rule) to the extent necessary to ensure that the MNE Group's Excess Profits in the jurisdiction is taxed at the Minimum Rate. Certain countries have enacted, and others have proposed, legislation to implement taxes based on the GloBE Model Rules for fiscal years beginning as early as December 31, 2023.⁹

⁷ In addition to adjustments to reflect common differences between the applicable financial accounting standard and the local income tax rules, the computation of a Low-Tax Entity's GloBE Income or Loss excludes any expense attributable to an Intragroup Financing Arrangement that can reasonably be anticipated to increase the expenses of the Low-Tax Entity without resulting in a commensurate increase in the taxable income of the High-Tax Counterparty.

⁸ However, a Stateless Constituent Entity (such as a Reverse Hybrid Entity) is treated as a single Constituent Entity located in a separate and unspecified jurisdiction; the GloBE Income or Loss of a Reverse Hybrid Entity is not aggregated with that of any other Constituent Entity.

⁹ The UTPR will generally be effective for Fiscal Years beginning on or after December 31, 2024. Under the European Union (EU) Directive requiring

On December 20, 2022, the OECD/G20 Inclusive Framework on BEPS published the Safe Harbours and Penalty Relief document, which includes guidelines on aspects of the design and operation of a Transitional CbCR Safe Harbour to the GloBE Model Rules. *See* OECD (2022), *Safe Harbours and Penalty Relief: Global Anti-Base Erosion Rules (Pillar Two)*, December 2022, OECD/G20 Inclusive Framework on BEPS, OECD, Paris.¹⁰ The Transitional CbCR Safe Harbour is designed to ameliorate the compliance burden of undertaking full GloBE calculations during the Transition Period¹¹ by limiting the circumstances in which an MNE will be required to perform such calculations to a smaller number of higher-risk jurisdictions. An MNE Group uses its Qualified CbC Report and financial accounting data to determine if its operations in a jurisdiction qualify for the Transitional CbCR Safe Harbour and, if such operations qualify, the jurisdiction is effectively excluded from the scope of the GloBE Model Rules. Specifically, under the Transitional CbCR Safe Harbour, the Jurisdictional Top-up Tax in a jurisdiction for a Fiscal Year beginning on or before December 31, 2026¹² is deemed to be zero if (i) the MNE Group reports Total Revenue of less than EUR 10 million and Profit (Loss) before Income Tax of less than EUR 1 million in the jurisdiction on its Qualified CbC Report for the Fiscal Year, (ii) the MNE Group has a Simplified ETR that is equal to or greater than the Transition Rate in the jurisdiction for the Fiscal Year, or (iii) the MNE Group's Profit (Loss) before Income Tax in such jurisdiction is equal to or less than the Substance-based Income Exclusion amount, for Constituent Entities resident in that jurisdiction under the Qualified CbC

the adoption of the GloBE Model Rules, EU Member States will apply the UTPR for years beginning on or after December 31, 2023, but only in limited circumstances. *See* Council Directive 2022/2523, art. 50, 2022 OJ (L 328) 1, 55.

¹⁰ <https://www.oecd.org/tax/beps/safe-harbours-and-penalty-relief-global-anti-base-erosion-rules-pillar-two.pdf>. The Safe Harbours have since been incorporated into the GloBE Model Rules Consolidated Commentary.

¹¹ The Transition Period covers all of the Fiscal Years beginning on or before December 31, 2026, but not including a Fiscal Year that ends after June 30, 2028.

¹² Other than a Fiscal Year that ends after June 30, 2028. The Safe Harbour takes a "once out, always out" approach under which, if an MNE Group does not apply the Safe Harbour with respect to a jurisdiction in a Fiscal Year in which it is subject to the GloBE Rules, the MNE Group cannot qualify for the Safe Harbour for that jurisdiction in a subsequent year, except where the MNE Group did not have any Constituent Entities located in the jurisdiction in the previous Fiscal Year.

Report, as calculated under the GloBE Model Rules. Expenses and losses are relevant in determining whether each of these three tests is satisfied.

B. Notice 2023–80

On December 11, 2023, the Treasury Department and the IRS released Notice 2023–80, which, among other things, described the interaction of the dual consolidated loss rules with the GloBE Model Rules. The notice explains that in certain cases, the aggregation of GloBE Income or Loss of Constituent Entities in the same jurisdiction in calculating the ETR can be viewed as giving rise to double-deduction outcomes that the dual consolidated loss rules were intended to address. Moreover, the notice recognizes that these concerns could exist with respect to a dual consolidated loss incurred in a taxable year ending before the effective date of foreign legislation implementing the GloBE Model Rules, for example, due to certain timing differences. The notice also recognizes that certain features of the GloBE Model Rules may differ from traditional foreign income tax systems. For example, the GloBE Model Rules do not include a mechanism that would permit taxpayers to forgo the aggregation of GloBE Income and GloBE Losses, and in some cases where the ETR in the jurisdiction is or would otherwise be at or above the Minimum Rate, a loss may not reduce the amount of a Jurisdictional Top-up Tax.

The notice announces limited guidance that would be proposed for certain "legacy DCLs," which in general are dual consolidated losses that a taxpayer incurred before the effective date of the GloBE Model Rules.¹³ Under that guidance, a foreign use does not occur with respect to a legacy DCL solely because all or a portion of the deductions or losses that comprise the legacy DCL are taken into account under the GloBE Model Rules, subject to an anti-abuse rule. Where a taxpayer uses a fiscal year for tax purposes that ends after 2024, the foreign use exception is conditioned on the relevant MNE Group using the same fiscal year when applying the GloBE Model Rules. This condition ensures that the legacy DCL rule applies only to the extent of book-tax timing differences, and not due to a mismatch between the U.S. taxable year

¹³ The notice defines legacy DCLs as dual consolidated losses incurred in (i) taxable years ending on or before December 31, 2023, or (ii) provided the taxpayer's taxable year begins and ends on the same dates as the Fiscal Year of the MNE Group that could take into account as an expense any portion of a deduction or loss comprising such a DCL, taxable years beginning before January 1, 2024, and ending after December 31, 2023.

and fiscal year used under the GloBE Model Rules.

Finally, the notice states that the Treasury Department and the IRS are studying the interaction of the dual consolidated loss rules and the GloBE Model Rules and the notice requests comments on the interaction of the dual consolidated loss rules with the GloBE Model Rules, including Article 3.2.7 (relating to Intragroup Financing Arrangements), which is intended to prevent certain avoidance transactions involving arbitrage. The notice also states that the Treasury Department and the IRS are studying the interaction of the GloBE Model Rules with the anti-hybrid rules under sections 245A(e) and 267A.

C. Administrative Guidance Addressing Hybrid Arbitrage Arrangements

On December 15, 2023, the OECD/G20 Inclusive Framework on BEPS published additional Administrative Guidance on the GloBE Model Rules (“December 2023 Administrative Guidance”). See OECD (2023), *Tax Challenges Arising from the Digitalisation of the Economy—Administrative Guidance on the Global Anti-Base Erosion Model Rules (Pillar Two)*, December 2023, OECD/G20 Inclusive Framework on BEPS, OECD, Paris.¹⁴ Among other issues, the December 2023 Administrative Guidance addresses the treatment under the Transitional CbCR Safe Harbour of Hybrid Arbitrage Arrangements entered into after December 15, 2022.

The December 2023 Administrative Guidance involving Hybrid Arbitrage Arrangements is intended, in part, to address avoidance transactions that are designed to exploit differences between tax and financial accounting treatment to allow a Tested Jurisdiction to qualify for the Transitional CbCR Safe Harbour, which would be contrary to the purposes of the GloBE Model Rules. One of the Hybrid Arbitrage Arrangements addressed under the guidance is a “duplicate loss arrangement.” A duplicate loss arrangement includes an arrangement that results in an expense or loss being included in the financial statement of a Constituent Entity to the extent that the arrangement also gives rise to a duplicate amount that is deductible for purposes of determining the taxable income of another Constituent Entity in another jurisdiction. An arrangement

will not be a duplicate loss arrangement, however, to the extent that the amount of the relevant expense is offset against revenue or income that is included in both (i) the financial statements of the Constituent Entity including the expense or loss in its financial statements; and (ii) the taxable income of the Constituent Entity claiming the deduction for the relevant expense or loss. Under this guidance, a Tested Jurisdiction’s Transitional CbCR Safe Harbour calculation is adjusted by excluding any expense or loss arising as a result of a duplicate loss arrangement from the Tested Jurisdiction’s profit before tax.

The December 2023 Administrative Guidance states that further guidance will be provided to address Hybrid Arbitrage Arrangements, including those addressed in the December 2023 Administrative Guidance, that may otherwise affect the application of the GloBE Model Rules outside the context of the Transitional CbCR Safe Harbour.

Explanation of Provisions

I. Dual Consolidated Loss Rules

A. Interaction With the Intercompany Transaction Regulations

As discussed in part I.B of the Background section of this preamble, the dual consolidated loss regulations provide that, in the case of an affiliated dual resident corporation or an affiliated domestic owner acting through a separate unit (a “section 1503(d) member”), the computation of income or dual consolidated loss takes into account rules under section 1502 regarding the computation of consolidated taxable income. No specific guidance is provided as to the interaction of rules under section 1502 and those under section 1503(d).

Comments with respect to proposed regulations addressing certain hybrid arrangements that were published in the **Federal Register** on December 28, 2018 (REG–104352–18, 83 FR 67612) (the “2018 proposed regulations”), addressed the interaction of the matching rule under § 1.1502–13(c) with the computation of income or dual consolidated loss. The preamble to final regulations published in the **Federal Register** on April 8, 2020 (TD 9896, 85 FR 19830), stated that the Treasury Department and the IRS were studying this issue.

The comments recommended that the Treasury Department and the IRS clarify that the matching rule does not apply to cause regarded items to be redetermined (and thus effectively disregarded) for purposes of the dual consolidated loss rules. The comments stated that such an

approach promotes the policies of the dual consolidated loss rules and leads to more accurate computations. In addition, a comment asserted that such an approach is consistent with how taxpayers generally apply the rules, and that for these taxpayers a contrary approach could have a significant and unanticipated effect on existing structures.

However, one of the comments cautioned that, if the dual consolidated loss rules were to apply differently with respect to an item arising from an intercompany transaction and an item arising from a disregarded transaction, then the disparity could produce inappropriate policy outcomes. For example, a taxpayer might structure its internal transactions so that (i) payments by separate units are made pursuant to disregarded transactions, such that the payments would not increase or create a dual consolidated loss, and (ii) payments to separate units are made pursuant to intercompany transactions, such that the payments would reduce or eliminate a dual consolidated loss. The comment described additional rules—including a rule that would require a consolidated group to treat intercompany transactions and disregarded payments consistently for purposes of the dual consolidated loss rules—that might minimize tax planning opportunities arising from any such disparity. These proposed regulations address the concern raised in this comment with the disregarded payment loss rules, as discussed in part II of this Explanation of Provisions.

Another comment raised the possibility that taxpayers may have differing views regarding the interaction of the matching rule with the dual consolidated loss rules under current law. As a result, taxpayers currently may be adopting different treatments of the section 1503(d) member’s intercompany (or corresponding) items. Accordingly, the comment recommended clarifying how these rules interact.

The dual consolidated loss rules are intended to take into account an item of a dual resident corporation, or attribute an item of a domestic owner to a separate unit, to the extent that the item is likely taken into account for foreign tax purposes. Because it is unlikely that a foreign jurisdiction would disregard an intercompany transaction (or, more generally, transactions between separate legal entities), it is consistent with the policies of the dual consolidated loss rules to take into account items arising from an intercompany transaction on a separate entity basis, to the extent of the application of section 1503(d). In

¹⁴ <https://www.oecd.org/tax/beps/administrative-guidance-global-anti-base-erosion-rules-pillar-two-december-2023.pdf>. The December 2023 Administrative Guidance has since been incorporated into the GloBE Model Rules Consolidated Commentary.

addition, the failure to take items arising from an intercompany transaction into account in an appropriate manner for the section 1503(d) rules could lead to distortive results—both an under- and over-inclusive application of the dual consolidated loss rules—and could create inappropriate planning opportunities.

Accordingly, and consistent with the approach recommended by the comments, the proposed regulations would amend § 1.1502–13 to clarify the treatment of items that are subject to the section 1503(d) rules and the intercompany transaction regulations. Specifically, the proposed regulations clarify that a section 1503(d) member has special status under § 1.1502–13(c)(5) for purposes of applying the dual consolidated loss rules. This approach is consistent with treating a member with losses from separate return limitation years as having special status under § 1.1502–13(c)(5) for purposes of determining the member's SRLY limitation. *See* § 1.1502–13(c)(7)(ii)(J)(4).

As a result, if a section 1503(d) member's intercompany (or corresponding) loss otherwise would be taken into account in the current year, and if the dual consolidated loss rules apply to limit the use of that loss (causing the loss to not be currently deductible), the intercompany transaction regulations would not redetermine that loss as not being subject to the limitation under section 1503(d). Therefore, a section 1503(d) member's intercompany (or corresponding) loss could be limited (and therefore not currently deductible) under the dual consolidated loss rules, even though such an outcome is inconsistent with single entity treatment.

In conjunction with the special status rule for the section 1503(d) member, the proposed regulations also clarify the treatment of the section 1503(d) member's counterparty in an intercompany transaction. Proposed § 1.1502–13(j)(10)(iv) applies § 1.1502–13(c) (the matching rule), or principles of the matching rule as relevant in § 1.1502–13(d) (the acceleration rule), to the counterparty member as if the section 1503(d) member were not subject to the dual consolidated loss rules. This approach is consistent with the special status rule in § 1.1502–13(c)(5), which provides that, even though the Code or regulations require certain treatment of the special status member's items by reason of its special status, that treatment does not affect the attributes of the counterparty member's items under the matching rule.

For example, assume that, in the current year, S (the counterparty member) has interest income, and B (a section 1503(d) member) has an interest deduction on an intercompany loan. Even if B's interest deduction were limited under the domestic use limitation under § 1.1503(d)–4(b) and therefore not currently deductible, S nevertheless would take its interest income into account in the current year under proposed § 1.1502–13(j)(10)(iv). In other words, this rule clarifies that the intercompany transaction regulations would not redetermine the attributes of S's interest income to match the treatment of B's interest deduction in situations where B's deduction is limited due to B's special status as a section 1503(d) member. The Treasury Department and the IRS are of the view that redetermining S's interest income as not currently includible in these situations effectively would give the consolidated group the benefit of B's deduction and would not achieve the appropriate result under dual consolidated loss policy.

These proposed regulations also clarify the order of operation between § 1.1502–13 and the dual consolidated loss rules. The dual consolidated loss rules apply to an item only to the extent that the item is otherwise taken into account in income or loss. Consistent with this general rule, the proposed regulations clarify that (i) the intercompany transaction regulations apply first to determine when an intercompany (or corresponding) item is taken into account, and (ii) such item is then included in the dual consolidated loss computations. Thus, for example, in a year in which an intercompany deduction of S (a section 1503(d) member) is deferred under the intercompany transaction regulations, the deduction would not be included in computing S's income or dual consolidated loss for that year under section 1503(d). Moreover, when S's deduction is taken into account under the matching rule in a later year, that deduction would be included in S's dual consolidated loss computations for that year. *See* proposed § 1.1502–13(j)(15)(xi) for an example illustrating the application of the matching rule.

B. Computing Income or Dual Consolidated Loss

1. Items Arising From Ownership of Stock

As discussed in part I.B of the Background section of this preamble, an item of income, gain, deduction, or loss is generally taken into account for purposes of computing income or dual

consolidated loss to the extent it is likely that the relevant foreign country would take into account the item (assuming the item is recognized) for tax purposes. In many cases, gain from the sale or exchange of stock of a corporation, or a dividend from a corporation, is unlikely to be included in income in the foreign country due to, for example, a participation exemption or indirect foreign tax credits. In addition, an inclusion with respect to stock of a foreign corporation (such as under section 951(a)(1)(A) or 951A(a)) is unlikely to be taken into account (and therefore is unlikely to be included in income) in the foreign country; moreover, the difference resulting from these inclusions is likely to be permanent because the related earnings of the foreign corporation are unlikely to be included in income in the foreign country when distributed.

Further, the Treasury Department and the IRS are aware that taxpayers may be affirmatively structuring into these rules to produce inappropriate double-deduction outcomes. For example, in order to eliminate a dual consolidated loss otherwise attributable to an interest in a disregarded entity, a domestic corporation could transfer the stock of a controlled foreign corporation (as defined in section 957(a)) that gives rise to inclusions under section 951A(a) to that disregarded entity, even though the foreign country in which the disregarded entity is subject to tax does not tax income of, or distributions from, the controlled foreign corporation.

In light of the prevalence of participation exemptions (or similar regimes that exempt income with respect to stock), coupled with taxpayers structuring into the rules to reduce or eliminate dual consolidated losses, the Treasury Department and the IRS are of the view that the rules should be revised. The proposed regulations therefore generally provide that items arising from the ownership of stock—such as gain recognized on the sale or exchange of stock, dividends (including by reason of section 1248), inclusions under section 951(a) (including by reason of section 245A(e)(2) or 964(e)(4)) or 951A(a), as well as deductions with respect thereto (including under section 245A(a) or 250(a)(1)(B))—are not taken into account for purposes of computing income or a dual consolidated loss. *See* proposed § 1.1503(d)–5(b)(2)(iv)(A) and (c)(4)(iv)(A). These rules are not limited to items arising from the ownership of stock of a foreign corporation because, for example, a dividend from a domestic corporation may be eligible for a

participation exemption under the laws of the foreign country.

However, these rules do not apply with respect to a dividend (or other inclusion) arising from a separate unit or dual resident corporation's ownership of portfolio stock of a corporation (domestic or foreign), which generally is defined as stock representing less than ten percent of the value of the corporation. *See* proposed § 1.1503(d)–5(b)(2)(iv)(B) and (c)(4)(iv)(B) and (C). In these cases, the items are likely to be included (or the related earnings are likely to be subsequently included when distributed) in income in the foreign country in which the separate unit or dual resident corporation is subject to tax. The proposed regulations are intended to ensure that these items, as offset or reduced by any deductions with respect to the items for U.S. tax purposes, are taken into account for purposes of computing income or a dual consolidated loss.

The Treasury Department and the IRS are of the view that this approach is simpler and more administrable than an alternative approach that would consider the extent to which an item is, or will be, actually taken into account under the tax law of the foreign country in which the separate unit or dual resident corporation is subject to tax and not offset or reduced by an exemption, exclusion, deduction, credit, or other similar relief particular to the item. Further, in most cases a more precise approach would not lead to significantly different results given the likelihood that items of income arising from the ownership of stock will be offset or reduced under the tax laws of the foreign country.

The Treasury Department and the IRS recognize that certain amounts included in the income of a domestic owner arising from the ownership of stock in a foreign corporation (in the case of a separate unit, regardless of whether the stock of the foreign corporation is held through the separate unit) may reflect amounts that have been subject to tax, to some extent, by both the foreign jurisdiction and the United States. For example, where a domestic owner of a separate unit that is taxed as a resident in a particular foreign jurisdiction holds stock of a controlled foreign corporation that is also taxed as a resident in the same foreign jurisdiction, the controlled foreign corporation's income may be taxed, to some extent, under the income tax laws of the foreign jurisdiction and by the United States through inclusions under section 951(a) or 951A(a); this could occur regardless of whether the inclusion itself is taken into account by

the same foreign jurisdiction. To the extent such amounts are taxed in the same manner and to the same extent as if they were earned directly by the domestic owner, they could be viewed as representing dual inclusion income (that is, items that are included in income in both the United States and the foreign country and not offset or reduced by certain amounts particular to the item) that could be taken into account when determining the dual consolidated loss attributable to the separate unit.

