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Contents

Federal Register

Vol. 89, No. 218

Tuesday, November 12, 2024

Bureau of Consumer Financial Protection
RULES
Consumer Financial Protection Circular:
Background Dossiers and Algorithmic Scores for Hiring, Promotion, and Other Employment Decisions, 88875–88877

Census Bureau
NOTICES
Hearings, Meetings, Proceedings, etc.:
Tribal Consultation, 88950

Centers for Medicare & Medicaid Services
RULES
Medicare Program:
End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, etc., 89084–89213
NOTICES
Medicare and Medicaid Programs:
Approval of Application by Community Health Accreditation Partner Inc. for Continued Approval of its Hospice Accreditation Program, 89015–89017
Approval of Application by the American Association for Accreditation of Ambulatory Surgery Facilities dba QUAD A for Continued Approval of its Ambulatory Surgical Center Accreditation Program, 89014–89015

Commerce Department
See Census Bureau
See Economic Analysis Bureau
See International Trade Administration
See National Oceanic and Atmospheric Administration

Defense Department
RULES
Federal Acquisition Regulation:
Clarification of System for Award Management Preaward Registration Requirements, 89472–89475
Federal Acquisition Circular 2025–01; Introduction, 89464
Federal Acquisition Circular 2025–01; Small Entity Compliance Guide, 89475–89476
Prohibition on Unmanned Aircraft Systems from Covered Foreign Entities, 89464–89472
NOTICES
Arms Sales, 88976–88986
Charter Amendments, Establishments, Renewals and Terminations:
Defense Advisory Committee for the Prevention of Sexual Misconduct, 88979
United States Military Academy Board of Visitors, United States Naval Academy Board of Visitors, and Board of Visitors of the United States Air Force Academy, 88978–88979

Economic Analysis Bureau
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Services Surveys: Quarterly Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons, 88952
Services Surveys: Quarterly Survey of Foreign Airline Operators' Revenues and Expenses in the United States, 88951
Services Surveys: Quarterly Survey of Ocean Freight Revenues and Foreign Expenses of U.S. Carriers and Quarterly Survey of U.S. Airline Operators' Foreign Revenues and Expenses, 88950–88951

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
High School and Beyond 2022 First Follow-up Field Test Data Collection, 88986–88987
Applications for New Awards:
Research Training Programs in the Education Sciences, 88987–88990

Energy Department
See Federal Energy Regulatory Commission
See Southwestern Power Administration
See Western Area Power Administration
NOTICES
Hearings, Meetings, Proceedings, etc.:
International Energy Agency, 88990–88991

Environmental Protection Agency
RULES
Reconsideration of the Dust-Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels, 89416–89461
PROPOSED RULES
Air Quality:
Definition of Volatile Organic Compounds—Exclusion of (Z)-1-chloro-2,3,3,3-tetrafluoropropene (HCFO-1224yd(Z)), 88940–88947
Pesticide Tolerance; Exemptions, Petitions, Revocations, etc.:
Chemicals in or on Various Commodities (September 2024), 88948–88949
NOTICES
Charter Amendments, Establishments, Renewals and Terminations:
Great Lakes Advisory Board, 89011
Pesticide Product Registration:
Application for New Active Ingredients (September 2024), 89011–89012

Export-Import Bank
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for Exporter Short Term Single Buyer Insurance, 89012

Federal Aviation Administration
RULES
Airworthiness Directives:
Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes, 88878–88881
Bombardier, Inc., Airplanes, 88884–88888
SAS Airplanes, 88881–88884
PROPOSED RULES
Airspace Designations and Reporting Points:
Roanoke Rapids, NC, 88915–88916
Airworthiness Directives:
ATR—GIE Avions de Transport Regional Airplanes, 88913–88915
De Havilland Aircraft of Canada Limited (Type Certificate Previously Held by Bombardier, Inc.) Airplanes, 88910–88913
International Aero Engines AG Engines, 88908–88910
The Boeing Company Airplanes, 88906–88908

Federal Communications Commission
RULES
Implementation of the National Suicide Hotline Act, 88890–88905

Federal Election Commission
NOTICES
Meetings; Sunshine Act, 89012

Federal Energy Regulatory Commission
NOTICES
Application:
Duke Energy Carolinas, LLC, 88991–88992
Combined Filings, 88993–88995
Environmental Issues:
Venice Gathering System, LLC, Proposed Venice Gathering System Pipeline Abandonment Project, 88995–88997
Records Governing Off-the-Record Communications, 88992–88993

Federal Highway Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 89079–89080

Federal Mediation and Conciliation Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 89012–89013

Federal Reserve System
RULES
Federal Reserve Bank Capital Stock, 88877–88878
NOTICES
Formations of, Acquisitions by, and Mergers of Bank Holding Companies, 89013

Federal Trade Commission
RULES
Premerger Notification:
Reporting and Waiting Period Requirements, 89216–89414

Foreign Assets Control Office
NOTICES
Sanctions Action, 89081–89082

General Services Administration
RULES
Federal Acquisition Regulation:
Clarification of System for Award Management Preaward Registration Requirements, 89472–89475
Federal Acquisition Circular 2025–01; Introduction, 89464
Federal Acquisition Circular 2025–01; Small Entity Compliance Guide, 89475–89476
Prohibition on Unmanned Aircraft Systems from Covered Foreign Entities, 89464–89472

Geological Survey
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Nonferrous Metals Surveys, 89025–89026

Great Lakes St. Lawrence Seaway Development Corporation
NOTICES
Hearings, Meetings, Proceedings, etc.:
Advisory Board, 89080

Health and Human Services Department
See Centers for Medicare & Medicaid Services
See National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 89017–89018

Homeland Security Department
See Transportation Security Administration
See U.S. Citizenship and Immigration Services

Indian Affairs Bureau
NOTICES
Proclaiming Certain Lands as Reservation:
Snoqualmie Indian Tribe, 89026–89028

Interior Department
See Geological Survey
See Indian Affairs Bureau
See National Park Service

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Certain Aluminum Foil from People's Republic of China, 88972–88975
Certain Aluminum Foil from the People's Republic of China, 88957–88959
Certain Hot-Rolled Carbon Steel Flat Products from India and Indonesia, 88964–88965
Certain Hot-Rolled Carbon Steel Flat Products from India, Indonesia, the People's Republic of China, Taiwan, Thailand, and Ukraine, 88971–88972
Certain Hot-Rolled Carbon Steel Flat Products from Thailand, 88966–88967
Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China, 88969–88970
Hydrofluorocarbon Blends from the People's Republic of China, 88970–88971
Laminated Woven Sacks from the People's Republic of China, 88965–88966
Phosphate Fertilizers from the Kingdom of Morocco, 88952–88953

Phosphate Fertilizers from the Russian Federation, 88960–88961
Sodium Nitrite from the People?s Republic of China, 88967–88968
Steel Propane Cylinders from the People's Republic of China, 88968–88969
Steel Wire Garment Hangers from the People's Republic of China, 88956–88957
Wooden Cabinet and Vanities and Components Thereof from the People's Republic of China, 88953–88956
Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China, 88962–88964
Request for Panel Review:
United States-Mexico-Canada Agreement, 88959–88960

International Trade Commission
NOTICES
Investigations; Determinations, Modifications, and Rulings, etc.:
Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof, 89041–89044
Steel Wire Garment Hangers from China, 89040–89041

Justice Department
See Parole Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Community Oriented Policing Services Community Policing Advancement Performance Report, 89044
Request for Registration under the Gambling Devices Act, 89044–89045

Labor Department
See Mine Safety and Health Administration

Mine Safety and Health Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Training Plans, New Miner Training, Newly-Hired Experienced Miner Training, 89045–89049

National Aeronautics and Space Administration
RULES
Federal Acquisition Regulation:
Clarification of System for Award Management Preaward Registration Requirements, 89472–89475
Federal Acquisition Circular 2025–01; Introduction, 89464
Federal Acquisition Circular 2025–01; Small Entity Compliance Guide, 89475–89476
Prohibition on Unmanned Aircraft Systems from Covered Foreign Entities, 89464–89472

National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Data Use Certification for the National Institutes of Health Brain Development Cohorts, 89019–89020
Hearings, Meetings, Proceedings, etc.:
Center for Scientific Review, 89018
Fogarty International Center, 89020
National Institute of Allergy and Infectious Diseases, 89019
National Institute of Diabetes and Digestive and Kidney Diseases, 89020–89021
National Institute of General Medical Sciences, 89018–89019
National Institute of Mental Health, 89021

National Oceanic and Atmospheric Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Office of Marine and Aviation Operations: Occupational Health, Safety, and Readiness Forms, 88975–88976

National Park Service
NOTICES
Intended Disposition:
U.S. Army Corps of Engineers, Albuquerque District, Albuquerque, NM, 89034–89035
U.S. Department of the Interior, Bureau of Land Management, Colorado State Office, Canyons of the Ancients National Monument, Dolores, CO, 89037–89038
Inventory Completion:
California State University, Sacramento, Sacramento, CA, 89036–89037
Gilcrease Museum, Tulsa, OK, 89029–89030
Museum of Us, San Diego, CA, 89037
Rochester Museum and Science Center, Rochester, NY, 89028–89029
San Diego State University, San Diego, CA, 89038–89040
The San Diego Archaeological Center, San Diego, CA, 89033–89034
Yale Peabody Museum, Yale University, New Haven, CT, 89040
Repatriation of Cultural Items:
Field Museum, Chicago, IL, 89034
Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA, 89030
San Francisco State University Native American Graves Protection and Repatriation Act Program, San Francisco, CA, 89035–89036
Turtle Bay Exploration Park, Redding, CA, 89028
Wesleyan University, Middletown, CT, 89031–89033
Yale Peabody Museum, Yale University, New Haven, CT, 89030–89031

Nuclear Regulatory Commission
NOTICES
Environmental Assessments; Availability, etc.:
Energy Northwest, Columbia Generating Station; Finding of No Significant Impact, 89049–89052
Pacific Gas and Electric Company; Diablo Canyon Independent Spent Fuel Storage Installation; Finding of No Significant Impact, 89056–89058
Licenses; Exemptions, Applications, Amendments, etc.:
Limerick Generating Station, Units 1 and 2, Constellation Energy Generation, LLC, 89052–89056

Parole Commission
NOTICES
Meetings; Sunshine Act, 89045

Postal Regulatory Commission
NOTICES
Negotiated Service Agreement Filings, 89058–89061

Presidential Documents
PROCLAMATIONS
Special Observances:
Veterans Day (Proc. 10855), 88871–88873

Securities and Exchange Commission
NOTICES
Meetings; Sunshine Act, 89061
Self-Regulatory Organizations; Proposed Rule Changes:
Cboe BYX Exchange, Inc., 89071–89074
Cboe BZX Exchange, Inc., 89063–89066
Cboe EDGA Exchange, Inc., 89067–89070
Cboe EDGX Exchange, Inc., 89074–89078
New York Stock Exchange LLC, 89061–89063, 89070–89071

Small Business Administration
NOTICES
Disaster Declaration:
Cheyenne River Sioux Tribe; Public Assistance Only, 89078
Florida; Public Assistance Only, 89079
U.S. Virgin Islands; Public Assistance Only, 89078–89079

Southwestern Power Administration
NOTICES
Integrated System Power Rates, 88997–88999

State Justice Institute
NOTICES
Hearings, Meetings, Proceedings, etc.:
Board of Directors, 89079

Transportation Department
See Federal Aviation Administration
See Federal Highway Administration
See Great Lakes St. Lawrence Seaway Development Corporation

Transportation Security Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Maryland Three Airports: Enhanced Security Procedures for Operations at Certain Airports in the Washington, DC, Metropolitan Area Flight Restricted Zone, 89022
TSA PreCheck Application Program Fee, 89022–89024

Treasury Department
See Foreign Assets Control Office

U.S. Citizenship and Immigration Services
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Change of Address, 89024–89025

Veterans Affairs Department
RULES
Changes in Rates VA Pays for Special Modes of Transportation, 88888–88889
PROPOSED RULES
Schedule for Rating Disabilities:
Neurological Conditions and Convulsive Disorders, 88917–88940
NOTICES
Hearings, Meetings, Proceedings, etc.:
Advisory Committee on Former Prisoners of War, 89082

Western Area Power Administration
NOTICES
Final 2028 Parker-Davis Project Power Marketing Plan and Call for Resource Pool Applications, 88999–89011

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 89084–89213

Part III
Federal Trade Commission, 89216–89414

Part IV
Environmental Protection Agency, 89416–89461

Part V
Defense Department, 89464–89476
General Services Administration, 89464–89476
National Aeronautics and Space Administration, 89464–89476

Reader Aids

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

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CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR

Proclamations:

10855 88871

12 CFR

X 88875

209 88877

14 CFR

39 (4 documents) 88878, 88881, 88884, 88886

Proposed Rules:

39 (4 documents) 88906, 88908, 88910, 88913

71 88915

16 CFR

801 89216

803 89216

38 CFR

70 88888

Proposed Rules:

3 88917

4 88917

40 CFR

745 89416

Proposed Rules:

51 88940

180 88948

42 CFR

410 89084

413 89084

494 89084

512 89084

47 CFR

52 88890

48 CFR

Ch. 1 (2 documents) 89464, 89475

4 89464

13 89464

39 89464

40 89464

52 (2 documents) 89464, 89472

Federal Register
Vol. 89, No. 218
Tuesday, November 12, 2024

Presidential Documents

Title 3—

The President

Proclamation 10855 of November 6, 2024

Veterans Day, 2024

By the President of the United States of America

A Proclamation

Today, we honor generations of America's veterans—patriots who have stood on the frontlines of freedom and kept the light of liberty shining bright around the world. Just as they have kept the ultimate faith in our Nation, we must keep ultimate faith in them.

Each one of our Nation's veterans is a link in a chain of honor that stretches back to our founding days—bound by a sacred oath to support and defend the United States of America. Throughout history, whenever and wherever the forces of darkness have sought to extinguish the flame of freedom, America's veterans have been fighting to keep it burning bright. I remember so clearly the pride the First Lady and I felt in our son Beau during his service in Iraq. He—like all our veterans from Belleau Wood, Baghdad, and Gettysburg to Guadalcanal, Korea, and Kandahar and beyond—lived, served, and sacrificed by a creed of duty. We owe them a debt of gratitude we can never fully repay, not just for fighting for our democracy, but for giving back to our communities and inspiring the next generation to serve, even after they hang up their uniforms.

As a Nation, we have one truly sacred obligation: to prepare and equip those we send into harm's way and to care for them and their families when they return home. Since I came into office, I have signed more than 34 bipartisan laws to support our veterans and their families, caregivers, and survivors. That includes the landmark Sergeant First Class Heath Robinson Honoring our Promise to Address Comprehensive Toxics (PACT) Act, which enacted the most significant expansion of benefits and services for veterans exposed to toxins in more than 30 years. Today, more than 1.1 million veterans and 11,000 survivors of deceased veterans are now receiving new service-connected disability benefits, and over 5.8 million veterans have been screened for toxic exposure—a critical step to ensuring they get access to the care they need. And as of last March, any exposed veteran who served during any conflict outlined in the PACT Act will be able to enroll in the Department of Veterans Affairs (VA) health care. My Administration is ensuring that women veterans enrolled in the Department of Veterans Affairs health care have equitable access to benefits and health services. My Administration has worked to reduce barriers and reach out to veterans to make sure they can access their earned benefits. As a result, the VA is delivering more benefits to more veterans than ever before. In 2024, the VA processed more claims than ever and is providing record level health care services. We have taken steps to eliminate barriers and disparities for all veterans, including people of color, LGBTQI+ people, and women. We have made progress in addressing veteran homelessness, and we are working to end the silent scourge of suicide by addressing financial and legal risk factors, promoting secure storage of firearms, and expanding access to mental health services. Last year, the VA housed nearly 48,000 veterans, expanded access to health care and legal assistance for homeless veterans, and helped more than 158,000 veterans and their families keep their homes. And we are committed to assisting the roughly 200,000 service members who transition from the military each year with finding good-paying jobs, including by connecting them to Registered Apprenticeship programs. My

Administration has also prioritized supporting veteran entrepreneurship. This year, service-disabled veteran-owned small businesses secured almost $32 billion in Federal contracts, nearly $4 billion more than in the prior year.

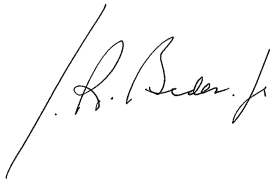
While our veterans are the steel spine of this Nation, their families are the courageous heart—they also serve and sacrifice so much for our country. Last year, I signed an Executive Order calling for the most comprehensive set of administrative actions in our Nation's history to support the economic security of military and veteran spouses, caregivers, and survivors. The Executive Order increases training and employment opportunities for military spouses in the workforce and encourages Federal agencies to do more to retain military and veteran spouses through flexible policies. Additionally, through the First Lady's Joining Forces initiative, my Administration is working to better support military and veteran families on everything from making school transitions easier for military children to expanding economic opportunities and improving well-being for military spouses, caregivers, and survivors.

Earlier this year, I had the opportunity to visit Normandy to mark the 80th anniversary of D-Day alongside so many World War II veterans. Their service and sacrifice helped free the world from tyranny. We learned then what we still know now: Democracy is never guaranteed. Every generation must preserve it, defend it, and fight for it. Today, we honor all our veterans, who have preserved, defended, and fought for our democracy. They prove that we are a Nation that can meet darkness with light again and again, no matter how high the cost or how heavy the burden. May we all strive to be worthy of their sacrifices for us, doing our part to keep the light of liberty burning bright for generations to come.

In respect and recognition of the contributions our veterans and their families, caregivers, and survivors have made to the cause of peace and freedom around the world, the Congress has provided (5 U.S.C. 6103(a)) that November 11 of each year shall be set aside as a legal public holiday to honor our Nation's veterans.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, do hereby proclaim November 11, 2024, as Veterans Day. I encourage all Americans to recognize the valor, courage, and sacrifice of these patriots through appropriate ceremonies and private prayers and by observing two minutes of silence for our Nation's veterans. I also call upon Federal, State, and local officials to display the flag of the United States of America and to participate in patriotic activities in their communities.

IN WITNESS WHEREOF, I have hereunto set my hand this sixth day of November, in the year of our Lord two thousand twenty-four, and of the Independence of the United States of America the two hundred and forty-ninth.



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Rules and Regulations

Federal Register

Vol. 89, No. 218

Tuesday, November 12, 2024

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CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Chapter X

Consumer Financial Protection Circular 2024–06: Background Dossiers and Algorithmic Scores for Hiring, Promotion, and Other Employment Decisions

AGENCY: Consumer Financial Protection Bureau.

ACTION: Consumer financial protection circular.

SUMMARY: The Consumer Financial Protection Bureau (CFPB) has issued Consumer Financial Protection Circular 2024–06, titled, ''Background Dossiers and Algorithmic Scores for Hiring, Promotion, and Other Employment Decisions.'' In this circular, the CFPB responds to the question, ''Can an employer make employment decisions utilizing background dossiers, algorithmic scores, and other third-party consumer reports about workers without adhering to the Fair Credit Reporting Act (FCRA)?''

DATES: The CFPB released this circular on its website on October 24, 2024.

ADDRESSES: Enforcers, and the broader public, can provide feedback and comments to *Circulars@cfpb.gov.*

FOR FURTHER INFORMATION CONTACT: 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.*

SUPPLEMENTARY INFORMATION:

Question Presented

Can an employer make employment decisions utilizing background dossiers, algorithmic scores, and other third-party consumer reports about workers without adhering to the Fair Credit Reporting Act (FCRA)?

Response

No. Similar to credit reports and credit scores used by lenders to make lending decisions, background dossiers—such as those that convey scores about workers—that are obtained from third parties and used by employers to make hiring, promotion, reassignment, or retention decisions are often governed by the FCRA. Many background dossiers that are compiled from databases collecting public records, employment history, collective-bargaining activity, or other information about a worker are ''consumer reports'' under the FCRA. Other types of consumer reports may include, for example, reports that convey scores assessing a current worker's risk level or performance.

Employers that use consumer reports—both initially when hiring workers and for subsequent employment purposes—must comply with FCRA obligations, including the requirement to obtain a worker's permission to procure a consumer report, the obligation to provide notices before and upon taking adverse actions, and a prohibition on using consumer reports for purposes other than the permissible purposes described in the FCRA.

The third-party providers furnishing these reports are ''consumer reporting agencies'' regulated by the FCRA, which (among other things) imposes an obligation to follow reasonable procedures to assure maximum possible accuracy, a requirement to disclose information in a worker's file to the worker upon request, and a requirement to investigate worker disputes alleging inaccuracies.

Consumer Reports for Employment Purposes

Similar to how credit reports and credit scores are commonly used by lenders, employers commonly purchase consumer reports to make employment decisions about workers. The most traditional form of consumer report in use in the United States for employment purposes is a background dossier that checks a worker's public records, including criminal history.

Recent technological advances have resulted in a rapid increase in the monitoring of workers across many sectors.[1] This has been compounded by an increase in remote work. Together, these phenomena have resulted in an increase in third-party technology companies that have made it easier and more cost effective to track, assess, and evaluate workers.[2]

Consumer reporting agencies and other background screening companies now offer a range of reports to employers, including those that record current workers' activities, personal habits and attributes, and even their biometric information. For example, some employers now use third parties to monitor workers' sales interactions, to track workers' driving habits, to measure the time that workers take to complete tasks, to record the number of messages workers send and the quantity and duration of meetings they attend, and to calculate workers' time spent off-task through documenting their web browsing, taking screenshots of computers, and measuring keystroke frequency.[3] In some circumstances, this information might be sold by ''consumer reporting agencies'' to prospective or current employers.

Some companies may analyze worker data[4] in order to provide reports containing assessments or scores of

[1] Veena Dubal, *On Algorithmic Wage Discrimination,* UC San Francisco Research Paper No. Forthcoming (2023) *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4331080* (hereinafter *Algorithmic Wage Discrimination*); Merve Hickok & Nestor Maslej, *A Policy Primer And Roadmap On AI Worker Surveillance And Productivity Scoring Tools* (2023) AI Ethics 3, 673–687 (2023) (hereinafter *Policy Primer*) *https://link.springer.com/article/10.1007/s43681-023-00275-8.*

[2] *Id.*

[3] *See, e.g.,* Diego Areas Munhoz, ''*Robot Bosses*'' *Spur Lawmaker Push to Police AI Job Surveillance,* Bloomberg Law (Sept. 8, 2023) *https://news.bloomberglaw.com/daily-labor-report/robot-bosses-spur-lawmaker-push-to-police-ai-job-surveillance;* Remarks of Benjamin Wiseman at the Harvard Journal of Law & Technology on Worker Surveillance and AI, *FTC.gov* (Feb. 8, 2024), Jolt-2-8-24-final.pdf (*ftc.gov*).

[4] Companies may engage in such analysis by making inferences and determinations about worker behavior and performance using algorithms, or sets of rules in computer programming code for solving a problem or performing a task based on input data. The algorithmic models used may also include ''artificial intelligence'' or ''AI'' models, which often develop and train algorithms using ''machine learning,'' which is the process of gathering data and supplying it to the computer program to train the algorithm to find patterns or make predictions. Conventional algorithms and AI models may also set performance goals or other parameters based on external data—for instance, by comparing a worker's output to an industry standard.

worker productivity or risk to employers.[5] Today, such scores are used to make automated recommendations or determinations related to worker pay; predict worker behavior, including potential union organizing activity and likelihood that a worker will leave their job; schedule shifts or job responsibilities; or issue warnings or other disciplinary actions.[6]

Analysis

Congress passed the FCRA in response to concerns about companies that assemble detailed dossiers about consumers and sell this information.[7] In doing so, Congress was particularly cognizant of the impact of so-called ''credit reporting'' on consumers' employment. Indeed, the Senate Report accompanying the bill that would be enacted as the FCRA noted in particular how ''a consumer's future employment career could be jeopardized because of an incomplete credit report.'' [8] To address those concerns, the FCRA regulates information in the form of ''consumer reports,'' a term defined to include ''any written, oral, or other communication of any information by a consumer reporting agency bearing on a consumer's credit worthiness, credit standing, credit capacity, character, general reputation, personal characteristics, or mode of living which is used or expected to be used or collected in whole or in part for the purpose of serving as a factor in establishing the consumer's eligibility for'' certain purposes, including ''employment purposes.'' [9]

While all of the general obligations of the FCRA apply to consumer reports provided for employment purposes, there are a few additional obligations that apply only to this kind of consumer report. For example, section 604(b) includes additional requirements when a consumer report is used for employment purposes, including a requirement to get permission from the worker.[10] It also generally requires employers to provide notice to workers and a copy of their report *before* taking adverse action.[11] In addition, upon request by a worker, ''consumer reporting agencies'' must disclose the identity of anyone who has used a consumer report for employment purposes in the two-year period preceding the date the request is made, which is longer than the one-year period used for other purposes.[12] And ''consumer reporting agencies'' must follow certain procedures when reporting public record information for employment purposes.[13]

Beyond the obligations that apply only to consumer reports used for employment purposes, the FCRA's general obligations also provide important protections for workers. Among other things, the FCRA provides workers the right to know what is in their file at a ''consumer reporting agency'' and dispute incomplete or inaccurate information,[14] requires such entities, in response to a consumer's dispute, to correct or delete inaccurate, incomplete, or unverifiable information,[15] and generally prohibits reporting of outdated negative information.[16] In addition to requiring that most employers give workers notice before taking an adverse action, the FCRA also generally requires that any person taking adverse action based on a consumer report provide notice to the consumer upon taking the adverse action.[17] Finally, the FCRA strictly limits ''consumer reporting agencies'' to providing consumer reports only for certain specified permissible purposes.[18] That means the background screener could not share consumer reports containing workers' data with employers or others, absent a FCRA permissible purpose.[19]

When looking at whether an employer that makes employment decisions based on a report from a third party is regulated by the FCRA, enforcers should consider two key questions:

1. Does the employer's use of data qualify as a use for ''employment purposes'' under the FCRA?

2. Is the report obtained from a ''consumer reporting agency,'' meaning that the report-maker ''assembled'' or ''evaluated'' consumer information to produce the report?

On the first question, the FCRA defines ''employment purposes'' to mean ''a report used for the purpose of evaluating a consumer for employment, promotion, reassignment or retention as an employee.'' [20] The FCRA thus applies both to information used for the purpose of evaluating a consumer for employment initially, and to information used for ongoing employment purposes—*i.e.,* promotion, reassignment, or retention.[21]

On the second question, a third party could be a ''consumer reporting agency'' that assembles or evaluates consumer information if they collect consumer information in order to furnish reports to employers.[22] A company that employers use to help make employment decisions could meet this standard in a number of ways. For example, similar to a ''nationwide consumer reporting agency,'' like

[5] *See, e.g., Policy Primer;* Diego Areas Munhoz, ''*Robot Bosses*'' *Spur Lawmaker Push to Police AI Job Surveillance,* Bloomberg Law (Sept. 8, 2023) *https://news.bloomberglaw.com/daily-labor-report/robot-bosses-spur-lawmaker-push-to-police-ai-job-surveillance.*

[6] *See, e.g., Algorithmic Wage Discrimination;* Theara Coleman, *The (ongoing) fight against workplace AI surveillance,* The Week (Jan. 15, 2024) *https://theweek.com/tech/workplace-ai-surveillance.*

[7] *See generally* 115 Cong. Rec. S2410–11 (daily ed. Jan. 31, 1969) (statement of Sen. William Proxmire).

[8] S. Rep. 91–517, at 4 (1970).

[9] 15 U.S.C. 1681(d)(1)(B). Under the FCRA, the ''term 'consumer' means an individual.'' 15 U.S.C. 1681a(c). Among other things, the FCRA excludes from the definition of ''consumer report'' certain communications made to employers in connection with investigations of ''suspected misconduct relating to employment'' or ''compliance with Federal, State, or local laws and regulations, the rules of a self-regulatory organization, or any pre-existing written policies of the employer.'' 15 U.S.C. 1681a(d)(2)(D), (y). This Circular does not focus on such communications.

[10] 15 U.S.C. 1681b(b)(1) (2). The issue of whether an employer can use dossiers, scores, or other surveillance on workers may also be a topic of negotiation at the individual or collective bargaining level.

[11] 15 U.S.C. 1681b(3)(A). *But see* 15 U.S.C. 1681b(b)(3)(B) (C), (4) (exceptions from § 1681b(b)(3)(A) for workers in the transportation industry in certain circumstances and for consumer reports relevant to national security investigations in certain circumstances).

[12] 15 U.S.C. 1681g(a)(3)(A)(i).

[13] 15 U.S.C. 1681k. Subject to an exemption for national security investigations, CRAs that compile and report for employment purposes public record information that is likely to have an adverse effect on a consumer's ability to obtain employment must (1) notify the consumer that the information is being reported and of the name and address of the recipient, or (2) maintain ''strict procedures'' to ensure that the public record information is complete and up to date. *Id.*

[14] 15 U.S.C. 1681g(a); 15 U.S.C. 1681i(a)(1).

[15] 15 U.S.C. 1681i(a)(5).

[16] 15 U.S.C. 1681c.

[17] 15 U.S.C. 1681b(b)(3)(A), 1681m(a).

[18] *See* 15 U.S.C. 1681b(a).

[19] For example, courts have held that consumer reporting agencies generally cannot furnish consumer reports for targeted marketing. *See Trans Union Corp.* v. *FTC,* 81 F.3d 228, 233–34 (D.C. Cir. 1996).

[20] 15 U.S.C. 1681a(h).

[21] The FCRA's application to both prospective and current workers is confirmed by FCRA section 603(k), which provides that an ''adverse action'' under FCRA includes ''a denial of employment or any other decision for employment purposes that adversely affects any *current or prospective* employee.'' 15 U.S.C. 1681a(k)(1)(B)(ii) (emphasis added). *See also Ernst* v. *Dish Network, LLC,* 49 F. Supp. 3d 377, 383 (S.D.N.Y. 2014) (background report was collected, expected to be used, and used for the employment purposes of ''evaluat[ing] [the] Plaintiff for reassignment or retention as an employee'').

[22] The FCRA regulates consumer reports as furnished by ''consumer reporting agencies,'' which it defines as: ''any person which, for monetary fees, dues, or on a cooperative nonprofit basis, regularly engages in whole or in part in the practice of assembling or evaluating consumer credit information or other information on consumers for the purpose of furnishing consumer reports to third parties, and which uses any means or facility of interstate commerce for the purpose of preparing or furnishing consumer reports.'' 15 U.S.C. 1681a(f).

Equifax, Experian, or TransUnion, some companies collect consumer data from third parties for dissemination to employers in background reports. Traditional background screening companies ''assemble'' or ''evaluate'' information about workers, often from public sources, such as criminal history records. Other firms might collect information from employers about workers' collective bargaining activity, or job performance, and then sell it to other employers to make hiring decisions.

In addition, an entity could ''assemble'' or ''evaluate'' consumer information within the meaning of the term ''consumer reporting agency'' if the entity collects consumer data in order to train an algorithm that produces scores or other assessments about workers for employers. For example, the developer of a phone app that monitors a transportation worker's driving activity and provides driving scores to companies for employment purposes could ''assemble'' or ''evaluate'' consumer information if the developer obtains or uses data from sources other than an employer receiving the report, including from other employer-customers or public data sources, to generate the scores.[23]

Not all third parties that assemble or evaluate data will qualify as ''consumer reporting agencies.'' For example, section 603(d)(2)(A)(i) of the FCRA excludes from the definition of ''consumer report'' any ''report containing information solely as to transactions or experiences between the consumer and the person making the report.'' But this exception applies only to reports containing information *solely* about transactions or experiences between the consumer and the report-maker. The exception by its own terms does not apply to a report containing information not about transactions or experiences between the report-maker and the consumer, such as when the report includes algorithmic scores, as described above.

About Consumer Financial Protection Circulars

Consumer Financial Protection Circulars are intended to promote consistency in approach across the various enforcement agencies and parties, pursuant to the CFPB's statutory objective to ensure Federal consumer financial law is enforced consistently. 12 U.S.C. 5511(b)(4).

Consumer Financial Protection Circulars are also intended to provide transparency to partner agencies regarding the CFPB's intended approach when cooperating in enforcement actions. *See, e.g.,* 12 U.S.C. 5552(b) (consultation with CFPB by State attorneys general and regulators); 12 U.S.C. 5562(a) (joint investigatory work between CFPB and other agencies).

Consumer Financial Protection Circulars are general statements of policy under the Administrative Procedure Act. 5 U.S.C. 553(b). They provide background information about applicable law, articulate considerations relevant to the Bureau's exercise of its authorities, and, in the interest of maintaining consistency, advise other parties with authority to enforce Federal consumer financial law. They do not restrict the Bureau's exercise of its authorities, impose any legal requirements on external parties, or create or confer any rights on external parties that could be enforceable in any administrative or civil proceeding. The CFPB Director is instructing CFPB staff as described herein, and the CFPB will then make final decisions on individual matters based on an assessment of the factual record, applicable law, and factors relevant to prosecutorial discretion.

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2024–26099 Filed 11–8–24; 8:45 am]

BILLING CODE 4810–AM–P

[23] That may be true even when the assessment is performed through a software program licensed to employers, because the software provider furnishes the reports. Federal Trade Commission (FTC) staff opined more than two decades ago that a seller of particular software that allowed users to compile and de-duplicate credit report information from the three major nationwide consumer reporting agencies was not itself a consumer reporting agency, reasoning that the software seller was not ''assembling or evaluating'' any information itself. FTC Advisory Opinion (Oct. 27, 1997), *https://www.ftc.gov/legal-library/browse/advisory-opinions/advisory-opinion-cast-10-27-97; see also* FTC, *40 Years of Experience with the Fair Credit Reporting Act: An FTC Staff Report with Summary of Interpretations* at 12–13, 29 (July 2011). The FTC's guidance, however, focused on technology that was in existence at the time the guidance was drafted. Significant changes in the software and general technological landscape have taken place in the years since, rendering the FTC's prior guidance inapplicable to many of the kinds of technology used today. For example, software developers today often take a more active role in providing ongoing services to clients, such as by performing ongoing maintenance of the software, or by licensing services to clients instead of selling software as a point-in-time product. Accordingly, a third-party software provider could meet the definition of a consumer reporting agency where it assembles or evaluates consumer information to develop software that produces reports used to evaluate a worker ''for employment, promotion, reassignment or retention,'' or where the software itself assembles or evaluates information about a worker to produce reports used for those purposes. Judicial decisions declining to find software providers to be CRAs are likewise distinguishable. For instance, in *Zabriskie* v. *Fed. Nat'l Mortg. Ass'n,* 940 F.3d 1022, 1029 (9th Cir. 2019), the court determined that Fannie Mae did not act as a CRA by licensing a proprietary software that allowed lenders to determine whether their loans met requirements for Fannie Mae to purchase, but relied on reasoning inapplicable to third-party software developers that analyze worker data that companies use for employment purposes. *Id.* (reasoning that Congress intended to exclude Fannie Mae from the definition of a ''consumer reporting agency'' and that Fannie Mae did not have the purpose of furnishing consumer reports to a third party, but rather to determine the loans' eligibility for purchase).

FEDERAL RESERVE SYSTEM

12 CFR Part 209

[Regulation I; Docket No. R–1844]

RIN 7100—AG 85

Federal Reserve Bank Capital Stock

AGENCIES: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors (Board) is publishing a final rule that applies an inflation adjustment to the threshold for total consolidated assets in Regulation I. Federal Reserve Bank (Reserve Bank) stockholders that have total consolidated assets above the threshold receive a different dividend rate on their Reserve Bank stock than stockholders with total consolidated assets at or below the threshold. The Federal Reserve Act requires that the Board annually adjust the total consolidated asset threshold to reflect the change in the Gross Domestic Product Price Index, published by the Bureau of Economic Analysis (BEA). Based on the change in the Gross Domestic Product Price Index as of September 26, 2024, the total consolidated asset threshold will be $12,841,000,000 through December 31, 2025.

DATES:

Effective date: December 12, 2024.

Applicability date: The adjusted threshold for total consolidated assets will apply beginning on January 1, 2025.

FOR FURTHER INFORMATION CONTACT: Benjamin Snodgrass, Senior Counsel (202/263–4877), Legal Division; or Kelsey Cassidy, Senior Financial Institutions Policy Analyst (202/465–6817), Reserve Bank Operations and Payments Systems Division. For users of TTY–TRS, please contact 711 from any telephone, anywhere in the United States or (202) 263–4869.