The proposed regulations do not provide a rule that would permit taxpayers to identify and take into account such amounts as dual inclusion income. Doing so would require complicated rules, and raise related administrability concerns, to isolate the amount of dual inclusion income with respect to a particular foreign jurisdiction (for example, where a controlled foreign corporation owns one or more disregarded entities that are subject to tax in different foreign jurisdictions). Such an approach would also need to take into account rate disparities (for example, as a result of the deduction allowed under section 250(a)(1)(B) with respect to inclusions under section 951A) and other differences that may result between income earned directly by a domestic owner and earned indirectly through a controlled foreign corporation.

2. Adjustments To Conform to U.S. Tax Principles

As discussed in part I.B of the Background section of this preamble, regarded items of a domestic owner generally are attributable to a hybrid entity separate unit to the extent they are reflected on the books and records of the hybrid entity. These items reflected on the books and records must, however, be adjusted to conform to U.S. tax principles. Such adjustments would include, for example, adjustments to reflect differences in the calculation of depreciation for accounting and tax purposes, and adjustments to eliminate items reflected on the books and records that are not deductible for tax purposes (such as a penalty or fine). *See* § 1.1503(d)–7(c)(25) for an example illustrating adjustments to conform to U.S. tax principles.

The Treasury Department and the IRS are aware that certain taxpayers may be taking the position that items that are not reflected on the books and records of a hybrid entity may nevertheless be attributable to the hybrid entity separate unit. Specifically, taxpayers may assert that the adjustments to the books and records necessary to conform to U.S. tax

principles can include an item that has not been (and will not be) reflected on the books and records of the hybrid entity. For example, if a hybrid entity provides services to its domestic owner and receives a payment as compensation for those services that is generally disregarded for U.S. tax purposes, a taxpayer may take the position that a portion of the domestic owner's regarded income can be reallocated to the books and records of the hybrid entity (and, thus, taken into account by the hybrid entity separate unit) under, for example, the principles of section 482 or section 864(c).

This position is incorrect under the current regulations and misinterprets the required adjustments under § 1.1503(d)–5(c)(3)(i). Such adjustments account for discrepancies between accounting treatment and U.S. tax treatment; they are not permitted to give effect to disregarded payments that § 1.1503(d)–5(c)(1)(ii) explicitly excludes from the calculation of income or dual consolidated loss. *See* § 1.1503(d)–7(c)(23) for an example illustrating the application of § 1.1503(d)–5(c). Further, this position is contrary to the policy underlying § 1.1503(d)–5(c)(3), which is to take into account only items that are regarded for U.S. tax purposes and also are (or have been or will be) reflected on the books and records of the hybrid entity. Nevertheless, for the avoidance of doubt, the proposed regulations clarify that the adjustments necessary to conform to U.S. tax principles do not permit the attribution to a hybrid entity separate unit, or an interest in a transparent entity, of any item that has not been and will not be reflected on the books and records of the hybrid entity or transparent entity. *See* proposed § 1.1503(d)–5(c)(3)(i); *see also* proposed § 1.1503(d)–7(c)(23)(iii) for an example illustrating the application of § 1.1503(d)–5(c); *but see* §§ 1.1503(d)–5(c)(4)(iii), 1.1503(d)–5(c)(4)(v) and 1.1503(d)–5(c)(4)(vi) (special attribution rules that do not require that an item be reflected on the books and records to be taken into account).

C. Anti-Avoidance Rule

As discussed in sections I.A (interaction with the matching rule), I.B.1 (items arising from ownership of stock), I.B.2 (adjustments to conform to U.S. tax principles), and II.A. (disregarded payment losses) of this Explanation of Provisions, the Treasury Department and the IRS continue to learn of transactions or structures that attempt to obtain a double-deduction outcome while avoiding the application of the dual consolidated loss rules. In

addition, the Treasury Department and the IRS are aware of other avoidance transactions that may facilitate a double-deduction outcome by manipulating the computation of income or a dual consolidated loss with items that are not included in income, or do not give rise to tax, in the foreign country. For example, income-producing assets located within the United States could be transferred to, or otherwise be acquired by, a separate unit that is a tax resident in a jurisdiction that, pursuant to a participation exemption or similar regime (including a regime that grants a foreign tax credit for foreign taxes paid on foreign income), would exempt or otherwise not tax the income derived from those assets. Because such assets are located in the United States, however, taxpayers could assert that they would not give rise to a foreign branch separate unit and, assuming they are not held by a transparent entity, take the position that income derived from those assets would reduce or eliminate a dual consolidated loss (despite not being subject to tax in the foreign jurisdiction).

Even if these particular transactions were also addressed by new rules in these proposed regulations, other avoidance transactions could continue to be developed. Accordingly, and rather than continuing to address these transactions on a case-by-case basis, the proposed regulations include an anti-avoidance rule that, in general, is intended to address additional transactions, or interpretations, that may attempt to avoid the purposes of the dual consolidated loss rules. *See* proposed § 1.1503(d)–1(f); *see also* § 1.1503(d)–7(c)(43) for an example illustrating the application of the anti-avoidance rule to a transfer of assets located in the United States to a separate unit. This anti-avoidance rule also applies with respect to transactions that attempt to avoid the purposes of the disregarded payment loss rules because, as discussed in part II of this Explanation of Provisions, such rules are also intended to address transactions that raise policy concerns similar to those arising under the dual consolidated loss rules. *See* proposed § 1.1503(d)–1(f).

D. GloBE Model Rules

1. General Applicability of Dual Consolidated Loss Rules

As discussed in part IV.B of the Background section of this preamble, Notice 2023–80 requested comments on the interaction of the dual consolidated loss rules with the GloBE Model Rules. In response, comments requested that

the dual consolidated loss rules be made inapplicable with respect to a foreign tax based on the GloBE Model Rules. In support of these recommendations, comments asserted that the QDMTT, IIR, and UTPR have unique characteristics that are not present in the income taxes that were in existence when section 1503(d) was enacted. According to some comments, these taxes are not based on the traditional concept of tax residency and thus do not present the possibility for the mismatches in tax residency that the dual consolidated loss rules were intended to address. Comments further noted that the QDMTT, IIR, and UTPR are minimum taxes based on an MNE Group's financial accounting income and, in contrast to typical tax consolidation or group relief regimes, the aggregation of revenue or expense under the GloBE Model Rules is not elective. Finally, comments asserted that the IIR differs from a typical foreign income tax because it is not a tax on an entity's income (including income imputed from a subsidiary) arising in the foreign jurisdiction where the entity is a tax resident. According to these comments, a foreign use cannot occur under the current dual consolidated loss rules as a result of a loss being taken into account under an IIR if the entity incurring the loss is not a tax resident in the foreign jurisdiction imposing the IIR—that is, these comments assert a foreign use can only occur if a dual consolidated loss is made available under the laws of the foreign jurisdiction in which the loss arises.

As indicated in Notice 2023–80, the Treasury Department and the IRS are of the view that the aggregation of items of revenue and expense of Constituent Entities in the same jurisdiction in calculating the ETR can result in double-deduction outcomes that the dual consolidated loss rules were intended to address. First, despite the differences between the GloBE Model Rules and more traditional foreign income tax systems, the GloBE Model Rules can also present a typical example of tax residency arbitrage that the dual consolidated loss rules were intended to address. For example, assume USP, a domestic corporation, owns all the interests in DEX, an entity organized under the laws of Country X that is disregarded as an entity separate from its owner. DEX, in turn, owns all the stock in CFCx, a foreign corporation organized under the laws of Country X. DEX incurs a \$100x loss and CFCx generates \$100x of income. If Country X does not impose an income tax on Country X entities, then the \$100x loss

incurred by DEX would not be a dual consolidated loss with respect to USP's interests in DEX. *See* § 1.1503(d)–1(b)(5)(ii), (b)(3), and (b)(4)(i). This is appropriate as the loss could not be used to offset CFCx's income and give rise to a double-deduction outcome because there is no Country X income tax that could be reduced as a result of the offset. If, however, Country X enacted a QDMTT that is an income tax, and absent the application of the dual consolidated loss rules, the \$100x loss of DEX could then be available to reduce U.S. tax imposed on USP's income as well as the Country X QDMTT imposed on CFCx's income. The Treasury Department and the IRS are of the view that as a matter of the policy underlying the dual consolidated loss rules there is no meaningful distinction between using DEX's \$100x loss to offset the Country X QDMTT versus using the loss to instead offset a more traditional income tax imposed by Country X; both cases give rise to a double-deduction outcome. Further, a double-deduction outcome could also occur if the loss were to offset income under another country's IIR, rather than under a QDMTT.

Moreover, the features of the IIR or QDMTT noted by comments—such as using financial accounting income as a starting point for purposes of determining GloBE Income or Loss, or being a minimum tax—do not preclude an IIR or QDMTT from being the type of tax to which the dual consolidated loss rules were intended to apply. Indeed, these types of features are included in the U.S. income tax. *See, for example*, sections 55, 56A, and 59 (corporate alternative minimum tax). The sharing of the loss through the mechanics of calculating Net GloBE Income similarly is an insufficient basis to distinguish the IIR or QDMTT from a more traditional foreign income tax where the loss is shared pursuant to a consolidation election or similar loss-sharing regime.

As an alternative to a foreign use exception, some comments recommended an anti-abuse rule that provides that a foreign use can only occur as a result of aggregation under the GloBE Model Rules if the losses were created for a tax-avoidance purpose. These proposed regulations do not provide such an anti-abuse rule because there is no indication in the statutory language or legislative history that the application of the dual consolidated loss rules should be limited to losses incurred for a tax-

avoidance purpose.¹⁵ Many deductions that can be structured to give rise to a double-deduction outcome are incurred for non-tax business reasons, such as interest expense incurred on external debt that is issued to acquire property or fund business operations.

Accordingly, the proposed regulations provide that an income tax may include a tax that is intended to ensure a minimum level of taxation on income or computes income or loss by reference to financial accounting net income or loss. *See* proposed § 1.1503(d)–1(b)(6)(ii). Therefore, an IIR or QDMTT may be an income tax for purposes of the dual consolidated loss rules and a foreign use may occur under such tax by reason of a loss being used in the calculation of Net GloBE Income or to qualify for a Transitional CbCR Safe Harbour. *See* proposed § 1.1503(d)–7(c)(3)(ii) for an example illustrating the application of the dual consolidated loss rules with respect to a QDMTT. These proposed regulations do not, however, provide specific guidance regarding the UTPR. The Treasury Department and the IRS continue to analyze issues related to the UTPR.

2. Effect on Certain Entities and Foreign Business Operations

As discussed in parts I.A, I.B, and I.E of the Background section of this preamble, the definitions of hybrid entity, hybrid entity separate unit, and dual resident corporation are each based, in part, on whether the relevant entity is subject to an income tax of a foreign country on its worldwide income or on a residence basis. The definition of a foreign branch separate unit, on the other hand, is based on the level of activities required to constitute a foreign branch under § 1.367(a)–6T(g)(1) (subject to an exception where business operations do not constitute a permanent establishment under an applicable income tax convention). Among other requirements, an entity is a transparent entity only if it is not subject to an income tax of a foreign country on its worldwide income or on a residence basis.

As discussed in part IV.A of the Background section of this preamble, a top-up tax may be collected by a jurisdiction with respect to the Net GloBE Income of a Constituent Entity under a QDMTT or an IIR. The top-up tax under an IIR with respect to the Net GloBE Income of an entity located in one jurisdiction may be collected by a

different jurisdiction from another Constituent Entity in the MNE Group. As mentioned in part I.D.1 of this Explanation of Provisions, comments have asserted that the IIR is not based on the traditional concept of tax residency and, if a loss does not arise in the foreign jurisdiction that assesses the tax, the dual consolidated loss rules do not apply.

The Treasury Department and the IRS are of the view, that where a loss reduces or eliminates the amount of Net GloBE Income in a jurisdiction, the results under the dual consolidated loss rules should be the same regardless of the jurisdiction collecting tax with respect to the amount of Jurisdictional Top-up Tax. For example, assume a domestic corporation (“DC”) owns a foreign disregarded entity (“FDEx”), a tax resident in Country X that imposes a QDMTT that is an income tax. Further assume that FDEx owns all the stock of a foreign corporation organized under the laws of Country X (“CFCx”) and that is also a tax resident in Country X. FDEx should be treated as subject to the QDMTT, and as a hybrid entity as a result of being subject to the QDMTT, to prevent the double-deduction outcome discussed in part I.D.1 of this Explanation of Provisions.

Alternatively, assume that DC owns another disregarded entity (“FDEy”), that is a tax resident in Country Y, a jurisdiction that imposes an IIR that is income tax, and FDEy owns FDEx, which owns CFCx, and that Country X does not impose a QDMTT. In this case, a loss of FDEx can reduce the GloBE Income of CFCx for purposes of the Country Y IIR and, as was the case with a Country X QDMTT (that is also calculated in part by reference to FDEx’s income), a double-deduction outcome may result. The treatment of an interest in FDEx as a separate unit should not be affected if, instead of the QDMTT being collected from FDEx with respect to its GloBE Income, an IIR is collected on FDEy, the owner of FDEx, with respect to the GloBE Income of FDEx. Moreover, a loss of FDEx cannot offset income of a Country Y Constituent Entity for purposes of the Country Y IIR and, therefore, the FDEx separate unit should not be part of a combined separate unit that includes FDEy, which would otherwise distort the calculation of income or loss attributable to the combined Country Y separate unit. In other words, specifically identifying these separate units is necessary to apply the separate unit combination rule, including for purposes of describing the location of separate units arising from a QDMTT or an IIR.

Accordingly, the proposed regulations generally provide that if the income or loss of a foreign entity that is not taxed as an association for Federal income tax purposes is taken into account in determining the amount of tax under an IIR, then a domestic corporation’s directly or indirectly held interest in such an entity is a hybrid entity separate unit. *See* proposed § 1.1503(d)–1(b)(4)(i)(B)(2). Further, such a hybrid entity separate unit would form part of a combined separate unit based on where the relevant entity is located for purposes of the IIR. *See* proposed § 1.1503(d)–1(b)(4)(ii)(A) and (b)(4)(ii)(B)(2). Thus, in both variations of the example in the preceding paragraph, the interest in FDEx would, by reason of the relevant foreign income tax, be treated as a separate unit in Country X, which is the country in which FDEx is located for purposes of the QDMTT and IIR. Further, because a double-deduction outcome may also result from a place of business conducted by a domestic corporation outside the United States that is treated as a Permanent Establishment with respect to a QDMTT or an IIR, the proposed regulations would treat such a place of business as a foreign branch separate unit. *See* proposed § 1.1503(d)–1(b)(4)(i)(A)(2).

These new definitions of hybrid entity separate unit and foreign branch separate unit do not apply to an interest in an entity, or place of business, respectively, that would otherwise qualify as a separate unit under the definitions included in the current regulations. This is because a loss attributable to a separate unit as defined under the current regulations is already a dual consolidated loss and, thus, additional rules are not necessary to prevent a double-deduction outcome from occurring as a result of the use of losses attributable to such separate units for purposes of a QDMTT or IIR. For example, if a hybrid entity’s loss is also taken into account in determining the amount of tax under an IIR, a foreign use may result if a dual consolidated loss attributable to an interest in the entity is made available to offset income either for purposes of the foreign income tax to which the entity is subject or for purposes of the IIR.

Under the proposed regulations, being subject to an IIR would not cause an interest in a Tax Transparent Entity to be a hybrid entity separate unit. *See* proposed § 1.1503(d)–1(b)(4)(i)(B)(2). Although a calculation of GloBE Income or Loss is required for a Tax Transparent Entity, for purposes of an IIR, all of the entity’s Financial Accounting Net Income or Loss is allocated to its owners

¹⁵ In contrast, the anti-avoidance rule under proposed § 1.1503(d)–1(f) is intended to backstop the dual consolidated loss rules, which apply to losses without regard to whether incurred for a tax-avoidance purpose.

(or to a permanent establishment of the entity) and, thus, it is unlikely that a loss attributable to an interest in such an entity could give rise to a double-deduction outcome. This treatment is also consistent with the treatment, and policy rationale, under the existing dual consolidated loss rules that an interest in a partnership that is not a hybrid entity is not a separate unit.

The Treasury Department and the IRS are of the view that the treatment of a foreign entity or a place of business outside the United States as a Stateless Constituent Entity should not preclude treating a domestic corporation's interest in such an entity or the place of business as an individual separate unit. Even though the GloBE Income or Loss of a Stateless Constituent Entity is not combined with the GloBE Income or Loss of any other Constituent Entity, treating an interest in such an entity or a place of business as an individual separate unit is appropriate to prevent double-deduction outcomes that may nevertheless arise (for example, if the foreign entity were to generate a loss during the first half of the taxable year and then elect to be treated as a foreign corporation for U.S. tax purposes).

The income or loss of a domestic entity may also be taken into account in determining the amount of tax imposed under an IIR (for example, if a domestic corporation were wholly owned by a foreign corporation organized under the laws of a jurisdiction that imposed an IIR). However, the Treasury Department and the IRS are of the view that the IIR alone should not cause a domestic entity to be treated as a dual resident corporation or a hybrid entity. The dual consolidated loss rules are intended to prevent double-deduction outcomes that can arise from structures involving the possibility of a form of arbitrage, such as from an entity or place of business being subject to tax in more than one country, or from the entity or place of business having different tax classifications under U.S. and foreign tax law. Absent this type of arbitrage, the dual consolidated loss rules would not apply to limit the deductibility of a domestic entity's loss due to that entity's income or loss being reflected in the amount of tax imposed under an IIR (or a similar shareholder-level tax). Moreover, if a loss of a domestic entity were viewed as giving rise to a second deduction because it is taken into account to determine the amount of tax imposed under an IIR, the loss is likely only available to offset dual inclusion income (and therefore would not give rise to a double-deduction outcome) since the income of any domestic affiliate that could be offset by the loss

for domestic tax purposes should also be taken into account in determining the amount of tax imposed under the IIR. Accordingly, under the proposed regulations a domestic entity is not treated as a dual resident corporation or a hybrid entity solely as a result of the domestic entity's income or loss being taken into account in determining the amount of an IIR. *See* proposed § 1.1503(d)–7(c)(3)(iii) for an example illustrating the treatment of domestic entities under an IIR. Applying the dual consolidated loss rules only when there is an element of hybridity (or mismatch) is consistent with the scope of both the current dual consolidated loss regulations and the OECD reports addressing hybrid and branch mismatch arrangements.¹⁶

3. Application to Transitional CbCR Safe Harbour

Comments requested guidance providing that, even if the dual consolidated loss rules apply with respect to the GloBE Model Rules, a foreign use should not occur solely because a dual consolidated loss is taken into account for purposes of the Transitional CbCR Safe Harbour. The comments noted that, unlike the QDMTT, IIR, and UTPR, the Transitional CbCR Safe Harbour is not a collection mechanism and thus does not operate to impose a tax liability. Instead, according to some comments, the Transitional CbCR Safe Harbour can be viewed as a “gating” mechanism to determine if a taxpayer is subject to tax, similar to a determination of whether activity rises to the level of a permanent establishment under an applicable tax treaty. Further, comments claimed that the calculation of income and expenses under the Transitional CbCR Safe Harbour is substantially different from such calculations under the general GloBE Model Rules and generally accepted accounting principles.

Because the Transitional CbCR Safe Harbour is intended to serve as a simplified proxy for determining whether the Tested Jurisdiction is likely to have an ETR that is at or above the minimum rate, the Treasury Department and the IRS are of the view that a foreign use exception for the Transitional CbCR Safe Harbour is not appropriate where, in the absence of the Transitional CbCR

Safe Harbour, a dual consolidated loss could be made available to reduce the amount of income subject to a Top-up Tax. In other words, the use of a loss or expense to qualify for the Transitional CbCR Safe Harbour, and thereby avoid tax that may otherwise be imposed under the GloBE Model Rules absent the application of the Transitional CbCR Safe Harbour, has the same double-deduction outcome effect as if the loss or expense were made available to directly reduce the tax. As a result, a foreign use may occur with respect to the application of the Transitional CbCR Safe Harbour. *See* proposed § 1.1503(d)–7(c)(3)(ii) for an example illustrating that duplicate loss arrangement rules may prevent such a foreign use.