SUPPLEMENTARY INFORMATION:

I. Background

Regulation I governs the issuance and cancellation of capital stock by the

Reserve Banks. Under section 5 of the Federal Reserve Act [1] and Regulation I,[2] a member bank must subscribe to capital stock of the Reserve Bank of its district in an amount equal to six percent of the member bank's capital and surplus. The member bank must pay for one-half of this subscription when the Reserve Bank issues the capital stock, while the remaining half of the subscription shall be subject to call by the Board.[3]

Section 7(a)(1) of the Federal Reserve Act [4] provides that Reserve Bank stockholders with $10 billion or less in total consolidated assets shall receive a six percent dividend on paid-in capital stock, while stockholders with more than $10 billion in total consolidated assets shall receive a dividend on paid-in capital stock equal to the *lesser* of six percent and ''the rate equal to the high yield of the 10-year Treasury note auctioned at the last auction held prior to the payment of such dividend.'' Section 7(a)(1) requires that the Board adjust the threshold for total consolidated assets annually to reflect the change in the Gross Domestic Product Price Index, published by the BEA.

Regulation I implements section 7(a)(1) of the Federal Reserve Act by (1) defining the term ''total consolidated assets,'' [5] (2) incorporating the statutory dividend rates for Reserve Bank stockholders [6] and (3) providing that the Board shall adjust the threshold for total consolidated assets annually to reflect the change in the Gross Domestic Product Price Index.[7] The Board has explained that it ''expects to make this adjustment [to the threshold for total consolidated assets] using the final second quarter estimate of the Gross Domestic Product Price Index for each year, published by the Bureau of Economic Analysis.'' [8]

II. Adjustment

The Board annually adjusts the $10 billion total consolidated asset threshold based on the change in the Gross Domestic Product Price Index between the second quarter of 2015 (the baseline year) and the second quarter of the current year.[9] The second quarter 2024 Gross Domestic Product Price Index estimate published by the BEA in September 2024 (124.942) is 28.41 percent higher than the second quarter 2015 Gross Domestic Product Price Index estimate published by the BEA in September 2024 (97.302). Based on this change in the Gross Domestic Product Price Index, the threshold for total consolidated assets in Regulation I will be $12,841,000,000 as of January 1, 2025.

III. Administrative Law Matters

Administrative Procedure Act

The provisions of 5 U.S.C. 553(b) relating to notice of proposed rulemaking have not been followed in connection with the adoption of these amendments. The amendments involve expected, ministerial adjustments that are required by statute and Regulation I and are consistent with a method previously set forth by the Board.[10] Accordingly, the Board finds good cause for determining, and so determines, that notice in accordance with 5 U.S.C. 553(b) is unnecessary.

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a general notice of proposed rulemaking is not required.[11] As noted previously, the Board has determined that it is unnecessary to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirements relating to an initial and final regulatory flexibility analysis do not apply.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995,[12] the Board has reviewed this final rule. No collections of information pursuant to the Paperwork Reduction Act are contained in the final rule.

List of Subjects in 12 CFR Part 209

Banks and banking, Federal Reserve System, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons set forth in the preamble, the Board amends Regulation I, 12 CFR part 209, as follows:

PART 209—ISSUE AND CANCELLATION OF FEDERAL RESERVE BANK CAPITAL STOCK (REGULATION I)

■ 1. The authority citation for part 209 continues to read as follows:

Authority: 12 U.S.C. 12 U.S.C. 222, 248, 282, 286–288, 289, 321, 323, 327–328, and 466.

§ 209.2 [Amended]

■ 2. Amend § 209.2 by removing ''$12,517,000,000'' and adding in its place ''$12,841,000,000''.

§ 209.3 [Amended]

■ 3. Amend § 209.3 by removing ''$12,517,000,000'' and adding in its place ''$12,841,000,000''.

§ 209.4 [Amended]

■ 4. Amend § 209.4 by removing ''$12,517,000,000'' and adding in their place ''$12,841,000,000'', wherever they appear.

By order of the Board of Governors of the Federal Reserve System, acting through the Secretary of the Board under delegated authority.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2024–26091 Filed 11–8–24; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0464; Project Identifier MCAI–2022–01556–T; Amendment 39–22875; AD 2024–22–04]

RIN 2120–AA64

Airworthiness Directives; Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2021–09–03, which applied to certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. AD 2021–09–03 required repetitive replacements of the emergency locator

[1] 12 U.S.C. 287.

[2] 12 CFR 209.4(a).

[3] 12 U.S.C. 287 and 12 CFR 209.4(c)(2).

[4] 12 U.S.C. 289(a)(1).

[5] 12 CFR 209.1(d)(3).

[6] 12 CFR 209.4(e), (c)(1)(ii), and (d)(1)(ii); 209.2(a); and 209.3(d)(5).

[7] 12 CFR 209.4(f).

[8] 81 FR 84415, 84417 (Nov. 23, 2016).

[9] The BEA makes ongoing revisions to its estimates of the Gross Domestic Product Price Index for historical calendar quarters. The Board calculates annual adjustments from the baseline year (rather than from the prior-year total consolidated asset threshold) to ensure that the adjusted total consolidated asset threshold accurately reflects the cumulative change in the BEA's most recent estimates of the Gross Domestic Product Price Index.

[10] *See* 12 CFR 209.4(f) and n. 8 and accompanying text, *supra.*

[11] 5 U.S.C. 603 and 604.

[12] 44 U.S.C. 3506; 5 CFR 1320.

transmitter (ELT) antenna and repetitive inspections of the exterior fuselage skin around the ELT antenna attachment area. This AD was prompted by a report that there was an in-service failure of an ELT antenna that occurred before the repetitive replacement interval required by AD 2021–09–03, and that a terminating action was developed. This AD continues to require the actions in AD 2021–09–03 and requires replacement of the ELT antenna with a new ELT antenna, inspection of the exterior fuselage skin around the ELT antenna attachment holes, and repair if necessary; as specified in a Transport Canada AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 17, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 17, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0464; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca*; website *tc.canada.ca/en/aviation.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–0464.

FOR FURTHER INFORMATION CONTACT:

Yaser Osman, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 860–386–1786; email: *yaser.m.osman@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2021–09–03, Amendment 39–21516 (86 FR 20266, April 19, 2021); corrected April 27, 2021 (86 FR 22111) (AD 2021–09–03). AD 2021–09–03 applied to certain Airbus Canada Limited Partnership Model BD–500–1A10 and BD–500–1A11 airplanes. AD 2021–09–03 required repetitive replacements of the ELT antenna and repetitive inspections of the exterior fuselage skin around the ELT antenna attachment area. The FAA issued AD 2021–09–03 to address ELT antenna failure, which can lead to the loss of the ELT antenna and the development of fuselage cracks that can result in an inability to maintain cabin pressure.

The NPRM published in the **Federal Register** on March 11, 2024 (89 FR 17343). The NPRM was prompted by AD CF–2022–67, dated December 6, 2022 (Transport Canada AD CF–2022–67) (also referred to as the MCAI), issued by Transport Canada, which is the aviation authority for Canada. The MCAI states that since Transport Canada AD CF–2021–10 (corresponds to AD 2021–09–03) was issued, an aluminum ELT antenna has been made available to prevent ELT antenna failures resulting from vibration loads induced by air vortices shed by the Gogo 2Ku antenna radome. In addition, there was an in-service failure of an ELT antenna that occurred before the repetitive replacement interval required by Transport Canada AD CF–2021–10 was reached. The MCAI also states installation of the aluminum ELT antenna terminates the requirements of Transport Canada CF–2022–67, and that the applicability has been limited to airplanes on which the aluminum ELT antenna has not been installed in production.

In the NPRM, the FAA proposed to continue to require the actions in AD 2021–09–03 and replacement of the ELT antenna with a new ELT antenna, inspection of the exterior fuselage skin around the ELT antenna attachment holes, and repair if necessary, as specified in Transport Canada AD CF–2022–67. The FAA is issuing this AD to address ELT antenna failure, which can lead to the loss of the ELT antenna and the development of fuselage cracks that can result in an inability to maintain cabin pressure.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0464.

Discussion of Final Airworthiness Directive

Comments

The FAA received one comment from a single commenter, Delta Air Lines (Delta). The following presents the comment received on the NPRM and the FAA's response to each comment.

Request To Clarify Applicability

Delta requested the FAA revise the applicability of the proposed AD to clarify it does not apply to airplanes that are not equipped with a Gogo 2Ku antenna radome, part number (P/N) P23743–605 or P/N P23743–606, as identified in the applicability of Transport Canada AD CF–2022–67. Delta stated that for AD 2021–09–03 (corresponding to Transport Canada AD CF–2021–10), the FAA clarified that if an airplane is not equipped with the part numbers identified in the applicability of Transport Canada AD CF–2021–10, then the requirements of AD 2021–09–03 do not apply to that airplane. As justification for its request, Delta noted that the applicability of Transport Canada AD CF–2021–10 mirrors the applicability of Transport Canada AD CF–2022–67.

The FAA agrees that if an airplane is not equipped with an affected part number identified in the MCAI referenced in paragraph (c) of this AD, then this AD does not apply to that airplane. The FAA has not changed this AD in this regard.

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

Transport Canada AD CF–2022–67 specifies procedures for:

- Repetitive replacements of the ELT antenna with a new ELT antenna and repetitive inspections for damage (including cracking) of the exterior

fuselage skin around the ELT antenna attachment area, and

• A one-time replacement of the ELT antenna with a new aluminum ELT antenna, and detailed inspection for damage (including cracking) of the exterior fuselage skin around the ELT antenna attachment holes, and repair of any damage, which terminate the repetitive replacements and inspections.

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

Costs of Compliance

The FAA estimates that this AD affects 56 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Retained actions from AD 2021–09–03	4 work-hours × $85 per hour = $340	$4,230	$4,570	$255,920
New actions	4 work-hours × $85 per hour = $340	5,561	5,901	330,456

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
4 work-hours × $85 per hour = $340	$2,000	$2,340

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2021–09–03, Amendment 39–21516 (86 FR 20266, April 19, 2021; corrected April 27, 2021 (86 FR 22111)); and

■ b. Adding the following new AD:

2024–22–04 Airbus Canada Limited Partnership (Type Certificate Previously Held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.): Amendment 39–22875; Docket No. FAA–2024–0464; Project Identifier MCAI–2022–01556–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 17, 2024.

(b) Affected ADs

This AD replaces AD 2021–09–03, Amendment 39–21516 (86 FR 20266, April 19, 2021); corrected April 27, 2021 (86 FR 22111) (AD 2021–09–03).

(c) Applicability

This AD applies to Airbus Canada Limited Partnership (Type Certificate previously held by C Series Aircraft Limited Partnership (CSALP); Bombardier, Inc.) Model BD–500–1A10 and BD–500–1A11 airplanes, certificated in any category, as identified in Transport Canada AD CF–2022–67, dated December 6, 2022 (Transport Canada AD CF–2022–67).

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings; 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by reports of the failure of emergency locator transmitter (ELT) antennas, including an in-service failure that occurred before the repetitive replacement interval required by AD 2021–09–03, and by the development of a terminating action. The

FAA is issuing this AD to address ELT antenna failure. The unsafe condition, if not addressed, could result in loss of the ELT antenna and the development of fuselage cracks that can result in an inability to maintain cabin pressure.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2022–67.

(h) Exception to Transport Canada AD CF–2022–67

(1) Where Transport Canada AD CF–2022–67 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where Transport Canada AD CF–2022–67 refers to April 1, 2021 (the effective date of Transport Canada AD CF–2021–10, dated March 18, 2021), this AD requires using May 4, 2021 (the effective date of AD 2021–09–03).

(3) Where Transport Canada AD CF–2022–67 refers to hours air time, this AD requires using flight hours.

(4) Where paragraph C of Transport Canada AD CF–2022–67 specifies to ''replace the ELT antenna with a new aluminum ELT antenna and inspect the exterior fuselage skin around the ELT antenna attachment holes for damage, repairing any damage found before further flight,'' this AD requires replacing that text with ''replace the ELT antenna with a new aluminum ELT antenna, including doing an inspection of the exterior fuselage skin around the ELT antenna attachment holes for damage, and, before further flight, repair any damage found.''

(i) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(ii) AMOCs approved previously for AD 2021–09–03 are not approved as AMOCs for the corresponding provisions of Transport Canada AD CF–2022–67 that are required by paragraph (g) of this AD.

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

(j) Additional Information

For more information about this AD, contact Yaser Osman, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 860–386–1786; email: *yaser.m.osman@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2022–67, dated December 6, 2022.

(ii) [Reserved]

(3) For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website *tc.canada.ca/en/aviation.*

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

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

Issued on October 24, 2024.

Peter A. White,

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

[FR Doc. 2024–25977 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–1894; Project Identifier MCAI–2024–00036–T; Amendment 39–22873; AD 2024–22–02]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2023–21–02, which applied to certain Airbus SAS Model A330–200 series, A330–200 Freighter series, A330–300 series, A330–800 series, and A330–900 series airplanes. AD 2023–21–02 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. This AD continues to require certain actions in AD 2023–21–02 and requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 17, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 17, 2024.

The Director of the Federal Register approved the incorporation by reference of certain other publications listed in this AD as of December 11, 2023 (88 FR 76107, November 6, 2023).

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–1894; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–1894.

FOR FURTHER INFORMATION CONTACT: Vladimir Ulyanov, Aviation Safety Engineer, FAA, 1600 Stewart Avenue,

Suite 410, Westbury, NY 11590; telephone 206–231–3229; email *vladimir.ulyanov@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2023–21–02, Amendment 39–22574 (88 FR 76107, November 6, 2023) (AD2023–21–02). AD 2023–21–02 applied to certain Airbus SAS Model 330–201, –202, –203, –223, –223F, –243, –243F, –301, –302, –303, –321, –322, –323, –341, –342, –343, –841 and –941 airplanes. AD 2023–21–02 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2023–21–02 to address fatigue cracking, accidental damage, and corrosion in principal structural elements; such fatigue cracking, accidental damage, and corrosion could result in reduced structural integrity of the airplane.

The NPRM published in the **Federal Register** on July 24, 2024 (89 FR 59853). The NPRM was prompted by AD 2024–0011, dated January 10, 2024 (EASA AD 2024–0011) (also referred to as the MCAI), issued by EASA, which is the Technical Agent for the Member States of the European Union. The MCAI states that new or more restrictive airworthiness limitations have been developed.

In the NPRM, the FAA proposed to continue to require certain actions in AD 2023–21–02 and to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, as specified in EASA AD 2024–0011. The FAA is issuing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–1894.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0011, dated January 10, 2024, specifies new or more restrictive airworthiness limitations for airplane structures.

This AD also requires EASA AD 2022–0187, dated September 13, 2022, and EASA AD 2023–0015, dated January 19, 2023, which the Director of the Federal Register approved for incorporation by reference as of December 11, 2023 (88 FR 76107, November 6, 2023).

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

Costs of Compliance

The FAA estimates that this AD affects 126 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

The FAA estimates the total cost per operator for the retained actions from AD 2023–21–02 to be $7,650 (90 work-hours × $85 per work-hour).

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

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

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2023–21–02, Amendment 39–22574 (88 FR 76107, November 6, 2023); and

■ b. Adding the following new AD:

2024–22–02 Airbus SAS: Amendment 39–22873; Docket No. FAA–2024–1894; Project Identifier MCAI–2024–00036–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 17, 2024.

(b) Affected ADs

This AD replaces AD 2023–21–02, Amendment 39–22574 (88 FR 76107, November 6, 2023) (AD 2023–21–02).

(c) Applicability

This AD applies to Airbus SAS airplanes, identified in paragraphs (c)(1) through (5) of this AD, certificated in any category, with an original airworthiness certificate or original export certificate of airworthiness issued on or before October 20, 2023.

(1) Model A330–201, –202, –203, –223, and –243 airplanes.

(2) Model A330–223F and –243F airplanes.

(3) Model A330–301, –302, –303, –321, –322, –323, –341, –342, and –343 airplanes.

(4) Model A330–841 airplanes.

(5) Model A330–941 airplanes.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address fatigue cracking, accidental damage, and corrosion in principle structural elements. The unsafe condition, if not addressed, could result in reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With New Terminating Action

This paragraph restates the requirements of paragraph (j) of AD 2023–21–02, with new terminating action. For airplanes with an original airworthiness certificate or original export certificate of airworthiness issued on or before November 18, 2022: Except as specified in paragraph (h) of this AD, comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0187, dated September 13, 2022 (EASA AD 2022–0187), and AD 2023–0015, dated January 19, 2023 (EASA AD 2023–0015); as applicable. Where EASA AD 2023–0015 affects the same airworthiness limitations as those in EASA AD 2022–0187, the airworthiness limitations referenced in EASA AD 2023–0015 prevail. Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2022–0187 and EASA AD 2023–0015, With No Changes

This paragraph restates the exceptions specified in paragraph (k) of AD 2023–21–02, with no changes.

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2022–0187 and of EASA AD 2023–0015.

(2) Paragraph (3) of EASA AD 2022–0187 and of EASA AD 2023–0015 specifies revising ''the AMP'' within 12 months after the respective EASA AD's effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after December 11, 2023 (the effective date of AD 2023–21–02).

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2022–0187 and of EASA AD 2023–0015 is at the applicable ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2022–0187 and of EASA AD 2023–0015, or within 90 days after December 11, 2023 (the effective date of AD 2023–21–02), whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2022–0187.

(5) Where EASA AD 2022–0187 defines ''The ALS,'' replace the text ''Airbus A330 Airworthiness Limitations Section (ALS) Part 2 Revision 05,'' with ''Airbus A330 Airworthiness Limitations Section (ALS) Part 2 Revision 05 Issue 02.''

(6) This AD does not adopt the provisions specified in paragraph (4) of EASA AD 2023–0015.

(7) This AD does not require incorporating Section 4, ''Damage Tolerant—Airworthiness Limitations Items—Tasks Beyond MPPT,'' of ''the ALS'' specified in EASA AD 2022–0187 and in EASA AD 2023–0015.

(8) This AD does not adopt the ''Remarks'' section of EASA AD 2022–0187 and of EASA AD 2023–0015.

(i) Retained Provisions for Alternative Actions and Intervals, With a New Exception

This paragraph restates the provisions of paragraph (l) of AD 2023–21–02, with a new exception. Except as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0187 or of EASA AD 2023–0015.

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

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2024–0011, dated January 10, 2024 (EASA AD 2024–0011). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2024–0011

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2024–0011.

(2) Paragraph (3) of EASA AD 2024–0011 specifies revising ''the approved AMP,'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA AD 2024–0011 is at the applicable ''associated thresholds'' as incorporated by the requirements of paragraph (3) of EASA AD 2024–0011, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2024–0011.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0011.

(6) This AD does not require incorporating Section 4, ''Damage Tolerant—Airworthiness Limitations Items—Tasks Beyond MPPT,'' of ''the ALS'' specified in EASA 2024–0011.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2024–0011.

(m) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(n) Additional Information

For more information about this AD, contact Vladimir Ulyanov, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3229; email *vladimir.ulyanov@faa.gov.*

(o) Material Incorporated by Reference

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

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

(3) The following material was approved for IBR on December 17, 2024.

(i) European Union Aviation Safety Agency (EASA) AD 2024–0011, dated January 10, 2024.

(ii) [Reserved]

(4) The following material was approved for IBR on December 11, 2023 (88 FR 76107, November 6, 2023).

(i) European Union Aviation Safety Agency (EASA) AD 2022–0187, dated September 13, 2022.

(ii) European Union Aviation Safety Agency (EASA) AD 2023–0015, dated January 19, 2023.

(5) For EASA AD 2022–0187, EASA AD 2023–0015, and EASA AD 2024–0011, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find these EASA ADs on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on October 23, 2024.

Suzanne Masterson,

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

[FR Doc. 2024–25980 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2007; Project Identifier MCAI–2023–01270–T; Amendment 39–22871; AD 2024–21–04]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Bombardier, Inc., Model BD–100–1A10 airplanes. This AD was prompted by a determination that new or more restrictive maintenance tasks are necessary. This AD requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance tasks. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 17, 2024.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in this AD as of December 17, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2007; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Bombardier, Inc. material identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–2007.

FOR FURTHER INFORMATION CONTACT: Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Bombardier, Inc., Model BD–100–1A10 airplanes. The NPRM published in the **Federal Register** on August 9, 2024 (89 FR 65267). The NPRM was prompted by AD CF–2023–78, dated December 19, 2023, issued by Transport Canada, which is the aviation authority for Canada (also referred to as the MCAI). The MCAI states that airplanes could experience misleading electrical system status indications (push button annunciators (PBA) and engine instrument and crew alerting system (EICAS)) as a result of contamination of electrical contacts in the left-hand (LH) direct current power center (DCPC) internal communication data bus. The MCAI states that new or more restrictive maintenance tasks have been developed to rectify lower time LH DCPC units not addressed by previously issued ADs.

In the NPRM, the FAA proposed to require revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive maintenance tasks. The FAA is issuing this AD to address erratic indications, which could cause the flightcrew to turn off fully operational electrical power sources, leading to partial or complete loss of electrical power. The unsafe condition, if not addressed, could result in loss of flight displays and reduced controllability of the airplane.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2007.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed the following documents:

- Task 24–61–01–101*, ''Restoration of the left DC Power Center (DCPC) (Pre SB100–24–30),'' Section 5–10–20, ''Time Limits—Supplementary Limitations,'' of Part 2, ''Airworthiness Limitations'', of the Bombardier Challenger 300 Time Limits/Maintenance Checks, Publication No. CH 300 TLMC, Revision 24, dated August 9, 2023.
- Task 24–61–01–101*, ''Restoration of the Left DC Power Center (DCPC) (Pre SB350–24–005),'' Section 5–10–20, ''Time Limits—Supplementary Limitations,'' of Part 2, ''Airworthiness Limitations,'' of the Bombardier Challenger 350 Time Limits/Maintenance Checks, Publication No. CH 350 TLMC, Revision 14, dated August 9, 2023.

This material specifies new or more restrictive airworthiness limitations for

safe life limits. These documents are distinct since they apply to different airplane configurations. The asterisk (or ''one star'') with the last three digits of the task numbers indicates that the task is an airworthiness limitation task.

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

Costs of Compliance

The FAA estimates that this AD affects 356 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD.

The FAA has determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, the agency estimates the average total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–21–04 Bombardier, Inc.: Amendment 39–22871; Docket No. FAA–2024–2007; Project Identifier MCAI–2023–01270–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 17, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Bombardier, Inc., Model BD–100–1A10 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 24, Electrical Power.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive maintenance tasks are necessary. The FAA is issuing this AD to address erratic indications, which could cause the flightcrew to turn off fully operational electrical power sources, leading to partial or complete loss of electrical power. The unsafe condition, if not addressed, could result in loss of flight displays and reduced controllability of the airplane.

(f) Compliance

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

(g) Maintenance or Inspection Program Revision

Within 60 days after the effective date of this AD, revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the tasks specified in figure 1 to paragraph (g) of this AD, of Part 2, ''Airworthiness Limitations,'' of the applicable Time Limits/Maintenance Checks (TLMC) manual. The initial compliance time for doing the tasks is at the interval specified in the applicable TLMC manual specified in figure 1 to paragraph (g) of this AD, or within 60 days after the effective date of this AD, whichever occurs later.

FIGURE 1 TO PARAGRAPH (g)—TIME LIMITS—SUPPLEMENTARY LIMITATIONS TASKS

Airplane model	Chapter 5 task No.	Task title	TLMC section	TLMC
BD–100–1A10 (Challenger 300).	24–61–01–101 *	Restoration of the Left DC Power Center (DCPC) (Pre SB100–24–30).	5–10–20, ''Time Limits—Supplementary Limitations''.	Revision 24, dated August 9, 2023.
BD–100–1A10 (Challenger 350).	24–61–01–101 *	Restoration of the Left DC Power Center (DCPC) (Pre SB350–24–005).	5–10–20, ''Time Limits—Supplementary Limitations''.	Revision 14, dated August 9, 2023.

Note 1 to paragraph (g): The asterisk (or ''one star'') with the last three digits of the task numbers listed in figure 1 to paragraph (g) of this AD indicates that the task is an airworthiness limitation task.

(h) No Alternative Actions or Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (i)(1) of this AD.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

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

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

(j) Additional Information

For more information about this AD, contact Steven Dzierzynski, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Task 24–61–01–101*, ''Restoration of the left DC Power Center (DCPC) (Pre SB100–24–30),'' Section 5–10–20, ''Time Limits—Supplementary Limitations,'' of Part 2, ''Airworthiness Limitations'', of the Bombardier Challenger 300 Time Limits/Maintenance Checks, Publication No. CH 300 TLMC, Revision 24, dated August 9, 2023.

Note 2 to paragraph (k)(2)(i): The asterisk (or ''one star'') with the last three digits of the task numbers listed in paragraphs (k)(2)(i) and (ii) of this AD indicates that the task is an airworthiness limitation task.

(ii) Task 24–61–01–101*, ''Restoration of the Left DC Power Center (DCPC) (Pre SB350–24–005),'' Section 5–10–20, ''Time Limits—Supplementary Limitations,'' of Part 2, ''Airworthiness Limitations,'' of the Bombardier Challenger 350 Time Limits/Maintenance Checks, Publication No. CH 350 TLMC, Revision 14, dated August 9, 2023.

(3) For Bombardier Inc. material identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514 855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

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

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

Issued on October 24, 2024.

Victor Wicklund,

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

[FR Doc. 2024–25979 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–0767; Project Identifier MCAI–2023–00723–T; Amendment 39–22786; AD 2024–14–05]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–700–2A12 airplanes. This AD was prompted by reports that the baggage bay discharge push-button annunciator (PBA) switch was making contact but was not fully engaged, and the tabs were not fully locked. This AD requires a verification of the baggage bay discharge PBA functionality and tab installation. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective December 17, 2024.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of December 17, 2024.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–0767; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For Bombardier material, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–0767.

FOR FURTHER INFORMATION CONTACT: William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Bombardier, Inc., Model BD–700–2A12 airplanes. The NPRM published in the **Federal Register** on March 28, 2024 (89 FR 21443). The NPRM was prompted by AD CF–2023–36, dated May 29, 2023, issued by Transport Canada, which is the aviation authority for Canada (referred to after this as the MCAI). The MCAI states that during the execution of a functional test procedure (FTP) during production, the baggage bay discharge PBA switch was partially engaged and failed to make electrical contact. Further investigation showed that in some instances, the baggage bay discharge PBA switch was making contact but was not fully engaged and the tabs were not fully locked, so while the PBA may pass the FTP, vibration could eventually lead to a loss of electrical contact and subsequent loss of baggage bay discharge PBA switch functionality.

In the NPRM, the FAA proposed to require a verification of the baggage bay discharge PBA functionality and tab installation. The FAA is issuing this AD to address the possible inability to discharge halon into the baggage compartment in case of a fire. The unsafe condition on these products, if not addressed, could result in the inability to control a baggage compartment fire.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–0767.

Discussion of Final Airworthiness Directive

Comments

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

Conclusion

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

Related Material Under 1 CFR Part 51

The FAA reviewed Bombardier Service Bulletin 700–26–7505, dated February 10, 2023. This service information specifies procedures for doing a general visual inspection of the baggage bay discharge PBA switch for proper installation and a functional operation test. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 42 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
2 work-hours × $85 per hour = $170	$0	$170	$7,140

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2024–14–05 Bombardier, Inc.: Amendment 39–22786; Docket No. FAA–2024–0767; Project Identifier MCAI–2023–00723–T.

(a) Effective Date

This airworthiness directive (AD) is effective December 17, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–2A12 airplanes, certificated in any category, serial numbers 70006 through 70099 inclusive.

(d) Subject

Air Transport Association (ATA) of America Code 26, Fire protection.

(e) Unsafe Condition

This AD was prompted by reports that the baggage bay discharge push-button annunciator (PBA) switch was making contact but was not fully engaged, and the tabs were not fully locked. The FAA is issuing this AD to address the possible inability to discharge halon into the baggage compartment in case of a fire. The unsafe condition, if not addressed, could result in the inability to control a baggage compartment fire.

(f) Compliance

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

(g) Required Actions

Within 36 months after the effective date of this AD: Perform the inspection and testing of the baggage bay discharge PBA switch, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 700–26–7505, dated February 10, 2023.

(h) Additional AD Provisions

The following provisions also apply to this AD:

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

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

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

(i) Additional Information

For more information about this AD, contact William Reisenauer, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

(j) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 700–26–7505, dated February 10, 2023.

(ii) [Reserved]

(3) For Bombardier material identified in this AD, contact Bombardier Business Aircraft Customer Response Center, 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–2999; email *ac.yul@aero.bombardier.com;* website *bombardier.com.*

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

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

Issued on July 10, 2024.

James D. Foltz,

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

Editorial Note: This document was received for publication by the Office of the Federal Register on November 5, 2024.

[FR Doc. 2024–25978 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 70

RIN 2900–AS19

Changes in Rates VA Pays for Special Modes of Transportation; Delay of Effective Date From February 16, 2025, Until February 16, 2029

AGENCY: Department of Veterans Affairs.

ACTION: Final rule; delay of effective date.

SUMMARY: The Department of Veterans Affairs (VA) published in the **Federal Register** on February 16, 2023, a final rule to amend its beneficiary travel regulations to establish a new payment methodology for special modes of transportation available through the VA beneficiary travel program. The preamble of that final rule stated the effective date was February 16, 2024. VA published in the **Federal Register** on December 29, 2023, a final rule to delay the effective date for the rule from February 16, 2024, to February 16, 2025. This rulemaking further delays the effective date of February 16, 2025, to February 16, 2029.

DATES: *Effective Date:* The effective date for the final rule published February 16, 2023, at 88 FR 10032, and delayed on December 29, 2023, at 88 FR 90120, until February 16, 2025, is further delayed until February 16, 2029.

FOR FURTHER INFORMATION CONTACT: Ben Williams, Director, Veterans Transportation Program (15MEM), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, (404) 828–5691. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: On November 5, 2020, VA proposed amending its beneficiary travel regulations to implement the discretionary authority in 38 U.S.C. 111(b)(3)(C), which permits VA to pay the lesser of the actual charge for ambulance transportation or the amount determined by the Centers for Medicare and Medicaid Services (CMS) Medicare Part B Ambulance Fee Schedule (hereafter referred to the CMS ambulance fee schedule) established under section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)), unless VA has entered into a contract for that transportation. We provided a 60-day comment period that ended on January 4, 2021, and we received six comments, five of which were substantive. Those five comments all raised similar concerns about 38 CFR 70.30(a)(4) introductory text and (a)(4)(i) and (ii) as proposed, related to using the CMS ambulance fee schedule or, in the case of travel by modes other than ambulance, the posted rates from each State. We responded to all comments in a final rule published in the **Federal Register** on February 16, 2023 (88 FR 10032), wherein we stated that we would not make changes from the proposed rule related to application of the CMS ambulance fee schedule but would delay the effective date of the final rule by one year (to be February 16, 2024) to ensure that ambulance providers have adequate time to adjust to VA's new methodology for calculating ambulance rates. (88 FR 10035). We further stated in the final rule that such adjustment could include ambulance providers entering negotiations with VA to contract for payment rates different than those under the CMS ambulance fee schedule, as contemplated in the final rule.

After the final rule was published, VA received feedback from both internal and external stakeholders, including VA employees, ambulance providers, and industry experts, that more time would be necessary for successful implementation of the rule. Specifically, delaying the effective date was intended to accommodate unforeseen difficulties in air ambulance broker contracting. At the time, VA believed it would be able to enter into contracts and/or subcontract relationships with air ambulance service providers for non-VA initiated service calls if given more time for negotiations. Based on this feedback and evaluation of the continued effort that would be required by air ambulance brokers to negotiate and enter into contracts before February 16, 2024, VA published a final rule on December 29, 2023, (88 FR 90120) that delayed the effective date of the regulation by one year to February 16, 2025.

After the final rule delaying the effective date to February 2025 was published, however, VA learned through continued discussions with industry experts, including air ambulance providers and brokers, that contracting for emergency, non-VA initiated air transportation is not feasible at this time. Impediments include the lack of air industry infrastructure for air ambulance brokers to enter into subcontracts with providers for non-VA initiated ambulance transports, as well as the general lack of authority of non-VA individuals to enter into orders or other contractually binding agreements for transportation on behalf of VA.

Air ambulance providers contend that the Medicare reimbursement rate that

will apply absent a contract is unsustainable for their business operations and may result in either a reduction in the availability of air ambulance services for both veterans and the public and/or will place veterans at risk of receiving bills for the balance of charges for services. As a result, VA is delaying the effective date of the regulation by four years to allow time for VA to establish additional protections to veterans against balance billing for non-VA initiated air emergency ambulance transports that are reimbursed at a rate other than actual charges. In addition, the delay will provide time for VA to examine alternative payment methodologies for non-VA initiated air ambulance transports. VA has determined that a 4-year delay is necessary to ensure sufficient time to evaluate and address these concerns, which may require additional notice and comment rulemaking.

Administrative Procedure Act

The Administrative Procedure Act (APA), codified in part at 5 U.S.C. 553, generally requires that agencies publish substantive rules in the **Federal Register** for notice of proposed rulemaking and to solicit public comment. However, pursuant to 5 U.S.C. 553(b)(B) of the APA, general notice and the opportunity for public comment are not required with respect to a rulemaking when an ''agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.''

VA finds that there is good cause under the APA to issue this rule without prior notice and opportunity for public comment. As stated previously, VA last delayed the effective date of the final rule (that published on February 16, 2023, at 88 FR 10032) in late December 2023, to provide additional time for air ambulance brokers to enter into subcontracts with ambulance providers for emergency, non-VA initiated transports. During the first few months of 2024, VA engaged in continued discussions and further contracting efforts with the ambulance industry generally, with a particular focus on emergent, non-VA initiated air ambulance transportation. In the spring of 2024, however, VA learned that contracting for emergency, non-VA initiated air transportation is not feasible at this time due to the lack of air industry infrastructure for ambulance brokers to enter into subcontracts with providers for non-VA initiated ambulance transports, as well as the general lack of authority of non-VA individuals to enter into orders or other contractually binding agreements for transportation on behalf of VA. As a result, VA promptly began developing alternative courses of action to address emergent non-VA initiated air ambulance transportation. However, due to the upcoming effective date of the final rule, VA ultimately determined that the best and most veteran-centric way forward would be to further delay the final rule, to allow additional time for VA to ensure that veterans would not be negatively impacted by balance billing from these ambulance providers.

The final rule published at 88 FR 10032 would become effective on February 16, 2025, pursuant to the final rule delaying its effective date that published at 88 FR 90120. Seeking prior notice and the opportunity for public comment on this delay is impracticable. Specifically, VA was not aware of the need to delay the effective date until summer of 2024. Given the process for publishing a notice of proposed rulemaking followed by an adequate public comment period on the proposed rule, and adequate time to respond to any comments and publish a final rule, VA does not believe there would be sufficient time to ensure that the new rule would be effective before February 16, 2025. As a result, the current final rule would become effective February 16, 2025, and ambulance providers who have been unable to contract for services would be subject to those payment methodologies, which is likely to cause confusion, uncertainty, and possibly result in veterans being billed directly.

Similarly, VA finds that prior notice and opportunity for comment would be contrary to the public interest because it could adversely impact veteran care or result in veterans being billed directly for services. If the new regulation becomes effective on February 16, 2025, VA will pay the lesser of actual charges associated with an air ambulance service or the CMS ambulance fee schedule rate for non-VA initiated ambulance services, because separate contract rates will not exist (as explained earlier, VA now knows that it cannot effectively establish contractual or sub contractual relationships with air ambulance service providers at this time for non-VA initiated emergency transportation). Air ambulance providers contend that the Medicare reimbursement rate that would apply is unsustainable for their business operations and may result in either a reduction in the availability of air ambulance services for veterans and the public, and/or place veterans at risk for being billed directly for the difference between the Medicare rate that VA pays for emergency, non-VA initiated trips and the amount billed by the ambulance provider. For these reasons, VA finds that good cause exists to dispense with the prior notice and public comment procedures for this final rule, as it concludes that such procedures are impracticable and contrary to the public interest pursuant to 5 U.S.C. 553(b)(B).

Executive Orders 12866, 13563, and 14094

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Executive Order on Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866 of September 30, 1993 (Regulatory Planning and Review), and Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review). The Office of Information and Regulatory Affairs has determined that this rulemaking is a significant regulatory action under Executive Order 12866, as amended by Executive Order 14094. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on October 31, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

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

[FR Doc. 2024–25975 Filed 11–8–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 52

[WC Docket No. 18–336; FCC 24–111; FR ID 258492]

Implementation of the National Suicide Hotline Act of 2018

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Federal Communications Commission (Commission) adopted a *Third Report and Order* that requires wireless providers to implement a georouting solution for calls to the 988 Suicide & Crisis Lifeline (988 Lifeline or Lifeline) to facilitate access to critical local intervention services. The majority of calls to the 988 Lifeline are made from wireless phones. However, the 988 Lifeline's system was originally designed to route calls to crisis centers based on a caller's area code and exchange, which may not correspond to the caller's physical location. With georouting data, the 988 Lifeline will be able to route wireless calls to local crisis centers based on the geographic area where the handset is located at the time the 988 call is initiated while maintaining privacy by not identifying the caller's precise location. The *Third Report and Order* also revises the Commission's existing 988 voice and texting rules to permit routing to the 988 Lifeline without translation to a toll free access number, giving wireless providers flexibility in implementing georouting solutions.

DATES:

Effective date: This rule is effective December 12, 2024.

Compliance dates: Compliance with the addition of 47 CFR 52.202 is required for nationwide Commercial Mobile Radio Service (CMRS) providers by 30 days after December 12, 2024 and compliance is required for all CMRS providers by 24 months after December 13, 2024.

ADDRESSES: Federal Communications Commission, 445 12th Street SW, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: For further information, contact Merry Wulff at *Merry.Wulff@fcc.gov* or at (202) 418–1084.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Third Report and Order* in WC Docket No. 18–336, FCC 24–111, adopted on October 17, 2024 and released on October 18, 2024. The full text of the document is available on the Commission's website at *https://docs.fcc.gov/public/attachments/FCC-24-111A1.pdf.* To request materials in accessible formats for people with disabilities (*e.g.,* Braille, large print, electronic files, audio format, etc.), send an email to *FCC504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at (202) 418–0530 (voice).

Congressional Review Act

The Commission has determined, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget, concurs, that this rule is non-major under the Congressional Review Act, 5 U.S.C. 804(2). The Commission sent a copy of this *Third Report & Order* to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A).

Synopsis

1. In this *Third Report and Order,* and consistent with our proposal in the *Implementation of the National Suicide Hotline Act of 2018, Second Further Notice of Proposed Rulemaking* (*SFNPRM*), 89 FR 46340 (May 29, 2024), we adopt a rule that would require wireless providers to implement a georouting solution for calls to the 988 Lifeline. We find that a georouting mandate will strengthen and improve access to the critical benefits of the 988 Lifeline for callers in crisis. We then define the type of location data that qualifies as georouting data. Next, we require nationwide and non-nationwide Commercial Mobile Radio Service (CMRS) providers to have the capability to provide georouting data with 988 calls to the Lifeline Administrator in a format that is compatible with the 988 Lifeline's routing platform to allow routing of calls by generating location data using cell-based location technology. We require CMRS providers to aggregate the cell-based location data to a level that will not identify the location of the cell site or base station receiving the 988 call or otherwise identify the precise location of the handset, thereby protecting the privacy of the caller.

2. To give wireless providers flexibility for this mandate, we do not specify a particular method for aggregating the location data and allow providers to use technically feasible options for meeting this requirement to the extent that they are compatible with the systems used by the 988 Lifeline. This approach is consistent with solutions deployed or being deployed by the three nationwide CMRS providers. We then establish an implementation timeline for georouting calls to the 988 Lifeline of 30 days following the effective date of the rule for nationwide CMRS providers, which is supported by the nationwide providers' representations that they will have already deployed compliant 988 georouting solutions by the compliance deadline. This action will ensure that as soon as possible, the vast majority of callers to the 988 Lifeline in the United States have access to support and resources most closely connected to their location with appropriate privacy safeguards. We expect that non-nationwide CMRS providers will be able to leverage the solutions implemented by the nationwide providers, and for that reason, we require non-nationwide providers to implement georouting 24 months after the effective date of the rule. Finally, we revise our existing 988 voice and texting rules to allow for routing to the national suicide prevention and mental health crisis hotline system maintained by the U.S. Department of Health and Human Services' (HHS) Substance Abuse and Mental Health Services Administration (SAMHSA) and the U.S. Department of Veterans Affairs (VA) without need for translation to the toll free number. Overall, we find that the reasonable and flexible georouting mandate and rule revisions we adopt will provide certainty that 988 callers will be connected to the crisis center nearest to them.

Georouting Will Improve Access and Efficiency of the 988 Lifeline

3. Under our current rules, calls to 988 must first be routed to the existing toll free ten-digit access number for the 988 Lifeline, from which they are then routed to one of over 200 regional crisis centers based on the area code and exchange of the caller's telephone number supplied by the originating service provider. The Commission's rules also require covered 988 text messages to be routed to the 988 Lifeline's current toll free ten-digit access number. The Wireline Competition Bureau granted a waiver to allow covered text providers to route covered 988 text messages to the 988 Lifeline using the short code protocol without translation to the Lifeline's current toll free access number. This allows return texts from the 988 Lifeline to appear on consumer devices as coming from 988 rather than 1–800–273–TALK. As technology trends have shifted from landline phones to mobile phones, many callers now rely on wireless devices with area codes that may not correspond to their physical

locations when contacting the 988 Lifeline, complicating their access to vital local services. In the *SFNPRM,* we explained that the majority of calls placed to the 988 Lifeline are from wireless phones, and the area codes of those phones often do not correspond to the location of the caller. The Lifeline Administrator estimates that 80% of calls placed to the 988 Lifeline are from wireless phones. While 988 call takers can provide support regardless of a caller's location, they may not be able to connect callers in crisis to local resources. We proposed to adopt a rule that would require wireless providers to implement one or more georouting solutions for calls to the 988 Lifeline in order to ensure more accurate routing of calls. After reviewing the record in this proceeding, we find that requiring wireless providers to support georouting for wireless 988 calls is essential to improve the public's access to the 988 Lifeline's critical mental health crisis and suicide prevention services.

4. The record demonstrates near-unanimous agreement for the assertion that there is a need to improve routing of wireless 988 calls to help ensure that callers are routed to geographically appropriate crisis centers. Commenters, including industry and mental health advocates, agree that georouting for 988 wireless calls will improve access to critical local resources and help connect callers to counselors who may be more knowledgeable about unique community stressors and other regional, cultural, and economic factors impacting callers in distress. As several mental health advocates emphasize, access to local resources and support can mean the ''difference between life and death for hundreds of thousands of individuals annually.'' Commenters also highlight that georouting for 988 calls will improve access to referral and follow-up services that may reduce the risk of future mental health crises and suicidality. For example, Mental Health America states that connecting callers to ''support based on their physical location can enable crisis contact centers to provide connections to local resources and follow-up services, reducing the risk of suicidality for individuals in crisis.'' Several commenters also assert that follow-up services are ''more meaningful when a caller is connected to local crisis support.''

5. Mental health and crisis counselors also emphasize that connecting callers with local crisis centers may avert unnecessary dispatch of emergency services and law enforcement. For example, Mental Health America states that ''the ability for 988 callers to be routed to local crisis centers allows counselors to better respond to unique factors and situations, which may also help avoid unnecessary use of emergency services and law enforcement.'' Similarly, as the current Lifeline Administrator explains, connecting callers to trained counselors who can offer ''emotional support and local care resources'' can avert ''unnecessary use of emergency services and law enforcement,'' which is paramount. Moreover, many commenters assert that implementing georouting solutions for wireless 988 calls will enhance the ability of crisis centers to respond effectively to emergency situations and facilitate the dispatch of mobile crisis services.

6. The record also demonstrates that a georouting mandate for wireless 988 calls will advance digital equity by helping to ensure that at-risk populations can more easily access resources in their communities. As the Lifeline Administrator explains, certain populations with a higher risk of suicide are disproportionately impacted by the Lifeline's area code-based routing system, including older adults, youth and young adults, non-Hispanic Black, American Indian, and Alaska Native communities.

Georouting Mandate for Wireless 988 Voice Calls

7. Based on the record presented and in furtherance of the policy goals articulated above, we require nationwide and non-nationwide CMRS providers to implement georouting solutions for calls to the 988 Lifeline. Specifically, we require that all CMRS providers have the capability to provide georouting data with 988 calls to the Lifeline Administrator in a format compatible with the Lifeline's routing platform, to allow routing of 988 calls by the Lifeline Administrator to the appropriate crisis center based on the geographic area where the handset is located at the time the 988 call is initiated. We further require that all CMRS providers must provide georouting data, when available, with 988 calls to the Lifeline Administrator sufficient to allow routing of the 988 call by the Lifeline Administrator. In conjunction with our mandate, we recognize the Lifeline Administrator's commitment to continue to ''safeguard user privacy and confidentiality'' as georouting is implemented.

8. *Georouting.* We define ''georouting data,'' for purposes of these rules, as location data generated from cell-based location technology that is aggregated to a level that will not identify the location of the cell site or base station receiving the 988 call or otherwise identify the precise location of the handset. We find that this definition of ''georouting data'' most appropriately balances the need to maintain the privacy of 988 callers while ensuring the 988 Lifeline has the information needed to route calls to geographically appropriate crisis centers. The record reflects significant support for georouting solutions that provide geographic routing information to the Lifeline without identifying a caller's precise location. Indeed, we received over 1,500 comments from National Alliance on Mental Illness (NAMI) advocates representing nearly every State expressing support for requiring wireless providers to implement georouting solutions for 988 calls while protecting privacy. Many commenters emphasized the importance of not disclosing more precise location information to maintain callers' privacy and ensure trust in the 988 Lifeline. Several commenters also highlight that the expectations of 988 callers differ from the context of 911 calls, where callers generally expect an immediate, location-specific medical or police response.

9. To ensure the privacy of 988 callers, we decline, at this time, to require wireless providers to provide more precise geolocation data with 988 calls. Commenters, including mental health advocates and crisis counseling experts, express significant privacy concerns about including geolocation information with wireless 988 calls, which, unlike georouting data, does involve the transmission of a caller's precise location. The Commission previously considered the potential benefits of including geolocation information with calls to the 988 Lifeline. In this regard, in April 2021, as directed by Congress pursuant to the National Suicide Hotline Designation Act of 2020, the Commission submitted a report that examined the costs and feasibility of transmitting dispatchable location information with calls to 988. As the Wireline Competition Bureau explained in the *988 Geolocation Report,* transmitting geolocation information with calls to the 988 Lifeline raised a variety of important privacy concerns, legal issues, and technical complexities that require extensive investigation and time to resolve. Several commenters highlight that the challenges identified in the *988 Geolocation Report* remain relevant today. Moreover, the record does not evidence a need to include geolocation information with wireless 988 calls to facilitate routing to the appropriate local crisis center.

10. The rules we adopt allow CMRS providers and the Lifeline Administrator flexibility in developing and implementing technical solutions, for example, aggregating georouting data at the county or wire center level, while protecting privacy interests by prohibiting the transmission of more granular cell site data or the precise location of the caller. In its comments, the Lifeline Administrator explains that the georouting solutions developed by the nationwide wireless providers, in conjunction with SAMHSA and the Lifeline Administrator were designed to ''minimize[ ] user-specific data to simply route the user to the nearest crisis center based on cell phone tower data, rather than using a callers' exact phone location.'' Similarly, T-Mobile asserts that its georouting solution ''protects the privacy interest of callers by not providing precise geolocation information.'' CX360 also states that the georouting solutions ''never capture[ ] a help seeker's precise location.'' We anticipate that the definition of ''georouting data'' that we adopt will give nationwide CMRS providers the flexibility to continue their efforts to implement georouting solutions and comply with their obligations to protect user location information. Additionally, we believe these privacy safeguards included in the definition alleviate record concerns that georouting rules may ''inadvertently suppress use of the 988 Lifeline'' due to concerns about disclosing geolocation information.

11. *Voluntary Implementation by Nationwide CMRS Providers.* We recognize that certain commenters contend that mandating georouting for wireless 988 calls is unnecessary at this time. Some telecommunications industry commenters oppose adoption of rules requiring CMRS providers to implement georouting solutions for wireless 988 calls, arguing that georouting solutions will soon be available through the voluntary efforts of nationwide CMRS providers. They also claim that mandating georouting may introduce uncertainty, potentially delaying or complicating the deployment of georouting solutions. While we recognize industry's assertions, these providers also acknowledge the importance of promptly implementing georouting solutions for wireless 988 calls. In mandating georouting, we carefully balance the request to proceed more cautiously, as voiced by providers, with the significant record support calling for the need for a georouting mandate that enhances access to critical local services for callers in crisis without delay, while giving providers the flexibility to develop georouting solutions that fit with their network capabilities to the extent that those solutions are compatible with the systems used by the Lifeline.

12. As we noted in the *SFNPRM,* certain stakeholders have already engaged with SAMHSA and the Lifeline Administrator to develop georouting solutions for 988 calls. The record reflects that the three nationwide wireless providers have already implemented georouting for wireless 988 calls or are in the process of deploying georouting solutions in their networks. We support the voluntary efforts by wireless providers and our Federal partners to deploy georouting solutions for 988 calls in their wireless networks. We decline, however, to allow deployment of georouting solutions on a purely voluntary basis. Given the clear public interest benefits of supporting georouting for wireless 988 calls, we find that deployment and implementation of georouting solutions for wireless 988 calls should not be optional.

13. We disagree with CTIA's contention that no commenters have offered ''a reason why rules are needed to ensure that 988 georouting solutions are implemented.'' As the Lifeline Administrator states, a georouting mandate is needed to ensure consistent access to the 988 Lifeline's localized resources, prevent variations in support based on an individual's service provider, and to allow the 988 Lifeline to better serve individuals in crisis. The nation's mental health and substance use disorder community also supports immediate action to require wireless providers to implement georouting solutions for wireless 988 calls, emphasizing the urgency of connecting individuals in crisis to local services. For these reasons, we conclude that allowing wireless providers to implement georouting solutions on a purely voluntary basis would undermine our goal of ensuring that the benefits of georouting are realized nationwide in a timely manner.

14. We further disagree with commenters that our georouting requirements would interfere with the efforts of the three major nationwide wireless providers to implement and deploy georouting solutions. The rules we adopt give wireless providers the flexibility to continue their efforts to implement the georouting solutions developed with SAMHSA and the Lifeline Administrator, ensuring that the benefits of improved 988 call routing can be realized without delay. ATIS asserts that ''[a] more flexible, requirements-based approach would facilitate the timely deployment of 988 routing solutions'' and allow wireless providers to ''continue their deployments.'' Further, as AT&T states, a general requirement will ''not interfere with existing efforts between wireless providers'' and will provide ''flexibility to adapt to changing technologies.''

15. *Georouting Required for all CMRS Providers.* We find that requiring all CMRS providers to have the capability to provide georouting data with 988 calls is necessary to ensure that wireless 988 callers receive the demonstrated benefits of georouting, regardless of the providers' network configurations. We define nationwide CMRS providers as those providers whose service extends to a majority of the population and land area of the United States. Non-nationwide CMRS providers include all CMRS providers other than a nationwide CMRS provider. We agree with Reimagine Crisis Response that ''[c]onnecting more people to timely and local crisis support and services through accurately routed 988 calls will save lives.'' For that reason, we decline to limit application of our rules to voice calls carried end-to-end on IP networks, as advocated by some commenters. However, we recognize that current georouting solutions may rely on the IP-based capabilities of the Lifeline and wireless providers' networks, which may impact wireless providers' ability to transmit georouting data with wireless 988 calls over non-IP networks. Therefore, the rules we adopt require nationwide and non-nationwide providers to provide georouting data when available and offer flexibility for wireless providers to work with the Lifeline Administrator on a case-by-case basis to address any individualized network considerations. We also provide non-nationwide providers an ample compliance deadline, as discussed below, to allow time for development of technical solutions. We conclude that this approach appropriately balances the public interest in providing critical improvements to life-saving services with CMRS providers' needs to develop technical solutions to implement the new requirements. We find that the targeted requirements we adopt give wireless providers sufficient flexibility to capitalize on their current technology and network configurations to ensure that the maximum number of wireless 988 callers benefit from georouting as quickly as possible. The Commission will take further action, if necessary, to ensure that wireless providers are providing the Lifeline Administrator

with georouting data when available to ensure the Administrator is capable of routing wireless 988 calls.

16. We are unpersuaded by arguments that non-nationwide CMRS providers should be exempt from implementing georouting for wireless 988 calls. Rural Wireless Association (RWA) claims that georouting solutions have not ''been tested in a real-world application and implemented by any CMRS provider.'' Southern Linc also claims that non-nationwide CMRS providers have not yet participated in the georouting ''solutions development process.'' The record reflects, however, that the nationwide providers have developed and implemented or are in the process of implementing georouting solutions for wireless 988 calls. While we acknowledge that non-nationwide CMRS providers may face operational limitations when implementing georouting solutions for wireless 988 calls, we agree with commenters that non-nationwide CMRS providers will be able to leverage the georouting solutions developed and implemented by nationwide providers in collaboration with SAMHSA and the Lifeline Administrator. Further, several commenters highlight the importance of implementing georouting solutions to improve access to the 988 Lifeline's crisis intervention services for people in rural areas, who face a disproportionate risk of suicide and may need to be aware of limited mental healthcare resources available near their communities. We encourage non-nationwide CMRS providers to collaborate with SAMHSA and the Lifeline Administrator in developing and implementing georouting solutions. To further reduce the burden on non-nationwide entities under the rules we adopt, we grant longer compliance timelines to non-nationwide CMRS providers, as discussed below.

Georouting Data Format Compatible With the Lifeline

17. In the *SFNPRM,* we described our goal to ''undertake a holistic review to ensure that any georouting solution deployed is compatible with the needs and systems of the 988 Lifeline, as determined by SAMHSA, and successfully connects callers in crisis with the local support they need.'' The requirements we adopt will ensure that the vast majority of wireless 988 callers receive the benefits of georouting as expeditiously as possible by ensuring that georouting data is provided in a format that is compatible with the Lifeline's routing platform, maintaining the centralized routing system of the 988 Lifeline, and giving wireless providers sufficient flexibility to implement and deploy georouting solutions.

18. *Capability to Provide Georouting Data.* Consistent with the *SFNPRM,* we require all CMRS providers to have the capability to provide georouting data with 988 calls to the Lifeline Administrator in a format that is compatible with the Lifeline's routing platform. The record evinces support for this requirement. For example, CX360 states that georouting solutions that leverage the Lifeline's existing infrastructure ''create technical efficiencies'' and align with the Lifeline's efforts to provide ''community-based support with national-level support for specific at-risk communities.'' T-Mobile asserts that compatibility with the Lifeline will avoid the significant costs incurred for network or system changes and ''minimize[ ] the risk of technological errors'' in efficiently delivering 988 calls. Several commenters also indicate that georouting data in a format that is compatible with the Lifeline's routing platform will prevent delays in deploying georouting solutions. Moreover, the Lifeline Administrator emphasizes, and we agree, that implementing georouting solutions that are compatible with the 988 Lifeline's ''existing infrastructure and a uniform standard developed in partnership with SAMHSA and the Administrator [will] allow the 988 Lifeline to better serve individuals in crisis.'' We emphasize that our rules create an ongoing obligation for wireless providers to ensure that georouting data is in a format that is compatible with the Lifeline's routing platform. We encourage wireless providers to collaborate with SAMHSA and the Lifeline Administrator in developing and testing georouting solutions that meet these compatibility requirements.

19. The record reflects that the three nationwide wireless providers have already developed and implemented, or are in the process of implementing georouting solutions, that are compatible with the needs and systems of the 988 Lifeline. As the Lifeline Administrator notes, these georouting solutions are the preferred solution for the Lifeline, were designed to be compatible with the Lifeline's existing routing structure, and do not require ''creation of an entirely new 988 Lifeline framework and architecture.'' We anticipate that the approach we adopt will allow wireless providers to build on the success of the efforts of the nationwide wireless providers, streamlining implementation and costs while facilitating faster deployment of georouting solutions.

20. Given the importance of providing meaningful support to help-seekers reaching out to the 988 Lifeline, we recognize that our Federal partners may choose to expand the functionality of the Lifeline's system in the future to support additional georouting data formats. We direct the Wireline Competition Bureau to routinely consult with our Federal partners at SAMHSA regarding the format of georouting data that is compatible with the Lifeline's system. We further direct the Wireline Competition Bureau to monitor the development of compatible georouting solutions and, if necessary, propose and seek comment on implementation parameters for wireless providers for any compatible georouting data that is substantially modified from the georouting rule adopted herein.

21. *Centralized Routing.* Today, routing to the appropriate crisis call center is handled by a centralized routing system overseen by the Lifeline Administrator and supported by a grant from SAMHSA, and we find it is critical to retain this structure. We agree with commenters that our rules should preserve the role of the Lifeline Administrator in routing 988 calls to geographically appropriate local crisis centers. Consistent with the *SFNPRM,* we recognize that SAMHSA and the Lifeline Administrator are best suited to ensure that calls are properly routed and ultimately answered by a crisis center once the call is received by the Lifeline Administrator from the originating wireless provider. The record highlights that the Lifeline Administrator, under the direction of SAMHSA, plays a critical role in managing the 988 Lifeline's system by balancing call volume, ensuring calls are efficiently routed to appropriate and available crisis centers, and minimizing the technical burdens placed on crisis centers so they can focus on saving lives. As USTelecom emphasizes, the challenges associated with routing calls to the Lifeline are not limited to directing calls to the ''correct crisis center,'' but also ensuring they reach available crisis centers, given that many have varying operating hours.

22. We find that the success of the Lifeline system in helping individuals in crisis underscores the importance of maintaining the centralized routing system. As the Lifeline Administrator notes, ''[e]valuations of the 988 Lifeline service have found that the majority of callers were significantly more likely to feel less depressed, less suicidal, less overwhelmed, and more hopeful after speaking with a 988 Lifeline crisis

counselor.'' We find that the requirements we adopt appropriately maintain the critical role of the Lifeline in routing calls to crisis centers. Additionally, we believe that this approach alleviates record concern about the roles of CMRS providers and the Lifeline in the 988 call path.

23. Although some commenters argue that alternative georouting solutions that bypass the Lifeline's centralized routing system may offer some benefits for 988 callers, we find that the benefits of centralized routing greatly exceed the costs of localized routing. In the *988 Report and Order,* 85 FR 57767 (Sept. 16, 2020), the Commission found that the Lifeline's centralized routing process offered numerous benefits for both the providers that route calls to the 988 Lifeline and the Lifeline itself, including faster implementation, lower costs to maintain 988 routing, and better Lifeline service. We are convinced by the record that these benefits still remain true today. In particular, we believe that maintaining the Lifeline's centralized routing process will simplify administration of the Lifeline and allow for faster implementation of georouting solutions. For example, the Lifeline Administrator states that the georouting solutions developed with the nationwide wireless providers using the Lifeline's centralized routing process ''would be cost-effective'' for both the Lifeline and providers, and would allow for faster deployment of georouting solutions.

24. *Specialized Services.* We decline, at this time, to take specific action to apply our georouting requirements to the Lifeline's specialized services. In the *SFNPRM,* we sought comment on whether georouting is necessary for specialized services, and whether there are any unique considerations for routing such calls that may impact our proposals. As discussed above, the 988 Lifeline's interactive voice response (IVR) system currently provides callers the opportunity to connect with specialized services by selecting ''1'' for the Veterans Crisis Line, ''2'' for a Spanish language line, and ''3'' for a specialized LGBTQI+ line.

25. We recognize that several commenters assert that georouting data may provide benefits for individuals who use the Lifeline's specialized services, such as the LGBTQI+ community and veterans. However, the record demonstrates that there are unique considerations for specialized services, including the need for access to specially trained counselors, resource constraints, and increased privacy concerns. For example, Trevor Project explains that while ''geographic location can provide a strong cultural connection for many 988 callers,'' research has shown that ''competency with LGBTQ+ youth issues is the critical element necessary to effectively support LGBTQ+ young people in crisis.'' We believe our Federal partners at SAMHSA and the VA are best positioned to evaluate the benefits and challenges of using georouting data provided with 988 calls for the Lifeline's subnetworks. We anticipate that maintaining the existing centralized routing process will provide the Lifeline flexibility to use its expertise in deciding the most geographically appropriate crisis centers to direct callers who select specialized services. We also anticipate that our rules will better allow the Lifeline to adapt and expand as necessary to meet the unique needs of 988 callers who select specialized services.

Cell-Based Location for Georouting

26. The definition of ''georouting data'' we adopt specifies that location data is generated using cell-based location technology. This aspect of the georouting rule is central to allowing the nationwide providers' solutions to proceed and maintain compatibility with the Lifeline's centralized routing platform. Mental health and crisis counseling experts emphasize the importance of connecting callers to local resources while still protecting the privacy of callers. As Trevor Project states, ''it is vital that a georouting solution is adopted so that those reaching out to 988 can trust it will not jeopardize their privacy.'' After considering the record, we find that generating location information using cell-based location technology will best identify a caller's location to enable routing of 988 calls to geographically appropriate crisis centers, while maintaining the privacy interests of callers. We anticipate that this approach will also provide nationwide providers flexibility to deploy current georouting solutions developed with the SAMHSA and the Lifeline Administrator. As discussed throughout this *Third Report and Order,* although there are commenters that argue an alternative routing solution is preferable, we decline to stray from the Lifeline's current routing structure and we encourage stakeholders and our Federal partners to continue to coordinate on the best way to get callers to the geographically appropriate crisis center.

Aggregation of Cell-Based Location Data

27. We require CMRS providers to aggregate location data generated from cell-based technology to a level that will not identify the location of the cell site or base station receiving the 988 call or otherwise identify the precise location of the handset. In the *SFNPRM,* we sought comment on whether the Commission should mandate the use of one or more particular geographic boundaries that would be applied for georouting solutions and asked commenters to address whether certain boundaries are sufficiently granular to achieve the goal of connecting callers with local resources during a time of crisis. Our decision carefully balances two core objectives of georouting: ensuring the location data is sufficiently granular to connect the caller with local resources and maintaining the caller's privacy.

28. We agree with commenters that CMRS providers need flexibility to facilitate timely deployment of 988 georouting solutions and account for providers' network capabilities. To give CMRS providers flexibility, we do not specify a particular method for ensuring that location data is aggregated to a sufficiently granular level and allow providers to use technically feasible options for meeting this requirement. Similarly, we decline to mandate the use of one or more particular geographic boundaries. We do, however, require wireless providers to aggregate location data to a level that does not identify the location of the cell site or base station receiving the 988 call or otherwise identify the precise location of the handset.

29. We observe that the georouting solutions the three nationwide wireless providers have deployed or are currently implementing employ different geographic boundaries. For example, T-Mobile's georouting solution obtains caller location information using cell-based technology, aggregates that location data using Federal Information Processing Series (''FIPS'') code boundaries, and transmits the georouting data as a 6-digit code in the P-Asserted-Identity (PAI) header of a Session Initiation Protocol (SIP) invite message to the Lifeline. The Federal FIPS codes are maintained and assigned by the Census Bureau to identify geographic areas. Whereas, AT&T's georouting solution aggregates location data using wire center boundaries correlating to the originating cell site. A wire center, as defined in 47 CFR 51.5, is the location of an incumbent Local Exchange Carrier (LEC) switching facility containing one or more central offices. The wire center boundaries define the area in which all customers served by a given wire center are located. The Lifeline Administrator has confirmed that these solutions are

compatible with the Lifeline's network configuration and centralized routing system. Commenters generally agree that county level or wire-center boundaries are sufficiently generalized to protect callers' privacy while still enabling the Lifeline to effectively route calls to geographically appropriate crisis centers.

30. NACO requests that we provide sufficient flexibility to allow State and local authorities ''to define the boundaries within their jurisdiction that are most suitable'' for georouting purposes. While we recognize the role that counties play in addressing the nationwide mental health crisis, we decline at this time to require wireless providers to aggregate location data based on a particular State or local authority's definition of appropriate geographic boundaries. Washington Department of Health claims that allowing wireless providers to use multiple geographic boundaries ''would negatively impact crisis centers' ability to accurately predict the volume of need and provide services,'' which would be particularly challenging ''in areas where multiple languages are spoken by different communities.'' As the Lifeline Administrator notes, states and localities are already involved in the ''operational decision making process with SAMHSA and Vibrant'' regarding routing of 988 calls and coverage areas of crisis centers. We acknowledge that wireless providers' geographic boundaries must align with the 988 network parameters of the Lifeline Administrator and encourage SAMHSA and the Lifeline Administrator to continue their collaborative efforts with stakeholders, and we believe that preserving the Lifeline's centralized routing process provides our Federal partners flexibility to develop and expand georouting solutions to meet the Lifeline's needs.

31. We anticipate that our flexible approach toward adopting a georouting mandate strikes the right balance between ensuring that location data is sufficiently granular to achieve the goal of connecting wireless 988 callers with local resources without delay, aligning with the requirements delineated by SAMHSA and the Lifeline Administrator, and maintaining the privacy of 988 callers. We believe that the requirement to aggregate georouting data to a level that does not identify the location of the cell site or base station receiving the 988 call or a more precise location of the handset alleviates record concern about protecting privacy of callers in more densely populated areas. We also anticipate that our approach gives wireless providers discretion to aggregate georouting data using technically feasible methods that are best suited for their networks.

Technical Considerations

32. In the *SFNPRM,* we recognized that there could be technological limitations associated with some georouting solutions and sought comment on whether solutions would work if, for instance, a caller is roaming or if a particular wireless call is out-of-scope for a georouting solution or presents with unreadable routing data. We find that the limitations commenters raised are addressable without jeopardizing the georouting rule we adopt, and which is so critical to further improve the 988 Lifeline for callers in crisis.

33. *Roaming.* Some commenters state technical limitations associated with georouting solutions may arise when individuals call 988 while roaming. CTIA asserts that the ''home network operator'' may not receive location information, such as the originating cell ID, or may not be able to ''correlate the visited provider's cell ID'' to geographic boundaries to generate georouting data. AT&T states that ''4G and newer wireless networks,'' as designed, do ''not support georouting a 988 call made while roaming.'' Although we acknowledge the substantial public interest benefits in requiring georouting for all wireless 988 calls, we exclude calls transmitted using roaming capabilities from application of the requirements we adopt to account for the technical limitations identified in the record. We anticipate that our targeted approach will give providers sufficient flexibility to maximize their current technology and network configurations to ensure that the vast majority of wireless 988 callers benefit from georouting as quickly as possible. Calls using roaming capabilities may be routed to qualified crisis counselors using the area code and exchange, as they are today. Upon development of a further record pertaining to the technical feasibility of transmitting georouting data with roaming calls, the Commission may further consider extending the georouting requirements to these calls. Issues raised in the *SFNPRM* that are not addressed in this *Third Report and Order* remain pending.

34. *Default Routing.* In the *SFNPRM,* we sought comment on whether 988 calls with unreadable routing data would default to routing by area code or be redirected to a national back-up center. The record demonstrates that, while the benefits of georouting for 988 calls are clear, it is critical that callers still have access to the Lifeline's vital services if georouting data is unavailable or unreadable. CX360, a service provider that contracts with the Lifeline Administrator to provide voice and SMS-based information services after calls reach the Lifeline, explains that the Lifeline's IVR system has ''built-in backup routing logic that routes the call based on the caller's area code.'' Several commenters that addressed this issue support defaulting to routing by area code and exchange when georouting data is unreadable. We agree, and we view retaining the centralized routing process will enable the Lifeline to route callers to crisis centers based on area code and exchange in the event that georouting data is unavailable or unreadable, and such calls will not be disconnected.

Alternative Georouting Solutions

35. We emphasized in the *SFNPRM* that we believe implementing a georouting solution without delay to connect callers to 988 with geographically appropriate crisis call centers provides better care. With this urgency in mind, we sought comment on the feasibility of requiring alternative georouting solutions that have not yet been tested, developed, or presented to SAMHSA or the Lifeline Administrator and asked whether such solutions would expedite or slow deployment of georouting. After reviewing the record, we decline, at this time, to adopt commenters' alternative georouting proposals that would bypass the Lifeline's centralized routing system or require CMRS providers to route directly to crisis centers. Several commenters argue that the Commission should consider adopting rules that allow routing of 988 calls directly to NG911 networks upon request from states that can manage 988 calls directly and have defined ''geospatial boundaries'' for 988 crisis centers. Intrado Life & Safety asks the Commission to adopt rules that support direct routing of 988 calls to ''state-designated IP Protocol (IP) points of interconnection (POI),'' such as the ''Emergency Services IP Network (ESInet)'' in alignment with Next Generation 911 (NG911), upon request from a state. Similarly, Comtech urges the Commission to adopt rules that provide ''state 988 authorities the flexibility to develop their own direct, dedicated, IP-based 988 call paths and system architecture to meet their local needs.'' The National Emergency Number Association (NENA) also urges the Commission to consider the use of NG911 technologies to support georouting for 988 calls and argues that

a 988 call should ''be treated as an emergency call.''

36. We do not adopt these proposals at this time as we work to expeditiously improve routing for 988 calls within the 988 Lifeline's system. Nevertheless, recognizing the importance of developing solutions capable of connecting callers to the most geographically appropriate resources, we encourage parties to continue exploring alternative localized georouting solutions. In the *SFNPRM,* we stated that the ultimate goal of the coordination between SAMHSA, the Lifeline Administrator, and the Commission was to identify one or more georouting solutions that are compatible with the 988 Lifeline's system and achieve the policy objectives of connecting callers in crisis with local support. We further stated that our goal was to build on the progress made by all stakeholders to identify a georouting solution to enhance the support and resources available to callers in crisis. The record reflects support for this approach.

37. We are also concerned that implementing a localized routing model at this time would be contrary to our goal of ensuring that georouting is available without delay to connect the majority of callers to 988 with geographically appropriate crisis centers that enhance the services available to those in crisis. CTIA asserts that proposals that require modification of the centralized routing process for 988 calls are inconsistent with the georouting solutions that have been developed by the nationwide wireless providers, major stakeholders, SAMHSA, and the Lifeline Administrator. The Lifeline Administrator and CX360 point to necessary infrastructure changes that could delay implementation of georouting solutions. Additionally, the Lifeline Administrator states that ''reliance on technologies, such as NG911, can impact the ability . . . to carry out its duties as Administrator, including responsibility for routing of contacts to the 988 Lifeline.'' Overall, we do not have the full and detailed record necessary to adopt a rule that requires providers to bypass the existing centralized routing system, and we find that doing so would jeopardize the important next step that we are taking by implementing georouting as soon as possible.

38. We decline NENA's request to establish an expiration date for mandatory georouting requirements. NENA emphasizes the potential benefits of implementing georouting solutions for wireless 988 calls that leverage NG911 technologies. While parties claim that NG911 technology could provide benefits for georouting calls to the 988 Lifeline, those benefits do not negate the current need for the requirements that we adopt in this *Third Report and Order.* Given the significant public interest benefits of supporting georouting for wireless 988 calls, we decline to set an end date for our rules, but we may consider further technological developments in the future.

Implementation Time Frame for Georouting 988 Calls to the Lifeline

39. Recognizing the urgency of the need to continue the Commission's work to provide meaningful access to the 988 Lifeline, we sought comment in the *SFNPRM* on the appropriate timeline for deployment of a georouting solution, and specifically asked commenters to identify technical, financial, operational, legal, or other factors that could influence a mandated time frame. Thanks in large part to the work of SAMHSA and nationwide CMRS providers to date, the record indicates that implementation of solutions for sending georouting data along with wireless calls is attainable in the near term. We therefore establish an implementation time frame following the effective date of the georouting rule of 30 days for nationwide CMRS providers and 24 months for all non-nationwide CMRS providers. As we define them above, nationwide CMRS providers are those providers whose service extends to a majority of the population and land area of the United States. Non-nationwide CMRS providers include all CMRS providers other than a nationwide CMRS provider.

40. The implementation time frame we provide nationwide CMRS providers corresponds to these providers' own solution-completion timelines. T-Mobile, for example, began sending georouting information to the 988 Lifeline even before the publication of our rules and has since announced that its customers now ''have their calls routed to crisis centers close to their actual location.'' All three nationwide providers have implemented, or are in the process of implementing, their georouting solutions for wireless 988 calls. Consistent with these expectations, we find sufficient a 30-day period after the effective date of our rules to require nationwide CMRS providers to begin sending georouting data with wireless 988 calls. Establishing such a time frame represents a critical first step toward ensuring that callers—a vast majority of whom subscribe to a nationwide CMRS provider—will be routed to a geographically appropriate call center.