Finally, one comment requested guidance that jurisdictional blending in a Tested Jurisdiction under the GloBE Model Rules does not constitute a foreign use of a dual consolidated loss if the Transitional CbCR Safe Harbour is satisfied in that Tested Jurisdiction after the application of the duplicate loss arrangement rules. This concern could arise because satisfying the Transitional CbCR Safe Harbour in a Tested Jurisdiction technically does not preclude the application of the GloBE Model Rules (and, thus, technically would not preclude a foreign use that could occur under the “made available” standard), but rather only deems the Jurisdictional Top-up Tax in the Tested Jurisdiction to be zero. Consistent with the guidance requested in this comment, the proposed regulations provide a limited foreign use exception under which there is deemed to be no foreign use with respect to the GloBE Model Rules where the Transitional CbCR Safe Harbour is satisfied and no foreign use occurs with respect to the Transitional CbCR Safe Harbour due to the application of the duplicate loss arrangement rules. *See* proposed § 1.1503(d)–3(c)(9). For the avoidance of doubt, however, this foreign use exception does not preclude a foreign use from occurring if the duplicate loss arrangement rules do not apply and a dual consolidated loss is taken into account in determining whether the Transitional CbCR Safe Harbour is satisfied.

4. Mirror Legislation

As discussed in part IV.C. of the Background section of this preamble, the December 2023 Administrative Guidance contains rules that disallow expenses for purposes of qualifying for the Transitional CbCR Safe Harbour if there is a duplicate loss arrangement. An arrangement qualifies as a duplicate loss arrangement, in relevant part, if an

¹⁶ *See, for example*, OECD/G20, Neutralising the Effects of Hybrid Mismatch Arrangements, Action 2: 2015 Final Report (October 2015) (“Hybrid Mismatch Report”), Part I recommendations, paragraph 13 (“While cross-border mismatches arise in other contexts (such as the payment of deductible interest to a tax exempt entity), the only types of mismatches targeted by this report are those that rely on a hybrid element to produce such outcomes.”).

expense or loss in the financial statements of a Constituent Entity also gives rise to a duplicate amount that is deductible in determining the taxable income of another Constituent Entity in another jurisdiction. Comments requested guidance as to whether the duplicate loss arrangement rules in the December 2023 Administrative Guidance constitute mirror legislation (within the meaning of § 1.1503(d)–3(e)(1)).

As discussed in part I.D of the Background section of this preamble, the taxpayer's ability to choose the jurisdiction in which a dual consolidated loss is used is a long-standing feature of the dual consolidated loss rules. The mirror legislation rule was issued to address situations where foreign legislation undermines the taxpayer's ability to choose by denying any opportunity for a foreign use of a particular dual consolidated loss and thereby compelling the taxpayer to make a domestic use election. However, not all forms of foreign law that deny the foreign use of deductions composing a dual consolidated loss are mirror legislation. *See* § 1.1503(d)–7(c)(18)(iii) for an example illustrating that a foreign law similar to the dual consolidated loss rules is not mirror legislation because it permits the loss to be used in that jurisdiction if the loss is not used in another jurisdiction.

The Treasury Department and the IRS are of the view that a taxpayer's ability to choose whether to put a dual consolidated loss to a domestic use or a foreign use can be preserved even if the foreign law does not explicitly provide an election to use the loss (like the dual consolidated loss rules) and instead only denies a loss to avoid a double-deduction outcome. The duplicate loss arrangement rules in the December 2023 Administrative Guidance preserve such a choice and thus do not constitute mirror legislation because a dual consolidated loss could be put to a foreign use for purposes of the Transitional CbCR Safe Harbour. That is, if no domestic use election is made with respect to a dual consolidated loss, then the loss is subject to the domestic use limitation, and the duplicate loss arrangement rules should not apply because the loss would not be deductible for purposes of determining the taxable income of another Constituent Entity in another jurisdiction. If, on the other hand, a domestic use election is made for a dual consolidated loss, then the loss would be put to a domestic use and the duplicate loss arrangement rules should prevent the expense or loss from being

taken into account for purposes of the Transitional CbCR Safe Harbour (that is, they should prevent a foreign use). Thus, through its ability to make or forgo a domestic use election, a taxpayer retains the choice to put a dual consolidated loss to a domestic use or a foreign use (but not both). For the same reason, the double-deduction rules included in the OECD report addressing hybrid and branch mismatch arrangements,¹⁷ which similarly deny the foreign use of a dual consolidated loss to the extent it is deductible in another jurisdiction, do not constitute mirror legislation.¹⁸ Accordingly, the proposed regulations clarify that foreign law that preserves a taxpayer's choice to put a dual consolidated loss to a domestic use or a foreign use (but not both) does not constitute mirror legislation, even if there are specific instances where the foreign law denies the foreign use of a deduction or expense to the extent necessary to prevent a double-deduction outcome. *See* proposed § 1.1503(d)–7(c)(18)(iv) for an example illustrating a foreign law that provides such a choice.

5. Transition Rules

As discussed in part IV.B of the Background section of this preamble, Notice 2023–80 announced that future regulations would be promulgated concerning legacy DCLs (that is, certain dual consolidated losses incurred before any legislation enacting the GloBE Model Rules is effective).

Several comments requested that the foreign use exception described in Notice 2023–80 be extended to include dual consolidated losses incurred in taxable years beginning after December 31, 2023 (for example, for taxable years ending on or before December 31, 2024, or taxable years beginning in the year

that final regulations concerning the applicability of the dual consolidated loss rules with respect to the QDMTT and IIR are issued). Comments asserted that the extension of the foreign use exception is warranted to provide certainty and to take into account further developments from the OECD, such as the possible future application of the duplicate loss arrangement rules outside the context of the Transitional CbCR Safe Harbour.

The Treasury Department and the IRS are of the view that it is appropriate to extend, for a limited period, relief from the application of the dual consolidated loss rules with respect to the GloBE Model Rules. This would provide taxpayers more certainty, allow for further consideration of these proposed regulations and comments that may be submitted, and allow for consideration of any future developments at the OECD. Extending the relief only for a limited period is intended to minimize the double-deduction outcomes that may result. Accordingly, and subject to an anti-abuse rule, these proposed regulations provide that the dual consolidated loss rules apply without taking into account QDMTTs or Top-up Taxes with respect to losses incurred in taxable years beginning before August 6, 2024. *See* proposed § 1.1503(d)–8(b)(12).

In addition to not being limited to legacy DCLs, this transition relief differs from the relief provided in Notice 2023–80 in that it applies beyond foreign use, applying with respect to all the dual consolidated loss rules (including foreign use). This broader relief is intended, in part, to relieve the administrative burden of having to file a domestic use election and annual certifications for dual consolidated losses that would otherwise qualify for the foreign use exception described in Notice 2023–80 (or for the additional relief provided under the proposed regulations). Further, this would prevent a loss from being subject to recapture as a result of a triggering event other than a foreign use, such as the failure to file an annual certification.

6. Interaction With Anti-Hybrid Rules

As noted in part IV.B of the Background section of this preamble, the Treasury Department and the IRS are studying the interaction of the GloBE Model Rules with the rules under sections 245A(e) and 267A and request comments in this regard. For example, the Treasury Department and the IRS are considering whether a foreign country's traditional income tax and a Top-up Tax with respect to the operations in the foreign country should be viewed as part of the same "tax laws"

¹⁷ *See* the Hybrid Mismatch Report; OECD/G20, Neutralising the Effects of Branch Mismatch Arrangements, Action 2: Inclusive Framework on BEPS (July 2017).

¹⁸ *See*, for example, New Zealand's Tax Information Bulletin, Vol. 31 No. 3 April 2019 at p. 50, which discusses New Zealand's deduction disallowance rules that are based on the double-deduction rules in the Hybrid Mismatch Report. In discussing the interaction of the New Zealand rules with the dual consolidated loss rules, the Bulletin provides:

Expenditure incurred by a US taxpayer, or a New Zealand hybrid entity which is deductible by a US owner, will not be subject to [New Zealand's deduction disallowance rules] so long as the US taxpayer is subject to the [dual consolidated loss] rules and has not made a domestic use election. If the US taxpayer has made a domestic use election, then [the New Zealand deduction disallowance rules] will apply to deny a deduction for the expenditure. That is because the domestic use election is an election that the [dual consolidated loss] rules do not apply to the US taxpayer in respect of the relevant expenditure.

of the country for purposes of section 267A.

E. Applicability Dates

Proposed § 1.1502–13(j)(10), relating to the interaction of the dual consolidated loss rules with the intercompany transaction regulations, is proposed to apply to taxable years for which the original Federal income tax return is due (without extensions) after the date that final regulations are published in the **Federal Register**. See proposed § 1.1502–13(l)(11). However, taxpayers may apply proposed § 1.1502–13(j)(10), once published in the **Federal Register** as final regulations, to an earlier taxable year that remains open, provided that the taxpayer and all members of its consolidated group apply the regulations consistently in that taxable year and each subsequent taxable year. See *id.*

The parenthetical in proposed § 1.1503(d)–1(c)(1)(ii), clarifying that a specified foreign tax resident that is a disregarded entity can be related to a domestic consenting corporation for purposes of § 1.1503(d)–1(c)(1)(ii), is proposed to apply to determinations relating to taxable years ending on or after August 6, 2024. See proposed § 1.1503(d)–8(b)(6).

Proposed § 1.1503(d)–5(b)(2)(iv) and (c)(4)(iv), relating to the attribution of items arising from ownership of stock, are proposed to apply to taxable years ending on or after August 6, 2024. See proposed § 1.1503(d)–8(b)(9).

The fourth and fifth sentences of proposed § 1.1503(d)–5(c)(3)(i), relating to the adjustments to conform to U.S. tax principles, are proposed to apply to taxable years ending on or after August 6, 2024. See proposed § 1.1503(d)–8(b)(10). As noted in part I.B.2 of this Explanation of Provisions, the proposed addition of these two sentences is intended merely to clarify the existing regulation for the avoidance of any doubt. The IRS may challenge contrary positions for taxable years ending before August 6, 2024 under the rules applicable to such taxable years.

Proposed § 1.1503(d)–8(b)(12), relating to the application of the dual consolidated loss rules without regard to QDMTTs or Top-up Taxes, applies with respect to losses incurred in taxable years beginning before August 6, 2024.

Proposed § 1.1503(d)–3(c)(9), relating to the foreign use exception for qualification for the Transitional CbCR Safe Harbour, is proposed to apply to taxable years beginning on or after August 6, 2024. See proposed § 1.1503(d)–8(b)(13).

Proposed §§ 1.1503(d)–1(b)(4)(i)(A)(2), 1.1503(d)–1(b)(4)(i)(B)(2), and 1.1503(d)–1(b)(4)(ii)(B)(2), relating to separate units arising as a result of a QDMTT or IIR, apply to taxable years beginning on or after August 6, 2024. See proposed § 1.1503(d)–8(b)(14).

Proposed § 1.1503(d)–1(f), relating to an anti-avoidance rule, is proposed to apply to taxable years ending on or after August 6, 2024. See proposed § 1.1503(d)–8(b)(15).

Proposed § 1.1503(d)–1(b)(6)(ii), relating to minimum taxes and taxes based on financial accounting principles, is proposed to apply to taxable years ending on or after August 6, 2024. See proposed § 1.1503(d)–8(b)(16).

A taxpayer may rely on these proposed regulations for any taxable year ending on or after August 6, 2024 and beginning on or before the date that regulations finalizing these proposed regulations are published in the **Federal Register**, provided that the taxpayer and all members of its consolidated group apply the proposed regulations in their entirety and in a consistent manner for all taxable years beginning with the first taxable year of reliance until the applicability date of those final regulations. In addition, a taxpayer may rely on the foreign use exception described in Notice 2023–80 for any taxable year ending on or after December 11, 2023 and before August 6, 2024, provided that the taxpayer and all members of its consolidated group apply those rules in their entirety and in a consistent manner for all taxable years beginning with the first taxable year of reliance until the applicability date of the final regulations on this topic.

II. Rules Regarding Disregarded Payment Losses

A. Overview

The preamble to the 2018 proposed regulations describes structures involving payments from foreign disregarded entities to their domestic corporate owners that are regarded for foreign tax purposes but disregarded for U.S. tax purposes. For foreign tax purposes, the payments give rise to a deduction or loss that, for example, can be surrendered (or otherwise used, such as through a consolidation regime) to offset non-dual inclusion income. The preamble notes that these structures are not addressed under the current section 1503(d) regulations but give rise to significant policy concerns that are similar to those arising under sections 245A(e), 267A, and 1503(d). In addition, the preamble states that the Treasury

Department and the IRS are studying these transactions and request comments.

In response to this request, a comment agreed that these structures can produce a deduction/no-inclusion (“D/Ni”) outcome. In a similar context, the comment asserted that arriving at the correct result would generally require, for U.S. tax purposes, disaggregating a disregarded payment into a regarded item of deduction and a regarded item of income, and taking such items into account for purposes of the dual consolidated loss rules to the extent reflected on the books and records of the entity. However, the comment did not recommend this approach due to complexity, noting, for example, that it would require tracking of transactions between a foreign disregarded entity and its domestic corporate owner, as well as determining the character and source of items that would not otherwise exist for U.S. tax purposes. To mitigate certain D/Ni outcomes, the comment recommended an alternative approach, which would track disregarded items only so as to offset regarded items, and thus not so as to create items of income and deduction. The comment conceded, however, that this approach would not address the paradigm structure involving only disregarded deductions that give rise to D/Ni outcomes and therefore would not address the policy concerns. The comment queried whether it might be better for the dual consolidated loss rules not to apply, with the expectation that the foreign jurisdiction could, in some cases, eliminate D/Ni outcomes by denying the foreign tax deduction.

The Treasury Department and the IRS are of the view that treating items otherwise disregarded for U.S. tax purposes as regarded could give rise to considerable complexity, and that the alternative approach recommended by the comment would not address the paradigm structure, and therefore would not sufficiently address the policy concerns underlying these structures. Accordingly, neither of these approaches is adopted. However, the Treasury Department and the IRS are not of the view that these structures should be addressed only to the extent of applicable foreign tax rules addressing D/Ni outcomes; in the absence of a foreign tax rule denying a foreign tax deduction, these structures would continue to give rise to the significant policy concerns noted above. In addition, the OECD/G20 recommends defensive rules that require income inclusions to neutralize D/Ni outcomes. See, for example, Hybrid Mismatch

Report Recommendations 1.1(b) and 3.1(b).

Accordingly, the proposed regulations address these structures through the entity classification rules under section 7701 and the dual consolidated loss rules under section 1503(d), in a manner that is consistent with the “domestic consenting corporation” approach under §§ 301.7701–3(c)(3) and 1.1503(d)–1(c) addressing domestic reverse hybrids. Under this approach, when certain eligible entities (“specified eligible entities”) are treated as disregarded entities for U.S. tax purposes, a domestic corporation that acquires, or on the effective date of the election directly or indirectly owns, interests in such a specified eligible entity consents to be subject to the rules of proposed § 1.1503(d)–1(d). *See* proposed § 301.7701–3(c)(4)(i).

Pursuant to these rules (the “disregarded payment loss” rules), and as further discussed in part II.B. of this Explanation of Provisions, the domestic corporation agrees that it will monitor a net loss of the entity under a foreign tax law that is composed of certain payments that are disregarded for U.S. tax purposes and, if a D/Ni outcome occurs as to the loss, include in gross income an amount equal to the loss. *See* proposed § 1.1503(d)–1(d)(1). The Treasury Department and the IRS are of the view that the domestic corporation’s inclusion of the amount in gross income generally neutralizes the D/Ni outcome, and places the parties in approximately the same position in which they would have been had the specified eligible entity not been permitted to be classified as a disregarded entity. In addition, the Treasury Department and the IRS are of the view that this approach is more administrable than alternative approaches, such as disaggregating each disregarded payment into a regarded item of deduction and income, or, upon a D/Ni outcome as to the loss, terminating the specified eligible entity’s classification retroactive to the taxable year in which the loss was incurred. These alternative approaches would have the same effect of giving rise to an item of income to the domestic corporation because the payment would be regarded.

The proposed regulations also include a deemed consent rule pursuant to which, beginning on the date that is twelve months after the date that the disregarded payment loss rules are applicable, a domestic corporation that directly or indirectly owns interests in a specified eligible entity is deemed to consent to be subject to the rules, to the extent it has not otherwise so consented. *See* proposed § 301.7701–3(c)(4)(iii) and

(vi). This default rule is intended to reflect the result that taxpayers would be expected to favor (for example, to avoid the various income inclusion rules that would typically apply upon the conversion of a hybrid entity to a foreign corporation). However, the deemed consent can be avoided if the specified eligible entity elects to be treated as an association.¹⁹ *See* proposed § 301.7701–3(c)(4)(iv). Further, the twelve-month delay for deemed consent provides an opportunity to restructure existing arrangements to avoid the application of the disregarded payment loss rules without changing the classification of a specified eligible entity.

B. Consequences of Consent

1. In General

When a domestic corporation consents to be subject to the disregarded payment loss rules, the domestic corporation agrees that if the specified eligible entity (described below) incurs a disregarded payment loss during a certification period (discussed in section II.B.3 of this Explanation of Provisions) and a triggering event occurs with respect to that loss, then the domestic corporation will include in gross income the DPL inclusion amount. *See* proposed § 1.1503(d)–1(d)(1)(i). These rules also apply to a disregarded payment loss of a foreign branch of the domestic corporation because disregarded payments from the domestic corporation to the specified eligible entity may, under the branch’s tax law, be attributable to, and deductible by, the branch and thus could produce a D/Ni outcome (for example, if the branch surrendered the loss to a foreign corporation). *See id.*

In general, a specified eligible entity is an entity that, when classified as a disregarded entity, could pay or receive amounts that could give rise to a D/Ni outcome by reason of being disregarded for U.S. tax purposes but deductible for foreign tax purposes. Thus, a specified eligible entity includes an eligible entity (regardless of whether domestic or foreign) that is a foreign tax resident (which, in the case of a domestic eligible entity, may occur, for example, if the entity is managed and controlled in a foreign country), because amounts paid by such an entity may be disregarded for U.S. tax purposes but deductible for foreign tax purposes. *See* proposed § 301.7701–3(c)(4)(i).

¹⁹ The deemed consent rule could also be avoided by restructuring such that the rule would not apply, for example, by contributing the interests in the specified eligible entity to a foreign corporation or by converting the entity into a partnership.

2. Disregarded Payment Loss Computation

A disregarded payment loss with respect to a specified eligible entity or a foreign branch (in either case, a “disregarded payment entity,” and the domestic corporation that consents to be subject to the disregarded payment loss rules, the “specified domestic owner” of the disregarded payment entity) is computed for each foreign taxable year of the entity. *See* proposed § 1.1503(d)–1(d)(6)(ii). The disregarded payment loss generally measures the entity’s net loss, if any, for foreign tax purposes that is composed of certain payments that are disregarded for U.S. tax purposes as transactions between the disregarded payment entity and its tax owner (for example, a payment by the disregarded payment entity to the specified domestic owner or to another disregarded payment entity of the specified domestic owner), or as a transaction between a foreign branch and its home office (for example, a payment by the foreign branch to a disregarded entity of the specified domestic owner). *See id.* That is, it generally measures the entity’s net loss that, but for the disregarded payment loss rules, could produce a D/Ni outcome. For example, if for a foreign taxable year a disregarded payment entity’s only items are a \$100x interest deduction and \$70x of royalty income, and if each item were disregarded for U.S. tax purposes as a payment between a disregarded entity and its tax owner (but taken into account under foreign law), then the entity would have a \$30x disregarded payment loss for the taxable year.

In general, the items of deduction taken into account for purposes of computing a disregarded payment loss include any item that is deductible under the relevant foreign tax law, is disregarded for U.S. tax purposes and, if regarded for U.S. tax purposes, would be interest, a structured payment, or a royalty within the meaning of § 1.267A–5(a)(12), (b)(5)(ii), or (a)(16), respectively. *See* proposed § 1.1503(d)–1(d)(6)(ii)(C). Similar rules apply for determining items of income that offset the items of income for purposes of determining a disregarded payment loss. *See* proposed § 1.1503(d)–1(d)(6)(ii)(D). The Treasury Department and the IRS are of the view that defining a duplicated payment loss in this manner tailors the application of the rules to arrangements that are likely structured to produce a D/Ni outcome. Moreover, this approach is consistent with the scope of section 267A. In addition, only items generated or incurred during a

period in which an interest in the disregarded payment entity is a separate unit are taken into account. *See* proposed § 1.1503(d)–1(d)(6)(ii). In other words, items generally are taken into account only to the extent they would be subject to the dual consolidated loss rules but for the items being disregarded for U.S. tax purposes. Thus, for example, if a domestic corporation becomes a dual resident corporation as a result of changing its place of management, disregarded payments made to or from a domestic disregarded entity held by the domestic corporation are not taken into account in computing a disregarded payment loss to the extent such payments gave rise to a deduction under the relevant foreign law before the domestic corporation was a dual resident corporation subject to the dual consolidated loss rules.

The rules for computing a disregarded payment loss therefore differ in certain respects from comparable rules applicable for purposes of computing a dual consolidated loss. For example, the latter rules do not take into account the deductibility of an item under a foreign tax law and are not limited to interest, structured payments, or royalties. *See* § 1.1503(d)–5(b) through (d).

3. Triggering Events

In general, the specified domestic owner must include in gross income the DPL inclusion amount with respect to a disregarded payment loss if either of two triggering events occurs with respect to the loss during a certification period (the “DPL certification period”). *See* proposed § 1.1503(d)–1(d)(2)(i). The DPL certification period includes the foreign taxable year in which the disregarded payment loss is incurred, any prior foreign taxable year, and the subsequent 60-month period. *See* proposed § 1.1503(d)–1(d)(6)(iii); *but see* proposed 1.1503(d)–1(d)(7)(iii) (terminating the certification period upon a sale of the disregarded payment entity). This proposed definition is consistent with the certification period under the dual consolidated loss rules, which is revised to include at least the 60-month period following the year in which the dual consolidated loss is incurred, as well as all taxable years (unlike the disregarded payment loss rules, as determined under U.S. tax law) before the taxable year in which a dual consolidated loss is incurred. *See* proposed § 1.1503(d)–1(b)(20).

The two triggering events are based on certain principles of the dual consolidated loss rules. *See* proposed § 1.1503(d)–1(d)(3). The first triggering event addresses likely D/NI outcomes—

that is, a foreign use of the disregarded payment loss (determined by taking into account the exceptions described in § 1.1503(d)–3(c)).²⁰ *See* proposed § 1.1503(d)–1(d)(3)(i). However, for purposes of determining whether a foreign use occurs (and unlike the approach under the dual consolidated loss rules), only persons that are related to the specified domestic owner are taken into account. *See id.* This limitation is intended to minimize triggering events resulting from transactions that are not tax motivated, such as a foreign use resulting from the sale of a disregarded payment entity to an unrelated person, yet still deter arrangements structured to produce D/NI outcomes that typically involve related parties. Thus, for example, a foreign use triggering event occurs if, under a foreign tax law, a deduction taken into account in computing the disregarded payment loss is made available (including by reason of a foreign consolidation regime or similar regime, or a sale, merger, or similar transaction) to offset an item of income that, for U.S. tax purposes, is an item of a foreign corporation, but only if that foreign corporation is related to the specified domestic owner of the disregarded payment entity.

The second triggering event is a failure by the specified domestic owner to comply with certification requirements. *See* proposed § 1.1503(d)–1(d)(3)(ii). In general, the specified domestic owner must, for the foreign taxable year in which a disregarded payment loss is incurred, and for each subsequent taxable year within the DPL certification period, file a statement providing information about the disregarded payment loss of such entity and certifying that a foreign use of the disregarded payment loss has not occurred. *See* proposed § 1.1503(d)–1(d)(4). Relief is available for a failure to properly comply with the certification requirements. *See* proposed § 1.1503(d)–1(e).

For simplicity purposes, the proposed regulations include fewer triggering events than the dual consolidated loss rules. For example, the disregarded payment loss triggering events do not include specific triggering events related to the transfer of assets of, or interests in, a disregarded payment entity.

²⁰ Because an expense resulting from an Intragroup Financing Arrangement is generally excluded from the calculation of a Low-Tax Entity's GloBE Income or loss if there is no commensurate increase in the taxable income of the High-Tax Counterparty, a disregarded payment loss (that is, a payment that generally does not increase U.S. taxable income) should generally not be put to a foreign use as a result of jurisdictional blending under the GloBE Model Rules.

Nevertheless, the scope of the disregarded payment loss triggering events is, in general, consistent with that of the dual consolidated loss triggering events because a foreign use triggering event typically occurs, or will occur, in connection with other dual consolidated loss triggering events that are not rebutted. For example, the transfer of all the interests in a disregarded entity by its domestic owner to a related and wholly owned foreign corporation would constitute a triggering event described in § 1.1503(d)–6(e)(1)(v) (transfer of 50 percent or more of an interest in a separate unit). However, such a transfer would also typically give rise to a foreign use triggering event described in § 1.1503(d)–6(e)(1)(i) because a portion of a deduction or loss taken into account in computing the dual consolidated loss would generally carry over under foreign law following the transfer and thus be made available to offset or reduce an item that is recognized as income or gain under foreign law and that is, or would be, considered under U.S. tax principles to be an item of a foreign corporation. *See* § 1.1503(d)–3(a)(1). Many of these non-foreign use dual consolidated loss triggering events are intended to heighten awareness that certain transactions or events are likely to give rise to a foreign use, which results in a double-deduction outcome, and therefore serve to increase compliance with the rules. Because D/NI outcomes from disregarded payment losses involve only related parties and typically are highly-structured, however, the Treasury Department and the IRS are of the view that the foreign use and certification triggering events are sufficient for purposes of the disregarded payment loss rules.

4. DPL Inclusion Amount

In general, the DPL inclusion amount is, with respect to a disregarded payment loss as to which a triggering event occurs during the DPL certification period, the amount of the disregarded payment loss. *See* proposed § 1.1503(d)–1(d)(2)(i). For U.S. tax purposes, the DPL inclusion amount is treated as ordinary income and characterized in the same manner as if the amount were interest or royalty income paid by a foreign corporation. *See* proposed § 1.1503(d)–1(d)(2)(ii).

In certain cases, the DPL inclusion amount is reduced by the positive balance, if any, of the “DPL cumulative register” with respect to the disregarded payment entity. *See* proposed § 1.1503(d)–1(d)(5)(i). The DPL cumulative register is similar to the cumulative register for dual

consolidated loss purposes, and generally reflects each disregarded payment loss or amount of “disregarded payment income” of a disregarded payment entity. *See* § 1.1503(d)–1(d)(5)(ii). Disregarded payment income is computed in a manner similar to that of computing a disregarded payment loss, and measures a disregarded payment entity’s net income, if any, for a foreign taxable year that is composed of certain disregarded payments attributable to interest, structured payments, or royalties. *See* proposed § 1.1503(d)–1(d)(6)(ii). Taking into account whether there is sufficient cumulative register to absorb a disregarded payment loss is intended to ensure that the DPL inclusion amount represents only the portion of the disregarded payment loss that is available to be put to a foreign use under the foreign tax law. For example, if a disregarded payment entity incurs a \$100x disregarded payment loss in year 1 and has \$80x of disregarded payment income in year 2, only \$20x of the disregarded payment loss is likely available under the foreign tax law to be put to a foreign use. As such, if a triggering event occurs at the end of year 2, then the specified domestic owner must include in gross income \$20x (rather than the entire \$100x of the disregarded payment loss).

5. Disregarded Payment Entity Combination Rule

Similar to the dual consolidated loss rules, the proposed regulations include a rule pursuant to which disregarded payment entities for which the relevant foreign tax law is the same (“individual disregarded payment entities”) are generally combined and treated as a single disregarded payment entity (“combined disregarded payment entity”) for purposes of the disregarded payment loss rules. *See* proposed § 1.1503(d)–1(d)(7)(i); *see also* § 1.1503(d)–1(b)(4)(ii) (combined separate unit rule for dual consolidated loss purposes). Accordingly, for a foreign taxable year, only a single amount of disregarded payment income or a single disregarded payment loss exists with respect to the combined disregarded payment entity. This amount is computed by first determining the disregarded payment income or loss with respect to each of the individual disregarded payment entities and then aggregating such amounts.

This combination rule is intended to prevent the application of the disregarded payment loss rules to cases in which, taking into account the overall effect of disregarded payments under a

foreign tax law, there is not an opportunity for a disregarded payment loss of an individual disregarded payment entity to produce a D/Ni outcome. For example, assume USP, a domestic corporation, wholly owns DE1X, which wholly owns DE2X, and each of DE1X and DE2X is a disregarded payment entity tax resident in Country X. Further assume that, computed on a separate basis during a foreign taxable year, DE1X has a \$100x disregarded payment loss (consisting solely of a \$100x payment by DE1X to DE2X), and DE2X has \$100x of disregarded payment income (consisting solely of the \$100x payment received by DE2X from DE1X). Absent the combination rule, the specified domestic owner of DE1X would be required to monitor DE1X’s disregarded payment loss and annually certify that no foreign use has occurred with respect to the loss. However, taking into account the overall effect of the payment under Country X law, there is likely to be no net loss attributable to the payment and, as a result, there likely is not an opportunity for the payment to give rise to a D/Ni outcome. The combination rule thus limits the application of the disregarded payment loss rules to cases in which it is likely that disregarded payments could give rise to a D/Ni outcome.

6. Application to Dual Resident Corporations

The proposed regulations include special rules pursuant to which the disregarded payment loss rules also apply to dual resident corporations, because a disregarded payment by a dual resident corporation to its disregarded entity could also give rise to a D/Ni outcome (for example, if the dual resident corporation surrenders the loss to a foreign corporation). Thus, pursuant to the consent rules described in part II.A of this Explanation of Provisions, a dual resident corporation that directly or indirectly owns interests in an eligible entity that is classified as a disregarded entity agrees, for purposes of the disregarded payment loss rules, to be treated as a disregarded payment entity and as a specified owner of such disregarded payment entity. *See* proposed §§ 1.1503(d)–1(d)(1)(ii) and 301.7701–3(c)(4)(ii).

C. Interaction With Dual Consolidated Loss Rules

Although the disregarded payment loss rules address similar policy concerns as, and rely on certain aspects of, the existing dual consolidated loss rules, the Treasury Department and the IRS are of the view that integrating the two regimes would result in

considerable complexity and administrative burden. For example, integrating the regimes could require rules pursuant to which a disregarded payment entity’s deduction under a foreign tax law for a disregarded payment is considered to in part offset the entity’s items of regarded income (which would have the effect of increasing a dual consolidated loss, relative to not taking into account the payment for purposes of the dual consolidated loss rules) and to in part offset the entity’s items of income that are disregarded for U.S. tax purposes (which would have the effect of decreasing a disregarded payment loss, relative to only taking into account the payment for purposes of the disregarded payment loss rules).

The disregarded payment loss rules therefore operate independently of the dual consolidated loss rules. Thus, for example, only items that are regarded for U.S. tax purposes are taken into account in computing a dual consolidated loss (or cumulative register), and only items that are disregarded for U.S. tax purposes are taken into account in computing a disregarded payment loss (or DPL cumulative register). In addition, a disregarded payment entity may have both a dual consolidated loss and a disregarded payment loss for the same taxable year, and both of these items could be triggered by a single event (such as a foreign use pursuant to a foreign loss surrender regime); in contrast, a foreign use could be avoided both for a dual consolidated loss and disregarded payment loss of the same disregarded payment entity if, for example, an election is required to enable a foreign use and no such election is made.

As discussed in part I.B of the Background section of this preamble, the dual consolidated loss rules do not take into account disregarded transactions (that typically are regarded for foreign tax purposes) for purposes of attributing items to a separate unit or an interest in a transparent entity. This approach, which minimizes the need for additional complex rules, can result in both the over- and under-application of the dual consolidated loss rules as compared to more precise rules that would take into account such items to the extent necessary to neutralize double-deduction outcomes. Thus, the decision to ignore disregarded transactions in the dual consolidated loss rules for this purpose reflects a balance of policy and administrability. In other contexts, various policy objectives have required giving effect to certain disregarded transactions. *See, for*

example, § 1.904–4(f)(2)(vi) (attributing gross income to a foreign branch) and § 1.951A–2(c)(7)(ii)(B)(2) (determining gross income for purposes of applying the high-tax exception). The Treasury Department and the IRS are of the view that, in light of the policies underlying the enactment of sections 245A(e), 267A, and 1503(d), the disregarded payment loss rules are another case where it is necessary to take into account disregarded transactions; the absence of such rules would otherwise permit taxpayers to continue to implement structures involving such payments to obtain D/NI outcomes. The Treasury Department and the IRS will continue to study the treatment of disregarded items for purposes of the dual consolidated loss rules, including whether it may be appropriate to take into account items of disregarded income, gain, deduction or loss in other cases.

D. Applicability Date

The proposed rules relating to consent to be subject to the disregarded payment loss rules are proposed to apply to entity classification elections filed on or after August 6, 2024 (regardless of whether the election is effective before August 6, 2024). See proposed § 301.7701–3(c)(4)(vi)(A). The proposed rule relating to deemed consent is proposed to apply on or after August 6, 2025. See proposed § 301.7701–3(c)(4)(vi)(B). The proposed rules relating to disregarded payment losses are proposed to apply to taxable years ending on or after August 6, 2024. See proposed § 1.1503(d)–8(b)(11).

Conforming Amendments to Other Regulations

The Treasury Department and the IRS intend to make conforming amendments to the regulations under section 1503(d), including with respect to examples, upon finalization of the proposed regulations.

Special Analyses

I. Regulatory Planning and Review

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

II. Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) (“PRA”) requires that a Federal agency obtain the approval of the OMB before collecting

information from the public, whether such collection of information is mandatory, voluntary, or required to obtain or retain a benefit. Section 1.1503(d)–1(d)(4) of these proposed regulations requires the collection of information.

As discussed in part II.B of this Explanation of Provisions, the proposed regulations require certain taxpayers to certify that no foreign use has occurred with respect to a disregarded payment loss. The IRS will use this information to determine the extent to which these taxpayers need to recognize income under the proposed regulations.

The reporting burden associated with this collection of information will be reflected in the PRA submissions associated with Form 1120 (OMB control number 1545–0123). The Treasury Department and the IRS do not have readily available data to determine the number of taxpayers affected by this collection of information because no reporting module currently identifies these types of disregarded payments. The Treasury Department and the IRS request comments on all aspects of information collection burdens related to the proposed regulations, including ways for the IRS to minimize the paperwork burden.

III. Regulatory Flexibility Act

When an agency issues a rulemaking proposal, the Regulatory Flexibility Act (5 U.S.C. chapter 6) (“RFA”) requires the agency to prepare and make available for public comment an initial regulatory flexibility analysis that will describe the impact of the proposed rule on small entities. See 5 U.S.C. 603(a). Section 605 of the RFA provides an exception to this requirement if the agency certifies that the proposed rulemaking will not have a significant economic impact on a substantial number of small entities. A small entity is defined as a small business, small nonprofit organization, or small governmental jurisdiction. See 5 U.S.C. 601(3) through (6).

The Treasury Department and the IRS do not expect that the proposed dual consolidated loss regulations described in parts I.A, I.B, and I.C of the Explanation of Provisions will have a significant economic impact on a substantial number of small entities because those regulations refine computations under the current dual consolidated loss regulations without changing the economic impact of the current regulations. Further, the Treasury Department and the IRS do not expect the proposed dual consolidated loss regulations described in parts I.D.1 through I.D.6 of the Explanation of

Provisions will have a significant economic impact on a substantial number of small entities because they provide exceptions and other rules that limit the application of the current dual consolidated loss regulations. However, because there is a possibility of significant economic impact on a substantial number of small entities, an initial regulatory flexibility analysis for the regulation is provided below. The Treasury Department and the IRS request comments from the public on the number of small entities that may be impacted and whether that impact will be economically significant.

A. Reasons Why Action Is Being Considered

The proposed dual consolidated loss regulations described in parts I.A through I.D of the Explanation of Provisions address potential uncertainty, and refine or adjust certain computations, under current law. In addition, the proposed dual consolidated loss regulations provide limited exceptions to the application of the dual consolidated loss rules where not inconsistent with the general policy underlying those rules. As a result, this portion of the proposed regulations increases the precision of the dual consolidated loss regulations and reduces inappropriate planning opportunities.

As explained in part II.A of the Explanation of Provisions, the proposed disregarded payment loss regulations address certain hybrid payments that can give rise to deduction/no-inclusion outcomes.

B. Objectives of, and Legal Basis for, the Proposed Regulations

The proposed regulations described in parts I.A, I.B, I.C, I.D.1, I.D.2, and I.D.4 of the Explanation of Provisions address potential uncertainty, and refine or adjust certain computations, under the current dual consolidated loss regulations. The proposed dual consolidated loss regulations described in parts I.D.3 and I.D.5 of the Explanation of Provisions limit the application of the current dual consolidated loss regulations. The proposed disregarded payment loss regulations described in part II of the Explanation of Provisions require an income inclusion for U.S. tax purposes to eliminate the deduction/no-inclusion outcome that would otherwise arise from certain hybrid payments. The legal basis for these regulations is contained in sections 1502, 1503(d), 7701, and 7805.

C. Small Entities to Which These Regulations Will Apply

Because an estimate of the number of small businesses affected is not currently feasible, this initial regulatory flexibility analysis assumes that a substantial number of small businesses will be affected. The Treasury Department and the IRS do not expect that these proposed regulations will affect a substantial number of small nonprofit organizations or small governmental jurisdictions.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements

The proposed dual consolidated loss regulations do not impose additional reporting or recordkeeping obligations. The proposed disregarded payment loss regulations impose a certification requirement that is filed with a domestic corporation's tax return.

E. Duplicate, Overlapping, or Relevant Federal Rules

These proposed regulations would replace portions of the dual consolidated loss regulations. The Treasury Department and the IRS are not aware of any Federal rules that duplicate, overlap, or conflict with these proposed regulations.

F. Alternatives Considered

The Treasury Department and the IRS did not consider any significant alternative to the proposed dual consolidated loss regulations. The proposed regulations described in parts I.A, I.B, I.C, I.D.1, I.D.2, and I.D.4 of the Explanation of Provisions simply address potential uncertainty, or refine or adjust certain computations, under current law. The proposed regulations described in parts I.D.3 and I.D.5 of the Explanation of Provisions limit the application of the dual consolidated loss regulations. As a result, the proposed dual consolidated loss regulations do not impose an additional economic burden and, consequently, the regulations represent the approach with the least economic impact.

As discussed in part II.A of the Explanation of Provisions, the proposed disregarded payment loss regulations address policy concerns that are similar to the concerns underlying the enactment of sections 245A(e), 267A, and 1503(d). Sections 245A, 267A, and 1503(d) apply uniformly to large and small business entities, and the Treasury Department and the IRS are of the view that the proposed disregarded payment loss regulations should generally apply without regard to the size of the corporation—a small business exception would undermine

the anti-hybridity policies underlying these regulations. Accordingly, there is no viable alternative to the proposed regulations for small entities.