41. Simultaneously, we conclude that 24 months provides sufficient time for non-nationwide CMRS providers to begin sending georouting information to the 988 Lifeline. Commenters agree that non-nationwide CMRS providers require more time to implement a georouting solution. For example, Intrado Life & Safety proposes that their solution could be completed within a year but acknowledge that additional time may be needed for non-nationwide CMRS providers. We find that 24 months strikes an appropriate balance between giving these providers the necessary time to come into compliance and the pressing need to expeditiously connect callers to a geographically appropriate call center. A 24-month period for implementation, as noted by CCA and Southern Linc, also accords with our decision to give providers 24 months to implement location-based routing for 911 call solutions.

42. RWA asserts that small rural CMRS providers lack the resources to implement a georouting solution before 36 months. Although we understand RWA's contention that a lack of funding and personnel comparable to the nationwide providers warrants additional time for small rural CMRS providers, RWA has not demonstrated the need for the additional 12 months beyond the two years we are providing. Recognizing that their 36-month recommendation exceeds the 24 months that were given for 911 location-based call solutions to be implemented, RWA contends that with 911, ''large nationwide CMRS providers had already begun implementing location-based solutions, which was an influential factor in . . . adopting a shorter implementation timeline,'' but that ''[i]n this case, such early implementation has not occurred.'' RWA argues then that the ''untested nature of the available 988 georouting solutions and lack of real-world implementation by *any* CMRS provider'' merits an additional 12 months for implementation of a georouting solution. Yet, as observed above, nationwide CMRS providers have implemented or are in the process of implementing their georouting solutions. And RWA does not otherwise justify their recommended timeline of 36 months, which—at minimum—adds two years beyond the time frames cited as necessary by existing proposals that account for small CMRS providers. INCOMPAS also argues, and CTIA agrees, that additional time would be needed—up to four years—for sending georouting information with text

messages. However, as we do not mandate that text messages send georouting information at this time, we need not address this argument. Additionally, we note that the Commission previously established a uniform 24-month implementation time frame for 988 itself, which involved implementing 10-digit dialing in 87 area codes as well as reprogramming, translating, or replacing telephone switches that would not otherwise support 988 as a three-digit dialing code. We do not anticipate, by comparison, that implementation of a georouting solution will prove more burdensome. It is our predictive judgment that 24 months accounts for the technical and cost-related challenges non-nationwide CMRS providers will face in implementing this lifesaving change to the 988 system.

Routing Voice Calls and Texts to 988

43. In the *SFNPRM,* we asked whether our existing 988 voice and texting rules should be broadened to allow for implementing a georouting solution. We conclude that it's appropriate to revise these rules to permit routing to the national suicide prevention and mental health crisis hotline system without need for translation to the toll free access number. In so doing, we better futureproof the use of 988, including by enabling georouting solutions that may require broader routing parameters. In making these changes, we also codify our 2022 waiver order permitting covered text providers to route covered 988 text messages to the 988 Lifeline without translation to the toll free number. We previously acknowledged that ''as implementation has progressed, providers have found that, in practice, translating 988 text messages to the current toll free access number for the Lifeline . . . may negatively impact the experience of individuals texting the Lifeline.'' Problems identified as arising from the current requirement included potential confusion when a number different than 988 appears on an individual's device when receiving responses, possibly resulting in delayed, frustrated, or abandoned efforts to seek help. Our revisions provide greater flexibility so as to avoid any similar such problems. Individuals will still be able to dial the toll free ten-digit access number to reach the 988 Lifeline.

44. We do not adopt iCERT's proposal to amend our rule to require providers to route directly to a State or local 988 call center. The amendment we adopt resolves the issues identified above without potential delay to the implementation of georouting solutions. We therefore decline at this time to adopt alternative approaches that would bypass the Lifeline's centralized routing platform.

Legal Authority

45. As we tentatively concluded in the *SFNPRM,* we find that Title II and Title III of the Communications Act of 1934, as amended (Act), provide us with the authority to adopt the rules we promulgate. The Supreme Court has previously recognized that Title III grants the Commission a ''comprehensive mandate'' in regulating spectrum usage, and lower courts have routinely determined that Title III confers broad authority to manage spectrum in the public interest. Consistent with these decisions, we find significant public interest benefits will likely inure as a result of our georouting mandate by connecting individuals in crisis with geographically appropriate public safety and counseling resources.

46. In the *SFNPRM,* we asked whether section 251(e), which provides the Commission its numbering authority, acts as an additional source of authority. Section 251(e)(4), specifically, designates 988 as the universal telephone number for the national suicide prevention and mental health crisis hotline system. We agree with commenters that our authority extends to mandating that a georouting solution be implemented. We also agree with commenters that in so doing, we further the goals of previous congressional directives, including to adopt regulations that will ease access to suicide prevention and mental health services. In mandating that a georouting solution be implemented and in modifying our voice and text routing rules, we thus exercise our numbering authority pursuant to Congress's direction and therefore find that 251(e) provides us authority to promulgate the rules we adopt.

Benefits and Costs of 988 Georouting

47. By reducing the geographic mismatch between caller locations and area codes and moving 988's life-saving interventions closer in time and space to those in distress, georouting will generate mortality-reduction and other benefits far exceeding implementation costs.

Benefits

48. *Reduced Suicide Mortality.* The number of Americans who are at risk of having their wireless 988 calls routed to a faraway 988 Lifeline call center is vast. Approximately 80% of calls to 988 are from wireless devices. In a mobile society where people hold on to familiar wireless phone numbers, there is often no connection between the geographic origins of 988 calls and the area codes of the callers' phone numbers. According to a study conducted by Pew Research Center, ''each year about 36 million Americans move residences and nearly half of adults living in urban areas have a cellphone number from somewhere else. Additionally, nationwide at least 10% of all adult Americans have a cellphone number from somewhere other than where they reside.'' While we recognize that 988 is a critical resource of growing importance for younger people, for the purposes of our analysis we focus on all adults, that is, individuals 18 years or older.

49. We use a three-step process to estimate reduced suicide mortality risk. First, we identify suicide victims who could have tried to summon 988 assistance and been misrouted. After the launch of 988 on July 16, 2022, a total of 2,395 American adult suicide victims 18 and older could have sought a 988 emergency intervention but had cellphone numbers prone to misrouting. Total suicides for adults 18 years or older in 2022 were 47,891. If we allocate by months, then there were ~23,946 in the latter half of the year (*i.e.,* 6/12 = 0.5). We can alternatively allocate by total suicides for July–December (*i.e.,* 24,742/49,746 = 0.500008085), which gives the same result. Polling results tell us that 431 (*i.e.,* 18% of 2,395) of these suicide victims could have been aware of 988 and possibly called. Kaiser Family Foundation polling indicates that as of mid-2023, only 18% of adults reported familiarity with 988. Second, we identify those victims subject to possible emergency-response delays: Nearly 13 (*i.e.,* 3% of 431) would have required the sort of immediate and follow-up care that could be more effectively provided by georouting 988 calls to the locality in which the caller resides without revealing the caller's precise location or otherwise compromising their privacy. We estimate that 2.2 (*i.e.,* 17% of 13) of these suicides could have been avoided by 988 georouting. Our rationale is that wireless call misrouting is suboptimal: localities have first-responder and follow-up resources tailored to local settings and circumstances to optimize their effectiveness; such resources can often only be deployed by local crisis centers. The delays, frictions, and mismatches triggered by misrouting increase response time, and every minute saved in a suicide intervention reduces suicide mortality. The Commission previously estimated that a one-minute reduction in emergency-

response time reduces mortality by 17%. Thus, while the rules promulgated do not impose a dispatchable location requirement—that is, a caller's exact location cannot be identified—by connecting callers to geographically appropriate crisis centers, we anticipate that better response times, and the benefits thereof, will result. Third, we estimate that Americans would have been collectively willing to pay $27.5 million annually and nearly $130 million over a five-year period for a mortality-risk reduction of this size. Using a recent Value of Reduced Mortality Risk (VRMR) of $12.5 million, a mortality-risk reduction equivalent to 2.2 lives is worth 2.20 * $12,500,000 = $27,500,000. The present value of five annual payments discounted at 2% according to Office of Management and Budget Circular A–4 is $129.620,136.

50. *Other Benefits and Possible Benefits Underestimation.* Our estimate of $120 million in benefits over five years is an underestimate because it excludes youth age 17 and under, who rely heavily on wireless devices and 6,542 of whom committed suicide in 2022. Studies indicate 53% of children in the United States have a smartphone by age 11, with over 95% of teens between 13 and 17 years of age having access to a cellphone. In addition, suicide attempts—more broadly acts of self-harm—demand medical treatment, put people out of work, and diminish survivors' quality of life. Yet, we have not estimated the savings from reduced medical expenses, lost work, and lost quality of life. We also do not count the benefits of less property damage attributable to suicide attempts and savings of 988 Lifeline call center resources from fewer misrouted calls. In addition, misrouted 988 callers often resort to calling 911. A reduction in these calls would likely save further costs. Lastly, we have neglected to estimate the devasting emotional toll 988 wireless call georouting would spare suicide victims' families, friends, and communities.

Costs

51. We estimate that the implementation costs of georouting 988 wireless calls will be relatively small. RWA claims ''RWA carrier members, all of whom are small rural non-nationwide CMRS providers, estimate that 988 georouting solutions could cost them at least $50,000 for implementation and over $15,000 per month for third-party services, not including continual labor costs for testing. Such a cost is an immense burden for a small rural non-nationwide CMRS provider.'' Some commenters propose cost-effective 988 routing solutions: CX360 that ''[t]here are no incremental service costs to wireless providers for CX360's georouting solution beyond the initial development expense for call header configuration by each wireless provider. All other parties in the existing 988 Lifeline call flow are already configured to support this model.'' Vibrant indicates that ''[t]he georouting solution developed in conjunction with Vibrant's partners for the 988 Lifeline telephony infrastructure and major wireless providers represents the preferred solution that would allow real-time routing updates without the creation of an entirely new 988 Lifeline framework and architecture. This solution would be cost-effective not only for the 988 Lifeline but for providers as well and is able to be deployed faster than other proposed solutions.'' In the nearer term, ''nationwide wireless providers AT&T, T-Mobile, and Verizon have achieved consensus with the Lifeline Administrator, Vibrant, on the contours of georouting solutions and are working to implement them as quickly as practicable.'' The georouting solutions rely on geographic information associated with call origination, such as the cell-site identification number, which the provider can translate into a county identifier. Based the record, we conclude that cost-effective 988 wireless call georouting solutions exist in theory and in practice. To minimize their financial burden, non-nationwide wireless providers facing greater financial constraints have been granted a full 24 months to find and implement a solution.

Additional Proposals

52. We appreciate the opportunity, as the expert regulatory agency on telecommunications in the United States, to help facilitate access to the 988 Lifeline's critical mental health and suicide prevention services. It is also important that we recognize the important role that our Federal partners and others play in operating the 988 Lifeline. In response to the *SFNPRM,* some commenters raised important issues that are more appropriately addressed by other parties or may fall outside the scope of this proceeding. We address these issues below and encourage interested parties to collaborate with our Federal partners at SAMHSA and the VA, along with other stakeholders, to continue their efforts in enhancing the effectiveness of the 988 Lifeline.

53. *Transparency.* Several commenters emphasized the importance of transparent communication and education about how georouting data is used for wireless 988 calls. For example, NAMI asserts that transparency regarding the use of georouting data will help ''build trust in the 988 Lifeline'' and alleviate fears about sharing location information, which may have resulted from factors such as a ''historic distrust'' of emergency response systems or misinformation about the use of such data. The Electronic Privacy Information Center (EPIC) also argues that transparently acknowledging the harms of non-consensual interventions for 988 callers can help mitigate ''the chilling effects of implementing mandated georouting on would-be 988 callers.'' We recognize the importance of transparent communication and believe that the Commission's website, together with continued collaboration with our Federal partners at SAMHSA, will serve as a valuable means of consumer education. We also expect that relevant 988 stakeholders will help contribute to these educational efforts.

54. EPIC also urges the Commission to be transparent about the actions taken in the rare instances when a 988 call is transferred to 911. The Lifeline Administrator states that ''[i]n rare situations, a 988 crisis counselor may contact a public safety answering point dispatcher because of concerns about an immediate risk of life, pursuant to the 988 Lifeline Suicide Safety policy.'' While we recognize harms can occur from a non-consensual interventions, the georouting requirements we adopt apply only to CMRS providers routing calls to the 988 Lifeline, which is distinct from the functions performed by the Lifeline Administrator or individual crisis centers after the Lifeline receives the calls. The Commission has had no role in establishing, maintaining, or operating the 988 Lifeline's routing system or the facilities and systems that enable it, and is not a party to any agreement that the Lifeline Administrator and/or SAMHSA has entered to establish, structure, operate, govern, or fund the system.

55. *988 Lifeline Funding and Services.* We also received comments regarding the need for adequate funding to ensure that the 988 Lifeline and crisis centers can effectively support georouting, as well as other recommendations that commenters claim would improve the general effectiveness of the 988 Lifeline. While these recommendations fall outside of our jurisdiction, we note that our Federal partners at SAMHSA are ''planning for anticipated operational, training and procedural updates [that] will require active engagement with partners including states, territories, tribes and crisis centers.'' We also encourage stakeholders to work with

Congress to ensure appropriate funding for the 988 Lifeline.

56. *911 Interoperability.* We received several comments urging the Commission to consider issues pertaining to the interoperability between the 988 Lifeline and 911 services. For example, NENA argues that ''988 must technically and operationally interoperate with [911] and first responder operations.'' Similarly, the National Association of State 911 Administrators (NASNA) argues that as the 988 system evolves, successful interoperability with NG911 will be essential ''when there is a crisis that requires an escalated response.'' We agree with commenters that facilitating interoperability between 988 and 911 services is an important goal, however these proposals are beyond the scope of this proceeding, and we decline to address them further here. We also note that the Lifeline Administrator is currently ''involved in ongoing efforts at the local, state, and national levels'' to address the interoperability between 988 and 911 services. We, therefore, encourage stakeholders to collaborate with our Federal partners.

57. *Coordination with American Indian and Alaska Native Communities.* Northwest Portland Area Indian Health Board (NPAIHB) recommends that the Commission, SAMHSA, and wireless providers consult with Tribal communities to ensure that American Indian and Alaska Native communities are ''able to utilize the 988 Lifeline and be connected to locally centralized suicide prevention and crisis service centers when using a wireless device.'' We support NPAIHB's suggestion and believe connecting Tribal community members with local crisis centers is crucial to providing these communities with the meaningful help they need. As such, we stand ready to work with our Federal partners and industry to assist American Indian and Alaska Native communities' access the life-saving resources of the 988 Lifeline.

58. *Opt-Out, website, and Call Disclosure Requirements.* We received comments urging the Commission to consider whether 988 callers will have the opportunity to opt out of sharing georouting data. The Massachusetts Association for Mental Health (MAMH) and EPIC urge the Commission to ''require 988 websites to indicate that georouting is used'' and provide information about accessing the Lifeline's national backup center or individual crisis centers. EPIC also argues that ''disclosure about georouting and non-georouted alternatives needs to occur during a call.'' To the extent that commenters raise concerns regarding disclosures about the use of georouting data on 988 websites or after the Lifeline's centralized routing system receives a call, such issues address actions by entities that are beyond the scope of this proceeding. Additionally, the georouting rules we adopt do not require wireless providers to transmit more precise geolocation information with wireless 988 calls, but rather require aggregated georouting data that maintains caller privacy in order to enhance the Lifeline's routing mechanism. Therefore, we decline, at this time, to require wireless providers to include specific disclosures regarding the use of georouting data.

59. *Cost Recovery.* RWA argues that the Commission should ''allocate funds to subsidize'' implementation efforts by non-nationwide CMRS providers to comply with a georouting mandate. RWA further argues that small rural non-nationwide CMRS providers ''cannot pass the costs of 988 georouting compliance onto their customers without jeopardizing their [Universal Service Fund] support.'' RWA's cost estimates lack any specificity or detail for us to determine whether those costs, which are also provided in isolation, would indeed jeopardize their universal service support. Further, we did not propose any cost recovery mechanisms in the *SFNPRM* and we will not adopt any here. As explained in the analysis of benefits and costs section, the benefits of implementing georouting for wireless 988 calls significantly outweigh the costs to CMRS providers. Moreover, the rules we adopt are flexible and we encourage non-nationwide CMRS providers to develop the most cost effective georouting solution with the technical parameters set forth herein.

60. *Customer Proprietary Network Information (CPNI) and Third Party Vendor Issues.* EPIC asks the Commission to prohibit wireless providers from ''sharing 988-related data even if the subscriber has opted in to sharing their CPNI'' and to ensure that wireless providers and ''their vendors meet basic cybersecurity requirements.'' EPIC argues that the Commission has authority under § 222 of the Communications Act, as amended ''to hold carriers responsible for safeguarding'' CPNI. We agree that protecting the privacy and security of callers is imperative. The rules we adopt make clear that wireless providers must aggregate location data generated from cell-based technology to a sufficiently granular level to maintain caller privacy.

Procedural Matters

61. *Regulatory Flexibility Act.* The Regulatory Flexibility Act of 1980, as amended (RFA), requires that an agency prepare a regulatory flexibility analysis for notice and comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' Accordingly, the Commission has prepared a Final Regulatory Flexibility Analysis (FRFA) concerning the potential impact of the rule and policy changes adopted in this *Third Report and Order* on small entities.

62. *Paperwork Reduction Act Analysis.* The *Third Report and Order* does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

63. *Congressional Review Act.* The Commission has determined, and the Administrator of the Office of Information and Regulatory Affairs, Office of Management and Budget concurs, that this rule is ''non-major'' under the Congressional Review Act, 5 U.S.C. 804(2). The Commission will send a copy of this *Third Report and Order* to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

Final Regulatory Flexibility Analysis

64. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), an Initial Regulatory Flexibility Analysis (IRFA) was incorporated in the *Implementation of the National Suicide Hotline Act of 2018, Second Further Notice of Proposed Rulemaking* (*SFNPRM*), 89 FR 46340 (May 29, 2024). The Commission sought written public comment on the proposals in the *SFNPRM,* including comments on the IRFA. The comments received are discussed below. This Final Regulatory Flexibility Analysis (FRFA) conforms to the RFA.

Need for, and Objectives of, the Report and Order

65. In the *Third Report and Order,* the Commission adopts rules to facilitate access to life-saving services for people in suicidal, mental health, and substance use crises by improving the routing of wireless calls to the 988 Lifeline. The 988 Lifeline was originally

designed to route calls to crisis centers based on the area code and exchange associated with a caller's device. However, as technology trends have shifted from landline phones to mobile phones, many callers now seek help from the 988 Lifeline using wireless devices with area codes that may not correspond to their physical locations. Although the 988 Lifeline provides meaningful support for help-seekers regardless of their location, discrepancies between callers' physical locations and the area codes associated with their wireless devices can complicate access to local resources, which mental health advocates emphasize are critical to achieving the full life-saving potential of the 988 Lifeline.

66. The rules adopted in the *Third Report and Order* aim to facilitate access to critical local resources for the vast majority of wireless 988 callers by requiring wireless providers to implement georouting solutions for 988 calls. Specifically, the *Third Report and Order* requires that all Commercial Mobile Radio Service (CMRS) providers have the capability to provide georouting data with 988 calls to the Lifeline Administrator in a format that is compatible with the Lifeline's routing platform. The Commission defines ''Lifeline Administrator'' as the entity that ''controls the 988 call routing platform pursuant to contract with the Substance Abuse Mental Health Services Administration.'' The *Third Report and Order* also requires that all CMRS providers must provide georouting data, when available, with 988 calls to the Lifeline Administrator. These requirements will enable the 988 Lifeline to route wireless calls to appropriate crisis centers based on the geographic area associated with the origin of a 988 call, rather than by area code and exchange. With ''georouting data'' as defined under the Commission's rule, CMRS providers must aggregate location data generated from cell-based technology to a level that does not identify the location of the cell site and base station receiving the 988 call or otherwise specify the caller's precise location. The *Third Report and Order* adopts a 30 day timeline for nationwide CMRS providers to implement georouting for wireless 988 calls and provides 24 months for implementation by non-nationwide CMRS providers. Finally, the *Third Report and Order* revises the Commission's existing 988 voice and texting rules to permit routing to the national suicide prevention and mental health crisis hotline system without need for translation to the toll free access number. This revision will provide greater flexibility and help futureproof the use of 988 by enabling wireless providers to implement georouting solutions that may require broader routing parameters.

Summary of Significant Issues Raised by Public Comments in Response to the IRFA

67. There were no comments filed that specifically addressed the proposed rules and policies presented in the *988 Georouting Further Notice* IRFA. However, several commenters discussed the potential impact of rules on non-nationwide CMRS providers.

68. The Competitive Carriers Association (CCA), Southern Communications Services, Inc. (Southern Linc), and the Rural Wireless Association (RWA) advocated for the Commission to give providers flexibility to account for their individual networks, the limitations of current georouting solutions, or the challenges faced by non-nationwide providers. In addition, RWA advocated for the Commission to allow small rural non-nationwide CMRS providers to implement georouting solutions on a voluntary basis. Alternatively, RWA called for the Commission to allow small rural non-nationwide CMRS providers additional time, funds to subsidize efforts, and flexibility in developing georouting solutions. Several commenters also urged the Commission to give non-nationwide CMRS providers sufficient time to implement georouting solutions. The approach taken by the *Third Report and Order* addresses these comments by adopting rules that allow wireless providers to build on the success of georouting solutions that have been developed with SAMHSA and the Lifeline Administrator, while also providing the flexibility for small and other providers to implement georouting solutions that account for their network capabilities and are compatible with the Lifeline's routing platform.

Response to Comments by the Chief Counsel for Advocacy of the Small Business Administration

69. Pursuant to the Small Business Jobs Act of 2010, which amended the RFA, the Commission is required to respond to any comments filed by the Chief Counsel for Advocacy of the Small Business Administration (SBA), and to provide a detailed statement of any change made to the proposed rules as a result of those comments. The Chief Counsel did not file any comments in response to the proposed rules in this proceeding.

Description and Estimate of the Number of Small Entities to Which the Rules Will Apply

70. The RFA directs agencies to provide a description of, and where feasible, an estimate of the number of small entities that may be affected by the rules adopted herein. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act. A ''small business concern'' is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

71. *Small Businesses, Small Organizations, Small Governmental Jurisdictions.* Our actions, over time, may affect small entities that are not easily categorized at present. We therefore describe, at the outset, three broad groups of small entities that could be directly affected herein. First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the Small Business Administration's (SBA) Office of Advocacy, in general a small business is an independent business having fewer than 500 employees. These types of small businesses represent 99.9% of all businesses in the United States, which translates to 33.2 million businesses.

72. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' The Internal Revenue Service (IRS) uses a revenue benchmark of $50,000 or less to delineate its annual electronic filing requirements for small exempt organizations. Nationwide, for tax year 2022, there were approximately 530,109 small exempt organizations in the U.S. reporting revenues of $50,000 or less according to the registration and tax data for exempt organizations available from the IRS.

73. Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' U.S. Census Bureau data from the 2022 Census of Governments indicate there were 90,837 local governmental jurisdictions consisting of general purpose

governments and special purpose governments in the United States. Of this number, there were 36,845 general purpose governments (county, municipal, and town or township) with populations of less than 50,000 and 11,879 special purpose governments (independent school districts) with enrollment populations of less than 50,000. Accordingly, based on the 2022 U.S. Census of Governments data, we estimate that at least 48,724 entities fall into the category of ''small governmental jurisdictions.''

74. *Wireless Carriers and Service Providers.* Wireless Telecommunications Carriers (*except* Satellite) is the closest industry with a SBA small business size standard applicable to these service providers. The SBA small business size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that there were 2,893 firms that operated in this industry for the entire year. Of this number, 2,837 firms employed fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 594 providers that reported they were engaged in the provision of wireless services. Of these providers, the Commission estimates that 511 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

75. *Wireless Communications Services.* Wireless Communications Services (WCS) can be used for a variety of fixed, mobile, radiolocation, and digital audio broadcasting satellite services. Wireless spectrum is made available and licensed for the provision of wireless communications services in several frequency bands subject to part 27 of the Commission's rules. Wireless Telecommunications Carriers (*except* Satellite) is the closest industry with an SBA small business size standard applicable to these services. The SBA small business size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that there were 2,893 firms that operated in this industry for the entire year. Of this number, 2,837 firms employed fewer than 250 employees. Thus under the SBA size standard, the Commission estimates that a majority of licensees in this industry can be considered small.

76. The Commission's small business size standards with respect to WCS involve eligibility for bidding credits and installment payments in the auction of licenses for the various frequency bands included in WCS. When bidding credits are adopted for the auction of licenses in WCS frequency bands, such credits may be available to several types of small businesses based average gross revenues (small, very small and entrepreneur) pursuant to the competitive bidding rules adopted in conjunction with the requirements for the auction and/or as identified in the designated entities section in part 27 of the Commission's rules for the specific WCS frequency bands.

77. In frequency bands where licenses were subject to auction, the Commission notes that as a general matter, the number of winning bidders that qualify as small businesses at the close of an auction does not necessarily represent the number of small businesses currently in service. Further, the Commission does not generally track subsequent business size unless, in the context of assignments or transfers, unjust enrichment issues are implicated. Additionally, since the Commission does not collect data on the number of employees for licensees providing these services, at this time we are not able to estimate the number of licensees with active licenses that would qualify as small under the SBA's small business size standard.

78. *Wireless Telephony.* Wireless telephony includes cellular, personal communications services, and specialized mobile radio telephony carriers. The closest applicable industry with an SBA small business size standard is Wireless Telecommunications Carriers (except Satellite). The size standard for this industry under SBA rules is that a business is small if it has 1,500 or fewer employees. For this industry, U.S. Census Bureau data for 2017 show that there were 2,893 firms that operated for the entire year. Of this number, 2,837 firms employed fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 331 providers that reported they were engaged in the provision of cellular, personal communications services, and specialized mobile radio services. Of these providers, the Commission estimates that 255 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

79. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves. Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services. The SBA size standard for this industry classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that there were 2,893 firms in this industry that operated for the entire year. Of that number, 2,837 firms employed fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 594 providers that reported they were engaged in the provision of wireless services. Of these providers, the Commission estimates that 511 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

80. *Wired Telecommunications Carriers.* The U.S. Census Bureau defines this industry as establishments primarily engaged in operating and/or providing access to transmission facilities and infrastructure that they own and/or lease for the transmission of voice, data, text, sound, and video using wired communications networks. Transmission facilities may be based on a single technology or a combination of technologies. Establishments in this industry use the wired telecommunications network facilities that they operate to provide a variety of services, such as wired telephony services, including VoIP services, wired (cable) audio and video programming distribution, and wired broadband internet services. By exception, establishments providing satellite television distribution services using facilities and infrastructure that they operate are included in this industry. Wired Telecommunications Carriers are also referred to as wireline carriers or fixed local service providers.

81. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 show that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 4,590 providers that reported they were engaged in the provision of fixed local services. Of these providers, the Commission

estimates that 4,146 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

82. *Local Exchange Carriers (LECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. Providers of these services include both incumbent and competitive local exchange service providers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. Wired Telecommunications Carriers are also referred to as wireline carriers or fixed local service providers. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 show that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 4,590 providers that reported they were fixed local exchange service providers. Of these providers, the Commission estimates that 4,146 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

83. *Incumbent Local Exchange Carriers (Incumbent LECs).* Neither the Commission nor the SBA have developed a small business size standard specifically for incumbent local exchange carriers. Wired Telecommunications Carriers is the closest industry with an SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 show that there were 3,054 firms in this industry that operated for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 1,212 providers that reported they were incumbent local exchange service providers. Of these providers, the Commission estimates that 916 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, the Commission estimates that the majority of incumbent local exchange carriers can be considered small entities.

84. *Competitive Local Exchange Carriers (CLECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to local exchange services. Providers of these services include several types of competitive local exchange service providers. Wired Telecommunications Carriers is the closest industry with a SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 show that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 3,378 providers that reported they were competitive local service providers. Of these providers, the Commission estimates that 3,230 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

85. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA have developed a small business size standard specifically for Interexchange Carriers. Wired Telecommunications Carriers is the closest industry with a SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 show that there were 3,054 firms that operated in this industry for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 127 providers that reported they were engaged in the provision of interexchange services. Of these providers, the Commission estimates that 109 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, the Commission estimates that the majority of providers in this industry can be considered small entities.

86. *Local Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Local Resellers. Telecommunications Resellers is the closest industry with a SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 207 providers that reported they were engaged in the provision of local resale services. Of these providers, the Commission estimates that 202 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

87. *Toll Resellers.* Neither the Commission nor the SBA have developed a small business size standard specifically for Toll Resellers. Telecommunications Resellers is the closest industry with a SBA small business size standard. The Telecommunications Resellers industry comprises establishments engaged in purchasing access and network capacity from owners and operators of telecommunications networks and reselling wired and wireless telecommunications services (except satellite) to businesses and households. Establishments in this industry resell telecommunications; they do not operate transmission facilities and infrastructure. Mobile virtual network operators (MVNOs) are included in this industry. The SBA small business size standard for Telecommunications Resellers classifies a business as small if it has 1,500 or fewer employees. U.S. Census Bureau data for 2017 show that 1,386 firms in this industry provided resale services for the entire year. Of that number, 1,375 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 457 providers that

reported they were engaged in the provision of toll services. Of these providers, the Commission estimates that 438 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

88. *Other Toll Carriers.* Neither the Commission nor the SBA has developed a definition for small businesses specifically applicable to Other Toll Carriers. This category includes toll carriers that do not fall within the categories of interexchange carriers, operator service providers, prepaid calling card providers, satellite service carriers, or toll resellers. Wired Telecommunications Carriers is the closest industry with a SBA small business size standard. The SBA small business size standard for Wired Telecommunications Carriers classifies firms having 1,500 or fewer employees as small. U.S. Census Bureau data for 2017 show that there were 3,054 firms in this industry that operated for the entire year. Of this number, 2,964 firms operated with fewer than 250 employees. Additionally, based on Commission data in the 2022 Universal Service Monitoring Report, as of December 31, 2021, there were 90 providers that reported they were engaged in the provision of other toll services. Of these providers, the Commission estimates that 87 providers have 1,500 or fewer employees. Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

89. *All Other Telecommunications.* This industry is comprised of establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation. This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems. Providers of internet services (*e.g.* dial-up ISPs) or Voice over Internet Protocol (VoIP) services, via client-supplied telecommunications connections are also included in this industry. The SBA small business size standard for this industry classifies firms with annual receipts of $40 million or less as small. U.S. Census Bureau data for 2017 show that there were 1,079 firms in this industry that operated for the entire year. Of those firms, 1,039 had revenue of less than $25 million. Based on this data, the Commission estimates that the majority of ''All Other Telecommunications'' firms can be considered small.

90. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment. Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment. The SBA small business size standard for this industry classifies businesses having 1,250 employees or less as small. U.S. Census Bureau data for 2017 show that there were 656 firms in this industry that operated for the entire year. Of this number, 624 firms had fewer than 250 employees. Thus, under the SBA size standard, the majority of firms in this industry can be considered small.

91. *Semiconductor and Related Device Manufacturing.* This industry comprises establishments primarily engaged in manufacturing semiconductors and related solid state devices. Examples of products made by these establishments are integrated circuits, memory chips, microprocessors, diodes, transistors, solar cells and other optoelectronic devices. The SBA small business size standard for this industry classifies entities having 1,250 or fewer employees as small. U.S. Census Bureau data for 2017 show that there were 729 firms in this industry that operated for the entire year. Of this total, 673 firms operated with fewer than 250 employees. Thus under the SBA size standard, the majority of firms in this industry can be considered small.

92. *Software Publishers.* This industry comprises establishments primarily engaged in computer software publishing or publishing and reproduction. Establishments in this industry carry out operations necessary for producing and distributing computer software, such as designing, providing documentation, assisting in installation, and providing support services to software purchasers. These establishments may design, develop, and publish, or publish only. The SBA small business size standard for this industry classifies businesses having annual receipts of $47 million or less as small. U.S. Census Bureau data for 2017 indicate that 7,842 firms in this industry operated for the entire year. Of this number 7,226 firms had revenue of less than $25 million. Based on this data, we conclude that a majority of firms in this industry are small.

Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

93. The *Third Report and Order* adopts rules that require small and other wireless providers to implement georouting solutions for wireless 988 calls. Specifically, the *Third Report and Order* requires providers to have the capability to provide georouting data with 988 calls to the Lifeline Administrator in a format that is compatible with the Lifeline's routing platform. Additionally, small and other providers must provide georouting data, when available, with 988 calls sufficient to allow routing of the 988 call by the Lifeline Administrator to the appropriate crisis center based on the geographic area where the handset is located at the time the 988 call is initiated. The *Third Report and Order* also adopts a definition of georouting data that requires wireless providers to aggregate location data generated from cell-based location technology to a level that will not identify the location of the cell site or base station receiving the 988 call or otherwise identify the precise location of the handset.

94. In the *SFNPRM,* the Commission sought comment on the costs and benefits of deploying georouting solutions to help the Commission evaluate the impact of relevant proposals on small entities. We recognize that small providers may face operational limitations and costs when implementing georouting solutions for wireless 988 calls. However, the record reflects that nationwide CMRS providers have already developed and implemented or are in the process of implementing georouting solutions for wireless 988 calls, which can minimize cost implications for small entities by serving as models for georouting solutions. The *Third Report and Order* adopts rules that allow wireless providers flexibility to leverage these georouting solutions, and we expect that our approach will reduce compliance costs for wireless providers, including small entities. Moreover, we estimate that the public safety benefits resulting from the requirements adopted in the *Third Report and Order* far exceed implementation costs.

Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

95. The RFA requires an agency to provide, ''a description of the steps the agency has taken to minimize the significant economic impact on small entities . . . 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.''

96. The *Third Report and Order* adopts rules that are designed to give flexibility where appropriate to ensure that wireless providers, including small providers, can determine the best approach for compliance based on the needs of their networks. The *Third Report and Order* considers comments advocating for allowing the deployment of georouting solutions for wireless 988 calls on a purely voluntary basis. We conclude, however, that purely voluntary implementation undermines our goal of ensuring that the clear public interest benefits of georouting are realized nationwide in a timely manner. The *Third Report and Order* also declines to exempt non-nationwide CMRS providers as requested by RWA, but instead adopts flexible requirements that allow small and other wireless providers to leverage the georouting solutions that have been developed by nationwide providers in collaboration with SAMHSA and the Lifeline Administrator to implement technically feasible solutions that are compatible with the Lifeline's routing platform.

97. With respect to ''georouting data,'' the *Third Report and Order* adopts a definition that balances the need to maintain callers' privacy by not requiring wireless providers to transmit more precise geolocation data with wireless 988 calls, while still ensuring that the 988 Lifeline has sufficient aggregated location data to route wireless 988 calls to geographically appropriate crisis centers. We decline to require wireless providers to use a specific method for aggregating cell-based location data or to mandate one particular geographic boundary for georouting solutions, minimizing potential burdens by allowing small and other wireless providers flexibility to employ technically feasible options that are best suited for their networks to meet this requirement.

98. The *Third Report and Order* further minimizes the potential burdens of wireless providers, including small providers, by excluding 988 calls transmitted using roaming capabilities from application of the georouting requirements to account for technical limitations identified in the record. The *Third Report and Order* declines, however, to limit the application of georouting rules to voice calls carried end-to-end on IP networks, as requested by some commenters. Instead, we adopt requirements that minimize potential burdens by giving wireless providers the flexibility to work with the Lifeline Administrator on a case-by-case basis to address any individualized network considerations and by providing non-nationwide providers with an ample compliance time frame to develop technical solutions.

99. The *Third Report and Order* considers alternative georouting solutions that bypass the 988 Lifeline's centralized routing system but concludes that the benefits of centralized routing far outweigh the costs of localized routing. Specifically, we find that maintaining the 988 Lifeline's centralized routing process will help preserve the Lifeline Administrator's critical role in routing 988 calls to crisis centers, simplify the administration of the Lifeline, and allow for faster implementation of georouting solutions.