Pursuant to section 7805(f) of the Code, the proposed regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses. The Treasury Department and the IRS also request comments from the public on the analysis in part III of the Special Analyses.

IV. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (“UMRA”) requires that agencies assess anticipated costs and benefits and take certain other actions before issuing a final rule that includes any Federal mandate that may result in expenditures in any one year by a State, local, or Tribal government, in the aggregate, or by the private sector, of \$100 million in 1995 dollars, updated annually for inflation. The proposed rules do not include any Federal mandate that may result in expenditures by State, local, or Tribal governments, or by the private sector in excess of that threshold.

V. Executive Order 13132: Federalism

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

Incorporation by Reference

Sections 1.1503(d)–1(b)(4)(i)(A)(2), (b)(4)(i)(B)(2), (b)(4)(ii)(B)(2), and (b)(21), and §§ 1.1503(d)–3(c)(9), 1.1503(d)–7(b)(16) and (c)(3), and 1.1503(d)–8(b)(12) of these proposed regulations use terminology based on their definitions under the GloBE Model Rules and the GloBE Model Rules Consolidated Commentary. The Office of the Federal Register has regulations concerning incorporation by reference. 1 CFR part 51. These regulations require that agencies must discuss in the preamble to a rule or proposed rule the way in which materials that the agency incorporates by reference are reasonably available to interested persons, and how

interested parties can obtain the materials. 1 CFR 51.5(b).

The GloBE Model Rules and Administrative Guidance addressing Hybrid Arbitrage Arrangements are discussed in Part IV of the Background section of this preamble. The GloBE Model Rules and the GloBE Model Rules Consolidated Commentary were issued by the OECD on December 20, 2021, and April 25, 2024, respectively, and are available at www.oecd.org/tax/beps/tax-challenges-arising-from-the-digitalisation-of-the-economy-global-anti-base-erosion-model-rules-pillar-two.htm. The Administrative Guidance was issued on December 15, 2023, and is available at www.oecd.org/tax/beps/administrative-guidance-global-anti-base-erosion-rules-pillar-two-june-2024.pdf.

Comments and Requests for Public Hearing

Before these proposed amendments to the final regulations are adopted as final regulations, consideration will be given to comments that are submitted timely to the IRS as prescribed in this preamble under the **ADDRESSES** heading. In addition to the comments specifically requested in the Explanation of Provisions, the Treasury Department and the IRS request comments on all other aspects of the proposed regulations. Any comments submitted will be made available at <https://www.regulations.gov> or upon request.

A public hearing will be scheduled if requested in writing by any person who timely submits electronic or written comments. Requests for a public hearing are also encouraged to be made electronically. If a public hearing is scheduled, notice of the date and time for the public hearing will be published in the **Federal Register**.

Drafting Information

The principal authors of these regulations are Andrew L. Wigmore of the Office of Associate Chief Counsel (International) and Julie Wang of the Office of Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in their development.

Statement of Availability of IRS Documents

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

List of Subjects**26 CFR Part 1**

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, the Treasury Department and the IRS propose to amend 26 CFR parts 1 and 301 as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by removing the

entry for section 1.1503(d) and adding entries for sections 1.1503(d)–1 through 1.1503(d)–8 in numerical order to read as follows:

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

Sections 1.1503(d)–1 through 8 also issued under 26 U.S.C. 953(d), 26 U.S.C. 1502, 26 U.S.C. 1503(d), 26 U.S.C. 1503(d)(2)(B), 26 U.S.C. 1503(d)(3), and 26 U.S.C. 1503(d)(4).

■ **Par. 2.** Section 1.1502–13, as proposed to be amended at 88 FR 52057 (August 7, 2023) and at 88 FR 78134 (November 14, 2023), is further amended by:

■ 1. In paragraph (a)(6)(ii) in the table revising the entry “(G) Miscellaneous operating rules”.

■ 2. In paragraph (c)(5), adding the language “See paragraph (j)(10) of this

section for rules regarding the special status of a section 1503(d) member.” after the last sentence.

■ 3. Redesignating paragraph (j)(10) as paragraph (j)(15).

■ 4. Adding new paragraph (j)(10).

■ 5. Adding and reserving paragraphs (j)(11) through (14).

■ 6. Adding paragraphs (j)(15)(x) and (xi), and (l)(11).

The additions and revision read as follows:

§ 1.1502–13 Intercompany transactions.

(a) * * *

(6) * * *

(ii) * * *

Rule	General location	Paragraph	Example
(G) Miscellaneous operating rules..	§ 1.1502–13(j)(15) ..	(i)	Example 1. Intercompany sale followed by section 351 transfer to member.
		(ii)	Example 2. Intercompany sale of member stock followed by recapitalization.
		(iii)	Example 3. Back-to-back intercompany transactions—matching.
		(iv)	Example 4. Back-to-back intercompany transactions—acceleration.
		(v)	Example 5. Successor group.
		(vi)	Example 6. Liquidation—80% distributee.
		(vii)	Example 7. Liquidation—no 80% distributee.
		(viii)	Example 8. Loan by section 987 QBU.
		(ix)	Example 9. Sale of property by section 987 QBU.
		(x)	Example 10. Interest on intercompany obligation.
		(xi)	Example 11. Loss of a section 1503(d) member.

* * * * *

(j) * * *

(10) *Dual consolidated loss rules*—(i) *Scope.* The rules of this paragraph (j)(10) apply to an intercompany transaction if either party to the transaction is a section 1503(d) member. A *section 1503(d) member* is a member that is—

(A) An affiliated dual resident corporation (as defined in § 1.1503(d)–1(b)(10)); or

(B) An affiliated domestic owner (as defined in § 1.1503(d)–1(b)(10)) acting through a separate unit (as defined in § 1.1503(d)–1(b)(4)) that is not regarded as separate from the domestic owner for Federal income tax purposes.

(ii) *Ordering rule for the section 1503(d) member.* In determining when the section 1503(d) member's intercompany (or corresponding) item is taken into account, the dual consolidated loss rules under section 1503(d) and the regulations thereunder (the *dual consolidated loss rules*) do not apply to the relevant item until that item would otherwise be taken into

account under paragraph (c) or (d) of this section.

(iii) *Status as a section 1503(d) member.* A section 1503(d) member has special status under paragraph (c)(5) of this section with respect to its intercompany (or corresponding) items for purposes of applying the dual consolidated loss rules to those items. Therefore, for purposes of applying the dual consolidated loss rules, paragraph (c)(1)(i) of this section does not apply to redetermine the attributes of the section 1503(d) member's intercompany (or corresponding) items.

(iv) *Application of the matching rule to the counterparty member.* The special status of a section 1503(d) member does not affect the application of the matching rule in paragraph (c) of this section (or under paragraph (d) of this section, to the extent the matching rule principles are applicable) to the counterparty member in an intercompany transaction. For example, assume S sells depreciable property to B (a section 1503(d) member) at a gain, and the property is also subject to depreciation in the hands of B. For

purposes of taking into account S's items, the matching rule applies as if B were not a section 1503(d) member. Therefore, even if B's annual depreciation deduction on the acquired property is limited under the dual consolidated loss rules and not currently deductible, S nevertheless takes into account a portion of its intercompany gain pursuant to the matching rule every year as if B were entitled to deduct the additional depreciation resulting from the intercompany sale.

* * * * *

(15) * * *

(x) *Example 10. Interest on intercompany obligation*—(A) *Facts.* S lends money to B, an affiliated dual resident corporation (a section 1503(d) member), with \$10 of interest due annually for Year 1 through Year 5. For the years at issue, B has a dual consolidated loss (within the meaning of § 1.1503(d)–1(b)(5)(ii)) with respect to which it makes a domestic use election (within the meaning of § 1.1503(d)–6(d)).

(B) *Analysis*—(1) *Interest expense deduction of the section 1503(d) member.* For each year at issue, B has \$10 of interest expense deduction. Under paragraph

(j)(10)(ii) of this section, the matching rule in paragraph (c) of this section applies first (before the dual consolidated loss rules) to determine if B's deduction is taken into account. Pursuant to paragraph (c)(2)(i) of this section, B would take its \$10 of interest deduction into account annually. Therefore, the amount of B's dual consolidated loss in each year reflects the \$10 of interest expense.

(2) *Interest income of the counterparty member.* For each year at issue, S has \$10 of interest income. Although B has a dual consolidated loss for each year at issue, B makes a domestic use election and deducts the \$10 of interest expense annually. Under the matching rule in paragraph (c) of this section, for each year, S takes into account its \$10 of interest income to match B's \$10 of interest deduction.

(C) *Treatment for counterparty member when deduction is deferred.* The facts are the same as in paragraph (j)(15)(x)(A) of this section, except that for the years at issue, B's interest expense deduction would be limited under the domestic use limitation rule of § 1.1503(d)–4(b) (and no exception under § 1.1503(d)–6 applies) and is not currently deductible for the years at issue. Under paragraph (j)(10)(iv) of this section, the matching rule applies to S (the counterparty member) as if B did not have section 1503(d) member status. Therefore, for the purpose of determining S's income inclusion, B is treated as deducting \$10 of interest expense per year. Thus, S's interest income is not redetermined to be deferred, even though B's interest expense deduction is deferred under the dual consolidated loss rules.

(D) *Treatment for counterparty member when a dual consolidated loss is recaptured.* The facts are the same as in paragraph (j)(15)(x)(A) of this section, with B making a domestic use election (within the meaning of § 1.1503(d)–6(d)) in Year 1 and deducting \$10 of interest expense in Year 1. Then in Year 2, B is required under § 1.1503(d)–6(e) to recapture and report as ordinary income \$10 (plus applicable interest) with respect to the \$10 of interest expense incurred in Year 1. Because the matching rule applies to S (the counterparty member) as if B did not have its section 1503(d) member status, the recapture of B's Year 1 dual consolidated loss will not affect the treatment of S's intercompany interest income. See paragraph (j)(10)(iv) of this section.

(E) *Intercompany obligation involving an affiliated domestic owner.* The facts are the same as in paragraph (j)(15)(x)(A) of this section, except that B is an affiliated domestic owner with respect to a directly owned foreign branch separate unit, S lends money to this separate unit of B, and the \$10 of interest expense, when it is taken into account under the section 1503(d) rules, would be attributable to B's foreign branch separate unit for the years at issue. The analysis and treatment of S's intercompany item and B's corresponding item (attributable to the separate unit) are the same as in paragraphs (j)(15)(x)(B), (C), and (D) of this section. However, if B does not act through its separate unit in entering the intercompany loan with S, the rules of paragraph (j)(10) of this section do not apply. See paragraph (j)(10)(i) of this section.

(xi) *Example 11. Loss of a section 1503(d) member—(A) Facts.* S is an affiliated dual resident corporation (a section 1503(d) member). S owns inventory with a basis of \$100. In Year 1, S sells the inventory to B for \$60. In Year 3, B sells the inventory to X for \$110. For the years at issue, S's \$40 of loss is subject to the domestic use limitation rule of § 1.1503(d)–4(b) (and no exception under § 1.1503(d)–6 applies) and would not be currently deductible.

(B) *Analysis—(1) Year 1 and Year 2: timing.* S recognizes \$40 of loss on the intercompany inventory sale to B. Pursuant to the ordering rule in paragraph (j)(10)(ii) of this section, in each year, the matching rule in paragraph (c) of this section applies first to determine whether S's loss is taken into account. In Year 1 and Year 2, because the \$40 of loss is deferred under the matching rule, no amount of loss from the sale is subject to the dual consolidated loss rules in those years.

(2) *Year 3: timing and attributes.* In Year 3, B sells the inventory to X for \$110, for a \$50 gain. Consequently, under the matching rule (disregarding the application of section 1503(d)), S's \$40 of loss would be taken into account in that year. Since S's item would otherwise be taken into account, the section 1503(d) rules are applicable to the \$40 loss in Year 3, and the loss would be subject to the domestic use limitation under § 1.1503(d)–4(b) and would not be currently deductible. The application of § 1.1503(d)–4(b) to limit S's loss is not subject to redetermination under paragraph (c)(1)(i) of this section, because S has special status. See paragraph (j)(10)(iii) of this section. Moreover, B's gain is taken into account in Year 3, without regard to S's status as a section 1503(d) member. See paragraph (j)(10)(iv) of this section.

(C) *Intercompany transaction involving a separate unit of an affiliated domestic owner.* The facts are the same as in paragraph (j)(15)(xi)(A) of this section, except that S is an affiliated domestic owner with respect to a directly owned foreign branch separate unit, and S acts through the foreign branch separate unit in selling the inventory to B such that the loss on the inventory, when it is taken into account under the section 1503(d) rules, would be attributable to S's foreign branch separate unit. The analysis and treatment of S's intercompany item (attributable to the foreign branch separate unit) and B's corresponding item are the same as in paragraphs (j)(15)(xi)(B)(1) and (2) of this section.

* * * * *

(l) * * *

(11) *Applicability date.* Paragraph (j)(10) of this section applies to taxable years for which the original Federal income tax return is due (without extensions) after [DATE OF PUBLICATION OF THE FINAL REGULATIONS IN THE FEDERAL REGISTER]. However, taxpayers may choose to apply these provisions to an earlier taxable year, if the period for the assessment of tax for that taxable year has not expired, provided the taxpayer

and all members of its consolidated group apply these provisions consistently for that taxable year and each subsequent taxable year.

* * * * *

■ **Par. 3.** Section 1.1503(d)–1 is amended by:

- 1. Revising the section heading.
- 2. Revising the third sentence in paragraph (a) and adding three new sentences at the end.
- 3. Revising paragraphs (b)(4)(i) and (ii), and (b)(6).
- 4. In the second sentence of paragraph (b)(16)(i), removing the language “An entity” and adding the language “Other than an entity described in paragraph (b)(4)(i)(B)(2) of this section, an entity” in its place.
- 5. In paragraph (b)(20),
 - a. Adding the language “(not less than 60 months)” after “time”; and
 - b. Adding the language “, as well as any prior taxable years” after “incurred” at the end of the sentence.
- 6. Adding paragraph (b)(21).
- 7. In paragraph (c)(1)(ii), adding the language “(including, in the case of a specified foreign tax resident that under §§ 301.7701–1 through 301.7701–3 of this chapter is disregarded as an entity separate from its owner for U.S. tax purposes, by reason of its tax owner bearing)” after the language “bears.”
- 8. Redesignating paragraph (d) as paragraph (e).
- 9. Adding paragraphs (d) and (f).

The revisions and additions read as follows:

§ 1.1503(d)–1 Definitions, special rules, and filings.

(a) * * * Paragraph (c) of this section provides rules for a domestic consenting corporation. Paragraph (d) of this section provides rules for disregarded payment losses. Paragraph (e) of this section provides relief for certain compliance failures due to reasonable cause and a signature requirement for filings. Paragraph (f) of this section provides an anti-avoidance rule.

(b) * * *

(4) * * *

(i) *In general.* The term *separate unit* means either a foreign branch separate unit or a hybrid entity separate unit.

(A) *Foreign branch separate unit.* The term *foreign branch separate unit* means either of the following that is carried on, directly or indirectly, by a domestic corporation (including a dual resident corporation):

(1) Except to the extent provided in paragraph (b)(4)(iii) of this section, a business operation outside the United States that, if carried on by a U.S. person, would constitute a foreign branch as defined in § 1.367(a)–6T(g)(1).

(2) A place of business (including a deemed place of business) outside the United States that is a Permanent Establishment with respect to a QDMTT or an IIR, provided that the Permanent Establishment is not otherwise described in paragraph (b)(4)(i)(A)(1) of this section.

(B) *Hybrid entity separate unit.* The term *hybrid entity separate unit* means either of the following that is owned, directly or indirectly, by a domestic corporation (including a dual resident corporation):

(1) An interest in a hybrid entity; and

(2) An interest in a foreign entity (other than a Tax Transparent Entity with respect to an IIR) that is not taxed as an association for Federal tax purposes and the net income or loss of which is taken into account in determining the amount of tax under an IIR, provided that the interest is not otherwise described in paragraph (b)(4)(i)(B)(1) of this section. See § 1.1503(d)–7(c)(3)(iii) for an example illustrating the application of this rule.

(ii) *Separate unit combination rule—*(A) *In general.* Except as otherwise provided in paragraph (b)(4)(ii)(B) of this section, if a domestic owner, or two or more domestic owners that are members of the same consolidated group, have two or more separate units (individual separate units), then all such individual separate units that are located (in the case of a foreign branch separate unit or a hybrid entity separate unit described in paragraph (b)(4)(i)(B)(2) of this section) or subject to an income tax either on their worldwide income or on a residence basis (in the case of a hybrid entity interest in which is a hybrid entity separate unit described in paragraph (b)(4)(i)(B)(1) of this section) in the same foreign country are treated as one separate unit (combined separate unit). See § 1.1503(d)–7(c)(1) for an example illustrating the application of this paragraph (b)(4)(ii)(A). Except as specifically provided in this section or §§ 1.1503(d)–2 through 1.1503(d)–8, any individual separate unit composing a combined separate unit loses its character as an individual separate unit.

(B) *Special rules—*(1) *Certain dual resident corporations.* Separate units of a foreign insurance company that is a dual resident corporation under paragraph (b)(2)(ii) of this section are not combined with separate units of any other domestic corporation.

(2) *Location of separate units arising from a QDMTT or an IIR.* For purposes of paragraph (b)(4)(ii)(A) of this section, a separate unit described in paragraph (b)(4)(i)(A)(2) or (b)(4)(i)(B)(2) of this section is located in the country in

which it is located for purposes of the relevant QDMTT or IIR. If such place of business or entity is not located in a specific jurisdiction (for example, because the entity is a stateless entity for purposes of an IIR), the individual separate unit is not combined with any other separate units. See § 1.1503(d)–7(c)(3)(iii) for an example illustrating the application of this paragraph (b)(4)(ii)(B)(2).

* * * * *

(6) *Tax determination—*(i) *Subject to tax.* For purposes of determining whether a domestic corporation or another entity is subject to an income tax of a foreign country on its income, the fact that it has no actual income tax liability to the foreign country for a particular taxable year shall not be taken into account.

(ii) *Minimum taxes and taxes computed by reference to financial accounting principles.* For purposes of section 1503(d) and the regulations in this part issued under section 1503(d), the determination of whether a tax is an income tax is made without regard to whether the tax is intended to ensure a minimum level of taxation on income or computes income or loss by reference to financial accounting net income or loss.

* * * * *

(21) *Pillar Two terminology.* Qualified Domestic Minimum Top-up Tax (QDMTT), Income Inclusion Rule (IIR), and any other capitalized terms that are used in connection with or are otherwise relevant to a minimum tax based on a QDMTT or IIR have the same meaning ascribed to such terms under the material listed in paragraphs (b)(21)(i) through (iii) of this section. These materials are incorporated by reference into §§ 1.1503(d)–1 through 1.1503(d)–8 with the approval of the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. This material is available for inspection at the IRS and at the National Archives and Records Administration (NARA). Contact the IRS at: IRS FOIA Request, Headquarters Disclosure Office, CL:GLD:D, 1111 Constitution Avenue NW, Washington, DC 20224; phone: +1 312 292 3297; website: <https://foiapublicaccessportal.for.irs.gov/app/Home.aspx>. 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. This material may be obtained from the Organisation for Economic Co-operation and Development (OECD) at: 2, rue André Pascal, 75016 Paris; phone: +33 1 45 24 82 00; website: www.oecd.org/tax/beps/tax-challenges-arising-from-the-digitalisation-of-the-economy-global-anti-base-erosion-model-rules-pillar-two.htm.

digitalisation-of-the-economy-global-anti-base-erosion-model-rules-pillar-two.htm.