100. With respect to compliance timelines, the *Third Report and Order* adopts an implementation time frame for nationwide CMRS providers that aligns with the timelines identified for deploying the georouting solutions developed in coordination with SAMHSA and the Lifeline Administrator. To further reduce the burden on small entities and address technical and resource challenges, we grant a longer compliance timeline to non-nationwide CMRS providers. Specifically, we establish an implementation time frame following the effective date of the georouting rule of 30 days for nationwide CMRS providers and 24 months for all non-nationwide CMRS providers.

101. Further, the *Third Report and Order* gives wireless providers flexibility to implement georouting solutions that may require broader routing requirements by revising existing 988 voice and texting rules to permit routing to the national suicide prevention and mental health crisis hotline system without need for translation to the toll free access number. Finally, we decline the National Emergency Number Association's (NENA) request to establish an expiration date for the georouting requirements set forth in the *Third Report and Order,* but may consider technological developments in the future.

Report to Congress

102. The Commission will send a copy of the *Third Report and Order,* including this FRFA, in a report to be sent to Congress pursuant to the Congressional Review Act. In addition, the Commission will send a copy of the *Third Report and Order,* including this FRFA, to the Chief Counsel for Advocacy of the SBA. A copy of the *Third Report and Order* and FRFA (or summaries thereof) will also be published in the **Federal Register**.

Ordering Clauses

103. Accordingly, *it is ordered* that, pursuant to the authority found in §§ 1, 2, 4, 201, 218, 251(e), 301, 303, 307, 309(a), 316, 332 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154, 154, 201, 218, 251(e), 301, 303, 307, 309(a), 316, and 332, this *Report and Order is adopted* and *will become effective* 30 days after publication in the **Federal Register**.

104. *It is further ordered* that part 52 of the Commission's rules *is amended* as set forth in appendix A, and such rule amendment will become effective 30 days after publication in the **Federal Register**.

105. *It is further ordered* that the Commission's Office of the Secretary, *shall send* a copy of this *Third Report and Order,* including the Final Regulatory Flexibility Analysis, to the Chief Counsel for Advocacy of the Small Business Administration.

106. *It is further ordered* that the Office of the Managing Director, Performance and Program Management, *shall send* a copy of this *Third Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 52

Communications common carriers, Telecommunications, Telephone.

Federal Communications Commission.

Marlene Dortch,

Secretary.

Final Rules

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 52 as follows:

PART 52—NUMBERING

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 47 U.S.C. 151, 152, 153, 154, 155, 201–205, 207–209, 218, 225–227, 251–252, 271, 303, 332, unless otherwise noted.

■ 2. Amend § 52.200 by revising paragraph (b) to read as follows:

§ 52.200 Designation of 988 for a National Suicide Prevention and Mental Health Crisis Hotline.

* * * * *

(b) All covered providers shall transmit all calls initiated by an end user dialing 988 to the national suicide prevention and mental health crisis hotline system maintained by the Assistant Secretary for Mental Health and Substance Use and the Secretary of Veterans Affairs.

* * * * *

■ 3. Amend § 52.201 by revising paragraph (a) to read as follows:

§ 52.201 Texting to the National Suicide Prevention and Mental Health Crisis Hotline.

(a) *Support for 988 text message service.* Beginning July 16, 2022, all covered text providers must route a covered 988 text message to the national suicide prevention and mental health crisis hotline system maintained by the Assistant Secretary for Mental Health and the Secretary of Veterans Affairs.

* * * * *

■ 4. Add § 52.202 to read as follows:

§ 52.202 Georouting of Wireless Calls to the National Suicide Prevention and Mental Health Crisis Hotline.

(a) *Georouting.* All CMRS providers must:

(1) Have the capability to provide georouting data with 988 calls to the Lifeline Administrator in a format that is compatible with the Lifeline's routing platform, to allow routing of the 988 call by the Lifeline Administrator to the appropriate crisis center based on the geographic area where the handset is located at the time the 988 call is initiated.

(2) Provide georouting data, when available, with 988 calls to the Lifeline Administrator sufficient to allow routing of the 988 call by the Lifeline Administrator to the appropriate crisis center based on the geographic area where the handset is located at the time the 988 call is initiated.

(b) *Scope of section.* The requirements of this section are only applicable to CMRS providers, excluding mobile satellite service (MSS) operators, to the extent that they:

(1)(i) Offer real-time, two way switched voice service that is interconnected with the public switched network; and

(ii) Use an in-network switching facility that enables the provider to reuse frequencies and accomplish seamless hand-offs of subscriber calls. These requirements are applicable to entities that offer voice service to consumers by purchasing airtime or capacity at wholesale rates from CMRS licensees.

(2) The requirements of this section do not apply to 988 calls transmitted using roaming capabilities.

(c) *Compliance.* (1) By 30 days after December 12, 2024: Nationwide CMRS providers shall provide georouting data with wireless 988 calls.

(2) By 24 months after December 12, 2024: All CMRS providers shall provide georouting data with wireless 988 calls.

(d) *Definitions.* For purposes of this section:

Commercial mobile radio service (CMRS). A mobile service that is:

(i)(A) Provided for profit, *i.e.,* with the intent of receiving compensation or monetary gain;

(B) An interconnected service; and

(C) Available to the public, or to such classes of eligible users as to be effectively available to a substantial portion of the public; or

(ii) The functional equivalent of such a mobile service described in paragraph (i)(A) of this definition.

(iii) A variety of factors may be evaluated to make a determination whether the mobile service in question is the functional equivalent of a commercial mobile radio service, including: Consumer demand for the service to determine whether the service is closely substitutable for a commercial mobile radio service; whether changes in price for the service under examination, or for the comparable commercial mobile radio service, would prompt customers to change from one service to the other; and market research information identifying the targeted market for the service under review.

(iv) Unlicensed radio frequency devices under part 15 of this chapter are excluded from this definition of Commercial mobile radio service.

Georouting data. Location data generated from cell-based location technology that is aggregated to a level that will not identify the location of the cell site or base station receiving the 988 call or otherwise identify the precise location of the handset.

Lifeline Administrator. The Lifeline Administrator controls the 988 call routing platform pursuant to contract with the Substance Abuse Mental Health Services Administration.

Nationwide CMRS provider. A CMRS provider whose service extends to a majority of the population and land area of the United States.

Non-nationwide CMRS provider. Any CMRS provider other than a nationwide CMRS provider.

[FR Doc. 2024–25912 Filed 11–8–24; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register

Vol. 89, No. 218

Tuesday, November 12, 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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2408; Project Identifier AD–2024–00362–T]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 747–400, 747–400F, 747–8F, and 747–8 series airplanes. This proposed AD was prompted by a report that, during potable water servicing, there were multiple engine indicating and crew alerting system messages. The cause was the separation of a fitting and steel water supply tube above an electronics equipment cooling air filter, behind the forward cargo compartment left sidewall. This proposed AD would require, depending on configuration, installing at certain locations: conduits on exposed potable water supply lines, envelope assemblies over all exposed potable water line fittings and exposed potable water supply lines, a slitted spray shield, a 2-piece deflector shield around the equipment cooling system air inlet, and/or a shroud on exposed potable water supply lines. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 27, 2024.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2408; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For the Boeing material identified in this proposed AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com*.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2024–2408.

FOR FURTHER INFORMATION CONTACT: Courtney Tuck, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3986; email: *Courtney.K.Tuck@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2024–2408; Project Identifier AD–2024–00362–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Courtney Tuck, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3986; email: *Courtney.K.Tuck@faa.gov.* Any commentary that the FAA receives that is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA has received a report indicating that during potable water servicing on a Model 777 freighter airplane, there were multiple engine indicating and crew alerting system messages. The cause was the separation of a fitting and steel water supply tube above an electronics equipment cooling air filter, behind the forward cargo compartment left sidewall. Water from the soaked filter was subsequently sprayed by the equipment cooling system onto multiple line replaceable units in the main electronics center. Due to similar designs to the Model 777 freighter airplanes, Boeing developed a precautionary solution for Model 747–400, 747–400F, 747–8F, and 747–8 airplane configurations having potable water supply lines and connections near

the equipment cooling supply (ECS) air inlet. The solution includes installing shrouding around the potable water lines and conduits near the ECS air equipment the electrical equipment cooling duct to collect any water leaks and allow collected water to flow gravitationally away and at a safe distance from the ECS air inlet and the electronic equipment cooling duct to the floor of the airplane, preventing water leaks into the main electronics center. This condition, if not addressed, could result in an adverse impact on the function of multiple electronics and line replaceable units (LRUs) in the equipment bay racks that are essential for safe flight, which can lead to the loss of continued safe flight and landing.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Material Incorporated by Reference Under 1 CFR Part 51

The FAA reviewed Boeing Alert Requirements Bulletin 747–38A2146 RB, dated August 7, 2024. This material specifies procedures for, depending on configuration, installing: conduits on exposed potable water supply lines between station (STA) 580 and STA 650, between STA 575 and STA 650, or between STA 595 and STA 650, as applicable; envelope assemblies over all exposed potable water line fittings and exposed potable water supply lines between STA 650 and STA 660, between STA 640 and STA 660, between STA 570 and STA 580, between STA 570 and STA 580 and between STA 650 and STA 660, between STA 580 and STA 600 and between STA 650 and STA 660, or between STA 580 and STA 600, as applicable; a slitted spray shield; a 2-piece deflector shield around the ECS air inlet STA 610; a spray shield; and/or a shroud on exposed potable water supply line between STA 550 and STA 680.

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the material already described, except for any differences identified as exceptions in the regulatory text of this proposed AD. For information on the procedures and compliance times, see this material at *regulations.gov* under Docket No. FAA–2024–2408.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 178 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Installations	Up to 22 work-hours × $85 per hour = Up to $1,870	Up to $4,980	Up to $6,850	Up to $1,219,300.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

The Boeing Company: Docket No. FAA–2024–2408; Project Identifier AD–2024–00362–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 27, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 747–400, 747–400F, 747–8F, and 747–8 series airplanes, certificated in any category, as identified in Boeing Alert Requirements Bulletin 747–38A2146 RB, dated August 7, 2024.

(d) Subject

Air Transport Association (ATA) of America Code 38, Water/waste.

(e) Unsafe Condition

This AD was prompted by a report that, during potable water servicing, there were multiple engine indicating and crew alerting system messages. The cause was the separation of a fitting and steel water supply tube above an electronics equipment cooling air filter, behind the forward cargo compartment left sidewall. The FAA is issuing this AD to address water leaks into the main electronics center. The unsafe condition, if not addressed, could result in an adverse impact on the function of multiple electronics and line replaceable units (LRUs) in the equipment bay racks that are essential for safe flight, which can lead to the loss of continued safe flight and landing.

(f) Compliance

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

(g) Required Actions

Except as specified by paragraph (h) of this AD: At the applicable times specified in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 747–38A2146 RB, dated August 7, 2024, do all applicable actions identified in, and in accordance with, the Accomplishment Instructions of Boeing Alert Requirements Bulletin 747–38A2146 RB, dated August 7, 2024.

Note 1 to paragraph (g): Guidance for accomplishing the actions required by this AD can be found in Boeing Alert Service Bulletin 747–38A2146, dated August 7, 2024, which is referred to in Boeing Alert Requirements Bulletin 747–38A2146 RB, dated August 7, 2024.

(h) Exception to Requirements Bulletin Specifications

Where the Compliance Time columns of the tables in the ''Compliance'' paragraph of Boeing Alert Requirements Bulletin 747–38A2146 RB, dated August 7, 2024, refer to the original issue date of Requirements Bulletin 747–38A2146 RB, this AD requires using the effective date of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (j)(1) of this AD. Information may be emailed to: *AMOC@faa.gov.*

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

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, AIR–520, Continued Operational Safety Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(j) Related Information

(1) For more information about this AD, contact Courtney Tuck, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3986; email: *Courtney.K.Tuck@faa.gov.*

(2) Material identified in this AD that is not incorporated by reference is available at the address specified in paragraph (k)(3) this AD.

(k) Material Incorporated by Reference

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

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

(i) Boeing Alert Requirements Bulletin 747–38A2146 RB, dated August 7, 2024.

(ii) [Reserved]

(3) For Boeing material identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; website *myboeingfleet.com.*

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

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

Issued on November 5, 2024.

Peter A. White,

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

[FR Doc. 2024–26128 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2423; Project Identifier AD–2024–00320–E]

RIN 2120–AA64

Airworthiness Directives; International Aero Engines AG Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain International Aero Engines (IAE AG) Model V2522–A5, V2524–A5, V2525–D5, V2527–A5, V2527E–A5, V2527M–A5, V2528–D5, V2530–A5, V2531–E5, and V2533–A5 engines. This proposed AD was prompted by further analysis of an event involving an IAE AG Model V2533–A5 engine that had an uncontained failure of a high-pressure turbine (HPT) 1st-stage hub that resulted in high-energy debris penetrating the engine cowling. This proposed AD would require revising the airworthiness limitations section (ALS) of the existing maintenance manual or instructions for continued airworthiness and the existing approved maintenance or inspection program, as applicable, to include new inspections of certain critical rotating parts. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 27, 2024.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2423; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Carol Nguyen, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198 phone: (781) 238–7655; email: *carol.nguyen@faa.gov*.

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2024–2423; Project

Identifier AD–2024–00320–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may revise this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Carol Nguyen, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA received a report of an event involving an IAE AG Model V2533–A5 engine that experienced an uncontained HPT 1st-stage hub failure that resulted in high-energy debris penetrating the engine cowling. Further analysis shows that new inspections of the HPT 1st-stage hub and HPT 2nd-stage hub should be added for certain IAE AG Model V2522–A5, V2524–A5, V2525–D5, V2527–A5, V2527E–A5, V2527M–A5, V2528–D5, V2530–A5, V2531–E5, and V2533–A5 engines to prevent failure of the HPT 1st-stage hub and HPT 2nd-stage hub. This condition, if not addressed, could result in an uncontained hub failure, release of high-energy debris, damage to the engine, damage to the airplane, and loss of the airplane.

FAA's Determination

The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the ALS of the existing approved engine maintenance manual or instructions for continued airworthiness and the existing approved maintenance or inspection program, as applicable, to include new inspections of the HPT 1st-stage hub and HPT 2nd-stage hub.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 1,514 engines installed on airplanes of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Revise the ALS	1 work-hour × $85 per hour = $85	$0	$85	$128,690

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

International Aero Engines AG: Docket No. FAA–2024–2423; Project Identifier AD–2024–00320–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 27, 2024.

(b) Affected ADs

None.

(c) Applicability

This proposed AD applies to International Aero Engines (IAE AG) Model V2522–A5, V2524–A5, V2525–D5, V2527–A5, V2527E–A5, V2527M–A5, V2528–D5, V2530–A5, V2531–E5, and V2533–A5 engines.

(d) Subject

Joint Aircraft System Component (JASC) Code 7250, Turbine Engine Compressor Sections.

(e) Unsafe Condition

This AD was prompted by further analysis of an event involving an IAE AG model V2533–A5 engines that experienced an uncontained high-pressure turbine (HPT) 1st-stage hub failure that resulted in high-energy debris penetrating the engine cowling. The FAA is issuing this AD to prevent failure of the HPT 1st-stage hub and HPT 2nd-stage hub. The unsafe condition, if not addressed, could result in an uncontained hub failure, release of high-energy debris, damage to the engine, damage to the airplane, and loss of the airplane.

(f) Compliance

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

(g) Required Action

Within 90 days after the effective date of this AD; revise the ''Maintenance Scheduling'' paragraph of the Airworthiness Limitations Section (ALS) of the existing approved engine maintenance manual (EMM) or instructions for continued airworthiness and your existing approved maintenance or inspection program, as applicable; by incorporating the information specified in table 1 to paragraph (g) of this AD, as applicable.

TABLE 1 TO PARAGRAPH (g)—ALS ADDITIONAL INSPECTIONS

Part nomenclature	Part No.	Inspection (engine manual reference)
HPT Stage 1 Hub	2A5001	TASK 72–45–11–200–006.
HPT Stage 2 Hub	2A4802	TASK 72–45–11–200–009.

(h) Provisions for Alternative Actions

After the action required by paragraph (g) of this AD has been done, no alternative actions are allowed unless they are approved as specified in the provisions of paragraph (i) of this AD.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520 Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the AIR–520 Continued Operational Safety Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: *AMOC@faa.gov*.

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

(j) Additional Information

For more information about this AD, contact Carol Nguyen, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781)238–7655; email: *carol.nguyen@faa.gov.*

(k) Material Incorporated by Reference

None.

Issued on November 4, 2024.

Peter A. White,

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

[FR Doc. 2024–26092 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2420; Project Identifier MCAI–2024–00143–T]

RIN 2120–AA64

Airworthiness Directives; De Havilland Aircraft of Canada Limited (Type Certificate Previously Held by Bombardier, Inc.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to supersede Airworthiness Directive (AD) 2022–01–02, which applies to certain De Havilland Aircraft of Canada Limited Model DHC–8–400, –401, and –402 airplanes. AD 2022–01–02 requires inspecting for corrosion of the nacelle to wing rear spar attachment pins, and the nacelle to landing gear attachment pins, and doing all applicable corrective actions. Since the FAA issued AD 2022–01–02, it was discovered that some operators were unable to identify the airplanes subject to each requirement. This proposed AD would continue to require the actions specified in AD 2022–01–02, clarify the affected airplanes for each required action, and revise the applicability by removing Model DHC–8–400 airplanes, as specified in a Transport Canada AD, which is proposed for incorporation by reference (IBR). This proposed AD would also revise a certain compliance time. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 27, 2024.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2420; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Transport Canada material identified in this proposed AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca*; website at *tc.canada.ca/en/aviation.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For

information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2024–2420; Project Identifier MCAI–2024–00143–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2022–01–02, Amendment 39–21890 (87 FR 4145, January 27, 2022) (AD 2022–01–02), for certain De Havilland Aircraft of Canada Limited Model DHC–8–400, –401, and –402 airplanes. AD 2022–01–02 was prompted by MCAI originated by Transport Canada, which is the aviation authority for Canada. Transport Canada issued AD CF–2020–51R1, dated February 24, 2021 (Transport Canada AD CF–2020–51R1), to correct an unsafe condition.

AD 2022–01–02 requires doing a detailed visual inspection of the nacelle to wing rear spar attachment pins, and the nacelle to landing gear attachment pins, for any corrosion, and doing all applicable corrective actions. The FAA issued AD 2022–01–02 to address premature corrosion and subsequent failure of the nacelle to landing gear and nacelle to rear wing spar attachment pins, which, if undetected, could lead to a single or dual collapse of the main landing gear.

Actions Since AD 2022–01–02 Was Issued

Since the FAA issued AD 2022–01–02, Transport Canada superseded AD CF–2020–51R1, dated February 24, 2021. Transport Canada AD CF–2020–51R2, dated February 27, 2024 (Transport Canada AD CF–2020–51R2) (referred to after this as the MCAI), was issued to correct an unsafe condition on certain De Havilland Aircraft of Canada Limited Model DHC–8–401 and –402 airplanes.

The MCAI provides clarification of the applicability for each of its parts (Parts I through V) and otherwise maintains the requirements of AD CF–2020–51R1. It also revises the applicability section to remove Model DHC–8–400 airplanes since no model DHC–8–400 airplanes have been delivered.

In addition, the FAA discovered an error in AD 2022–01–02, which included a compliance time that incorrectly used the number of flight cycles on the airplane instead of on the pins.

The FAA is proposing this AD to address premature corrosion and subsequent failure of the nacelle to landing gear and nacelle to rear wing spar attachment pins, which, if undetected, could lead to a single or dual collapse of the main landing gear.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2420.

Explanation of Retained Requirements

Although this proposed AD does not explicitly restate the requirements of AD 2022–01–02, this proposed AD would retain all of the requirements of AD 2022–01–02. Those requirements are referenced in Transport Canada AD CF–2020–51R2, which, in turn, is referenced in paragraph (g) of this proposed AD.

Related Material Under 1 CFR Part 51

Transport Canada AD CF–2020–51R2 specifies procedures for doing a detailed visual inspection of the nacelle to wing rear spar attachment pins, and the nacelle to landing gear attachment pins, for any corrosion; and doing all applicable corrective actions. Corrective actions include applying epoxy primer to the bore surface of the pins, performing a fluorescent magnetic particle inspection for any cracking, removing corrosion, reworking and part marking certain pins, and replacing any cracked or corroded pins with serviceable pins.

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

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would retain all requirements of AD 2022–01–02 and clarify the airplanes subject to each requirement. This proposed AD would remove Model DHC–8–400 airplanes from the applicability and revise a certain compliance time as specified in an exception in paragraph (h)(2) of this proposed AD.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 41 airplanes of U.S. registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 25 work-hours × $85 per hour = Up to $2,125	Up to $21	Up to $2,146	Up to $87,986.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2022–01–02, Amendment 39–21890 (87 FR 4145, January 27, 2022); and

■ b. Adding the following new AD:

De Havilland Aircraft of Canada Limited (Type Certificate Previously Held by Bombardier, Inc.): Docket No. FAA–2024–2420; Project Identifier MCAI–2024–00143–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 27, 2024.

(b) Affected ADs

This AD replaces AD 2022–01–02, Amendment 39–21890 (87 FR 4145, January 27, 2022) (AD 2022–01–02).

(c) Applicability

This AD applies to De Havilland Aircraft of Canada Limited (type certificate previously held by Bombardier, Inc.) Model DHC–8–401 and –402 airplanes, certificated in any category, as identified in Transport Canada AD CF–2020–51R2, dated February 27, 2024 (Transport Canada AD CF–2020–51R2).

(d) Subject

Air Transport Association (ATA) of America Code 54, Nacelles/pylons.

(e) Unsafe Condition

This AD was prompted by a report that the epoxy primer on the internal bore of the nacelle and landing gear attachment pins was not applied, and corrosion on the internal bore of the wing rear spar attachment pins was found. The FAA is issuing this AD to address premature corrosion and subsequent failure of the nacelle to landing gear and nacelle to rear wing spar attachment pins. The unsafe condition, if not addressed, could result a single or dual collapse of the main landing gear.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2020–51R2.

(h) Exceptions to Transport Canada AD 2022–01–02

(1) Where Transport Canada AD 2022–01–02 refers to ''the effective date of CF–2020–51, 9 December 2020,'' this AD requires using March 3, 2022 (the effective date of AD 2022–01–02).

(2) Where paragraph A. of Parts I, II, and III, and Parts IV and V, of Transport Canada AD CF–2020–51R2 specify the compliance time, for this AD, the compliance time for paragraph A. of Parts I, II, and III, and for Parts IV and V, of Transport Canada AD CF–2020–51R2 is at the later of the times in paragraphs (h)(2)(i) and (ii) of this AD.

(i) Prior to the pins reaching 14 years from their entry-into-service or prior to the pins reaching 30,000 total flight cycles, whichever occurs first.

(ii) Within 30 days after the effective date of this AD.

(i) Additional AD Provisions

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

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

(ii) AMOCs approved previously for AD 2022–01–02 are approved as AMOCs for the corresponding provisions of Transport Canada AD CF–2020–51R2 that are required by paragraph (g) of this AD.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or Transport Canada; or De Havilland Aircraft of Canada Limited's Transport Canada Design Approval Organization (DAO). If approved by the DAO, the approval must include the DAO-authorized signature.

(j) Additional Information

For more information about this AD, contact Fatin Saumik, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 516–228–7300; email *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2020–51R2, dated February 27, 2024.

(ii) [Reserved]

(3) For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca;* website *tc.canada.ca/en/aviation.*

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

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

Issued on November 4, 2024.

Victor Wicklund,

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

[FR Doc. 2024–25982 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2024–2422; Project Identifier MCAI–2024–00378–T]

RIN 2120–AA64

Airworthiness Directives; ATR—GIE Avions de Transport Régional Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all ATR—GIE Avions de Transport Régional Model ATR72 airplanes. This proposed AD was prompted by reports of the main landing gear (MLG) rear hinge pin being ruptured. This proposed AD would require replacing affected parts and prohibit the installation of affected parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by December 27, 2024.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2024–2422; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA material identified in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.* It is also available at *regulations.gov* under Docket No. FAA–2024–2422.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th Street, Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3220; email: *Shahram.Daneshmandi@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2024–2422; Project Identifier MCAI–2024–00378–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3220; email: *Shahram.Daneshmandi@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2024–0124, dated July 1, 2024 (EASA AD 2024–0124) (also referred to as the MCAI), to correct an unsafe condition on all ATR—GIE Avions de Transport Régional Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes. The MCAI states that several occurrences of a ruptured MLG rear hinge pin having part number (P/N) D61000 have been reported (including cracked or burnt pins). An investigation on all MLG rear hinge pin batches revealed that six pins were subjected to non-detected thermal abuse in production during grinding process. This condition, if not corrected, could lead to structural failure and consequent

collapse of the MLG, possibly resulting in damage to the airplane and injury to the occupants.

The FAA is proposing this AD to address the unsafe condition on these products.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2024–2422.

Material Incorporated by Reference Under 1 CFR Part 51

EASA AD 2024–0124 specifies replacing certain serial numbered MLG rear hinge pin part number (P/N) D61000 with a serviceable part and prohibits the installation of affected parts. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in EASA AD 2024–0124 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate EASA AD 2024–0124 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2024–0124 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in EASA AD 2024–0124 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2024–0124. Material required by EASA AD 2024–0124 for compliance will be available at *regulations.gov* under Docket No. FAA–2024–2422 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 41 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 8 work-hours × $85 per hour = Up to $680	Up to $14,940	Up to $15,620	Up to $640,420.

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

ATR—GIE Avions de Transport Régional: Docket No. FAA–2024–2422; Project Identifier CAI–2024–00378–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by December 27, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all ATR—GIE Avions de Transport Régional Model ATR72–101, –102, –201, –202, –211, –212, and –212A airplanes, certificated in any category.

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by several occurrences of a ruptured main landing gear (MLG) rear hinge pin. The FAA is issuing this AD to address MLG rear hinge pins that might rupture due to a manufacturing defect. The unsafe condition, if not addressed, could result in structural failure and consequent collapse of the MLG, possibly resulting in damage to the airplane and injury to the occupants.

(f) Compliance

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

(g) Requirements

Except as specified in paragraphs (h) and (i) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2024–0124, dated July 1, 2024 (EASA AD 2024–0124).

(h) Exceptions to EASA AD 2024–0124

(1) Where EASA AD 2024–0124 refers to its effective date, this AD requires using the effective date of this AD.

(2) Where EASA AD 2024–0124 defines a serviceable part as ''Any MLG hinge pin, eligible for installation in accordance with applicable ATR instructions, that is not an affected part,'' for this AD replace that text with ''Any MLG hinge pin, eligible for installation, that is not an affected part.''

(3) This AD does not adopt the ''Remarks'' section of EASA AD 2024–0124.

(i) No Reporting Requirement

Although the material referenced in EASA AD 2024–0124 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Additional AD Provisions

The following provisions also apply to this AD:

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

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

(k) Additional Information

For more information about this AD, contact Shahram Daneshmandi, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 206–231–3220; email: *Shahram.Daneshmandi@faa.gov.*

(l) Material Incorporated by Reference

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

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

(i) European Union Aviation Safety Agency (EASA) AD 2024–0124, dated July 1, 2024.

(ii) [Reserved]

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

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

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

Issued on November 4, 2024.

Victor Wicklund,

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

[FR Doc. 2024–25981 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2024–1966; Airspace Docket No. 24–ASO–19]

RIN 2120–AA66

Amendment of Class E Airspace; Roanoke Rapids, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface for Roanoke Rapids, NC, by adding airspace for Halifax Regional Medical Center Heliport, Roanoke Rapids, NC. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations at this airport.

DATES: Comments must be received on or before December 27, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2024–1966 and Airspace Docket No. 24–ASO–19 using any of the following methods:

* *Federal eRulemaking Portal:* Go to *www.regulations.gov* and follow the online instructions for sending your comments electronically.

* *Mail:* Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays.

* *Fax:* Fax comments to Docket Operations at (202) 493–2251.

Docket: Background documents or comments received may be read at *www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except for Federal holidays.

FAA Order JO 7400.11J Airspace Designations and Reporting Points and subsequent amendments can be viewed online at *www.faa.gov/air_traffic/publications/.* You may also contact the Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Robert Scott Stuart, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305–5926.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the

authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend Class E airspace in Roanoke Rapids, NC.

Comments Invited

The FAA invites interested persons to participate in this rulemaking by submitting written comments, data, or views. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should submit only one time if comments are filed electronically, or commenters should send only one copy of written comments if comments are filed in writing.

The FAA will file in the docket all comments it receives, as well as a report summarizing each substantive public contact with FAA personnel concerning this proposed rulemaking. Before acting on this proposal, the FAA will consider all comments it receives on or before the closing date for comments. The FAA will consider comments filed after the comment period has closed if it is possible to do so without incurring expense or delay. The FAA may change this proposal in light of the comments it receives.

Privacy: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edits, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

Availability of Rulemaking Documents

An electronic copy of this document may be downloaded through the internet at *www.regulations.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Operations office (see **ADDRESSES** section for address, phone number, and hours of operations). An informal docket may also be examined during regular business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Ave., College Park, GA 30337.

Incorporation by Reference

Class E airspace designations are published in Paragraph 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document proposes to amend the current version of that order, FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024. These updates will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11J is publicly available as listed in the **ADDRESSES** section of this document. FAA Order JO 7400.11J lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class E airspace by adding airspace extending upward from 700 feet above the surface within a 6-mile radius of the Halifax Regional Medical Center Heliport, Roanoke Rapids, NC. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

Regulatory Notices and Analyses

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

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures,'' prior to any final regulatory action by the FAA.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11J, Airspace Designations and Reporting Points, dated July 31, 2024, and effective September 15, 2024, is amended as follows:

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

* * * * *

ASO NC E5 Roanoke Rapids, NC [Amended]

Halifax-Northampton Regional Airport, NC
(Lat. 36°19′47″ N, long. 77°38′07″ W)
Halifax Regional Medical Center Heliport, NC
(Lat. 36°25′56″ N, long. 77°38′42″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of Halifax-Northampton Regional Airport and within a 6-mile radius of Halifax Regional Medical Center Heliport.

* * * * *

Issued in College Park, Georgia, on November 5, 2024.

Patrick Young,

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

[FR Doc. 2024–26037 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF VETERANS AFFAIRS

38 CFR Parts 3 and 4

RIN 2900–AQ73

Schedule for Rating Disabilities: Neurological Conditions and Convulsive Disorders

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: The Department of Veterans Affairs (VA) proposes to amend the portion of the VA Schedule for Rating Disabilities (VASRD or Rating Schedule) that addresses neurological conditions and convulsive disorders. The purpose of these changes is to incorporate medical advancements that have occurred since the last revision, update current medical terminology, and provide clear evaluation criteria. The proposed rule reflects advances in medical knowledge and recommendations contained in the report from the Institute of Medicine, part of the National Academy of Sciences, titled ''A 21st Century System for Evaluating Veterans for Disability Benefits,'' National Academies Press, 2007.

DATES: Comments must be received on or before January 13, 2025.

ADDRESSES: Comments must be submitted through *www.regulations.gov*. Except as provided below, comments received before the close of the comment period will be available at *www.regulations.gov* for public viewing, inspection, or copying, including any personally identifiable or confidential business information that is included in a comment. We post the comments received before the close of the comment period on *www.regulations.gov* as soon as possible after they have been received. VA will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. VA encourages individuals not to submit duplicative comments; however, we will post comments from multiple unique commenters even if the content is identical or nearly identical to other comments. Any public comment received after the comment period's closing date is considered late and will not be considered in the final rulemaking. In accordance with the Providing Accountability Through Transparency Act of 2023, a plain language summary (not more than 100 words in length) of this proposed rule is available at *www.regulations.gov*, under RIN 2900–AQ73.

FOR FURTHER INFORMATION CONTACT: Gary Reynolds, M.D., Medical Officer, Part 4 VASRD Staff (218), Compensation Service, Veterans Benefits Administration, Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, *218VASRDPMO.VBACO@va.gov*, (202) 461–9700. (This is not a toll-free telephone number.)

SUPPLEMENTARY INFORMATION: VA has periodically revised portions of the Schedule for Rating Disabilities, to include the Neurological Conditions and Convulsive Disorders (herein referred to as the Neurological body system), since it was created in 1919. Important advances in the neurological sciences—particularly in the areas related to biochemistry, genetics, physiopathology, as well as electrodiagnosis and imaging of the nervous system—have produced drastic changes in the understanding of neurological diseases since the second half of the 20th century. The extent and repercussion of these advances triggered profound changes in approaches to diagnosis, classification of disease, and care of patients with neurological illnesses. As part of VA's ongoing revision of the VA Schedule for Rating Disabilities (VASRD or rating schedule), VA proposes changes to 38 Code of Federal Regulations (38 CFR) §§ 4.120 and 4.123–4.124a, which pertain to the neurological conditions and convulsive disorders. The proposed changes will: (1) update the medical terminology of certain neurological conditions and convulsive disorders; (2) add medical conditions frequently encountered but not currently found in the rating schedule; (3) refine evaluation criteria based on medical advances that have occurred since the last revision and current understanding of functional changes associated with or resulting from disease or injury (pathophysiology), and; (4) remove or modify certain diagnostic codes (DC) that are outdated or obsolete.

I. Retitle and Revise §§ 4.120 Evaluations by Comparison, 4.123 Neuritis, Cranial or Peripheral, and 4.124 Neuralgia, Cranial or Peripheral

VA proposes to retitle and revise § 4.120, *Evaluations by comparison,* because the approach to evaluating neurologic conditions has evolved over the time since this section was included in the 1945 rating schedule. See 29 FR 6718, 6749–6750 (May 22, 1964). As medical understanding has increased, the additional knowledge permits VA to develop evaluation criteria within the individual diagnostic codes that more accurately consider motor, sensory, and mental impairment. The instructions contained in the last sentence of § 4.120, which apply to peripheral nerves, will be updated to better align with modern medical knowledge and relocated to the revised § 4.123, titled ''Cranial and peripheral nerve impairment,'' paragraph (a)(1). VA proposes to relocate instructions relating to organic diseases of the central nervous system to § 4.120. See section II B. Orgranic diseases of the central nervous system below for additional detail.

VA also proposes to retitle and revise §§ 4.123 *Neuritis, cranial or peripheral* and 4.124 *Neuralgia, cranial or peripheral.* These sections provide information regarding symptoms and evaluations associated with neuritis and neuralgia. Neuritis and neuralgia are used to describe symptoms associated with motor and sensory neuropathy involving cranial and peripheral nerves. However, VA proposes their removal in favor of more objective criteria to assess disability in the cranial and peripheral nerves.

In the 1940s, the term neuritis was advanced by Dr. S.A. Kinnier Wilson as an all-encompassing term for most peripheral nerve conditions. Dr. S.A. Kinnier Wilson, ''Neurology,'' 279 (Ninian Bruce ed., 1970). As the field of peripheral neuropathology evolved, it became apparent that use of the term neuritis was obsolete and should be replaced by neuropathy, the preferred term for peripheral nerve diseases. While neuritis is sometimes used as a synonym for neuropathy, this use is erroneous and should only be used for certain specified inflammatory diseases. Drs. A.K. Asbury & Peter Johnson, ''Neurology,'' 258 (James Bennington ed., 1978). While the term neuragia is still used today, for compensation purposes, VA evaluates nerves affected by neuralgia by the sensory impairment caused by neuralgia, not the diagnosis itself. To that end, and as discussed in more detail below, VA proposes to remove neuritis as a separate ratable condition for both cranial nerves (DC series 8300) and peripheral nerves (DC series 8600) and neuralgia as a separate ratable condition for both cranial nerves (DC series 8400) and peripheral nerves (DC series 8700). VA will address evaluations for motor neuropathy and sensory neuropathy in revised § 4.123, as discussed below.

The underlying purpose behind the § 4.123 revision is to provide a central location for instructions specific to cranial and peripheral nerve conditions. This revision will promote rating

quality and consistency. First, VA proposes to retitle the section as ''Cranial and peripheral nerve impairment.'' Next, VA proposes informational language explaining, generally, how disabilities from cranial and peripheral nerve impairment are evaluated. After that, VA proposes to describe how disability from motor neuropathy (complete and incomplete paralysis) will be evaluated. Finally, VA proposes to describe how disability from sensory neuropathy will be evaluated.