(i) OECD (2021), *Tax Challenges Arising from the Digitalisation of the Economy—Global Anti-Base Erosion Model Rules (Pillar Two): Inclusive Framework on BEPS*, OECD, Paris, December 20, 2021. (Available at www.oecd.org/tax/beps/tax-challenges-arising-from-the-digitalisation-of-the-economy-global-anti-base-erosion-model-rules-pillar-two.htm.)

(ii) OECD (2024), *Tax Challenges Arising from the Digitalisation of the Economy—Consolidated Commentary to the Global Anti-Base Erosion Model Rules (2023): Inclusive Framework on BEPS*, OECD/G20 Base Erosion and Profit Shifting Project, OECD Publishing, Paris, April 23, 2024. (Available at <https://doi.org/10.1787/b849f926-en>.)

(iii) OECD (2024), *Tax Challenges Arising from the Digitalisation of the Economy—Administrative Guidance on the Global Anti-Base Erosion Model Rules (Pillar Two)*, June 2024, OECD/G20 Inclusive Framework on BEPS, OECD, Paris, December 15, 2023. (Available at www.oecd.org/tax/beps/administrative/guidance/global-anti-base-erosion-rules-pillar-two-june-2024.pdf.)

* * * * *

(d) *Disregarded payment loss rules—*(1) *Consequences of consent—*(i) *In general.* As provided in § 301.7701–3(c)(4)(i) of this chapter, a domestic corporation that directly or indirectly owns interests in a specified eligible entity (as defined in § 301.7701–3(c)(4)(i) of this chapter) classified as a disregarded entity consents to be subject to the disregarded payment loss rules of this paragraph (d). Pursuant to such consent, the domestic corporation agrees that if the specified eligible entity or a foreign branch of the domestic corporation (the specified eligible entity or such a foreign branch, a *disregarded payment entity*, and the domestic corporation, a *specified domestic owner*) incurs a disregarded payment loss (other than a disregarded payment loss described in paragraph (d)(7)(iii) of this section) and a triggering event occurs with respect to the disregarded payment loss during the DPL certification period, then, for the taxable year of the specified domestic owner during which the triggering event occurs, the specified domestic owner includes in gross income the DPL inclusion amount. See § 1.1503(d)–7(c)(42) for an example illustrating the application of the disregarded payment loss rules.

(ii) *Special rule regarding dual resident corporations.* As provided in

§ 301.7701–3(c)(4)(ii) of this chapter, a dual resident corporation that directly or indirectly owns an interest in an eligible entity classified as a disregarded entity consents to be subject to the disregarded payment loss rules of this paragraph (d). Pursuant to such consent, the dual resident corporation agrees, for purposes of this paragraph (d), to be treated as a disregarded payment entity and as a specified domestic owner of such disregarded payment entity. In such a case, if the dual resident corporation has disregarded payment income or a disregarded payment loss for a foreign taxable year, then with respect to a disregarded payment loss, it generally must comply with the certification requirements of paragraph (d)(4) of this section and, upon a triggering event, include in gross income an amount equal to the DPL inclusion amount.

(2) *DPL inclusion amount*—(i) *In general.* A DPL inclusion amount means, with respect to a disregarded payment loss as to which a triggering event occurs during the DPL certification period, an amount equal to the disregarded payment loss (or, if applicable, the reduced amount, as described in paragraph (d)(5)(i) of this section).

(ii) *Character and source.* A DPL inclusion amount is, for U.S. tax purposes, treated as ordinary income, and characterized, including for purposes of sections 904(d) and 907, in the same manner as if the amount were interest or royalty income paid by a foreign corporation (taking into account, for example, section 904(d)(3) if such foreign corporation would be a controlled foreign corporation). For these purposes, the DPL inclusion amount is considered comprised of interest or royalty income based on the proportion of interest or royalty deductions taken into account, respectively, in computing the disregarded payment loss relative to all the deductions taken into account in computing the disregarded payment loss.

(iii) *Translation into U.S. dollars.* A DPL inclusion amount is translated into U.S. dollars (if necessary) using the yearly average exchange rate (within the meaning of § 1.987–1(c)(2)) for the taxable year of the specified domestic owner during which the triggering event occurs.

(3) *Triggering events.* An event described in paragraph (d)(3)(i) or (ii) of this section is a triggering event with respect to a disregarded payment loss of a disregarded payment entity.

(i) *Foreign use.* A foreign use of the disregarded payment loss. For this

purpose, a foreign use is determined under the principles of § 1.1503(d)–3 (including the exceptions in § 1.1503(d)–3(c)), by treating the disregarded payment loss as a dual consolidated loss, treating the disregarded payment entity as a separate unit (or, in the case of a disregarded payment entity that is a dual resident corporation, by treating the disregarded payment entity as a dual resident corporation), and, in § 1.1503(d)–3(a)(1)(i) and (ii), only taking into account a person that is related to the specified domestic owner of the disregarded payment entity. Thus, for example, a foreign use of a disregarded payment loss occurs if, under a relevant foreign tax law, any portion of a deduction taken into account in computing the disregarded payment loss is made available (including by reason of a foreign consolidation regime or similar regime, or a sale, merger, or similar transaction) to offset an item of income that, for U.S. tax purposes, is an item of a foreign corporation, but only if such foreign corporation is related to the specified domestic owner of the disregarded payment entity.

(ii) *Failure to comply with certification requirements.* A failure by the specified domestic owner of the disregarded payment entity to comply with the certification requirements of paragraph (d)(4) of this section.

(4) *Certification requirements.* Except as otherwise provided in publications, forms, instructions, or other guidance, a specified domestic owner of a disregarded payment entity must satisfy the certification requirements of this paragraph (d)(4) with respect to a disregarded payment loss of the disregarded payment entity, other than a disregarded payment loss described in paragraph (d)(7)(iii) of this section. To satisfy the certification requirements, the specified domestic owner must meet the requirements in paragraphs (d)(4)(i) and (ii) of this section.

(i) For its taxable year that includes the date on which the foreign taxable year in which the disregarded payment loss is incurred ends, the specified domestic owner must attach with its timely filed tax return a certification labeled “Initial Disregarded Payment Loss Certification,” which must contain—

(A) The information set forth in § 1.1503(d)–6(c)(2)(ii) (determined by substituting the phrase “disregarded payment entity” for the phrase “separate unit”);

(B) A statement of the amount of the disregarded payment loss; and

(C) A statement that a foreign use of the disregarded payment loss has not

occurred during the DPL certification period.

(ii) During the DPL certification period, for each of its subsequent taxable years that includes a date on which a foreign taxable year ends, the specified domestic owner must attach with its timely filed tax return a certification labeled “Annual Disregarded Payment Loss Certification” and satisfying the requirements of this paragraph (d)(4)(ii). Certifications with respect to multiple disregarded payment losses may be combined in a single certification, but each disregarded payment loss must be separately identified. To satisfy the requirements of this paragraph (d)(4)(ii), the certification must—

(A) Identify the disregarded payment loss to which it pertains by setting forth the foreign taxable year in which the disregarded payment loss was incurred and the amount of such loss;

(B) State that there has been no foreign use of the disregarded payment loss; and

(C) Warrant that arrangements have been made to ensure that there will be no foreign use of the disregarded payment loss and that the specified domestic owner will be informed of any such foreign use.

(5) *Reduction of DPL inclusion amount in certain cases.* With respect to a disregarded payment loss as to which a triggering event occurs during the DPL certification period, the following rules apply:

(i) The *reduced amount* means the excess (if any) of the disregarded payment loss over the positive balance (if any) of the DPL cumulative register with respect to the disregarded payment entity, computed as of the end of the foreign taxable year during which the triggering event occurs but not taking into account the disregarded payment loss. If during a taxable year of a specified domestic owner a triggering event occurs as to multiple disregarded payment losses of a disregarded payment entity of the specified domestic owner (each such loss, a *triggered loss*), then, when computing the DPL cumulative register for purposes of determining the reduced amount with respect to a triggered loss incurred in an earlier foreign taxable year, a triggered loss incurred in a later foreign taxable year is not taken into account.

(ii) The term *DPL cumulative register* means, with respect to the disregarded payment entity, an account the balance of which is computed at the end of each foreign taxable year of the entity, and which (except as provided in paragraph (d)(5)(i) of this section) is increased by

disregarded payment income of the entity for the taxable year or decreased by a disregarded payment loss of the entity for the foreign taxable year. The account balance may be positive or negative.

(iii) The reduced amount must be demonstrated to the satisfaction of the Commissioner. To so demonstrate, the specified domestic owner of the disregarded payment entity must attach a statement labeled “Reduction of Disregarded Payment Loss Amount” to the income tax return for the taxable year in which the triggering event occurs and provide any other information as requested by the Commissioner. The statement must show the disregarded payment income or disregarded payment loss of the disregarded payment entity for each foreign taxable year up to and including the foreign taxable year during which the triggering event occurs.

(6) *Definitions.* The following definitions apply for purposes of this paragraph (d).

(i) The term *disregarded payment entity* has the meaning set forth in paragraph (d)(1)(i) of this section, and includes a dual resident corporation treated as a disregarded payment entity pursuant to paragraph (d)(1)(ii) of this section.

(ii) The terms *disregarded payment income* and *disregarded payment loss* have the meanings set forth in this paragraph (d)(6)(ii). For purposes of computing the disregarded payment income or disregarded payment loss of a disregarded payment entity, an item is taken into account only if it gives rise to income or a deduction under the relevant foreign tax law during a period in which an interest in the disregarded payment entity is a separate unit (or the disregarded payment entity is a dual resident corporation); for purposes of allocating an item to a period, the principles of § 1.1502-76(b) apply. Items taken into account in computing disregarded payment income or disregarded payment loss are calculated in the currency used to determine tax under the relevant foreign tax law.

(A) *Disregarded payment income.* Disregarded payment income means, with respect to a disregarded payment entity and a foreign taxable year of the entity, the excess (if any) of the sum of the items described in paragraph (d)(6)(ii)(D) of this section over the sum of the items described in paragraph (d)(6)(ii)(C) of this section.

(B) *Disregarded payment loss.* Disregarded payment loss means, with respect to a disregarded payment entity and a foreign taxable year of the entity, the excess (if any) of the sum of the

items described in paragraph (d)(6)(ii)(C) of this section over the sum of the items described in paragraph (d)(6)(ii)(D) of this section.

(C) *Items of deduction.* With respect to a disregarded payment entity and a foreign taxable year of the entity, an item is described in this paragraph (d)(6)(ii)(C) to the extent that it satisfies the requirements set forth in paragraphs (d)(6)(ii)(C)(1) through (3) of this section. In addition, an item is described in this paragraph (d)(6)(ii)(C) if, under the relevant foreign tax law, it is a deduction with respect to equity (including deemed equity) allowed to the entity in such taxable year (for example, a notional interest deduction) or a deduction for an imputed interest payment with respect to a debt instrument (such as a deduction for an imputed interest payment with respect to an interest-free loan).

(1) Under the relevant foreign tax law, the entity is allowed a deduction in such taxable year for the item.

(2) The payment, accrual, or other transaction giving rise to the item is disregarded for U.S. tax purposes as a transaction between a disregarded entity and its tax owner (for example, a payment by a disregarded entity to its tax owner or to another disregarded entity held by its tax owner, or a payment from a dual resident corporation to its disregarded entity) or as a transaction between a foreign branch and its home office (for example, a payment attributable to a foreign branch to a disregarded entity of its home office).

(3) If the payment, accrual, or other transaction were regarded for U.S. tax purposes, it would be interest, a structured payment, or a royalty within the meaning of § 1.267A-5(a)(12), (b)(5)(ii), or (a)(16), respectively.

(D) *Items of income.* With respect to a disregarded payment entity and a foreign taxable year of the entity, an item is described in this paragraph (d)(6)(ii)(D) to the extent that it satisfies the requirements set forth in paragraphs (d)(6)(ii)(D)(1) through (3) of this section.

(1) Under the relevant foreign tax law, the entity includes the item in income in such taxable year.

(2) The payment, accrual, or other transaction giving rise to the item is disregarded for U.S. tax purposes as a transaction between a disregarded entity and its tax owner (for example, because it is a payment to a disregarded entity from the disregarded entity's tax owner or from another disregarded entity held by its tax owner, or a payment to a dual resident corporation from its disregarded entity) or as a transaction

between a foreign branch and its home office (for example, a payment to a foreign branch by a disregarded entity of its home office).

(3) If the payment, accrual, or other transaction were regarded for U.S. tax purposes, it would be interest, a structured payment, or a royalty with the meaning of § 1.267A-5(a)(12), (b)(5)(ii), or (a)(16), respectively.

(iii) The term *DPL certification period* includes, with respect to a disregarded payment loss, the foreign taxable year in which the disregarded payment loss is incurred, any prior foreign taxable years, and, except as provided in paragraph (d)(7)(iv) of this section, the 60-month period following the foreign taxable year in which the disregarded payment loss is incurred.

(iv) The term *foreign branch* means a branch (within the meaning of § 1.267A-5(a)(2)) that gives rise to a taxable presence under the tax law of the foreign country where the branch is located.

(v) The term *foreign taxable year* means, with respect to a disregarded payment entity, the entity's taxable year for purposes of a relevant foreign tax law.

(vi) The term *related* has the meaning provided in this paragraph (d)(6)(vi). A person is related to a specified domestic owner if the person is a related person within the meaning of section 954(d)(3) and the regulations thereunder, determined by treating the specified domestic owner as the “controlled foreign corporation” referred to in that section.

(vii) The term *relevant foreign tax law* means, with respect to a disregarded payment entity, any tax law of a foreign country of which the entity is a tax resident (within the meaning of § 1.267A-5(a)(23)(i)) or, in the case of a disregarded payment entity that is a foreign branch, the tax law of the foreign country where the branch is located.

(viii) The term *specified domestic owner* has the meaning provided in paragraph (d)(1)(i) of this section, and includes a dual resident corporation treated as a specified domestic owner pursuant to paragraph (d)(1)(ii) of this section and any successor to the corporation described in either of those paragraphs.

(7) *Special rules—(i) Disregarded payment entity combination rule.* For purposes of this paragraph (d), disregarded payment entities for which the relevant foreign tax law is the same (for example, because the entities are tax residents of the same foreign country) are combined and treated as a combined disregarded payment entity under the principles of paragraph (b)(4)(ii) of this

section, provided that the entities have the same foreign taxable year and are owned either by the same specified domestic owner or by specified domestic owners that are members of the same consolidated group. However, this paragraph (d)(7)(i) does not apply with respect to a dual resident corporation treated as a disregarded payment entity pursuant to paragraph (d)(1)(ii) of this section. In determining the disregarded payment income or disregarded payment loss of a combined disregarded payment entity, the principles of § 1.1503(d)–5(c)(4)(ii) apply. Thus, for example, if multiple individual disregarded payment entities are treated as a combined disregarded payment entity pursuant to this paragraph (d)(7)(i), then the combined disregarded payment entity has either a single amount of disregarded payment income or a single amount of disregarded payment loss.

(ii) *Partial ownership of disregarded payment entity.* If a specified domestic owner of a disregarded payment entity indirectly owns less than all the interests in the entity (for example, if the specified domestic owner and another person are partners in a partnership that owns all the interests in the entity), then the rules of this paragraph (d) are applied on a proportionate basis as to the specified domestic owner, based on the percentage of interests (by value) of the disregarded payment entity that the specified domestic owner directly or indirectly owns. In such a case, as to the specified domestic owner, only a proportionate share of the disregarded payment entity's items of deduction or income are taken into account in computing disregarded payment income or disregarded payment loss of the entity. In addition, with respect to the disregarded payment loss as so computed, the specified domestic owner generally must comply with the certification requirements of paragraph (d)(4) of this section and, upon a triggering event, directly include in gross income an amount equal to the DPL inclusion amount.

(iii) *Termination of DPL certification period.* With respect to a disregarded payment loss of a disregarded payment entity, the DPL certification period does not include any date after the end of the specified domestic owner's taxable year during which the specified domestic owner, or a person related to the specified domestic owner, no longer holds directly or indirectly any of the interests in, or, in the case of a disregarded payment entity that is a foreign branch, substantially all of the assets of the foreign branch. In such a

case, the specified domestic owner ceases to be subject to the rules of paragraph (d)(1) of this section with respect to the disregarded payment loss; thus, for example, beyond the end of such taxable year the specified domestic owner is not subject to the certification requirements of paragraph (d)(4)(ii) of this section with respect to the loss, and will not be required to include in gross income the DPL inclusion amount with respect to such loss.

(iv) *Common parent as agent for specified domestic owner.* If a specified domestic owner is a member, but not the common parent, of a consolidated group, then the common parent is the agent of the specified domestic owner under § 1.1502–77(a)(1). Thus, for example, the common parent must attach to its tax return any certification or statement required or permitted to be filed pursuant to this paragraph (d), and references in this paragraph (d) to a timely-filed tax return of the specified domestic owner include a timely-filed tax return of the consolidated group.

(v) *Coordination with foreign hybrid mismatch rules.* Whether a disregarded payment entity is allowed a deduction under a relevant foreign tax law is determined with regard to hybrid mismatch rules, if any, under the relevant foreign tax law. Thus, for example, if a relevant foreign tax law denies a deduction for an item to prevent a deduction/no-inclusion outcome (that is, a payment that is deductible for the payer jurisdiction and is not included in the ordinary income of the payee), the item is not taken into account for purposes of computing the amount of disregarded payment income or disregarded payment loss. For this purpose, the term *hybrid mismatch rules* has the meaning provided in § 1.267A–5(b)(10).

(vi) *DPL inclusion amount not taken into account for dual consolidated loss purposes.* A DPL inclusion amount included in the gross income of a dual resident corporation or a domestic owner of a separate unit is not taken into account for purposes of determining the income or dual consolidated loss of the dual resident corporation, or the income or dual consolidated loss attributable to the separate unit, under § 1.1503(d)–5(b) or (c).

(f) *Anti-avoidance rule.* If a transaction, series of transactions, plan, or arrangement is engaged in with a view to avoid the purposes of section 1503(d) and the regulations in this part issued under section 1503(d), then appropriate adjustments will be made.

A transaction, series of transactions, plan, or arrangement (including an arrangement to reflect, or not reflect, items on books and records) engaged in with a view to avoid the purposes of section 1503(d) and the regulations issued in this part under section 1503(d) includes one engaged in with a view to reduce or eliminate a dual consolidated loss or a disregarded payment loss while putting an item of deduction or loss that composes (or would compose) the dual consolidated loss or disregarded payment loss to a foreign use (determined under § 1.1503(d)–3 or the principles thereof). Such appropriate adjustments may include adjustments to disregard the transaction, series of transactions, plan, or arrangement, or adjustments to modify the items that are taken into account for purposes of determining the income or dual consolidated loss of or attributable to a dual resident corporation or a separate unit, or for purposes of determining income or loss of an interest in a transparent entity under § 1.1503(d)–5. See § 1.1503(d)–7(c)(43) for an example illustrating the application of this paragraph (f).

* * * * *

■ **Par. 4.** Section 1.1503(d)–3 is amended by:

■ **1.** In paragraph (c)(1), removing the language “Paragraphs (c)(2) through (9)” and adding the language “Paragraphs (c)(2) through (10)” in its place.

■ **2.** Redesignating paragraph (c)(9) as paragraph (c)(10) and adding a new paragraph (c)(9).

The addition reads as follows:

§ 1.1503(d)–3 Foreign use.