Concerning the general instructions described in the revised § 4.123, VA proposes to relocate to this section several instructions that are currently located in multiple areas. The current VASRD contains an instruction directly above diagnostic code 8205; this instruction explains that disability from lesions of peripheral portions of first, second, third, fourth, sixth, and eighth nerves are rated under the Organs of Special Sense. Additionally, it explains that the ratings for the cranial nerves are for unilateral involvement; when bilateral, combine but without the bilateral factor. VA proposes to revise these two sentences, add an additional sentence, and include them in § 4.123. Specifically, proposed § 4.123(a)(3) explains that a cranial nerve will be evaluated strictly as a cranial nerve, regardless of any portions which lie outside the cranium (skull). This is consistent with current medical practice which considers cranial nerves outside of the cranium as separate and distinct from other peripheral nerves. Proposed § 4.123(a)(3) further explains that the evaluations in the rating schedule for the cranial nerves are for unilateral involvement; when bilateral involvement occurs, evaluate separately, then combine under § 4.25 without using the bilateral factor. While all cranial nerves begin inside the cranium, most exit the cranium to insert at various destinations, where they function in a manner similar to peripheral nerves. Nevertheless, VA proposes to evaluate the entire nerve, uniformly, as a cranial nerve. Proposed § 4.123(a)(2) explains that disability from impairments of the first, second, third, fourth, sixth, and eighth cranial nerves will be rated under the Organs of Special Sense. Additionally, the current VASRD contains an instruction directly above diagnostic code 8510; this instruction states, in part, that ratings for the peripheral nerves are for unilateral involvement; when bilateral, combine with application of the bilateral factor. VA will add a reference to evaluate bilateral disabilities separately, then combine using § 4.25 whenever bilateral involvement occurs; this will specify, as opposed to merely imply, how bilateral disabilities are to be evaluated. Additionally, VA will move the instruction to § 4.123(a)(4) because it is a general instruction since it applies to both motor and sensory impairment. Section 4.120 currently includes a sentence explaining that when rating peripheral nerve injuries and their residuals, attention should be given to the site and character of the injury, the relative impairment in motor function, trophic changes, or sensory disturbances. VA proposes the following changes to this sentence: clarify that the sentence applies to cranial and peripheral nerves; remove the reference to trophic changes, which do not consistently correlate to disability; replace the reference to motor function with a reference to movement or muscle strength, corresponding with the proposed evaluation criteria for cranial and peripheral motor nerve function, respectively; and relocate the sentence to § 4.123(a)(1). The purpose of these changes is to remedy confusion and inconsistent application of the instructions caused by the current placement of instructions in multiple locations. Therefore, VA proposes to combine them into a centralized location.

Motor nerve impairment affects muscle function (typically by decreased muscle strength), which can have a significant impact on movement activities, including, but not limited to, walking and grasping. Therefore, VA proposes to focus the complete and incomplete paralysis sections of each cranial and peripheral nerve on motor nerve impairment.

Concerning incomplete paralysis of cranial motor nerves, VA proposes to evaluate disability by replacing the current ''severe'' with ''[a]ttempted movement with inability to complete such movement (muscle twitching present).'' Additionally, VA proposes to revise the cranial evaluation criteria for ''moderate'' incomplete paralysis with ''[m]uscle movement intact, but task performed with difficulty.'' The proposed revisions replace subjective criteria with objective and measurable criteria, which will promote rating consistency and accuracy.

Regarding cranial nerve notes, in the current VASRD, each cranial nerve criteria set contains a note describing functions of that particular nerve. These notes are currently placed after the ''paralysis, incomplete'' diagnostic code section of the individual nerve. VA proposes to update the notes to provide more detailed examples of affected nerve functions and move them, placing them below the evaluation criteria of each individual cranial nerve. VA proposes this change because each note applies to both sensory and motor impairment of the particular cranial nerve.

Concerning peripheral motor nerves, VA proposes to evaluate disability by replacing the current rating criteria, which refer to complete and incomplete paralysis at the severe, moderate, and mild incomplete paralysis level, with criteria that align with the Medical Research Council (MRC) Scale for Muscle Strength (this is also commonly referred to as manual muscle testing). This scale is universally known and used throughout the medical community to evaluate peripheral nerves. ''How to Assess Muscle Strength,'' Merck Manual, *https://www.merckmanuals.com/professional/neurologic-disorders/neurologic-examination/how-to-assess-muscle-strength?query=Medical*, (last reviewed February 2018). The MRC grades muscle strength on a range from ''0'' (completely paralyzed) to ''5'' (normal muscle function). ''To distinguish among the various degrees of muscle strength within a given level, this scale has been modified with the addition of intermediate levels (*e.g.,* 4+ and 4 −).'' Frontera, W.R. ''Delisa's Physical Medicine & Rehabilitation: Principles and Practice,'' 5th Edition, p 74 (2010).

Instead of ''mild,'' VA will use Grade 4 muscle strength. This represents measurable muscle weakness. Instead of ''moderate,'' VA will use Grade 3 muscle strength. This represents muscle strength that can oppose gravity, but cannot oppose resistance greater than gravity. Instead of ''moderately severe,'' VA will use Grade 2+ muscle strength. This represents muscle strength that is unable to oppose gravity completely, though muscle strength with gravity eliminated is present. That is, muscle strength that is greater than Grade 2, but less than Grade 3. Only the sciatic nerve has a ''moderately severe'' category. Instead of ''severe,'' VA will use Grade 2 muscle strength. This represents muscle strength that, though present, cannot oppose gravity at all. Complete paralysis will be identified as Grade 0 muscle strength (no muscle contraction or complete paralysis) or Grade 1 muscle strength (meaning a flicker or trace of contraction). Id. The proposed revisions replace subjective criteria with objective and measurable criteria, which will promote rating consistency and accuracy.

Regarding peripheral nerve instructions, in the current VASRD, there is a three-sentence instruction

directly above DC 8510; this instruction explains, in part, that incomplete paralysis with peripheral nerve injuries indicates a degree of impaired function substantially less than the type picture for complete paralysis, whether due to varied level of the nerve lesion or to partial regeneration. VA proposes to leave this sentence intact with two aesthetic revisions. These revisions involve changing ''picture'' to ''pictured'' and ''level'' to ''levels.'' VA believes these revisions will enable the verbiage to flow more smoothly without changing the meaning. The third sentence will remain intact, with the addition of a reference to § 4.25 in the third sentence, as discussed above. Both sentences will be moved to this instructional section. The remaining sentence will be removed, as it refers to sensory nerve evaluation criteria that VA is proposing to revise. The purpose of these changes is to remedy confusion and inconsistent application of the instructions caused by the current placement of instructions in multiple locations. Therefore, VA proposes to combine them into the most appropriate location.

Currently, each peripheral nerve includes a description in the entry for complete paralysis. For example, the entry for complete paralysis for DC 8510 for the upper radicular group (fifth and sixth cervicals) contains a description of all shoulder and elbow movements lost or severely affected, hand and wrist movements not affected. VA proposes to remove all peripheral nerve descriptions. Since VA is changing the subjective criteria to objective criteria and examiners are aware of the muscles affected by each nerve, VA believes the descriptions are no longer needed.

Concerning sensory neuropathy, sensory nerve impairment affects the ability to notice sensations, to include but not limited to, sharpness, heat, or coldness, and it can also produce abnormal spontaneous sensations, to include but not limited to, burning, tingling, and pain (pins and needles). Therefore, VA proposes to focus the sensory neuropathy sections of each nerve on sensory nerve impairment and remove neuritis and neuralgia as separate ratable conditions. Having separate diagnostic codes for neuritis and neuralgia requires VA to change the diagnostic code a veteran is rated under when the impairment associated with the condition changes, which creates additional work and complexity with no benefit to the veteran or VA. VA proposes to remove the diagnostic codes for neuritis and neuralgia, retitle the diagnostic codes addressing paralysis, and address motor and sensory impairment as criteria under the retitled diagnostic codes. Additionally, in light of the removal of DCs 8619 and 8719, VA proposes to number the notes that will appear under DC 8519.

In the current VASRD, the instructions under § 4.124, *Neuralgia, cranial or peripheral,* consist of three sentences. The first two sentences provide information regarding symptoms associated with neuralgia and instructions regarding the maximum evaluations for neuralgia. The last sentence provides rating instructions for tic douloureux. VA proposes to address sensory impairments in a new section, § 4.123(c). Instead of defining neuralgia, § 4.123(c)(1) will address altered sensation, with or without pain, on the basis of incomplete or complete sensory neuropathy. VA proposes to delete the last sentence of § 4.124, which addresses tic douloureux, because it is redundant. A note under the entry for the fifth (trigeminal) cranial nerve provides instructions on how to evaluate tic douloureux.

The current evaluation criteria focus on neuritis, neuralgia, and degrees of paralysis, with a maximum rating for neuritis equal to severe, incomplete, paralysis of the nerve involved, and a maximum rating for neuralgia equal to moderate incomplete paralysis. There is also an instruction at the beginning of the schedule of ratings for diseases of the peripheral nerves indicating that the rating should be for the mild, or at most, the moderate degree when the involvement is wholly sensory. Certain cranial and all peripheral nerves are evaluated using neuritis, neuralgia, and degrees of paralysis, regardless if the nerve has only sensory function, only muscle function, or both sensory function and muscle function (found in mixed nerves). There are several problems with the current approach. While both neuritis and neuralgia involve distorted sensation, the disability associated with these distorted sensations cannot be quantified by objective diagnostic testing and is unpredictable. Furthermore, the evaluation criteria for pure sensory nerves are the same as for pure motor nerves and mixed nerves, which is incorrect from a medical science perspective. For example, the external cutaneous nerve of the thigh and the obturator nerve have the same evaluation criteria (varying degrees of paralysis, which currently form the basis for rating neuritis and neuralgia), even though it is scientifically incorrect to evaluate a pure sensory nerve, such as the external cutaneous nerve of the thigh, for paralysis. It is this difficulty with measurement, unpredictability, and inappropriate application of certain evaluation criteria that VA seeks to remedy with the following proposed changes.

VA proposes to change the sensory evaluation criteria to a more easily measured sensory deprivation standard. Impairment of sensory function will be quantified as either incomplete or complete sensory deprivation. This simplifies the evaluation criteria and is much more easily measured during physical examination. These criteria will be applied to certain cranial nerves as well as all peripheral nerves. Muscle function in certain cranial nerves and all peripheral nerves will be evaluated in isolation using the previously discussed methods.

Using the incomplete/complete characterization of sensory deprivation described above, VA proposes to use a more straightforward description for disability when sensory neuropathy is involved. VA will consider sensory neuropathy as incomplete when sensation is impaired, although not absent, or when unpleasant sensations are experienced by the nerve such as dysesthesia, numbness, or paresthesia. Dysesthesia refers to any unpleasant sensation produced by a stimulus that is normally painless. Numbness refers to a sense of heaviness, weakness, or deadness in part of the body. Paresthesia refers to abnormal spontaneous sensations such as burning, tingling, pins and needles, etc. Clinical Neurology, 11th Edition, 2021, Chapter 10: Sensory Disorders. editors Greenberg, D.A., Aminoff, M.J., and Simon, R.P.

VA will consider sensory neuropathy complete when sensation is absent. In cranial nerves, which have compensable evaluations at the moderate evaluation level, VA will assign an evaluation at the moderate evaluation level if there is incomplete or complete sensory neuropathy. However, this will not be applied to the eleventh cranial nerve, also known as the spinal accessory nerve, because it only has a muscle function. For peripheral nerves, which mostly have compensable evaluations at the mild evaluation level, VA will assign an evaluation similar to the mild evaluation if there is incomplete sensory neuropathy. VA will assign an evaluation similar to the moderate evaluation if there is complete sensory neuropathy. Where the evaluation of a peripheral nerve remains the same whether it is at the mild or moderate evaluation level (DCs 8525, 8527, 8528, 8529, and 8530), VA will assign an evaluation at the moderate evaluation if there is incomplete or complete sensory neuropathy.

II. Schedule of Ratings—Neurological Conditions and Convulsive Disorders

A. Location of Section

Currently, the schedule of ratings for the Neurological body system is located in 38 CFR 4.124a. When the 1945 VA Schedule for Rating Disabilities was originally published in title 38 of the Code of Federal Regulations in 1964, VA organized it such that specific body systems started at specific locations. The Musculoskeletal body system, for example, began in § 4.40 even though the preceding section was § 4.31, leaving sections §§ 4.32 through 4.39 without content. See 29 FR 6718, 6722 (May 22, 1964). VA also designed the Rating Schedule so that the Mental Disorders body system started with § 4.125; however, due to the number of sections necessary to establish the Neurological body system, which precedes the Mental Disorders body system, the schedule of ratings for neurological conditions and convulsive disorders was placed in § 4.124a. See 29 FR 6718, 6749–53 (May 22, 1964). As proposed above, disability previously addressed in § 4.124 will now be addressed in the revision of § 4.123, which makes § 4.124 available. Therefore, VA also proposes to relocate the Schedule of Ratings from § 4.124a to § 4.124 and remove § 4.124a. VA proposes corresponding revisions to the references to § 4.124a in 38 CFR 3.809(d) and 38 CFR 4.71a, DC 5244.

B. Organic Diseases of the Central Nervous System

Currently, the introductory instruction under § 4.124a provides guidance concerning how to evaluate residuals of organic diseases of the central nervous system. There is a note currently located under DC 8025, Myasthenia gravis, which also provides guidance concerning how to evaluate residuals of organic diseases of the central nervous system. VA proposes to consolidate both notes, revising them and relocating them to § 4.120. VA further proposes to specify the diagnostic codes to which the instructions apply in order to promote consistent application of the VASRD.

First, VA proposes to clarify when ascertainable residuals are required. For diagnostic codes 8000–8036, there are 2 categories of diagnostic codes that consider minimum evaluations: unconditional and conditional minimums. Unconditional minimum diagnostic codes are 8002, 8004, 8007, 8010, 8018, 8021, 8023, 8024, and 8025. The aforementioned diagnostic codes do not require ascertainable residuals for a minimum evaluation, and will not require ascertainable residuals in this proposed regulation.

For DCs 8004 and 8007, which have unconditional minimums within the proposed General Rating Formula, VA proposes Note (1) to direct the rater to grant a minimum evaluation of 30 percent for Parkinson's disease (8004), regardless of examination findings. VA proposes Note (2) to direct the rater to grant a minimum evaluation of 10 percent for stroke residuals (8007), regardless of examination findings. No minimum evaluations will be available for DCs 8026, 8027, and 8028.

Conditional minimum DCs 8000, 8003, 8011, 8012, 8019, 8020, 8022, and new 8036 all require ascertainable residuals. Examples of ascertainable residuals to be considered include, but are not limited to, psychotic manifestations, loss of use of an extremity (partial or complete), as well as abnormal speech, vision, gait, or coordination. Finally, in the portion of the instruction addressing determinations as to the presence of residuals not capable of objective verification, VA proposes to specify that such determinations must be approached on the basis of disability related to the diagnosis recorded, rather than simply the diagnosis recorded, as the current instruction provides. The revised language is more consistent with 38 CFR 4.1, which provides that the rating schedule is primarily a guide in the evaluation of disability resulting from diseases and injuries encountered as a result of or incident to military service.

In regard to peripheral nerves and paralysis, VA proposes to replace the reference to mild, moderate, severe, or complete paralysis of peripheral nerves with a reference to complete or incomplete paralysis to account for changes in the way paralysis of peripheral nerves will be evaluated as referenced above.

With respect to ratings in excess of the prescribed minimum ratings, VA proposes to replace the current language directing raters to cite the diagnostic codes utilized as bases of evaluation in addition to the codes identifying the diagnoses with a reference to § 4.27, as that section includes instructions for the use of diagnostic code numbers when a disease is rated on the basis of residual conditions.

C. Diagnostic Code 8000, Encephalitis, Infectious

Current DC 8000 is titled ''Encephalitis, epidemic, chronic.'' The use of the term ''epidemic'' was used to describe an outbreak of encephalitis lethargica from 1918 to 1930. Dr. R.R. Dourmashkin, ''What Caused the 1918–1930 Epidemic of Encephalitis Lethargica?,'' 90 Journal of the Royal Society of Medicine 515, 515–520 (1997). Since that outbreak, a recurrence of the epidemic has not been reported. ''Encephalitis Lethargica Information Page,'' National Institute of Health—National Institute of Neurological Disorders and Stroke, *https://www.ninds.nih.gov/health-information/disorders/encephalitis* (last visited September 18, 2024). Given the infrequency with which this specific type of encephalitis occurs, VA proposes to rename DC 8000 as ''Encephalitis, infectious'' to better reflect the disabilities currently evaluated under this DC.

As a broader disease category, infectious encephalitis refers to an irritation and swelling of the brain caused by viral, bacterial, fungal, or parasitic infection. Symptoms of this disease can be quite severe and include loss of consciousness, seizures, paralysis, and sudden change in mental functions. The residuals of infectious encephalitis vary from full recovery to permanent disabilities and, in some cases, death. ''Encephalitis,'' National Institute of Health—U.S. National Library of Medicine (Aug. 31, 2016), *https://medlineplus.gov/ency/article/001415.htm* (last visited April 3, 2018). No changes to the evaluation criteria are proposed.

D. Diagnostic Code 8002, Brain, New Growth of, Malignant and Diagnostic Code 8003, Brain, New Growth of, Benign

Current DC 8002 is titled ''Malignant,'' and current DC 8003 is titled ''Benign, minimum.'' VA proposes changes to these diagnostic codes to correct current poor formatting. Both are intended to be read in conjunction with the general category of ''Brain, new growth of.'' To clarify the conditions covered under these DCs, VA proposes to rename these disabilities as DC 8002, ''Brain, new growth of, malignant,'' and DC 8003, ''Brain, new growth of, benign.''

Current DC 8002 also contains a note that is located between the 100 percent and the 30 percent evaluation levels. Previously, this diagnostic code had a 100 percent evaluation level and its note contained information regarding the 30 percent minimum rating. See 43 FR 45348, 45362 (Oct. 2, 1978). However, revisions to Part 4 have placed the note between the 100 percent and the 30 percent evaluation levels. Notes are typically found after evaluative criteria. Therefore, VA proposes to relocate this note after the 30 percent evaluation

level and to revise it to ensure that rating personnel understand how it applies to the both the 100 percent and 30 percent evaluation levels.

Current DC 8003 provides a minimum evaluation of 60 percent in the presence of a benign growth of the brain and then directs raters to evaluate based upon residuals, with a minimum evaluation of 10 percent. VA proposes to clarify the 60 percent evaluation by indicating that it applies during the presence of an active benign growth of the brain or during active treatment. By adding this additional information to the 60 percent evaluation criteria, VA will promote consistency of evaluations and avoid premature re-evaluation of the disability prior to successful treatment of the benign growth. VA proposes no other changes to these diagnostic codes.

E. Diagnostic Code 8004, Parkinson's Disease (Paralysis Agitans)

Current DC 8004 is titled ''Paralysis agitans,'' which is Latin for shaking palsy. While these terms are accurate descriptors of the disability, the more commonly used and accepted medical terminology is Parkinson's disease (PD). To clarify the disability evaluated under this diagnostic code as well as to make the VASRD more user-friendly to non-medical personnel, VA proposes to rename this diagnostic code ''Parkinson's disease.'' VA proposes to preserve the historical reference in parentheses.

VA also proposes to adopt evaluation criteria that reflect a modern understanding of this condition within a proposed general rating formula (GRF). VA proposes the creation of a GRF for certain movement disorders within the neurological body system due to the similarities of disabling effects and high frequency of misdiagnosis. By implementing a GRF, the rating process will be standardized as well as simplified based on disability presentation for a group of conditions. Additionally, the use of a GRF for these movement disorders will ensure the avoidance of pyramiding when more than one movement disorder is service connected. Pyramiding occurs when two or more evaluation percentages are awarded for the same disability under various diagnoses. In accordance with 38 CFR 4.14, pyramiding must be avoided. When two or more movement disorders are service-connected, unless none of the symptomatology of a movement disorder is duplicative of or overlapping with the symptomatology of another movement disorder, one evaluation percentage will be awarded based on the highest level of disability represented by the rating criteria that more nearly approximates the disability picture attributable to the service-connected movement disorders. 38 CFR 4.7. VA proposes to title the GRF ''General Rating Formula for Specified Neurologic Conditions (DCs 8004, 8007, 8026, 8027, and 8028)''. VA proposes 0, 10, 30, 60, and 100 percent evaluations to the newly proposed GRF, and it will be placed immediately below DC 8004. Lastly, specific to PD, VA proposes to continue the minimum 30 percent evaluation for a formal diagnosis of PD, as explained in the first note following the proposed GRF.

Recent advances in the understanding of PD have produced several assessment scales that describe discrete levels of increasing disability. The Revised Unified Parkinson's Disease Rating Scale (2008) is a sophisticated, complex scale widely used by clinicians. The level of sophistication and specificity, however, is not required to describe occupationally significant disability. The Hoehn-Yahr Parkinson's Disease scale, which has been in use since 1967, is far simpler to use and apply. VA proposes to base the disability criteria on this scale with direct reference to Hoehn-Yahr stages and descriptions of functional limitation associated with that severity of disease. VA recognizes that this scale was specifically developed for PD. However, other movement disorder evaluation tools are similar to Hoehn-Yahr. Thus, it was determined this was a reliable tool to adapt to multiple movement disorders. Parkinson's Resource Organization, The Five Stages of Parkinson's Disease, *http://www.parkinsonsresource.org/wp-content/uploads/2012/01/The-FIVE-Stages-of-Parkinsons-Disease.pdf,* May 2002. In addition, where appropriate, VA considered and incorporated features of other movement disorder scales. Those additions are noted under the specific movement disorder discussions below. The GRF will list the evaluation criteria first, followed by several notes.

The first note will direct raters to evaluate all cases of PD with a minimum rating of 30 percent. A second note is specific to stroke residuals rated under DC 8007 and directs raters to evaluate stroke residuals with a minimum rating of 10 percent. A third note defines activities of daily living. A fourth note instructs the rater how to evaluate symptoms versus separate and distinct diagnoses. For example, when an impairment such as depression is noted as a symptom versus a formal diagnosis, then it will be evaluated using the GRF for Specified Neurologic Conditions. Conversely, if there is a formal diagnosis, then the disorder will be evaluated separately under § 4.130 (Schedule of ratings—mental disorders). These instructions mirror the current instructions related to the Residuals of Traumatic Brain Injury. The fifth note addresses overlap of manifestations. It instructs rating specialists to evaluate comorbid conditions together when they cannot be delineated. These instructions also mirror the current instructions related to the Residuals of Traumatic Brain Injury. The sixth note reminds raters to consider special monthly compensation.

VA proposes the rating criteria under the GRF to consist of the following. A 100 percent evaluation will be given for ''Hoehn-Yahr stage 4 or stage 5, or; the inability to live independently because of neurologically-related disability.'' A 60 percent evaluation will be given for ''Impairment of mobility (*e.g.,* transfers, balance, or gait) requiring daily use of an assistive device such as a wheelchair, brace(s), crutch(es), cane(s), or walker.'' A 30 percent evaluation will be given for ''Hoehn-Yahr stage 3, or; impairment of mobility (*e.g.,* transfers, balance, or gait) requiring less than daily use of an assistive device such as a wheelchair, brace(s), crutch(es), cane(s), or walker.'' A 10 percent evaluation will be given for ''Hoehn-Yahr stage 2, or; impairment in at least one of the following areas: facial expression (*e.g.,* masking, blinking, or eye motion abnormalities); speech (*e.g.,* soft voice, slurring, difficulty speaking or swallowing); posture (*e.g.,* stooping, instability); mobility not requiring an assistive device (*e.g.,* decreased speed with transfers, gait ataxia, unstable balance); problems initiating or controlling motor movements (*e.g.,* stiffness, tremors); cognitive (*e.g.,* memory or executive problems); mental (*e.g.,* anxiety, depression, social phobia); sensory abnormalities (*e.g.,* olfactory deficits); involuntary muscle contractions resulting in pain and impairment, such as but not limited to, spontaneous neck turning or writing difficulty.'' A 0 percent evaluation will be given for ''Hoehn-Yahr stage 1, or; formal diagnosis without impairment.''

F. Diagnostic Code 8007, Stroke (Ischemic, Hemorrhagic, or Thrombotic), Including Cerebral Infarction or Cerebrovascular Accident (Brain, Vessels, Embolism, Thrombosis, and Hemorrhage); Diagnostic Code 8008 Brain, Vessels, Thrombosis of (Delete); Diagnostic Code 8009 Brain, Vessels, Hemorrhage From (Delete)

VA proposes to combine three DCs (8007, Brain, vessels, embolism of; 8008, Brain, vessels, thrombosis of; and 8009, Brain, vessels, hemorrhage from) under

DC 8007 and rename it as ''Stroke (ischemic, hemorrhagic, or thrombotic), including cerebral infarction or cerebrovascular accident (Brain, vessels, embolism, thrombosis, and hemorrhage).'' Since most clinicians document the condition as ''stroke'' rather than embolism, thrombosis, or hemorrhage, raters are unable to distinguish which title most accurately aligns with ''stroke,'' which means there is a risk that rating specialists will not consistently apply these DCs. For example, three raters evaluate three veterans diagnosed with residuals of a stroke. One rater chooses to use DC 8007; another uses DC 8008; and the other uses DC 8009. All three disabilities currently have the same evaluation criteria. Therefore, the veterans are not at a disadvantage from receiving one DC over the other. However, for statistical purposes, combining these three DCs would promote consistency in future research associated with stroke residuals. Because all three of the current diagnostic codes evaluate stroke residuals in the same way, VA proposes to combine them in order to create diagnostic code application consistency. Additionally, while the distinction concerning the type of stroke is a medical necessity for treatment purposes, it is irrelevant for rating purposes. This proposed update will create more consistent data tracking for disability compensation research purposes.

Currently, rating personnel grant a 100 percent evaluation for the first six months, then assign a minimum rating of 10 percent for stroke residuals, unless an evaluation of residuals under separate body systems results in a higher evaluation. Under the proposed changes, whenever diagnostic imaging, which is part of standard care for a stroke, identifies a stroke, rating personnel will continue to grant a 100 percent evaluation for the first six months; they will also continue to assign a minimum 10 percent for stroke residuals regardless of examination findings. Rating personnel will assign evaluations higher than the minimum in accordance with the General Rating Formula for Specified Neurologic Conditions (GRF). As explained in the fourth note of the GRF, if a residual is a symptom of the stroke, it will be evaluated as such. Contrarily, if a residual has a separate and distinct formal diagnosis, it will be service connected and evaluated separately. For example, if depression is noted as a symptom, it will be evaluated as part of the minimum 10 percent evaluation. However, if depression is a separate and distinct formal diagnosis, it will be service connected on a secondary basis and evaluated under § 4.130 (Schedule of ratings—mental disorders). See DC 8004 for details about the GRF.

G. Diagnostic Code 8018, Multiple Sclerosis and Other Demyelinating Diseases of the Central Nervous System

VA proposes to revise the title for this diagnostic code. The new title will be Multiple sclerosis (MS) and other demyelinating diseases of the Central Nervous System. The underlying basis for this revision is the existence of two conditions which present with disabilities similar to MS. VA proposes to evaluate neuromyelitis optica spectrum disorder (NMOSD) under this DC. Previously, NMOSD was rated analogously with DC 8010, Myelitis. Myelin oligodendrocyte glycoprotein antibody—associated disease (MOGAD) is the other condition to be captured with this DC. Like NMOSD, MOGAD also presents with a similar disability picture to MS. Wu, H. and Fisher, K., Current Diagnosis & Treatment Pediatric Neurology, Chapter 35. 2023.

H. Diagnostic Code 8021, Spinal Cord, New Growths of, Malignant and Diagnostic Code 8022, Spinal Cord, New Growths of, Benign

Current DC 8021 is titled ''Malignant,'' and current DC 8022 is titled ''Benign.'' VA proposes changes to these DCs to correct current poor formatting. Both were intended to be read in conjunction with the general category ''Spinal cord, new growths of.'' For the same reasons set forth above in the discussion for DC 8002, VA proposes to rename DC 8021 ''Spinal cord, new growths of, malignant,'' and DC 8022 ''Spinal cord, new growths of, benign.'' VA also proposes to clarify the 60 percent evaluation criteria for DC 8022 for the same reasons set forth in the discussion for DC 8003.

Additionally, current DC 8021 also contains a note that is located between the 100 percent and the 30 percent evaluation levels. Previously, this DC had a 100 percent evaluation level and its note contained information regarding the 30 percent minimum rating. See 43 FR 45348, 45362 (Oct. 2, 1978). However, revisions to Part 4 have placed the note between the 100 percent and the 30 percent evaluation levels. Notes are typically found after evaluative criteria. Therefore, VA proposes to relocate this note after the 30 percent evaluation level and to revise it to ensure that rating personnel understand how it applies to the both the 100 percent and 30 percent evaluation levels. VA proposes no other changes to these DCs.

I. Diagnostic Code 8025, Myasthenia Gravis

VA proposes to relocate and modify the note currently located directly below the rating criteria of DC 8025. It will be relocated to the introductory instruction under § 4.124. Refer to the above section, ''B. Organic diseases of the central nervous system,'' and § 4.124 for further details concerning this instruction.

J. New Diagnostic Code 8026, Parkinson's Plus, or Secondary Parkinsonism Syndromes

VA proposes to add a new DC 8026, titled ''Parkinson's plus, or secondary parkinsonism syndromes,'' in order to account for impairment due to this condition in the veteran population. Parkinson's plus syndromes cause similar symptoms and impairment to Parkinson's disease, but have other features that make them different. Parkinson's plus syndromes have several causes, which include but are not limited to different location of protein buildup, brain injury, encephalitis, meningitis, stroke, medications, and chemical poisonings. Parkinson's plus syndromes can cause impairment in facial expressions, problems with initiating or controlling motor movements, paralysis, vocal impairment, stiffness, and tremor. Treatment for Parkinson's plus syndromes, as well as the likelihood and extent of residual disability, depends on the underlying cause of the disorder. This is in contrast to primary Parkinson's, or Parkinson's disease, where there is a predictable progression. For this reason, Parkinson's plus syndrome will not have a minimum evaluation. ''Secondary Parkinsonism,'' National Institute of Health—U.S. National Library of Medicine (Jan. 19, 2018), *https://medlineplus.gov/ency/article/000759.htm* (last visited April 3, 2018). VA is proposing a specific diagnostic code for Parkinson's plus syndromes to allow for proper tracking of Parkinson's plus and Parkinson's disease in the veteran population. Parkinson's plus will be evaluated under the General Rating Formula for Specified Neurologic Conditions (GRF). See DC 8004 for details about the GRF.

K. New Diagnostic Code 8027, Essential Tremor

VA proposes to add a new DC 8027, titled ''Essential tremor,'' in order to account for impairment due to this condition. There is currently no standalone diagnostic code to account

for essential tremor, forcing rating personnel to rely on analogous coding and leading to inconsistent evaluations.

''Tremor is defined as a rhythmical, involuntary, oscillatory movement of a body part and is one of the most frequent movement disorders.'' Teive, H.A.G., ''Essential Tremor: phenotypes,'' (18) S1, pp 140–142, 140, Parkinsonism and Related Disorders (2012). ''Essential tremor (ET) is one of the most common neurological diseases and the [most common] cause of pathological tremor.'' Id. ''Historically[,] ET was defined as a benign entity.'' Id. However, recently it ''was suggested that it is time to remove the 'benign' from the ET label, as it has been shown to be progressive in nature and quite disabling for most patients.'' Id. ''In the last [several] years[,] ET has evolved into two different meanings.'' Id. First, ''the classical ET, as a monosymptomatic disorder, and second, a heterogeneous disorder, the Essential Tremors, or a family of diseases.'' Id. Currently, ''ET can be classified with both motor and non-motor elements. Tremor may occur also in the legs, feet, trunk, jaw, chin, tongue, and voice. Although postural and kinetic tremors are the main features of ET, intentional tremor and tremor at rest may also occur in some patients. Other motor features described in patients with ET are gait ataxia, postural instability[,] and eye-motion abnormalities. Non-motor features include cognitive (memory and executive problems and dementia), psychiatric (anxiety, depression[,] and social phobia), and sensory abnormalities (olfactory deficits [and] hearing loss).'' Id.

In developing evaluation criteria for ET, one of the most significant challenges is little, if any, outcomes research that would assist in criteria development. However, there are two well-recognized tools VA used to research this condition. The first tool is the International Classification of Functioning, Disability, and Health (2001), published by the World Health Organization, that provided terminology and definitions. According to this resource, ET involves the dysfunction of specific elements within the central nervous system. The tremors with ET are the impairments resulting from that nervous system dysfunction. Those tremors cause activity limitations and participation restrictions that can lead to earnings loss. The second tool is the 6th Edition Guides to the Evaluation of Permanent Impairment (2008), published by the American Medical Association. The guide has impairment tables for the upper extremities, gait, and station. These tools were considered in the creation of a general rating formula.

Another significant challenge in developing evaluation criteria for ET is the high rate of misdiagnosis with other movement disorders, such as dystonia and Parkinson's disease. Misdiagnosis occurs in up to 50 percent of cases, with Parkinson's disease (particularly in elderly patients) and dystonia (tremulous cervical dystonia) being the most common disorders mistaken for ET. Therefore, VA proposes the creation and use of a General Rating Formula for Specified Neurologic Conditions (GRF) for this and other movement disorders, allowing evaluation to focus on the symptoms and impairment present, even when misdiagnosis and/or a change in diagnosis occurs. See diagnostic code 8004 for details about the GRF. Teive, H.A.G., ''Essential Tremor: phenotypes,'' (18) S1, pp 140–142, Parkinsonism and Related Disorders (2012).

L. New Diagnostic Code 8028, Dystonia

VA proposes to add a new DC 8028, titled ''Dystonia,'' in order to account for impairment due to this condition. There is currently no standalone diagnostic code to account for dystonia, forcing rating personnel to rely on analogous coding and leading to inconsistent evaluations.

Dystonia causes involuntary muscle contractions that lead to slow, repetitive, and sometimes painful movement or abnormal posture. Dystonia can affect only one muscle, groups of muscles (torticollis), or muscles throughout the entire body. The specific symptoms and impairment experienced depend highly on the type of dystonia and the muscles affected, but can include difficulty walking, involuntary neck turning, difficulty speaking, writing, and uncontrollable blinking. Some cases of dystonia only affect a muscle group when performing a specific action. ''Dystonias Fact Sheet,'' National Institute of Health—National Institute of Neurological Disorders and Stroke (June 3, 2014), *https://www.ninds.nih.gov/health-information/disorders/tremor#toc-where-can-i-find-more-information-about-tremor-* (last visited September 18, 2024).

The Dystonia Study Group composed of renowned international movement disorder experts developed the unified dystonia rating scale and the global dystonia rating scale to serve as instruments to medically assess dystonia severity. ''Rating Scales for Dystonia: A Multicenter Assessment,'' Comella C et al., 2003 Movement Disorders 18 No.3 pp 303–12. These scales were considered during the creation of the general rating formula. Due to similarity and overlap of symptoms with other movement disorders, along with the high prevalence of misdiagnosis, VA proposes application of a General Rating Formula for Specified Neurologic Conditions (GRF). See DC 8004 for details about the GRF.

M. New Diagnostic Code 8036, Primary Lateral Sclerosis

VA proposes to add a new DC 8036, titled ''Primary lateral sclerosis,'' in order to account for impairment due to this condition. There is currently no standalone diagnostic code to account for primary lateral sclerosis (PLS). A standalone diagnostic code will permit more accurate tracking of this condition, and its associated disability.

PLS is a motor neuron disease that affects the upper motor neurons in the arms, legs, and face. Individuals with PLS first experience loss of muscle control in the feet and legs, then the disease progresses up the trunk and into the arms, hands, and the muscles that control speech, swallowing, and chewing. PLS can be differentiated from amyotrophic lateral sclerosis in that it only affects the upper motor neurons and progresses gradually. While there is no cure for PLS, it is not considered a fatal disease, and many individuals maintain the ability to walk without assistance, although they may eventually need a cane or walker due to the development of high degrees of spasticity. Due to the wide range of symptoms and severity upon confirmation of diagnosis, VA proposes to evaluate PLS according to the residual impairment under the appropriate diagnostic code with a minimum rating of 10 percent when there are ascertainable residuals. See R. Ramanathan, et al., ''Demographics and clinical characteristics of primary lateral sclerosis: case series and a review of literature,'' Neurodegener. Dis. Manag., vol 8(1), pp 17–23. 2018.