* * * * *

(c) * * *

(9) *Qualification for Transitional CbCR Safe Harbour.* This paragraph (c)(9) applies with respect to a dual consolidated loss incurred in a taxable year in a Tested Jurisdiction where the Transitional CbCR Safe Harbour is satisfied (such that the Jurisdictional Top-up Tax in that jurisdiction is deemed to be zero for that taxable year), and no foreign use occurs with respect to the Transitional CbCR Safe Harbour due to the application of rules addressing Duplicate Loss Arrangements. In such a case, no foreign use is considered to occur with respect to that dual consolidated loss solely because any portion of the deductions or losses that compose the dual consolidated loss is taken into account in determining the Net GloBE Income in that jurisdiction for that taxable year. See § 1.1503(d)–7(c)(3)(ii)(C) for an

example illustrating the application of this paragraph (c)(9).

* * * * *

■ **Par. 5.** Section 1.1503(d)–5 is amended by:

■ 1. In paragraph (b)(1):

■ a. Adding the language “(including the special rules under § 1.1502–13(j)(10) concerning the treatment of intercompany (or corresponding) items (as defined in § 1.1502–13(b)(2) and (3))” in the second sentence after the language “1502.”

■ b. Adding a sentence after the second sentence.

■ 2. Removing the language “the following shall not be taken into account—” from the introductory text of paragraph (b)(2) and adding the language “any item described in paragraphs (b)(2)(i) through (iv) is not taken into account.” in its place.

■ 3. Revising paragraphs (b)(2)(i) through (iii).

■ 4. Adding paragraph (b)(2)(iv).

■ 5. In paragraph (c)(1)(i):

■ a. Adding the language “(including the special rules under § 1.1502–13(j)(10) concerning the treatment of intercompany (or corresponding) items (as defined in § 1.1502–13(b)(2) and (3)) attributable to a separate unit” in the second sentence after the language “1502.”

■ b. Adding a sentence after the second sentence.

■ 6. Adding two sentences after the third sentence of paragraph (c)(3)(i).

■ 7. Revising paragraph (c)(4)(iv).

The revisions and additions read as follows:

§ 1.1503(d)–5 Attribution of items and basis adjustments.

* * * * *

(b) * * *

(1) * * * For examples illustrating the interaction of the intercompany transaction rules in § 1.1502–13 with the dual consolidated loss rules, see § 1.1502–13(j)(15)(x) and (xi). * * *

(2) * * *

(i) *Net capital loss.* An item described in this paragraph (b)(2)(i) is any net capital loss of the dual resident corporation.

(ii) *Carryover or carryback loss.* An item described in this paragraph (b)(2)(ii) is any carryover or carryback loss.

(iii) *Item attributable to a separate unit or transparent entity.* An item described in this paragraph (b)(2)(iii) is any item of income, gain, deduction, or loss that is attributable to a separate unit or an interest in a transparent entity of the dual resident corporation.

(iv) *Items arising from ownership of stock—(A) In general.* Except as

provided in paragraph (b)(2)(iv)(B) of this section, an item described in this paragraph (b)(2)(iv)(A) is an amount that the dual resident corporation takes into account in its gross income as a result of ownership of stock in a corporation (including as a result of a sale or other disposition), as well as any deduction or loss with respect to such amount. Thus, for example (and except as provided in paragraph (b)(2)(iv)(B) of this section), an item described in this paragraph (b)(2)(iv)(A) includes gain recognized on the sale or exchange of stock, a dividend (including an amount under section 78), a deduction allowed under section 245A(a) with respect to a dividend, an amount included in gross income under section 951 or 951A, foreign currency gain or loss under section 986(c), and a deduction allowed under section 250(a)(1)(B) with respect to an inclusion under section 951A.

(B) *Exception for portfolio stock.* Paragraph (b)(2)(iv)(A) of this section does not apply to a dividend received by the dual resident corporation from a corporation, any other amount that the dual resident corporation includes in its gross income as a result of ownership of stock in a corporation, or any deduction with respect to either such amount, if the dual resident corporation owns less than ten percent of the sum of the value of all classes of stock of the corporation. For purposes of the preceding sentence, the percentage of stock owned by the dual resident corporation is determined as of the beginning of the taxable year of the dual resident corporation in which it receives the dividend, includes in gross income another amount as a result of ownership of stock, or claims a deduction with respect to the dividend or inclusion in gross income, and by applying the rules of section 318(a) (except that in applying section 318(a)(2)(C), the phrase “ten percent” is used instead of the phrase “50 percent”).

(c) * * *

(1) * * *

(i) * * * For examples illustrating the interaction of the intercompany transaction rules in § 1.1502–13 with the dual consolidated loss rules, see § 1.1502–13(j)(15)(x) and (xi). * * *

* * * * *

(3) * * *

(i) * * * For this purpose, an adjustment to conform to U.S. tax principles does not include the attribution to a hybrid entity separate unit or an interest in a transparent entity of any items that have not and will not be reflected on the books and records of the hybrid entity or transparent entity; for example, items that are reflected on

the books and records of the domestic owner cannot be attributed to a hybrid entity separate unit or an interest in a transparent entity as a result of disregarded payments made between the domestic owner and the hybrid entity or transparent entity. See § 1.1503(d)–5(c)(1)(ii) (providing that items reflected on the books and records of the hybrid entity or transparent entity are eliminated if they are otherwise disregarded for U.S. tax purposes). See also § 1.1503(d)–7(c)(6) and (c)(23) through (25) for examples illustrating the application of this paragraph (c)(3)(i). * * *

(4) * * *

(iv) *Items arising from ownership of stock—(A) In general.* Except as provided in paragraph (c)(4)(iv)(B) of this section, for purposes of determining the items of income, gain, deduction, and loss of a domestic owner that are attributable to a separate unit or an interest in a transparent entity, any amount that the domestic owner includes in gross income as a result of ownership of stock in a corporation (including as a result of a sale or other disposition), as well as any deduction or loss with respect to such an amount, is not taken into account. Thus, for example (and except as provided in paragraph (c)(4)(iv)(B) of this section), gain recognized by a domestic owner on the sale or exchange of stock is not attributable to a separate unit of the domestic owner; in addition, neither a dividend received by a domestic owner (including an amount under section 78), nor any deduction allowed under section 245A(a) with respect to a dividend, is attributable to a separate unit of the domestic owner; further, neither an amount included in gross income by a domestic owner under section 951 or 951A, foreign currency gain or loss under section 986(c), nor any deduction under section 250(a)(1)(B) with respect to an inclusion under section 951A, is attributable to a separate unit of the domestic owner. See § 1.1503(d)–7(c)(24) for an example illustrating the application of this paragraph (c)(4)(iv)(A).

(B) *Exception for portfolio stock.* Paragraph (c)(4)(iv)(A) of this section does not apply to a dividend received by a domestic owner from a corporation, any other amount that is included in gross income by the domestic owner as a result of ownership of stock in a corporation, or any deduction with respect to either such amount, if the domestic owner owns less than ten percent of the sum of the value of all classes of stock of the corporation. For purposes of the preceding sentence, the percentage of stock owned by the

domestic owner is determined as of the beginning of the taxable year of the domestic owner in which it receives the dividend or includes in gross income the other amount, and by applying the rules of section 318(a) (except that in applying section 318(a)(2)(C), the phrase “ten percent” is used instead of the phrase “50 percent”).

(C) *Additional rules for portfolio stock.* For purposes of determining the items of income, gain, deduction, and loss of a domestic owner that are attributable to a separate unit or an interest in a transparent entity—

(1) The amount of a dividend described in paragraph (c)(4)(iv)(B) of this section that is taken into account is equal to the amount of the dividend less the amount of any deduction with respect to the dividend; and

(2) Any other amount described in paragraph (c)(4)(iv)(B) of this section is taken into account if an actual dividend from the corporation described in paragraph (c)(4)(iv)(B) of this section would be attributable to the separate unit or interest in the transparent entity.

* * * * *

§ 1.1503(d)–6 [Amended]

■ **Par. 6.** Section 1.1503(d)–6 is amended by:

■ 1. In paragraph (d)(2):

■ a. Removing the language “there is a triggering event in the year the dual consolidated loss is incurred” in the paragraph heading and adding the language “a triggering event has occurred” in its place; and

■ b. Adding the language “or before” immediately before the language “such taxable year” in the first sentence.

■ **Par. 7.** Section 1.1503(d)–7 is amended by:

■ 1. Adding paragraph (b)(16).

■ 2. Revising and republishing paragraph (c)(3).

■ 3. Adding a sentence after the first sentence in paragraph (c)(6)(iii)(B).

■ 4. In paragraph (c)(18)(iii):

■ a. Removing the language “the Country X mirror legislation” from the first sentence and adding the language “instead of Country X mirror legislation, Country X law” in its place.

■ b. Removing the language “mirror legislation” from the third sentence and adding the language “law” in its place.

■ c. Removing the language

“§ 1.1503(d)–(4)(e)” from the last sentence and adding the language “§ 1.1503(d)–(3)(e)” in its place.

■ 5. Adding paragraph (c)(18)(iv).

■ 6. Adding a sentence after the third sentence in paragraph (c)(23)(ii).

■ 7. Adding paragraph (c)(23)(iii).

■ 8. Adding the language “not” before the language “attributable” in the paragraph (c)(24) heading.

■ 9. In paragraph (c)(24)(i):

■ a. Removing the language “(or related section 78 gross-up)” from the fourth sentence.

■ b. Revising the fifth sentence.

■ c. Removing the last sentence.

■ 10. In paragraph (c)(24)(ii), revising the first sentence and removing the second, fifth, and sixth sentences.

■ 11. In paragraph (c)(25)(ii)(B), adding a sentence after the fifth sentence.

■ 12. In paragraph (c)(26)(i), removing the language from the fifth sentence “all of the interests” and adding the language “90 percent of the interests” in its place.

■ 13. Adding paragraphs (c)(42) and (43).

The revisions and additions read as follows:

§ 1.1503(d)–7 Examples.

* * * * *

(b) * * *

(16) No country imposes a tax collected under either a Qualified Domestic Minimum Top-up Tax, IIR, or UTPR.

(c) * * *

(3) *Domestic use limitation and certain top-up taxes—(i) Example 3.* *Domestic use limitation—foreign branch separate unit owned through a partnership—(A) Facts.* P and S organize a partnership, PRSX, under the laws of Country X. PRSX is treated as a partnership for both U.S. and Country X tax purposes. PRSX owns FBX. PRSX earns U.S. source income that is unconnected with its FBX branch operations, and such income is not subject to tax by Country X. In addition, such U.S. source income is not attributable to FBX under § 1.1503(d)–5.

(B) *Result.* Under § 1.1503(d)–1(b)(4)(i)(A), P’s and S’s shares of FBX owned indirectly through their interests in PRSX are individual foreign branch separate units. Pursuant to § 1.1503(b)–1(b)(4)(ii), these individual separate units are combined and treated as a single separate unit of the consolidated group of which P is the parent. Unless an exception under § 1.1503(d)–6 applies, any dual consolidated loss attributable to FBX cannot offset income of P or S (other than income attributable to FBX, subject to the application of § 1.1503(d)–4(c)), including their distributive share of the U.S. source income earned through their interests in PRSX, nor can it offset income of any other domestic affiliates.

(ii) *Example 3A. QDMTT—(A) Facts.* P owns DE1X. DE1X owns FSX.

Effective January 1, 2025, Country X imposes a Qualified Domestic Minimum Top-up Tax (Country X QDMTT). The Country X QDMTT is a foreign income

tax for purposes of section 1503(d) and the regulations thereunder. Other than the Country X QDMTT, Country X does not impose an income tax on Country X entities. For the taxable year and Fiscal Year ending December 31, 2025, DE1X incurs a \$100x deduction for interest expense. The \$100x of interest expense is reflected on the books and records of DE1X and is taken into account to determine the amount of income or loss for purposes of the Country X QDMTT. If the \$100x expense were deducted by P in determining U.S. taxable income, the loan and \$100x of interest expense thereon would be a Duplicate Loss Arrangement under the Transitional CbCR Safe Harbour for the Country X QDMTT (Safe Harbour) and, as a result of Country X’s rules for Duplicate Loss Arrangements (Country X DLA rules), the \$100x of interest expense would be excluded from Country X’s Profit (Loss) before Income Tax (PBT) for purposes of the Safe Harbour calculation. If the \$100x of interest expense were taken into account in determining whether the Safe Harbour is satisfied (that is, if it were not excluded from PBT by the Country X DLA rules), the Safe Harbour would be satisfied; if it were not so taken into account, the Safe Harbour would not be satisfied. Because the Country X DLA rules apply only for purposes of the Safe Harbour, in all cases the \$100x of interest expense would be taken into account in determining Net GloBE Income under the Country X QDMTT for the 2025 Fiscal Year.

(B) *Result—(1) General application to QDMTT.* Because DE1X is not taxable as an association for U.S. tax purposes and is subject to a foreign income tax (that is, the Country X QDMTT), DE1X is a hybrid entity, P’s interest in DE1X is a hybrid entity separate unit, and the \$100x interest expense deduction gives rise to a \$100x dual consolidated loss attributable to P’s interest in DE1X. See § 1.1503(d)–1(b)(3), (b)(4)(i)(B)(1) and (b)(5)(ii). Unless an exception applies, the \$100x dual consolidated loss is subject to the domestic use limitation under § 1.1503(d)–4(b). The result would be the same if, in addition to the Country X QDMTT, Country X imposed another income tax on Country X entities and, under the laws of that income tax, the loss of DE1X is not available to offset or reduce items of income or gain of FSX without an election, and no such election is made.

(2) *Ability to make a domestic use election.* P cannot make a domestic use election with respect to the \$100x dual consolidated loss if there is a foreign use of the dual consolidated loss in the year in which it was incurred (or in any prior

year). § 1.1503(d)–6(d)(2). Thus, to determine whether a domestic use election can be made it must first be determined whether the dual consolidated loss has been or will be put to a foreign use under the Country X QDMTT, including whether it would be put to a foreign use if a domestic use election were made. If a domestic use election were made, such that the dual consolidated loss could be deducted by P in determining its taxable income for U.S. tax purposes, then the Country X DLA rules would apply and prevent the \$100x expense from being taken into account for purposes of the Safe Harbour. As a result, the \$100x loss would not be put to a foreign use under the Safe Harbour, and the Safe Harbour would not be satisfied. Accordingly, it must also be determined whether the dual consolidated loss would be put to a foreign use under a full application of the Country X QDMTT rules. Since the Country X DLA rules only apply for purposes of the Safe Harbour, the \$100x expense would be taken into account in determining the Country X Net GloBE Income under a full application of the Country X QDMTT rules and, because the \$100x interest expense would thus be made available to offset or reduce items of income or gain of FSX, the \$100x dual consolidated loss would be put to a foreign use and a domestic use election cannot be made.

(C) *Alternative facts.* The facts are the same as in paragraph (c)(3)(ii)(A) of this section, except that even though the DLA Rules would exclude the \$100x of interest expense from Country X's PBT if a domestic use election were made, the Safe Harbour is nevertheless satisfied and, as a result, the Jurisdictional Top-up Tax under a full application of the Country X QDMTT rules is deemed to be zero. The result is the same as set forth in paragraph (c)(3)(ii)(B) of this section, except that because the Safe Harbour for Country X is satisfied (and no foreign use occurs pursuant to the application of the Safe Harbour due to the Country X DLA rules), no foreign use is considered to occur with respect to the \$100x dual consolidated loss solely as a result of it being taken into account in determining the Net GloBE Income in Country X. See § 1.1503(d)–3(c)(9). Accordingly, P can make a domestic use election for the \$100x dual consolidated loss attributable to its interest in DE1X.

(iii) *Example 3B. IIR—(A) Facts.* P owns DE3Y. DE3Y owns DE1X, S, USLLC, FLLC, and a 90 percent interest in PRS. For U.S. tax purposes: S is a domestic corporation; USLLC is a domestic entity that is disregarded as an entity separate from its owner; FLLC is

a foreign entity that is disregarded as an entity separate from its owner; and PRS is a domestic partnership. FLLC is not subject to an income tax in a foreign country. Country X does not impose an income tax on Country X entities. Effective January 1, 2025, Country Y imposes an IIR (Country Y IIR). The Country Y IIR is an income tax for purposes of section 1503(d) and the regulations thereunder. For purposes of the Country Y IIR: DE1X is not a Flow-through Entity or a Tax Transparent Entity and is located in Country X; each of USLLC and FLLC is a Flow-through Entity, a Reverse Hybrid Entity and a Stateless Constituent Entity; and PRS is a Flow-through Entity and a Tax Transparent Entity.

(B) *Analysis—(1) DE1X and FLLC.* Neither DE1X nor FLLC is subject to a foreign income tax on their worldwide income or on a residence basis, and thus neither DE1X nor FLLC is a hybrid entity (within the meaning of § 1.1503(d)–1(b)(3)). However, the income or loss of each of DE1X and FLLC is taken into account in determining the amount of tax under the Country Y IIR and each of DE1X and FLLC is a foreign entity other than a Tax Transparent Entity for purposes of the Country Y IIR. As such, P's indirect interest in each of DE1X and FLLC is a hybrid entity separate unit (within the meaning of § 1.1503(d)–1(b)(4)(i)(B)(2)). Because DE1X is located in Country X for purposes of the Country Y IIR, the DE1X separate unit would form part of a combined separate unit including any other individual Country X separate units. See § 1.1503(d)–1(b)(4)(ii)(A) and (b)(4)(ii)(B)(2). Because FLLC is a Stateless Constituent Entity and thus not located in a specific jurisdiction for purposes of the Country Y IIR, the FLLC separate unit cannot be combined with any individual separate unit. See § 1.1503(d)–1(b)(4)(ii)(B)(2).

(2) *S and USLLC.* Neither S nor USLLC is subject to a foreign income tax on their worldwide income or on a residence basis, even though the income or loss of S and USLLC is taken into account in determining the amount of tax under the Country Y IIR. As a result, S is not a dual resident corporation (within the meaning of § 1.1503(d)–1(b)(2)) and USLLC is not a hybrid entity (within the meaning of § 1.1503(d)–1(b)(3)). Further, because USLLC is a domestic entity, P's interest in USLLC is not a hybrid entity separate unit within the meaning of § 1.1503(d)–1(b)(4)(i)(B)(2). Finally, USLLC is a transparent entity (within the meaning of § 1.1503(d)–1(b)(16)) with respect to the DE3Y separate unit because it is not taxable as an association for Federal tax

purposes, is not subject to an income tax in a foreign country, and is not a pass-through entity under the laws of Country Y (the applicable foreign country).

(3) *PRS.* PRS is a Tax Transparent Entity for purposes of the Country Y IIR because it is fiscally transparent in the United States and is not tax resident in any foreign jurisdiction. PRS is not a hybrid entity (within the meaning of § 1.1503(d)–1(b)(3)), and P's indirect interest in PRS is not a hybrid entity separate unit within the meaning of § 1.1503(d)–1(b)(4)(i)(B)(1)) because PRS is not subject to a foreign tax on its worldwide income or on a residence basis. Further, P's indirect interest in PRS is not a hybrid entity separate unit within the meaning of § 1.1503(d)–1(b)(4)(i)(B)(2), even though the income or loss of PRS is taken into account in determining the amount of tax under the Country Y IIR, because PRS is not a foreign entity. PRS is also not a transparent entity (within the meaning of § 1.1503(d)–1(b)(16)) with respect to the DE3Y separate unit because, as a Tax Transparent Entity, it is a pass-through entity under the laws of Country Y (the applicable foreign country). The result would be the same if, instead of PRS being a domestic entity, PRS were a foreign entity (P's indirect interest in PRS would not be a separate unit in this case because PRS is a Tax Transparent Entity).