N. Diagnostic Code 8103, Hemifacial Spasm (Tic, Convulsive)

Current DC 8103 is titled ''Tic, convulsive,'' a facial nerve disorder that causes involuntary spasms and contractions of the facial nerves. For consistency, clarity, and ease of use of the VASRD by non-medical personnel, VA proposes to rename this diagnostic code ''Hemifacial spasm.'' Hemifacial spasm, an alternative name for convulsive tic, provides a much more explicit indication as to the condition to be evaluated under this diagnostic code

in terms of the anatomical location to be considered. VA proposes to preserve the historical reference to the nomenclature in parentheses. VA proposes no other changes to this diagnostic code.

O. Diagnostic Code 8104, Paramyoclonus Multiplex (Convulsive State, Myoclonic Type)

The current evaluation criteria for DC 8104, Paramyoclonus multiplex (convulsive state, myoclonic type), directs rating personnel to rate this condition as convulsive tic, which is DC 8103. As discussed above, VA is updating this term to hemifacial spasm in order to reflect current medical terminology. As such, VA proposes to replace ''tic; convulsive'' in the evaluation criteria of DC 8104 to maintain consistency throughout this portion of the VASRD. VA proposes no other changes to this DC.

P. Diagnostic Code 8107, Athetosis, Acquired

Current DC 8107, Athetosis, acquired, directs rating personnel to evaluate this condition as chorea. To clarify these instructions and promote consistency in evaluations, VA proposes to specify that this condition should be evaluated as Sydenham's chorea, matching the title of the DC that provides the appropriate evaluation criteria. VA proposes no other changes to this DC.

Q. Title Changes to Certain Peripheral Nerves

To reflect current medical terminology, VA proposes to update the names of the following peripheral nerves. The proposed titles are the current accepted nomenclature to describe these nerves. VA proposes to preserve the historical reference to the nomenclature in parentheses.

Diagnostic code	Current title for nerve	Proposed title for nerve
8514	Musculospiral nerve (radial nerve)	Radial nerve (musculospiral).[1]
8518	Circumflex nerve	Axillary nerve (circumflex).[2]
8521	External popliteal nerve (common peroneal)	Common peroneal nerve (external popliteal).[3]
8522	Musculocutaneous nerve (superficial peroneal)	Superficial peroneal nerve (musculocutaneous).[1]
8523	Anterior tibial nerve (deep peroneal)	Deep peroneal nerve (anterior tibial).[1]
8524	Internal popliteal nerve (tibial)	Tibial nerve (internal popliteal).[4]
8526	Anterior crural nerve (femoral)	Femoral nerve (anterior crural).[5]
8527	Internal saphenous nerve	Saphenous nerve (internal saphenous).[1]
8529	External cutaneous nerve of thigh	Lateral cutaneous nerve of the thigh (external cutaneous).[5]

[1] ''Dorland's Illustrated Medical Dictionary,'' 1123 (Douglas M. Anderson et al. eds., 27th ed. 1988).
[2] Wolf, J., ''Segmental Neurology'', page 20, 1981.
[3] ''Common Peroneal Nerve Dysfunction,'' National Institute of Health—U.S. National Library of Medicine (Aug. 7, 2017), *https://medlineplus.gov/ency/article/000791.htm* (last visited April 3, 2018).
[4] ''Dorland's Illustrated Medical Dictionary,'' 1124 (Douglas M. Anderson et al. eds., 27th ed. 1988).
[5] ''Dorland's Illustrated Medical Dictionary,'' 1120 (Douglas M. Anderson et al. eds., 27th ed. 1988).

R. Diagnostic Code 8514, Paralysis of the Musculospiral (Radial) Nerve

Current DC 8514 addresses motor impairment from diseases affecting the musculospiral nerve. The current evaluation criteria include a note that references dissociation of extensor communis digitorum and paralysis below the extensor communis digitorum, as well as instructing evaluations of these findings should not exceed a moderate rating. As stated previously, this nerve will be retitled as the radial nerve. Additionally, the note will be revised, as the evaluation criteria will be revised to employ the grade of muscle strength as the means to distinguish evaluation levels, with the maximum evaluation level corresponding to Grade 3 muscle strength for dissociation of extensor communis digitorum and paralysis below the extensor communis digitorum.

S. Diagnostic Code 8520, Paralysis of the Sciatic Nerve

Current DC 8520 addresses motor impairment due to diseases of the sciatic nerve. The nerve referenced by this diagnostic code stimulates the muscles of the entire lower extremity. While all other peripheral nerve criteria consist of mild, moderate, and severe, this one includes an extra category labeled moderately severe. In order to preserve the current evaluation levels and account for this extra category, VA proposes to revise the incomplete paralysis criteria at the 60 percent, 40 percent, 20 percent, and 10 percent levels. A 60 percent evaluation will be granted for muscles that have grade 2 strength (previously labeled severe). A 40 percent evaluation will be granted for muscles that have grade 2+ strength (previously labeled moderately severe). A 20 percent evaluation will be granted for muscles that have grade 3 strength (previously labeled moderate). A 10 percent evaluation will be granted for muscles that have grade 4 strength (previously labeled mild). Refer to the discussion above regarding § 4.123 for further details concerning the grading scale for motor impairment.

T. Diagnostic Code 8527, Sensory Neuropathy of the Internal Saphenous Nerve

Current DC 8527 addresses paralysis of the internal saphenous nerve. Paralysis refers to the lack of muscle function in muscle fibers. Posterior roots of the spinal nerves, including the saphenous nerve, do not have motor fibers, making it a pure sensory nerve. M. De Maeseneer, et al., ''Normal Anatomy and Compression Areas of Nerves of the Foot and Ankle: US and MR Imaging With Anatomic Correlation,'' Radiographics, vol 35, 1474–1475, 1469–1482 (2015). As a purely sensory nerve, the saphenous nerve has no muscle involvement and therefore using paralysis to describe impairment of this nerve is medically inaccurate. VA proposes to retitle DC 8527 to improve medical accuracy, and motor neuropathy will not be included in the criteria for this nerve. Because this nerve currently has a compensable rating only at the severe to complete paralysis level and sensory neuropathy, wholly sensory evaluations, will only be rated up to the moderate level, this nerve will no longer have a compensable rating.

U. Diagnostic Code 8529, Sensory Neuropathy of the External Cutaneous Nerve of the Thigh

Current DC 8529 addresses paralysis of the external cutaneous nerve of the thigh. Current medical terminology refers to this nerve as the lateral cutaneous nerve of the thigh, or LCNT. This nerve is part of the lumbar plexus. ''It functions primarily as a sensory nerve and its composition varies among individuals with several different

combinations of lumbar nerves that originate from L1 to L3. The LCNT then emerges at the lateral border of the psoas major, crosses the iliacus, to the anterior superior iliac spine. The nerve then passes under the inguinal ligament and over the sartorius muscle and enters the thigh as it divides into an anterior and posterior branch.'' Cheatham, S., et al. ''Meralgia Paresthetica: A Review of the Literature,'' International Journal of Sports Physical Therapy, 8(6): 884, December 2013. Paralysis refers to the lack of muscle function in muscle fibers. This nerve lacks motor fibers. As a purely sensory nerve, it has no muscle involvement and therefore using paralysis to describe impairment of this nerve is medically inaccurate. VA proposes to retitle DC 8529 to improve medical accuracy, and motor neuropathy will not be included in the criteria for this nerve. Because this nerve currently has a compensable rating only at the severe to complete paralysis level and sensory neuropathy, wholly sensory evaluations, will only be rated up to the moderate level, this nerve will no longer have a compensable rating.

V. Diagnostic Code 8540, Soft Tissue Sarcoma of Neurogenic Origin

VA proposes to place a section subheading, ''Other Neoplasms of the Neurological System,'' just above this diagnostic code as a separator between diagnostic codes for peripheral nerves and other neoplasms of the neurological system. No other changes are proposed for this DC.

W. Diagnostic Code 8910, Epilepsy, Grand Mal (Including Tonic-Clonic Seizures)

Current DC 8910 is titled ''Epilepsy, grand mal.'' VA proposes to update the title of this code to indicate that this includes tonic-clonic seizures. Tonic-clonic seizures involve the entire body, and the terminology is synonymous with grand mal seizures. ''Generalized tonic-clonic seizure,'' National Institute of Health—U.S. National Library of Medicine (September 3, 2019), *https://medlineplus.gov/ency/article/000695.htm* (last visited September 10, 2019). VA proposes no other changes to this DC.

X. Diagnostic Code 8911, Epilepsy, Petit Mal (Including Absence Seizures)

Current DC 8911 is titled ''Epilepsy, petit mal.'' VA proposes to update the title of this code to indicate that this includes absence seizures. Absence seizures typically last only a few seconds and may involve staring episodes, also called absence spells. Absence seizure is used synonymously with petit mal seizures. ''Absence Seizure,'' National Institute of Health—U.S. National Library of Medicine (September 3, 2019), *http://www.nlm.nih.gov/medlineplus/ency/article/000696.htm* (last visited September 10, 2019). VA proposes no other changes to this DC.

Y. Non-Substantial Changes to Relocated 38 CFR 4.124a

VA will also make some non-substantial changes to relocated 38 CFR 4.124a. In 2008, DC 8045, Residuals of traumatic brain injury (TBI), was revised to include a table titled ''Evaluation of Cognitive Impairment and Other Residuals of TBI Not Otherwise Classified.'' See 73 FR 54693, 54705–54708 (September 23, 2008). This table was added after the table titled ''Organic Diseases of the Central Nervous System.'' This had the effect of placing DC 8046, Cerebral arteriosclerosis, between the evaluation criteria of DC 8045, Residuals of traumatic brain injury, and the newly added table for TBI residuals. To improve readability and ease of use for both DCs 8045 and 8046, VA proposes to relocate the table titled ''Evaluation of Cognitive Impairment and Other Residuals of TBI Not Otherwise Classified'' directly below the evaluation criteria for DC 8045.

Z. Military Occupational Blast Exposure

VA is currently in the process of investigating the potential neurological residuals of repeated exposure to low-level military occupational blasts or Military Occupational Blast Exposure. VA invites public comment on this subject.

Executive Orders 12866, 13563 and 14094

Executive Order 12866 (Regulatory Planning and Review) directs agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 14094 (Executive Order on Modernizing Regulatory Review) supplements and reaffirms the principles, structures, and definitions governing contemporary regulatory review established in Executive Order 12866 of September 30, 1993 (Regulatory Planning and Review), and Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review). The Office of Information and Regulatory Affairs has determined that this rulemaking is a significant regulatory action under Executive Order 12866, Section 3(f)(1), as amended by Executive Order 14094. The Regulatory Impact Analysis associated with this rulemaking can be found as a supporting document at *www.regulations.gov.*

Regulatory Flexibility Act

The Secretary hereby certifies that this proposed rule would not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (5 U.S.C. 601–612).

The factual basis for this certification is based on the fact that no small entities or businesses determine the rating criteria revisions or assign evaluations for disability claims. Therefore, pursuant to 5 U.S.C. 605(b), the initial and final regulatory flexibility analysis requirements of 5 U.S.C. 603 and 604 do not apply.

Unfunded Mandates

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

Paperwork Reduction Act (PRA)

This proposed rule contains no provisions constituting a collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521).

Assistance Listing

The Assistance Listing numbers and titles for the programs affected by this document are 64.102, Compensation for Service-Connected Deaths for Veterans' Dependents; 64.105, Pension to Veterans, Surviving Spouses, and Children; 64.109, Veterans Compensation for Service-Connected Disability; and 64.110, Veterans Dependency and Indemnity Compensation for Service-Connected Death.

List of Subjects

38 CFR Part 3

Administrative practice and procedure, Claims, Disability benefits.

38 CFR Part 4

Disability benefits, Pensions, Veterans.

Signing Authority

Denis McDonough, Secretary of Veterans Affairs, approved and signed this document on October 29, 2024, and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs.

Luvenia Potts,

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

For the reasons stated in the preamble, VA proposes to amend 38 CFR parts 3 and 4 as set forth below:

PART 3—ADJUDICATION

Subpart A—Pension, Compensation, and Dependency and Indemnity Compensation

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

Authority: 38 U.S.C. 501(a), unless otherwise noted.

■ 2. Amend § 3.809 by revising paragraph (d) to read as follows:

§ 3.809 Specially adapted housing under 38 U.S.C. 2101(a)(2)(A)(i).

* * * * *

(d) *Amyotrophic lateral sclerosis.* VA considers § 3.809(b) satisfied if the veteran or member of the Armed Forces serving on active duty has service-connected amyotrophic lateral sclerosis rated 100 percent disabling under 38 CFR 4.124, diagnostic code 8017.

* * * * *

PART 4—SCHEDULE FOR RATING DISABILITIES

Subpart B—Disability Ratings

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

Authority: 38 U.S.C. 1155, unless otherwise noted.

■ 4. In § 4.71a, amend the table The Spine by revising the entry for diagnostic code 5244 under General Rating Formula for Diseases and Injuries of the Spine to read as follows:

§ 4.71a Schedule of ratings—musculoskeletal system.

* * * * *

THE SPINE

	Rating
General Rating Formula for Diseases and Injuries of the Spine	
* * * * * * *	
5244 Traumatic paralysis, complete: *Paraplegia:* Rate under diagnostic code 5110. *Quadriplegia:* Rate separately under diagnostic codes 5109 and 5110 and combine evaluations in accordance with § 4.25. **Note:** If traumatic paralysis does not cause loss of use of both hands or both feet, it is incomplete paralysis. Evaluate residuals of incomplete traumatic paralysis under the appropriate diagnostic code (*e.g.,* § 4.124, Diseases of the Peripheral Nerves).	
* * * * * * *	

■ 5. Revise § 4.120 to read as follows:

§ 4.120 Minimum evaluations for organic diseases of the central nervous system.

(a) *Necessity of residuals for minimum evaluations.* The minimum evaluations for diagnostic codes 8002, 8004, 8007, 8010, 8018, 8021, 8023, 8024, and 8025 do not require ascertainable residuals. However, ascertainable residuals are required to provide the minimum evaluation for diagnostic codes 8000, 8003, 8011, 8012, 8019, 8020, 8022, and 8036.

(b) *Definition.* Ascertainable residuals include, but are not limited to, psychotic manifestations, complete or partial loss of use of one or more extremities, speech disturbances, impairment of vision, disturbances of gait, tremors, visceral manifestations, etc., referring to the appropriate bodily system of the schedule. With partial loss of use of one or more extremities from neurological lesions, rate by comparison with complete or incomplete paralysis of peripheral nerves. Determinations as to the presence of subjective residuals not capable of objective verification, *e.g.,* headaches, dizziness, fatigability, must be approached on the basis of disability related to the diagnosis recorded. VA will only accept subjective residuals when they are consistent with the disease and not more likely attributable to another disease or no disease.

(c) *Ratings in excess of the minimum evaluation.* When one or more compensable evaluations assigned for the residuals of the diagnostic codes noted in this section meet or exceed the minimum evaluation for that diagnostic code, then the minimum evaluation for that diagnostic code is no longer applicable. When a rating in excess of the prescribed minimum rating is assigned based on the presence of ascertainable residuals, the diagnostic codes associated with the evaluation of those residuals must be cited in accordance with § 4.27.

■ 6. Revise § 4.123 to read as follows:

§ 4.123 Cranial and peripheral nerve impairment.

(a) *General.* (1) In rating cranial and peripheral nerve injuries and their residuals, attention should be given to the site and character of the injury, the relative impairment in movement or muscle strength, and sensory disturbances.

(2) Disability from impairments of the first, second, third, fourth, sixth, and eighth cranial nerves will be rated under the Organs of Special Sense.

(3) A cranial nerve will be evaluated strictly as a cranial nerve, regardless of any portions which lie outside the cranium (skull). The evaluations in the rating schedule for the cranial nerves are for unilateral involvement; when bilateral, evaluate separately, then

combine using § 4.25 but without application of the bilateral factor.

(4) The evaluations in the rating schedule for the peripheral nerves are for unilateral involvement; when bilateral, evaluate separately, then combine using § 4.25 with application of the bilateral factor.

(b) *Motor neuropathy (complete and incomplete paralysis).*

(1) *General.* The evaluation criteria for impairment to muscle function, with or without pain, of both cranial and peripheral nerves will be categorized as either complete paralysis or incomplete paralysis.

(2) *Cranial nerves.* Complete paralysis for cranial nerves is characterized by the complete inability to move. Incomplete paralysis is characterized as either movement with difficulty, or attempted movement with inability to complete such movement (muscle twitching present).

(3) *Peripheral nerves.* VA will evaluate peripheral nerve motor neuropathy using the Medical Research Council (MRC) Scale for Muscle Strength (commonly referred to as manual muscle testing). Complete paralysis for peripheral nerves will be identified as Grade 0 or Grade 1 muscle strength (no movement for Grade 0 and a flicker or trace of contraction for Grade 1). Incomplete paralysis will be determined by the following muscle strength grades: Grade 2 (only able to move if gravity is eliminated; unable to move at all against gravity), Grade 2+, which only applies to DC 8520 Sciatic nerve, (muscle strength, which, though present, can only partially move against gravity), Grade 3 (only able to move against gravity; unable to move against resistance), or Grade 4 (weakness is present, but able to move against resistance and gravity). If muscle strength falls in between grades (Grade + or −) for peripheral nerves other than Grade 2+ for DC 8520, then evaluate as follows: (1). for a − grade, reduce the grade by one integer (*e.g.,* Grade 3 − shall be evaluated as Grade 2), and (2.) for a + grade, maintain the current grade (*e.g.,* a Grade 3+ shall be evaluated as Grade 3). The term ''incomplete paralysis,'' with this and other peripheral nerve injuries, indicates a degree of lost or impaired function substantially less than the type pictured for complete paralysis given with each nerve, whether due to varied levels of the nerve lesion or to partial regeneration.

(4) *Mixed nerves.* When mixed nerves within a single diagnostic code are involved, an evaluation for both motor and sensory neuropathy is not permitted. The evaluation should be based on motor neuropathy with or without sensory neuropathy involvement.

(c) *Sensory neuropathy (complete and incomplete).*

(1) *General.* Impairments, with or without pain, to the sensory function of the cranial and peripheral nerves may be categorized as either incomplete or complete sensory neuropathy.

(2) *Complete sensory neuropathy.* Complete sensory neuropathy is characterized by the complete absence of sensation in an affected nerve.

(3) *Incomplete sensory neuropathy.* Incomplete sensory neuropathy involves sensation that is impaired, but not absent, or unpleasant sensations experienced by the nerve such as dysesthesia, numbness, or paresthesia. Dysesthesia refers to any unpleasant sensation produced by a stimulus that is normally painless. Numbness refers to a sense of heaviness, weakness, or deadness in part of the body. Paresthesia refers to abnormal spontaneous sensations such as burning, tingling, pins and needles, etc. VA will only accept subjective sensations when they are consistent with the disease and not more likely attributable to another disease or no disease.

§ 4.124 [Removed]

■ 7. Remove § 4.124.

§ 4.124a [Redesignated as § 4.124]

■ 8. Redesignate § 4.124a as § 4.124.

■ 9. Revise and republish newly redesignated § 4.124 to read as follows:

§ 4.124 Schedule of ratings—Neurological conditions and convulsive disorders.

ORGANIC DISEASES OF THE CENTRAL NERVOUS SYSTEM

	Rating
Guidance for rating organic diseases of the central nervous system is located under § 4.120.	
8000 Encephalitis, infectious:	
As active febrile disease	100
Rate residuals, minimum	10
8002 Brain, new growth of, malignant	100
Minimum rating	30
Note: The 100 percent evaluation will be continued for 2 years following cessation of surgical, chemotherapeutic or other treatment modality. At this point, if the residuals have stabilized, the rating will be made on neurological residuals according to symptomatology or the minimum rating, whichever results in a higher evaluation.	
8003 Brain, new growth of, benign:	
Minimum during active disease or during a treatment phase	60
Rate residuals, minimum	10
General Rating Formula for Specified Neurologic Conditions (DCs 8004, 8007, 8026, 8027, and 8028):	
Hoehn-Yahr stage 4 or stage 5, or; the inability to live independently because of neurologically-related disability	100
Impairment of mobility (*e.g.,* transfers, balance, or gait) requiring daily use of an assistive device such as a wheelchair, brace(s), crutch(es), cane(s), or walker	60
Hoehn-Yahr stage 3, or; impairment of mobility (*e.g.,* transfers, balance, or gait) requiring less than daily use of an assistive device such as a wheelchair, brace(s), crutch(es), cane(s), or walker	30
Hoehn-Yahr stage 2, or; impairment in at least one of the following areas:	10
• facial expression (*e.g.,* masking, blinking, or eye motion abnormalities);	
• speech (*e.g.,* soft voice, slurring, difficulty speaking or swallowing);	
• posture (*e.g.,* stooping, instability);	
• mobility not requiring an assistive device (*e.g.,* decreased speed with transfers, gait ataxia, unstable balance);	
• problems initiating or controlling motor movements (*e.g.,* stiffness, tremors);	
• cognitive (*e.g.,* memory or executive problems);	
• mental (*e.g.,* anxiety, depression, social phobia);	
• sensory abnormalities (*e.g.,* olfactory deficits);	
• involuntary muscle contractions resulting in pain and impairment, such as but not limited to, spontaneous neck turning or writing difficulty	
Hoehn-Yahr stage 1, or; formal diagnosis without impairment	0

ORGANIC DISEASES OF THE CENTRAL NERVOUS SYSTEM—Continued

	Rating
Note (1): Regardless of examination findings, the minimum rating for Parkinson's disease (DC 8004) shall be 30 percent.	
Note (2): Regardless of examination findings, the minimum rating for stroke residuals (DC 8007) shall be 10 percent.	
Note (3): Activities of daily living (ADLs) refers to basic self-care and includes bathing or showering, dressing, eating, getting in or out of bed or a chair, and using the toilet.	
Note (4): Evaluate any residual under the appropriate body system when there is a formal diagnosis of a condition. When there is no formal diagnosis, evaluate the residual under the General Rating Formula for Specified Neurologic Conditions. For example, evaluate emotional dysfunction under § 4.130 (Schedule of ratings—mental disorders) when there is a diagnosis of a mental disorder. When there is no diagnosis of a mental disorder, evaluate emotional symptoms under the General Rating Formula for Specified Neurologic Conditions.	
Note (5): There may be an overlap of manifestations of conditions evaluated under the General Rating Formula for Specified Neurologic Conditions with manifestations of a comorbid mental or neurologic or other physical disorder that can be separately evaluated under another diagnostic code. In such cases, do not assign more than one evaluation based on the same manifestations. If the manifestations of two or more conditions cannot be clearly separated, assign a single evaluation under whichever set of diagnostic criteria allows the better assessment of overall impaired functioning due to both conditions. However, if the manifestations are clearly separable, assign a separate evaluation for each condition.	
Note (6): Consider the need for special monthly compensation.	
Note (7): When evaluating a neurological condition under the General Rating Formula for Specified Neurological Conditions based on subjective symptoms and not a Hoehn-Yahr stage, a medical opinion finding that the subjectively reported symptom(s) is consistent with the claimed disease and not another disease or no disease is required.	
8004 Parkinson's disease (paralysis agitans):	
Rate under the General Rating Formula for Specified Neurologic Conditions (DCs 8004, 8007, 8026, 8027, and 8028).	
8005 Bulbar palsy	100
8007 Stroke (ischemic, hemorrhagic, or thrombotic), including cerebral infarction or cerebrovascular accident (Brain, vessels, embolism, thrombosis, and hemorrhage):	
During and for six months following a stroke, documented by diagnostic imaging	100
Thereafter, rate under the General Rating Formula for Specified Neurologic Conditions (DCs 8004, 8007, 8026, 8027, and 8028).	
8010 Myelitis:	
Minimum rating	10
8011 Poliomyelitis, anterior:	
As active febrile disease	100
Rate residuals, minimum	10
8012 Hematomyelia:	
For 6 months	100
Rate residuals, minimum	10
8013 Syphilis, cerebrospinal.	
8014 Syphilis, meningovascular.	
8015 Tabes dorsalis.	
Note: Rate upon the severity of convulsions, paralysis, visual impairment or psychotic involvement, etc.	
8017 Amyotrophic lateral sclerosis	100
Note: Consider the need for special monthly compensation.	
8018 Multiple sclerosis and and other demyelinating diseases of the central nervous system:	
Minimum rating	30
8019 Meningitis, cerebrospinal, epidemic:	
As active febrile disease	100
Rate residuals, minimum	10
8020 Brain, abscess of:	
As active disease	100
Rate residuals, minimum	10
8021 Spinal cord, new growths of, malignant	100
Minimum rating	30
Note: The 100 percent evaluation will be continued for 2 years following cessation of surgical, chemotherapeutic or other treatment modality. At this point, if the residuals have stabilized, the rating will be made on neurological residuals according to symptomatology or the minimum rating, whichever results in a higher evaluation.	
8022 Spinal cord, new growths of, benign:	
Minimum during active disease or during a treatment phase	60
Rate residuals, minimum	10
8023 Progressive muscular atrophy:	
Minimum rating	30
8024 Syringomyelia:	
Minimum rating	30
8025 Myasthenia gravis:	
Minimum rating	30
8026 Parkinson's plus, or secondary parkinsonism syndromes.	
Rate under the General Rating Formula for Specified Neurologic Conditions (DCs 8004, 8007, 8026, 8027, and 8028).	
8027 Essential tremor.	
Rate under the General Rating Formula for Specified Neurologic Conditions (DCs 8004, 8007, 8026, 8027, and 8028).	
8028 Dystonia.	
Rate under the General Rating Formula for Specified Neurologic Conditions (DCs 8004, 8007, 8026, 8027, and 8028).	
8036 Primary lateral sclerosis:	
Rate residuals, minimum	10
8045 Residuals of traumatic brain injury (TBI):	

ORGANIC DISEASES OF THE CENTRAL NERVOUS SYSTEM—Continued

	Rating
There are three main areas of dysfunction that may result from TBI and have profound effects on functioning: cognitive (which is common in varying degrees after TBI), emotional/behavioral, and physical. Each of these areas of dysfunction may require evaluation.	
Cognitive impairment is defined as decreased memory, concentration, attention, and executive functions of the brain. Executive functions are goal setting, speed of information processing, planning, organizing, prioritizing, self-monitoring, problem solving, judgment, decision making, spontaneity, and flexibility in changing actions when they are not productive. Not all of these brain functions may be affected in a given individual with cognitive impairment, and some functions may be affected more severely than others. In a given individual, symptoms may fluctuate in severity from day to day. Evaluate cognitive impairment under the table titled ''Evaluation of Cognitive Impairment and Other Residuals of TBI Not Otherwise Classified.''	
Subjective symptoms may be the only residual of TBI or may be associated with cognitive impairment or other areas of dysfunction. Evaluate subjective symptoms that are residuals of TBI, whether or not they are part of cognitive impairment, under the subjective symptoms facet in the table titled ''Evaluation of Cognitive Impairment and Other Residuals of TBI Not Otherwise Classified.'' However, separately evaluate any residual with a distinct diagnosis that may be evaluated under another diagnostic code, such as migraine headache or Meniere's disease, even if that diagnosis is based on subjective symptoms, rather than under the ''Evaluation of Cognitive Impairment and Other Residuals of TBI Not Otherwise Classified'' table.	
Evaluate emotional/behavioral dysfunction under § 4.130 (Schedule of ratings—mental disorders) when there is a diagnosis of a mental disorder. When there is no diagnosis of a mental disorder, evaluate emotional/behavioral symptoms under the criteria in the table titled ''Evaluation of Cognitive Impairment and Other Residuals of TBI Not Otherwise Classified.''	
Evaluate physical (including neurological) dysfunction based on the following list, under an appropriate diagnostic code: Motor and sensory dysfunction, including pain, of the extremities and face; visual impairment; hearing loss and tinnitus; loss of sense of smell and taste; seizures; gait, coordination, and balance problems; speech and other communication difficulties, including aphasia and related disorders, and dysarthria; neurogenic bladder; neurogenic bowel; cranial nerve dysfunctions; autonomic nerve dysfunctions; and endocrine dysfunctions.	
The preceding list of types of physical dysfunction does not encompass all possible residuals of TBI. For residuals not listed here that are reported on an examination, evaluate under the most appropriate diagnostic code. Evaluate each condition separately, as long as the same signs and symptoms are not used to support more than one evaluation, and combine under § 4.25 the evaluations for each separately rated condition. The evaluation assigned based on the ''Evaluation of Cognitive Impairment and Other Residuals of TBI Not Otherwise Classified'' table will be considered the evaluation for a single condition for purposes of combining with other disability evaluations.	
Consider the need for special monthly compensation for such problems as loss of use of an extremity, certain sensory impairments, erectile dysfunction, the need for aid and attendance (including for protection from hazards or dangers incident to the daily environment due to cognitive impairment), being housebound, etc.	

EVALUATION OF COGNITIVE IMPAIRMENT AND OTHER RESIDUALS OF TBI NOT OTHERWISE CLASSIFIED

Facets of cognitive impairment and other residuals of TBI not otherwise classified	Level of impairment	Criteria
Memory, attention, concentration, executive functions.	0	No complaints of impairment of memory, attention, concentration, or executive functions.
	1	A complaint of mild loss of memory (such as having difficulty following a conversation, recalling recent conversations, remembering names of new acquaintances, or finding words, or often misplacing items), attention, concentration, or executive functions, but without objective evidence on testing.
	2	Objective evidence on testing of mild impairment of memory, attention, concentration, or executive functions resulting in mild functional impairment.
	3	Objective evidence on testing of moderate impairment of memory, attention, concentration, or executive functions resulting in moderate functional impairment.
	Total	Objective evidence on testing of severe impairment of memory, attention, concentration, or executive functions resulting in severe functional impairment.
Judgment	0	Normal.
	1	Mildly impaired judgment. For complex or unfamiliar decisions, occasionally unable to identify, understand, and weigh the alternatives, understand the consequences of choices, and make a reasonable decision.
	2	Moderately impaired judgment. For complex or unfamiliar decisions, usually unable to identify, understand, and weigh the alternatives, understand the consequences of choices, and make a reasonable decision, although has little difficulty with simple decisions.
	3	Moderately severely impaired judgment. For even routine and familiar decisions, occasionally unable to identify, understand, and weigh the alternatives, understand the consequences of choices, and make a reasonable decision.
	Total	Severely impaired judgment. For even routine and familiar decisions, usually unable to identify, understand, and weigh the alternatives, understand the consequences of choices, and make a reasonable decision. For example, unable to determine appropriate clothing for current weather conditions or judge when to avoid dangerous situations or activities.
Social interaction	0	Social interaction is routinely appropriate.
	1	Social interaction is occasionally inappropriate.
	2	Social interaction is frequently inappropriate.
	3	Social interaction is inappropriate most or all of the time.

EVALUATION OF COGNITIVE IMPAIRMENT AND OTHER RESIDUALS OF TBI NOT OTHERWISE CLASSIFIED—Continued

Facets of cognitive impairment and other residuals of TBI not otherwise classified	Level of impairment	Criteria
Orientation	0	Always oriented to person, time, place, and situation.
	1	Occasionally disoriented to one of the four aspects (person, time, place, situation) of orientation.
	2	Occasionally disoriented to two of the four aspects (person, time, place, situation) of orientation or often disoriented to one aspect of orientation.
	3	Often disoriented to two or more of the four aspects (person, time, place, situation) of orientation.
	Total	Consistently disoriented to two or more of the four aspects (person, time, place, situation) of orientation.
Motor activity (with intact motor and sensory system).	0	Motor activity normal.
	1	Motor activity normal most of the time, but mildly slowed at times due to apraxia (inability to perform previously learned motor activities, despite normal motor function).
	2	Motor activity mildly decreased or with moderate slowing due to apraxia.
	3	Motor activity moderately decreased due to apraxia.
	Total	Motor activity severely decreased due to apraxia.
Visual spatial orientation	0	Normal.
	1	Mildly impaired. Occasionally gets lost in unfamiliar surroundings, has difficulty reading maps or following directions. Is able to use assistive devices such as GPS (global positioning system).
	2	Moderately impaired. Usually gets lost in unfamiliar surroundings, has difficulty reading maps, following directions, and judging distance. Has difficulty using assistive devices such as GPS (global positioning system).
	3	Moderately severely impaired. Gets lost even in familiar surroundings, unable to use assistive devices such as GPS (global positioning system).
	Total	Severely impaired. May be unable to touch or name own body parts when asked by the examiner, identify the relative position in space of two different objects, or find the way from one room to another in a familiar environment.
Subjective symptoms	0	Subjective symptoms that do not interfere with work; instrumental activities of daily living; or work, family, or other close relationships. Examples are: mild or occasional headaches, mild anxiety.
	1	Three or more subjective symptoms that mildly interfere with work; instrumental activities of daily living; or work, family, or other close relationships. Examples of findings that might be seen at this level of impairment are: intermittent dizziness, daily mild to moderate headaches, tinnitus, frequent insomnia, hypersensitivity to sound, hypersensitivity to light.
	2	Three or more subjective symptoms that moderately interfere with work; instrumental activities of daily living; or work, family, or other close relationships. Examples of findings that might be seen at this level of impairment are: marked fatigability, blurred or double vision, headaches requiring rest periods during most days.
Neurobehavioral effects	0	One or more neurobehavioral effects that do not interfere with workplace interaction or social interaction. Examples of neurobehavioral effects are: Irritability, impulsivity, unpredictability, lack of motivation, verbal aggression, physical aggression, belligerence, apathy, lack of empathy, moodiness, lack of cooperation, inflexibility, and impaired awareness of disability. Any of these effects may range from slight to severe, although verbal and physical aggression are likely to have a more serious impact on workplace interaction and social interaction than some of the other effects.
	1	One or more neurobehavioral effects that occasionally interfere with workplace interaction, social interaction, or both but do not preclude them.
	2	One or more neurobehavioral effects that frequently interfere with workplace interaction, social interaction, or both but do not preclude them.
	3	One or more neurobehavioral effects that interfere with or preclude workplace interaction, social interaction, or both on most days or that occasionally require supervision for safety of self or others.
Communication	0	Able to communicate by spoken and written language (expressive communication), and to comprehend spoken and written language.
	1	Comprehension or expression, or both, of either spoken language or written language is only occasionally impaired. Can communicate complex ideas.
	2	Inability to communicate either by spoken language, written language, or both, more than occasionally but less than half of the time, or to comprehend spoken language, written language, or both, more than occasionally but less than half of the time. Can generally communicate complex ideas.
	3	Inability to communicate either by spoken language, written language, or both, at least half of the time but not all of the time, or to comprehend spoken language, written language, or both, at least half of the time but not all of the time. May rely on gestures or other alternative modes of communication. Able to communicate basic needs.
	Total	Complete inability to communicate either by spoken language, written language, or both, or to comprehend spoken language, written language, or both. Unable to communicate basic needs.

EVALUATION OF COGNITIVE IMPAIRMENT AND OTHER RESIDUALS OF TBI NOT OTHERWISE CLASSIFIED—Continued

Facets of cognitive impairment and other residuals of TBI not otherwise classified	Level of impairment	Criteria
Consciousness	Total	Persistently altered state of consciousness, such as vegetative state, minimally responsive state, coma.