* * * * *

(6) * * *
(iii) * * *

(B) * * * But see § 1.1503(d)–1(d), which takes into account certain payments that are otherwise disregarded for purposes of section 1503(d) and the regulations thereunder. * * *

* * * * *

(18) * * *

(iv) *Alternative facts.* The facts are the same as in paragraph (c)(18)(i) of this section, except that instead of Country X mirror legislation, Country X law denies the ability to use the loss to offset income of Country X affiliates if the loss is deductible in another jurisdiction to offset income that is not dual inclusion income (for example, if a domestic use election were made with respect to FBX's dual consolidated loss and the loss became deductible by P); Country X law does not, however, deny the use of the loss of a Country X branch or permanent establishment to offset income of Country X affiliates if under the law of the other jurisdiction the loss can only offset income of the Country X branch or permanent establishment (for example, if a domestic use election is not made with respect to FBX's dual

consolidated loss and the domestic use limitation applied). Accordingly, Country X law does not deny any opportunity for the foreign use of the dual consolidated loss and, therefore, is not mirror legislation (within the meaning of § 1.1503(d)–3(e)(1)).

* * * * *

(23) * * *

(ii) * * * But see § 1.1503(d)–1(d), which takes into account certain payments that are otherwise disregarded for purposes of section 1503(d) and the regulations thereunder. * * *

(iii) *Alternative facts.* The facts are the same as in paragraph (c)(23)(i) of this section, except that P borrows from DE1X (instead of from a third party) and P on-lends the proceeds to a third party (instead of to DE1X). In addition, in year 1, P earns interest income attributable to the third-party loan. Also in year 1, DE1X earns \$40x of interest income on its loan to P (which is generally disregarded for U.S. tax purposes) and DE1X incurs an unrelated \$30x deduction for salary expense (which is regarded). The loan from DE1X to P, the disregarded interest income, and the regarded salary expense are reflected on the books and records of DE1X. The third-party loan and related interest income have not and will not be reflected on the books and records of DE1X because they are reflected on the books and records of P. Because the interest income on P's third-party loan is not reflected on the books and records of DE1X, no portion of such income is attributable to P's interest in DE1X pursuant to § 1.1503(d)–5(c)(3) for purposes of calculating the year 1 income or dual consolidated loss attributable to such interest. Adjustments of DE1X's books and records to conform to U.S. tax principles do not result in the attribution of any portion of the third-party interest income, or any other item reflected on the books and records of P, to P's interest in DE1X because such item has not and will not be reflected on DE1X's books and records. See § 1.1503(d)–5(c)(3)(i). Further, even though the disregarded interest income is reflected on the books and records of DE1X, it is not taken into account for purposes of calculating income or a dual consolidated loss. See § 1.1503(d)–5(c)(1)(ii). But see § 1.1503(d)–1(d), which takes into account certain payments that are otherwise disregarded for purposes of section 1503(d) and the regulations thereunder. The \$30x deduction for the salary expense is reflected on DE1X's books and records and, thus, there is a \$30x dual

consolidated loss attributable to P's interest in DE1X in year 1.

(24) * * *

(i) * * * In year 1, FSX distributes \$50x to DE3Y, the entire amount of which is a dividend for U.S. tax purposes and is included in gross income by P. * * *

(ii) Pursuant to § 1.1503(d)–5(c)(4)(iv)(A), neither the \$50x dividend nor any deduction or loss with respect to the dividend (for example, a deduction allowed to P under section 245A(a)) is taken into account for purposes of determining the items of income, gain, deduction, and loss of P that are attributable to P's interest in DE3Y; thus, regardless of whether the dividend is reflected on the books and records of DE3Y, no portion of the dividend or any deduction or loss with respect to the dividend is attributable to P's interest in DE3Y. * * *

(25) * * *

(ii) * * *

(B) * * * But see § 1.1503(d)–1(d), which takes into account certain payments that are otherwise disregarded for purposes of section 1503(d) and the regulations thereunder. * * *

* * * * *

(42) *Example 42. Disregarded payment loss—inclusion in gross income of DPL inclusion amount upon occurrence of triggering event—(i) Facts.* P owns DE1X, and DE1X owns FSX. P owned all the interests in DE1X on the effective date of DE1X's election to be disregarded as an entity separate from its owner. In year 1, DE1X pays \$100x to P pursuant to a note. For U.S. tax purposes, the payment is disregarded as a transaction between DE1X and P, but if the payment were regarded it would be interest within the meaning of § 1.267A–5(a)(12). Under Country X tax law, the \$100x is interest for which DE1X is allowed a deduction in year 1. In year 1, pursuant to a Country X group relief regime, DE1X's \$100x deduction is made available to offset income of FSX.

(ii) *Result.* Because P owned interests in DE1X, a specified eligible entity (as defined in § 301.7701–3(c)(4)(i) of this chapter), on the effective date of DE1X's election to be a disregarded entity, P consented to be subject to the disregarded payment loss rules of § 1.1503(d)–1(d). See § 301.7701–3(c)(4)(i) of this chapter. In addition, DE1X, a disregarded payment entity, incurs a \$100x disregarded payment loss with respect to its Country X taxable year for year 1. See § 1.1503(d)–1(d)(1)(i) and (d)(6)(ii)(B). DE1X's \$100x deduction being made available to offset income of FSX pursuant to the Country

X group relief regime constitutes a foreign use of, and thus a triggering event with respect to, the disregarded payment loss during the DPL certification period. See § 1.1503(d)–1(d)(3)(i) and (d)(6)(iii). As a result, in year 1, P must include in gross income \$100x, the DPL inclusion amount with respect to the disregarded payment loss. See § 1.1503(d)–1(d)(1)(i) and (d)(2)(i). The \$100x DPL inclusion amount is treated for U.S. tax purposes as ordinary interest income, the source and character of which is determined as if P received the interest payment from a wholly owned foreign corporation. See § 1.1503(d)–1(d)(2)(ii). The result would be the same if the payment were not treated as interest (or a structured payment or a royalty) for U.S. tax purposes, if it were regarded, and the transaction, series of transactions, plan, or arrangement that gave rise to the payment was engaged in with a view to avoid the purposes of the disregarded payment loss rules under § 1.1503(d)–1(d). See § 1.1503(d)–1(f).

(43) *Example 43. Income from U.S. business operations to avoid the purposes of the dual consolidated loss rules—(i) Facts.* P owns DE1X. DE1X owns FSX. P conducts business operations in the United States that are expected to generate items of income or gain (U.S. business operations). With a view to avoid the purposes of section 1503(d) by eliminating what would otherwise be a dual consolidated loss, P transfers the U.S. business operations to DE1X. But for P's items of income or gain from the U.S. business operations (held indirectly through DE1X), there would be a dual consolidated loss attributable to USP's interest in DE1X and a foreign use of that dual consolidated loss (as a result of the Country X consolidation regime). For purposes of determining taxable income under the income tax laws of Country X, items of income, gain, deduction, and loss attributable to a permanent establishment (or similar taxable presence) in another country, which would include the U.S. business operations, are not taken into account.

(ii) *Result.* Because P transferred the U.S. business operations to DE1X with a view to avoid the purposes of section 1503(d), the anti-avoidance rule in § 1.1503(d)–1(f) applies. As a result, the income or gain that P takes into account from the U.S. business operations (held through DE1X) will not be taken into account for purposes of determining the amount of income or dual consolidated loss attributable to P's interest in DE1X under § 1.1503(d)–5(c). The result would be the same if, instead of the income tax laws of Country X not taking

into account the items of income, gain, deduction, and loss attributable to a permanent establishment (or similar taxable presence) in another country for purposes of determining taxable income, the income tax laws of Country X took such items into account for this purpose but provided a foreign tax credit with respect to taxes paid on such items.

* * * * *

■ **Par. 8.** Section 1.1503(d)–8 is amended by:

■ 1. Revising the section heading.

■ 2. In paragraph (b)(6):

■ a. Removing the language “as well 1.1503(d)–3(e)(1) and (e)(3)” in the first sentence and adding the language “as well as 1.1503(d)–3(e)(3)” in its place.

■ b. Removing the second sentence.

■ c. Adding a sentence at the end of the paragraph.

■ 3. Adding paragraphs (b)(9) through (16).

The revisions and additions read as follows:

§ 1.1503(d)–8 Applicability dates.

* * * * *

(b) * * *

(6) * * * The parenthetical in § 1.1503(d)–1(c)(1)(ii) applies to determinations under §§ 1.1503(d)–1 through 1.1503(d)–7 relating to taxable years ending on or after August 6, 2024.

* * * * *

(9) *Attribution of items arising from ownership of stock.* Section 1.1503(d)–5(b)(2)(iv) and (c)(4)(iv) apply to taxable years ending on or after August 6, 2024.

(10) *Adjustments to conform to U.S. tax principles.* The fourth and fifth sentences of § 1.1503(d)–5(c)(3)(i) apply to taxable years ending on or after August 6, 2024.

(11) *Disregarded payment loss rules.* Section 1.1503(d)–1(d) applies to taxable years ending on or after August 6, 2024. *See also* section 301.7701–3(c)(4)(vi) (applicability dates for consent to be subject to disregarded payment loss rules).

(12) *Transition rule for QDMTTs and Top-up Taxes—(i) In general.* Except as provided in paragraph (b)(12)(ii) of this section, §§ 1.1503(d)–1 through 1.1503(d)–7 apply without taking into account QDMTTs or Top-up Taxes with respect to losses incurred in taxable years beginning before August 6, 2024. Thus, for example, a foreign use is not considered to occur with respect to a dual consolidated loss incurred in a taxable year beginning before August 6, 2024 solely because all or a portion of the deductions or losses that comprise the dual consolidated loss is taken into account (including in a taxable year

beginning on or after August 6, 2024) in determining the Net GloBE Income for a jurisdiction or whether the Transitional CbCR Safe Harbour applies for a jurisdiction. As an additional example, an entity is not treated as a hybrid entity in a taxable year beginning before August 6, 2024 solely because it is subject to a QDMTT.

(ii) *Anti-abuse rule.* Paragraph (b)(12)(i) of this section does not apply with respect to a loss that was incurred or increased with a view to reduce the amount of tax under a QDMTT or IIR, or to qualify for the Transitional CbCR Safe Harbour. For example, a loss may be put to a foreign use under a QDMTT where a taxpayer causes the loss to be taken into account in a taxable year beginning before August 6, 2024, with a view to reducing the amount of tax under a QDMTT in a taxable year beginning after August 6, 2024.

(13) *Foreign use exception for qualification for the Transitional CbCR Safe Harbour.* Section 1.1503(d)–3(c)(9) applies to taxable years beginning on or after August 6, 2024.

(14) *Separate units arising from a QDMTT or IIR.* Sections 1.1503(d)–1(b)(4)(i)(A)(2), 1.1503(d)–1(b)(4)(i)(B)(2), and 1.1503(d)–1(b)(4)(ii)(B)(2) apply to taxable years beginning on or after August 6, 2024.

(15) *Anti-avoidance rule.* Section 1.1503(d)–1(f) applies to taxable years ending on or after August 6, 2024.

(16) *Minimum taxes and taxes computed by reference to financial accounting principles.* Section 1.1503(d)–1(b)(6)(ii) applies to taxable years ending on or after August 6, 2024.

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 9.** The authority citation for part 301 continues to read in part as follows:

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

■ **Par. 10.** Section 301.7701–3 is amended by revising the sixth sentence of paragraph (a) and adding paragraph (c)(4) to read as follows:

§ 301.7701–3 Classification of certain business entities.

(a) * * * Paragraph (c) of this section provides rules for making express elections, including a rule under which a domestic eligible entity that elects to be classified as an association consents to be subject to the dual consolidated loss rules of section 1503(d), as well as a rule under which certain owners of certain eligible entities that are disregarded as entities separate from their owners consent to be subject to the

disregarded payment loss rules of § 1.1503(d)–1(d). * * *

* * * * *

(c) * * *

(4) *Consent to be subject to disregarded payment loss rules—(i) General rule.* If a specified eligible entity elects to be (or is formed or acquired after August 6, 2024 and classified without an election as) disregarded as an entity separate from its owner, then a domestic corporation, if any, that on the effective date of the election (or on the date of formation or acquisition absent an election) owns directly or indirectly interests in the specified eligible entity consents to be subject to the disregarded payment loss rules of § 1.1503(d)–1(d) of this chapter. For this purpose, a *specified eligible entity* means an eligible entity (regardless of whether domestic or foreign), provided that the entity is a foreign tax resident or is owned by a domestic corporation that has a foreign branch.

(ii) *Special rule regarding dual resident corporations.* If an eligible entity elects to be disregarded as an entity separate from its owner, then a dual resident corporation, if any, that on the effective date of the election directly or indirectly owns interests in the eligible entity consents to be subject to the disregarded payment loss rules of § 1.1503(d)–1(d) of this chapter.

(iii) *Deemed consent.* This paragraph (c)(4)(iii) applies to a domestic corporation that directly or indirectly owns interests in a specified eligible entity disregarded as an entity separate from its owner, but that has not pursuant to paragraph (c)(4)(i) of this section consented to be subject to the disregarded payment loss rules of § 1.1503(d)–1(d) of this chapter. This paragraph (c)(4)(iii) also applies to a dual resident corporation that owns directly or indirectly interests in an eligible entity disregarded as an entity separate from its owner, but that has not pursuant to paragraph (c)(4)(ii) of this section consented to be subject to the disregarded payment loss rules of § 1.1503(d)–1(d) of this chapter. When this paragraph (c)(4)(iii) applies, the domestic corporation or dual resident corporation, as applicable, is deemed to consent to be subject to the disregarded payment loss rules of § 1.1503(d)–1(d) of this chapter. This deemed consent rule applies, for example, to a domestic corporation that directly or indirectly acquires interests in a pre-existing disregarded entity, and a domestic corporation that owns interests in a disregarded entity by reason of a conversion of a partnership to a

disregarded entity (provided that, in each case, the disregarded entity is a specified eligible entity). As additional examples, the deemed consent rule applies to a domestic corporation that owns interests in a disregarded entity that defaulted to such status under paragraph (b)(1)(ii) or (b)(2)(i)(C) of this section, as well as a domestic corporation that owns interests in a disregarded entity that elected such status before the applicability date relating to paragraph (c)(4)(i) of this section (provided that, in each case, the disregarded entity is a specified eligible entity).

(iv) *Election to avoid deemed consent.* The deemed consent rule of paragraph (c)(4)(iii) of this section does not apply to a domestic corporation or dual resident corporation if the eligible entity elects to be classified as an association effective before August 6, 2025. For

purposes of such an election, the sixty-month limitation under paragraph (c)(1)(iv) of this section does not apply.

(v) *Definitions.* For purposes of paragraph (c)(4) of this section, the following definitions apply:

(A) The term *domestic corporation* has the meaning provided in § 1.1503(d)–1(b)(1) of this chapter.

(B) The term *dual resident corporation* has the meaning provided in § 1.1503(d)–1(b)(2) of this chapter.

(C) The term *foreign branch* means a branch (within the meaning of § 1.267A–5(a)(2) of this chapter) that gives rise to a taxable presence under the tax law of the foreign country where the branch is located.

(D) The term *foreign tax resident* means a tax resident (within the meaning of § 1.267A–5(a)(23)(i) of this chapter) of a foreign country.

(E) The term *indirectly*, when used in reference to ownership, has the same

meaning as provided in § 1.1503(d)–1(b)(19) of this chapter.

(vi) *Applicability dates*—(A) *In general.* Except as provided in paragraph (c)(4)(vi)(B) of this section, paragraph (c)(4) of this section applies as of August 6, 2024, as well as in regard to any election of an eligible entity to be classified as disregarded as an entity separate from its owner filed on or after August 6, 2024 (regardless of whether the election is effective before August 6, 2024).

(B) *Special rule regarding deemed consent.* Paragraph (c)(4)(iii) of this section applies on or after August 6, 2025.

* * * * *

Douglas W. O'Donnell,

Deputy Commissioner.

[FR Doc. 2024–16665 Filed 8–6–24; 8:45 am]

BILLING CODE 4830–01–P

Reader Aids

Federal Register

Vol. 89, No. 152

Wednesday, August 7, 2024

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids **202-741-6000**

Laws **741-6000**

Presidential Documents

Executive orders and proclamations **741-6000**

The United States Government Manual **741-6000**

Other Services

Electronic and on-line services (voice) **741-6020**

Privacy Act Compilation **741-6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: www.govinfo.gov.

Federal Register information and research tools, including Public Inspection List and electronic text are located at: www.federalregister.gov.

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to <https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new>, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to <http://listserv.gsa.gov/archives/publaws-l.html> and select *Join or leave the list (or change settings)*; then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: fedreg.info@nara.gov

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, AUGUST

62653-63072.....	1
63073-63280.....	2
63281-63812.....	5
63813-64352.....	6
64353-64778.....	7

CFR PARTS AFFECTED DURING AUGUST

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR	128.....62653
700.....	63073
Proposed Rules:	
700.....	63111
3 CFR	
Administrative Orders:	
Memorandums:	
Memorandum of July	
3, 2024.....	64343
Memorandum of July	
11, 2024.....	64345
Memorandum of July	
19, 2024.....	64347
Memorandum of July	
29, 2024.....	64349
Presidential	
Determinations:	
No. 2024-08 of July	
26, 2024.....	64351
7 CFR	
959.....	63079
9 CFR	
Proposed Rules:	
381.....	64678
10 CFR	
50.....	64353
51.....	64166
52.....	64353
54.....	64353
72.....	63813
11 CFR	
Proposed Rules:	
100.....	62670, 62671
104.....	62672
106.....	62670, 62671
109.....	62670, 62671
110.....	62670, 62671
111.....	62673
300.....	62670, 62671
12 CFR	
34.....	64538
225.....	64538
303.....	64353
308.....	64353
323.....	64538
722.....	64538
741.....	64538
1026.....	64538
1222.....	64538
Proposed Rules:	
Ch. I.....	62679
Ch. II.....	62679
Ch. III.....	62679
13 CFR	
125.....	62653
14 CFR	
39.....	63813
71.....	63082
97.....	63281, 63282
Proposed Rules:	
25.....	63111, 63845
39.....	62685
71.....	63114, 63116, 63329
73.....	62688
21 CFR	
Proposed Rules:	
73.....	63330
24 CFR	
203.....	63082
Proposed Rules:	
200.....	63847
26 CFR	
Proposed Rules:	
1.....	64750
301.....	64750
29 CFR	
103.....	62952
33 CFR	
100.....	62653, 63284
117.....	63815, 64367
165.....	62654, 63286, 63288,
	63290, 63816, 64369, 64371
Proposed Rules:	
165.....	62689, 63331
34 CFR	
Ch. VI.....	62656
Proposed Rules:	
Ch. III.....	64399
38 CFR	
78.....	62659
39 CFR	
Proposed Rules:	
111.....	63850
40 CFR	
52.....	63818, 64373
60.....	62872
62.....	63099
81.....	62663
180.....	63291, 63821
282.....	63101
Proposed Rules:	
52.....	62691, 63030, 63117,
	63258, 63852, 63860
282.....	63134
42 CFR	
412.....	64276, 64582

413.....	64048	171.....	63498	73.....	63381	50 CFR	
417.....	63825	172.....	63498	76.....	63381	300.....	63841
418.....	64202			79.....	63135	622.....	63843, 64397
422.....	63825	46 CFR				635.....	62666, 63109
423.....	63825	10.....	63830	48 CFR		660.....	62667, 62668
460.....	63825	Proposed Rules:		501.....	63325	Proposed Rules:	
488.....	64048	401.....	63334	502.....	63325	17.....	62707, 63888
43 CFR		47 CFR		512.....	62665	32.....	63139
2.....	63828	0.....	63296	538.....	63325	223.....	63393
8360.....	64383	1.....	63296	552.....	63325	648.....	63394
45 CFR		2.....	63296	570.....	63108	660.....	63153
Proposed Rules:		26.....	63296	49 CFR		665.....	63155
170.....	63498	Proposed Rules:		40.....	62665		
		25.....	63381				

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion

in today's **List of Public Laws**.

Last List August 1, 2024

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.