	Rating
8046 Cerebral arteriosclerosis:	
Purely neurological disabilities, such as hemiplegia, cranial nerve paralysis, etc., due to cerebral arteriosclerosis will be rated under the diagnostic codes dealing with such specific disabilities, with citation of a hyphenated diagnostic code (*e.g.,* 8046–8207).	
Purely subjective complaints such as headache, dizziness, tinnitus, insomnia and irritability, recognized as symptomatic of a properly diagnosed cerebral arteriosclerosis, will be rated 10 percent and no more under diagnostic code 9305. This 10 percent rating will not be combined with any other rating for a disability due to cerebral or generalized arteriosclerosis. Ratings in excess of 10 percent for cerebral arteriosclerosis under diagnostic code 9305 are not assignable in the absence of a diagnosis of multi-infarct dementia with cerebral arteriosclerosis.	
Note: The ratings under code 8046 apply only when the diagnosis of cerebral arteriosclerosis is substantiated by the entire clinical picture and not solely on findings of retinal arteriosclerosis.	
Miscellaneous Diseases	
8100 Migraine:	
With very frequent completely prostrating and prolonged attacks productive of severe economic inadaptability	50
With characteristic prostrating attacks occurring on an average once a month over last several months	30
With characteristic prostrating attacks averaging one in 2 months over last several months	10
With less frequent attacks	0
8103 Hemifacial spasm (tic, convulsive):	
Severe	30
Moderate	10
Mild	0
Note: Depending upon frequency, severity, muscle groups involved.	
8104 Paramyoclonus multiplex (convulsive state, myoclonic type):	
Rate as hemifacial spasm; severe cases	60
8105 Chorea, Sydenham's:	
Pronounced, progressive grave types	100
Severe	80
Moderately severe	50
Moderate	30
Mild	10
Note: Consider rheumatic etiology and complications.	
8106 Chorea, Huntington's.	
Rate as Sydenham's chorea. This, though a familial disease, has its onset in late adult life, and is considered a ratable disability.	
8107 Athetosis, acquired.	
Rate as Sydenham's chorea.	
8108 Narcolepsy.	
Rate as for epilepsy, petit mal.	
Diseases of the Cranial Nerves	
Guidance for rating cranial nerves is located under § 4.123.	
Fifth (trigeminal) cranial nerve	
8205 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis	50
Incomplete paralysis:	
Attempted movement with inability to complete such movement (muscle twitching present)	30
Muscle movement intact, but task performed with difficulty	10
Sensory neuropathy, complete or incomplete	10
Note (1): Tic douloureux may be rated under DC 8205 in accordance with severity, up to complete paralysis.	
Note (2): Rate dependent upon relative loss of sensation or muscle function. Examples of nerve functions include, but are not limited to, movement and sensation to the scalp, forehead, nose, cheeks, lower eye lid, nasal mucosa, upper lip, upper teeth, palate, anterior tongue, skin over mandible and lower teeth, and muscles of mastication.	
Seventh (facial) cranial nerve	
8207 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis	30
Incomplete paralysis:	
Attempted movement with inability to complete such movement (muscle twitching present)	20
Muscle movement intact, but task performed with difficulty	10
Sensory neuropathy, complete, or incomplete	10
Note: Rate dependent upon relative loss of sensation or muscle function. Examples of nerve functions include, but are not limited to, facial expressions, taste, and production/drainage of tears.	

	Rating
Ninth (glossopharyngeal) cranial nerve	
8209 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis	30
Incomplete paralysis:	
Attempted movement with inability to complete such movement (muscle twitching present)	20
Muscle movement intact, but task performed with difficulty	10
Sensory neuropathy, complete, or incomplete	10
Note: Rate dependent upon relative loss of ordinary sensation or muscle function. Examples of nerve functions include, but are not limited to, taste and sensing carotid blood pressure.	
Tenth (pneumogastric, vagus) cranial nerve	
8210 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis	50
Incomplete paralysis:	
Attempted movement with inability to complete such movement (muscle twitching present)	30
Muscle movement intact, but task performed with difficulty	10
Sensory neuropathy, complete, or incomplete	10
Note: Rate dependent upon relative loss of sensation or muscle function. Examples of nerve functions include, but are not limited to, speech and taste, along with movement and sensation to the larynx, pharynx, thoracic viscera, and abdominal viscera.	
Eleventh (spinal accessory, external branch) cranial nerve	
8211 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis	30
Incomplete paralysis:	
Attempted movement with inability to complete such movement (muscle twitching present)	20
Muscle movement intact, but task performed with difficulty	10
Note: Rate dependent upon relative loss of muscle function. Examples of nerve functions include, but are not limited to, movement of the sternocleidomastoid and trapezius muscles.	
Twelfth (hypoglossal) cranial nerve	
8212 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis	50
Incomplete paralysis:	
Attempted movement with inability to complete such movement (muscle twitching present)	30
Muscle movement intact, but task performed with difficulty	10
Sensory neuropathy, complete, or incomplete	10
Note: Rate dependent upon relative loss of sensation or muscle function. Examples of nerve functions include, but are not limited to, movement and sensation to the tongue.	

Schedule of ratings	Rating	
	Major	Minor
Diseases of the Peripheral Nerves		
Guidance for rating peripheral nerves, along with a description of the grading system, is located under § 4.123.		
Upper radicular group (fifth and sixth cervicals)		
8510 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	70	60
Incomplete paralysis:		
Grade 2	50	40
Grade 3	40	30
Grade 4	20	20
Sensory neuropathy, complete	40	30
Sensory neuropathy, incomplete	20	20
Middle radicular group		
8511 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	70	60
Incomplete paralysis:		
Grade 2	50	40
Grade 3	40	30
Grade 4	20	20
Sensory neuropathy, complete	40	30
Sensory neuropathy, incomplete	20	20
Lower radicular group		
8512 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	70	60
Incomplete paralysis:		
Grade 2	50	40
Grade 3	40	30
Grade 4	20	20
Sensory neuropathy, complete	40	30
Sensory neuropathy, incomplete	20	20

Schedule of ratings	Rating	
	Major	Minor
All radicular groups		
8513 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	90	80
Incomplete paralysis:		
Grade 2	70	60
Grade 3	40	30
Grade 4	20	20
Sensory neuropathy, complete	40	30
Sensory neuropathy, incomplete	20	20
Radial nerve (musculospiral)		
8514 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	70	60
Incomplete paralysis:		
Grade 2	50	40
Grade 3	30	20
Grade 4	20	20
Sensory neuropathy, complete	30	20
Sensory neuropathy, incomplete	20	20
Note: Lesions involving only ''dissociation of extensor communis digitorum'' and ''paralysis below the extensor communis digitorum,'' will not exceed Grade 3 for diagnostic code 8514.		
The median nerve		
8515 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	70	60
Incomplete paralysis:		
Grade 2	50	40
Grade 3	30	20
Grade 4	10	10
Sensory neuropathy, complete	30	20
Sensory neuropathy, incomplete	10	10
The ulnar nerve		
8516 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	60	50
Incomplete paralysis:		
Grade 2	40	30
Grade 3	30	20
Grade 4	10	10
Sensory neuropathy, complete	30	20
Sensory neuropathy, incomplete	10	10
Musculocutaneous nerve		
8517 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	30	20
Incomplete paralysis:		
Grade 2	20	20
Grade 3	10	10
Grade 4	0	0
Sensory neuropathy, complete	10	10
Sensory neuropathy, incomplete	0	0
Axillary nerve (circumflex)		
8518 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	50	40
Incomplete paralysis:		
Grade 2	30	20
Grade 3	10	10
Grade 4	0	0
Sensory neuropathy, complete	10	10
Sensory neuropathy, incomplete	0	0
Long thoracic nerve		
8519 Motor neuropathy (complete and incomplete paralysis):		
Complete paralysis (Grade 0 or 1)	30	20
Incomplete paralysis:		
Grade 2	20	20
Grade 3	10	10
Grade 4	0	0
Sensory neuropathy, complete	10	10
Sensory neuropathy, incomplete	0	0
Note (1): Not to be combined with lost motion above shoulder level.		
Note (2): Combined nerve injuries should be rated by reference to the major involvement, or if sufficient in extent, consider radicular group ratings.		

	Rating
Sciatic nerve	
8520 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis (Grade 0 or 1)	80
Incomplete paralysis:	
Grade 2	60
Grade 2+	40
Grade 3	20
Grade 4	10
Sensory neuropathy, complete	20
Sensory neuropathy, incomplete	10
Common peroneal nerve (external popliteal)	
8521 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis (Grade 0 or 1)	40
Incomplete paralysis:	
Grade 2	30
Grade 3	20
Grade 4	10
Sensory neuropathy, complete	20
Sensory neuropathy, incomplete	10
Superficial peroneal nerve (musculocutaneous)	
8522 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis (Grade 0 or 1)	30
Incomplete paralysis:	
Grade 2	20
Grade 3	10
Grade 4	0
Sensory neuropathy, complete	10
Sensory neuropathy, incomplete	0
Deep peroneal nerve (anterior tibial)	
8523 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis (Grade 0 or 1)	30
Incomplete paralysis:	
Grade 2	20
Grade 3	10
Grade 4	0
Sensory neuropathy, complete	10
Sensory neuropathy, incomplete	0
Tibial nerve (internal popliteal)	
8524 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis (Grade 0 or 1)	40
Incomplete paralysis:	
Grade 2	30
Grade 3	20
Grade 4	10
Sensory neuropathy, complete	20
Sensory neuropathy, incomplete	10
Posterior tibial nerve	
8525 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis (Grade 0 or 1)	30
Incomplete paralysis:	
Grade 2	20
Grade 3 or Grade 4	10
Sensory neuropathy, complete or incomplete	10
Femoral nerve (anterior crural)	
8526 Motor neuropathy (complete and incomplete paralysis):	
Complete paralysis (Grade 0 or 1)	40
Incomplete paralysis:	
Grade 2	30
Grade 3	20
Grade 4	10
Sensory neuropathy, complete	20
Sensory neuropathy, incomplete	10
Saphenous nerve (internal saphenous)	
8527 Sensory neuropathy, complete or incomplete	0
Obturator nerve	
8528 Motor neuropathy (complete and incomplete paralysis):	
Grade 0, Grade 1, or Grade 2	10
Grade 3 or Grade 4	0
Sensory neuropathy, complete or incomplete	0

	Rating
Lateral cutaneous nerve of the thigh (external cutaneous)	
8529 Sensory neuropathy, complete or incomplete	0
Ilio-inguinal nerve	
8530 Motor neuropathy (complete and incomplete paralysis):	
Grade 0, Grade 1, or Grade 2	10
Grade 3 or Grade 4	0
Sensory neuropathy, complete or incomplete	0
Other Neoplasms of the Neurological System	
8540 Soft-tissue sarcoma (of neurogenic origin)	100
Note: The 100 percent rating will be continued for 6 months following the cessation of surgical, X-ray, antineoplastic chemotherapy or other therapeutic procedure. At this point, if there has been no local recurrence or metastases, the rating will be made on residuals.	
The Epilepsies	
A thorough study of all material in §§ 4.121 and 4.122 of the preface and under the ratings for epilepsy is necessary prior to any rating action.	
8910 Epilepsy, grand mal (including tonic-clonic seizures).	
Rate under the general rating formula for major seizures.	
8911 Epilepsy, petit mal (including absence seizures).	
Rate under the general rating formula for minor seizures.	
Note (1): A major seizure is characterized by the generalized tonic-clonic convulsion with unconsciousness.	
Note (2): A minor seizure consists of a brief interruption in consciousness or conscious control associated with staring or rhythmic blinking of the eyes or nodding of the head (''pure'' petit mal), or sudden jerking movements of the arms, trunk, or head (myoclonic type) or sudden loss of postural control (akinetic type).	
General Rating Formula for Major and Minor Epileptic Seizures:	
Averaging at least 1 major seizure per month over the last year	100
Averaging at least 1 major seizure in 3 months over the last year; or more than 10 minor seizures weekly	80
Averaging at least 1 major seizure in 4 months over the last year; or 9–10 minor seizures per week	60
At least 1 major seizure in the last 6 months or 2 in the last year; or averaging at least 5 to 8 minor seizures weekly	40
At least 1 major seizure in the last 2 years; or at least 2 minor seizures in the last 6 months	20
A confirmed diagnosis of epilepsy with a history of seizures	10
Note (1): When continuous medication is shown necessary for the control of epilepsy, the minimum evaluation will be 10 percent. This rating will not be combined with any other rating for epilepsy.	
Note (2): In the presence of major and minor seizures, rate the predominating type.	
Note (3): There will be no distinction between diurnal and nocturnal major seizures.	
8912 Epilepsy, Jacksonian and focal motor or sensory.	
8913 Epilepsy, diencephalic.	
Rate as minor seizures, except in the presence of major and minor seizures, rate the predominating type.	
8914 Epilepsy, psychomotor.	
Major seizures:	
Psychomotor seizures will be rated as major seizures under the general rating formula when characterized by automatic states and/or generalized convulsions with unconsciousness.	
Minor seizures:	
Psychomotor seizures will be rated as minor seizures under the general rating formula when characterized by brief transient episodes of random motor movements, hallucinations, perceptual illusions, abnormalities of thinking, memory or mood, or autonomic disturbances.	

Mental Disorders in Epilepsies: A nonpsychotic organic brain syndrome will be rated separately under the appropriate diagnostic code (e.g., 9304 or 9326). In the absence of a diagnosis of non-psychotic organic psychiatric disturbance (psychotic, psychoneurotic or personality disorder) if diagnosed and shown to be secondary to or directly associated with epilepsy will be rated separately. The psychotic or psychroneurotic disorder will be rated under the appropriate diagnostic code. The personality disorder will be rated as a dementia (e.g., diagnostic code 9304 or 9326).

Epilepsy and Unemployability: (1) Rating specialists must bear in mind that the epileptic, although his or her seizures are controlled, may find employment and rehabilitation difficult of attainment due to employer reluctance to the hiring of the epileptic.

(2) Where a case is encountered with a definite history of unemployment, full and complete development should be undertaken to ascertain whether the epilepsy is the determining factor in his or her inability to obtain employment.

(3) The assent of the claimant should first be obtained for permission to conduct this economic and social survey. The purpose of this survey is to secure all the relevant facts and data necessary to permit of a true judgment as to the reason for his or her unemployment and should include information as to:

(a) Education;

(b) Occupations prior and subsequent to service;

(c) Places of employment and reasons for termination;

(d) Wages received;

(e) Number of seizures.

(4) Upon completion of this survey and current examination, the case should have rating board consideration. Where in the judgment of the rating board the veteran's unemployability is due to epilepsy and jurisdiction is not vested in that body by reason of schedular evaluations, the case should be submitted to the Compensation Service or the Director, Pension and Fiduciary Service.

(Authority: 38 U.S.C. 1155)

■ 10. Amend Appendix A to part 4 by:

■ a. Revising the entry for diagnostic code 5244;

■ b. Adding, in numerical order, entries for §§ 4.120 and 4.123;

■ c. Redesignating the entries for § 4.124a (all diagnostic codes listed under § 4.124a) as new entries for § 4.124;

■ d. Revising and republishing newly redesignated § 4.124; and

■ e. Adding, in numerical order, a new entry for § 4.124a.

The revisions and additions read as follows:

APPENDIX A TO PART 4—TABLE OF AMENDMENTS AND EFFECTIVE DATES SINCE 1946

Sec.	Diagnostic code No.	
*	*	* * * * *
	5244	Added February 7, 2021; note [Effective date of final rule].
*	*	* * * * *
4.120		Title and revised [Effective date of final rule].
4.123		Title and revised [Effective date of final rule].
4.124		Re-designated from § 4.124a [Effective date of final rule].
	8000	Title [Effective date of final rule].
	8002	Criteria September 22, 1978; title, note [Effective date of final rule].
	8003	Title, criteria [Effective date of final rule].
	8004	Title, criteria, notes [Effective date of final rule].
	8007	Title, criteria [Effective date of final rule].
	8008	Removed [Effective date of final rule].
	8009	Removed [Effective date of final rule].
	8018	Title [Effective date of final rule].
	8021	Criteria September 22, 1978; criteria October 1, 1961; criteria March 10, 1976; criteria March 1, 1989; title, note [Effective date of final rule].
	8022	Title, criteria [Effective date of final rule].
	8025	Note removed [Effective date of final rule].
	8026	Added [Effective date of final rule].
	8027	Added [Effective date of final rule].
	8028	Added [Effective date of final rule].
	8036	Added [Effective date of final rule].
	8045	Criterion and evaluation October 23, 2008.
	8046	Added October 1, 1961; criterion March 10, 1976; criterion March 1, 1989.
	8100	Evaluation June 9, 1953.
	8103	Title [Effective date of final rule].
	8104	Criteria [Effective date of final rule].
	8107	Criteria [Effective date of final rule].
	8205	Title, criteria, notes [Effective date of final rule].
	8207	Title, criteria, note [Effective date of final rule].
	8209	Title, criteria, note [Effective date of final rule].
	8210	Title, criteria, note [Effective date of final rule].
	8211	Title, criteria, note [Effective date of final rule].
	8212	Title, criteria, note [Effective date of final rule].
	8305	Removed [Effective date of final rule].
	8307	Removed [Effective date of final rule].
	8309	Removed [Effective date of final rule].
	8310	Removed [Effective date of final rule].
	8311	Removed [Effective date of final rule].
	8312	Removed [Effective date of final rule].
	8405	Removed [Effective date of final rule].
	8407	Removed [Effective date of final rule].
	8409	Removed [Effective date of final rule].
	8410	Removed [Effective date of final rule].
	8411	Removed [Effective date of final rule].
	8412	Removed [Effective date of final rule].
	8510	Title, criteria [Effective date of final rule].
	8511	Title, criteria [Effective date of final rule].
	8512	Title, criteria [Effective date of final rule].
	8513	Title, criteria [Effective date of final rule].
	8514	Title, criteria, note [Effective date of final rule].
	8515	Title, criteria [Effective date of final rule].
	8516	Title, criteria [Effective date of final rule].
	8517	Title, criteria [Effective date of final rule].
	8518	Title, criteria [Effective date of final rule].
	8519	Title, criteria, notes [Effective date of final rule].
	8520	Title, criteria [Effective date of final rule].
	8521	Title, criteria [Effective date of final rule].
	8522	Title, criteria [Effective date of final rule].
	8523	Title, criteria [Effective date of final rule].
	8524	Title, criteria [Effective date of final rule].
	8525	Title, criteria [Effective date of final rule].

APPENDIX A TO PART 4—TABLE OF AMENDMENTS AND EFFECTIVE DATES SINCE 1946—Continued

Sec.	Diagnostic code No.	
	8526	Title, criteria [Effective date of final rule].
	8527	Title, criteria [Effective date of final rule].
	8528	Title, criteria [Effective date of final rule].
	8529	Title, criteria [Effective date of final rule].
	8530	Title, criteria [Effective date of final rule].
	8610	Removed [Effective date of final rule].
	8611	Removed [Effective date of final rule].
	8612	Removed [Effective date of final rule].
	8613	Removed [Effective date of final rule].
	8614	Removed [Effective date of final rule].
	8615	Removed [Effective date of final rule].
	8616	Removed [Effective date of final rule].
	8617	Removed [Effective date of final rule].
	8618	Removed [Effective date of final rule].
	8619	Removed [Effective date of final rule].
	8620	Removed [Effective date of final rule].
	8621	Removed [Effective date of final rule].
	8622	Removed [Effective date of final rule].
	8623	Removed [Effective date of final rule].
	8624	Removed [Effective date of final rule].
	8625	Removed [Effective date of final rule].
	8626	Removed [Effective date of final rule].
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	8628	Removed [Effective date of final rule].
	8629	Removed [Effective date of final rule].
	8630	Removed [Effective date of final rule].
	8710	Removed [Effective date of final rule].
	8711	Removed [Effective date of final rule].
	8712	Removed [Effective date of final rule].
	8713	Removed [Effective date of final rule].
	8714	Removed [Effective date of final rule].
	8715	Removed [Effective date of final rule].
	8716	Removed [Effective date of final rule].
	8717	Removed [Effective date of final rule].
	8718	Removed [Effective date of final rule].
	8719	Removed [Effective date of final rule].
	8720	Removed [Effective date of final rule].
	8721	Removed [Effective date of final rule].
	8722	Removed [Effective date of final rule].
	8723	Removed [Effective date of final rule].
	8724	Removed [Effective date of final rule].
	8725	Removed [Effective date of final rule].
	8726	Removed [Effective date of final rule].
	8727	Removed [Effective date of final rule].
	8728	Removed [Effective date of final rule].
	8729	Removed [Effective date of final rule].
	8730	Removed [Effective date of final rule].
	8910	Added October 1, 1961; evaluation September 9, 1975; title [Effective date of final rule].
	8911	Added October 1, 1961; evaluation September 9, 1975; title [Effective date of final rule].
	8912	Added October 1, 1961; evaluation September 9, 1975.
	8913	Added October 1, 1961; evaluation September 9, 1975.
	8914	Added October 1, 1961; evaluation September 9, 1975.
4.124a		Re-designated as § 4.124 [Effective date of final rule].

* * * * * * *

■ 11. Amend Appendix B to part 4 by revising and republishing the entries in the table under ''Neurological Conditions and Convulsive Disorders'' to read as follows:

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES

Diagnostic code No.	
*	* * * * * *
Neurological Conditions and Convulsive Disorders	
Organic Diseases of the Central Nervous System	
8000	Encephalitis, infectious.
8002	Brain, new growth of, malignant.
8003	Brain, new growth of, benign.
8004	Parkinson's disease (paralysis agitans).
8005	Bulbar palsy.
8007	Stroke (ischemic, hemorrhagic, or thrombotic), including cerebral infarction or cerebrovascular accident.
8010	Myelitis.
8011	Poliomyelitis, anterior.
8012	Hematomyelia.
8013	Syphilis, cerebrospinal.
8014	Syphilis, meningovascular
8015	Tabes dorsalis.
8017	Amyotrophic lateral sclerosis.
8018	Multiple sclerosis and neuromyelitis optica spectrum disorder (NMOSD).
8019	Meningitis, cerebrospinal, epidemic.
8020	Brain, abscess.
8021	Spinal cord, new growths of, malignant.
8022	Spinal cord, new growths of, benign.
8023	Progressive muscular atrophy.
8024	Syringomyelia.
8025	Myasthenia gravis.
8026	Parkinson's plus, or secondary parkinsonism syndromes.
8027	Essential tremor.
8028	Dystonia.
8036	Primary lateral sclerosis.
8045	Residuals of traumatic brain injury (TBI).
8046	Cerebral arteriosclerosis.
Miscellaneous Diseases	
8100	Migraine.
8103	Hemifacial spasm (tic, convulsive).
8104	Paramyoclonus multiplex (convulsive state, myoclonic type).
8105	Chorea, Sydenham's.
8106	Chorea, Huntington's.
8107	Athetosis, acquired.
8108	Narcolepsy.
The Cranial Nerves	
8205	Fifth (trigeminal), motor neuropathy.
8207	Seventh (facial), motor neuropathy.
8209	Ninth (glossopharyngeal), motor neuropathy.
8210	Tenth (pneumogastric, vagus), motor neuropathy.
8211	Eleventh (spinal accessory, external branch), motor neuropathy.
8212	Twelfth (hypoglossal), motor neuropathy.
Peripheral Nerves	
8510	Upper radicular group, motor neuropathy.
8511	Middle radicular group, motor neuropathy.
8512	Lower radicular group, motor neuropathy.
8513	All radicular groups, motor neuropathy.
8514	Radial nerve (musculospiral), motor neuropathy.
8515	Median nerve, motor neuropathy.
8516	Ulnar nerve, motor neuropathy.
8517	Musculocutaneous nerve, motor neuropathy.
8518	Axillary nerve (circumflex), motor neuropathy.
8519	Long thoracic nerve, motor neuropathy.
8520	Sciatic nerve, motor neuropathy.
8521	Common peroneal nerve (external popliteal), motor neuropathy.
8522	Superficial peroneal nerve (musculocutaneous), motor neuropathy.
8523	Deep peroneal nerve (anterior tibial), motor neuropathy.
8524	Tibial nerve (internal popliteal), motor neuropathy.
8525	Posterior tibial nerve, motor neuropathy.
8526	Femoral nerve (anterior crural), motor neuropathy.
8527	Saphenous nerve (internal saphenous), sensory neuropathy.

APPENDIX B TO PART 4—NUMERICAL INDEX OF DISABILITIES—Continued

Diagnostic code No.	
8528	Obturator nerve, motor neuropathy.
8529	Lateral cutaneous nerve of the thigh (external cutaneous), sensory neuropathy.
8530	Ilio-inguinal nerve, motor neuropathy.
Other Neoplasms of the Neurological System	
8540	Soft tissue sarcoma (Neurogenic origin).
The Epilepsies	
8910	Epilepsy, grand mal (includes tonic-clonic seizures).
8911	Epilepsy, petit mal (includes absence seizures).
8912	Jacksonian and focal motor or sensory.
8913	Diencephalic.
8914	Psychomotor.

* * * * * * *

■ 12. Amend Appendix C to part 4 by:
■ a. Adding, in alphabetical order, an entry for ''Dystonia'';
■ b. Removing the entry for ''Embolism, brain'';
■ c. Revising the entry for ''Encephalitis, epidemic'';
■ d. Under the entry for ''Epilepsies'', revising the entries for ''Grand mal'' and ''Petit mal'';
■ e. Adding, in alphabetical order, entries for ''Essential tremor'' and ''Hemifacial spasm (tic, convulsive)'';
■ f. Removing the entry for ''Hemorrhage'';
■ g. Adding, in alphabetical order, an entry for ''Intraocular hemorrhage'';
■ h. Adding, in alphabetical order, an entry for ''Motor/sensory neuropathy'';
■ i. Revising the entry for ''Multiple sclerosis'';
■ j. Removing the entry for ''Neuralgia'';
■ k. Removing the entry for ''Neuritis'';
■ l. Adding an entry for ''Optic neuropathy'';
■ m. Under the entry for ''Paralysis'', removing the entry for ''Agitans'';
■ n. Removing the entry for ''Paralysis, nerve'';
■ o. Revising the entry for ''Paramyoclonus multiplex'';
■ p. Adding, in alphabetical order, entries for ''Parkinson's disease (paralysis agitans)'', ''Parkinson's plus, or secondary parkinsonism syndromes'', ''Primary lateral sclerosis'', and ''Stroke (ischemic, hemorrhagic, or thrombotic), including cerebral infarction or cerebrovascular accident''; and
■ q. Removing the entries for ''Thrombosis, brain'' and ''Tic, convulsive''.

The revisions and additions read as follows:

APPENDIX C TO PART 4—ALPHABETICAL INDEX OF DISABILITIES

	Diagnostic code No.
* * * * * * *	
Dystonia	8028
* * * * * * *	
Encephalitis, infectious	8000
* * * * * * *	
Epilepsies:	
* * * * * * *	
Grand mal (includes tonic-clonic seizures)	8910
* * * * * * *	
Petit mal (includes absence seizures)	8911
* * * * * * *	
Essential tremor	8027
* * * * * * *	
Hemifacial spasm (tic, convulsive)	8103
* * * * * * *	
Intraocular hemorrhage	6007
* * * * * * *	
Motor/sensory neuropathy:	
Cranial nerves:	
Eleventh (spinal accessory, external branch)	8211
Fifth (trigeminal)	8205
Ninth (glossopharyngeal)	8209

APPENDIX C TO PART 4—ALPHABETICAL INDEX OF DISABILITIES—Continued

	Diagnostic code No.
Seventh (facial)	8207
Tenth (pneumogastric, vagus)	8210
Twelfth (hypoglossal)	8212
Peripheral nerves:	
All radicular groups	8513
Axillary (circumflex)	8518
Common peroneal (external popliteal)	8521
Deep peroneal (anterior tibial)	8523
Femoral (anterior crural)	8526
Ilio-inguinal	8530
Lateral cutaneous nerve of the thigh (external cutaneous)	8529
Long thoracic	8519
Lower radicular group	8512
Median	8515
Middle radicular group	8511
Musculocutaneous	8517
Obturator	8528
Posterior tibial	8525
Radial (musculospiral)	8514
Saphenous (internal saphenous)	8527
Sciatic	8520
Superficial peroneal (musculocutaneous)	8522
Tibial (internal popliteal)	8524
Ulnar	8516
Upper radicular group	8510
* * * * * * *	
Multiple sclerosis and other demyelinating diseases of the central nervous system	8018
* * * * * * *	
Optic neuropathy	6026
* * * * * * *	
Paramyoclonus multiplex (convulsive state, myoclonic type)	8104
* * * * * * *	
Parkinson's disease (paralysis agitans)	8004
Parkinson's plus, or secondary parkinsonism syndromes	8026
* * * * * * *	
Primary lateral sclerosis	8036
* * * * * * *	
Stroke (ischemic, hemorrhagic, or thrombotic), including cerebral infarction or cerebrovascular accident	8007
* * * * * * *	

[FR Doc. 2024–25665 Filed 11–8–24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 51

[EPA–HQ–OAR–2023–0295; FRL–10823–01–OAR]

RIN 2060–AW00

Air Quality: Revision to the Regulatory Definition of Volatile Organic Compounds—Exclusion of (Z)-1-chloro-2,3,3,3-tetrafluoropropene (HCFO-1224yd(Z))

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing to revise the EPA's regulatory definition of volatile organic compounds (VOC) under the Clean Air Act (CAA). This action proposes to add (Z)-1-chloro-2,3,3,3-tetrafluoropropene (also known as HCFO-1224yd(Z); CAS number 111512–60–8) to the list of compounds excluded from the regulatory definition on the basis that this compound makes a negligible contribution to tropospheric ozone (O_3) formation.

DATES: Comments must be received on or before January 13, 2025.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2023–0295, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket No. EPA–HQ–OAR–2023–0295, Office of Air and Radiation Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this

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

FOR FURTHER INFORMATION CONTACT: Dr. Souad Benromdhane, Office of Air Quality Planning and Standards, Health and Environmental Impacts Division, Mail Code C539–07, Environmental Protection Agency, P.O. Box 12055, Research Triangle Park, NC 27711; telephone: (919) 541–4359; email address: *benromdhane.souad@epa.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation

Written comments: Submit your comments, identified by Docket ID No. EPA–HQ–OAR–2023–0295, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). Please visit *https://www.epa.gov/dockets/commenting-epa-dockets* for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

Table of Contents

I. Does this action apply to me?
II. Background
A. The EPA's VOC Exemption Policy
B. Petition To List HCFO-1224yd(Z) as an Exempt Compound
III. The EPA's Assessment of the Petition
A. Contribution to Tropospheric Ozone Formation
B. Potential Impacts on Other Environmental Endpoints
1. Contribution to Stratospheric Ozone Depletion
2. Toxicity
3. Contribution to Climate Change
C. Conclusions
IV. Proposed Action
V. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review
B. Paperwork Reduction Act (PRA)
C. Regulatory Flexibility Act (RFA)
D. Unfunded Mandates Reform Act (UMRA)
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use
I. National Technology Transfer and Advancement Act (NTTAA)
J. Executie Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All
VI. References

I. Does this action apply to me?

Entities potentially affected by this proposed rule include, but are not necessarily limited to, the following: State and local air pollution control agencies that adopt and implement regulations to control air emissions of VOC; and industries manufacturing and/or using HCFO-1224yd(Z) for use in foam blowing, refrigeration, as well as applications in solvents and aerosol propellants, and other minor uses. Potential entities that may be affected by this action include the following:

TABLE 1—POTENTIALLY AFFECTED ENTITIES BY NORTH AMERICAN INDUSTRIAL CLASSIFICATION SYSTEM (NAICS) CODE

Category	NAICS code	Description of regulated entities
Industry	333415	Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing.
Industry	811310	Commercial and industrial machinery and equipment (except automotive and electronic) repair and maintenance.
Industry	221116	Geothermal Electric Power Generation.
Industry	221117	Biomass Electric Power Generation.
Industry	221118	Other Electric Power Generation.

This table is not intended to be exhaustive but rather provides a guide for readers regarding entities that might be affected by this deregulatory action. This table lists the types of entities that the EPA is now aware of that could potentially be affected to some extent by this action. Other types of entities not listed in the table could also be affected to some extent. To determine whether your entity is directly or indirectly affected by this action, you should consult your State or local air pollution control and/or air quality management agencies.

II. Background

A. The EPA's VOC Exemption Policy

Tropospheric O_3, commonly known as smog, is formed when VOC and nitrogen oxides (NO_X) react in the atmosphere in the presence of sunlight. Because of the harmful health effects of O_3, the EPA and State governments limit the amount of VOC that can be released into the atmosphere. VOC form O_3 through atmospheric photochemical reactions, and different VOC have different levels of reactivity. That is, different VOC do not react to form O_3 at the same speed or form different amounts of O_3. Some VOC react more slowly or form less O_3; therefore, changes in their emissions have limited effects on local or regional O_3 pollution episodes. It has been the EPA's policy since 1971 that certain organic compounds with a negligible level of reactivity should be excluded from the regulatory definition of VOC to focus VOC control efforts on compounds that significantly affect O_3 concentrations. The EPA also believes that exempting such compounds creates an incentive for industry to use negligibly reactive compounds in place of more highly reactive compounds that are regulated as VOC. The EPA lists compounds that

it has determined to be negligibly reactive in its regulations as being excluded from the regulatory definition of VOC (40 CFR 51.100(s)).

The CAA requires the regulation of VOC for various purposes. Section 302(s) of the CAA specifies that the EPA has the authority to define the meaning of ''VOC'' and, hence, what compounds shall be treated as VOC for regulatory purposes. The policy of excluding negligibly reactive compounds from the regulatory definition of VOC was first laid out in the ''Recommended Policy on Control of Volatile Organic Compounds'' (42 FR 35314, July 8, 1977) (''1977 Recommended Policy'') and was supplemented subsequently with the ''Interim Guidance on Control of Volatile Organic Compounds in Ozone State Implementation Plans'' (70 FR 54046, September 13, 2005) (''2005 Interim Guidance''). The EPA uses the reactivity of ethane as the threshold for determining whether a compound has negligible reactivity. Compounds that are less reactive than, or equally reactive to, ethane under certain assumed conditions may be deemed negligibly reactive and, therefore, suitable for exemption from the regulatory definition of VOC. Compounds that are more reactive than ethane continue to be considered VOC for regulatory purposes and, therefore, are subject to control requirements. The selection of ethane as the threshold compound was based on a series of smog chamber experiments that underlay the 1977 Recommended Policy.

The EPA has used three different metrics to compare the reactivity of a specific compound to that of ethane: (i) the rate constant for reaction with the hydroxyl radical (OH) (known as k_{OH}); (ii) the maximum incremental reactivity (MIR) on a reactivity per unit mass basis; and (iii) the MIR expressed on a reactivity per mole basis. Differences between these three metrics are discussed below.

The k_{OH} is the rate constant of the reaction of the compound with the OH radical in the air. This reaction is often, but not always, the first and rate-limiting step in a series of chemical reactions by which a compound breaks down in the air and contributes to O_3 formation. If this step is slow, the compound will likely not form O_3 at a very fast rate. The k_{OH} values have long been used by the EPA as metrics of photochemical reactivity and O_3-forming activity, and they were the basis for most of the EPA's early exemptions of negligibly reactive compounds from the regulatory definition of VOC. The k_{OH} metric is inherently a molar-based comparison, *i.e.,* it measures the rate at which molecules react.

The MIR, both by mole and by mass, is a more updated metric of photochemical reactivity derived from a computer-based photochemical model, and it has been used as a metric of reactivity since 1995. This metric considers the complete O_3-forming activity of a compound over multiple hours and through multiple reaction pathways, not merely the first reaction step with OH. Further explanation of the MIR metric can be found in Carter (1994).

The EPA has considered the choice between MIRs with a molar or mass basis for the comparison to ethane in past rulemakings and guidance. In the 2005 Interim Guidance, the EPA stated that a comparison to ethane's MIR on the mass basis strikes the right balance between a threshold that is low enough to capture chemicals that significantly affect ozone formation and a threshold that is high enough to allow for the exemption of some other chemicals that may usefully substitute for more reactive compounds. The guidance also stated that EPA will continue to compare chemicals to ethane using k_{OH} expressed on a molar basis and MIR values expressed on a mass basis during the review of suggested chemicals for VOC-exempt status.[1] The 2005 Interim Guidance notes that the EPA will consider a compound to be negligibly reactive if it is equally reactive as or less reactive than ethane based on either k_{OH} expressed on a molar basis *or* MIR values expressed on a mass basis (70 FR 54046).

The molar comparison of MIR is more consistent with the original smog chamber experiments, which compared equal molar concentrations of individual VOC, supporting the selection of ethane as the threshold, while the mass-based comparison of MIR is consistent with how MIR values and other reactivity metrics are applied in reactivity-based emission limits. It is, however, important to note that the mass-based comparison is less restrictive than the molar-based comparison in that more compounds would qualify as negligibly reactive.

Given the two goals of the exemption policy articulated in the 2005 Interim Guidance, the EPA believes that ethane continues to be an appropriate threshold for defining negligible reactivity. And, to encourage the use of environmentally beneficial substitutions, the EPA continues to believe that a comparison to ethane on a mass basis strikes the right balance between a threshold that is low enough to capture compounds that significantly affect O_3 concentrations and a threshold that is high enough to exempt some compounds that may usefully substitute for more highly reactive compounds.

The 2005 Interim Guidance also noted that concerns have sometimes been raised about the potential impact of a VOC exemption on environmental endpoints other than O_3 concentrations, including fine particle formation, air toxics exposures, stratospheric O_3 depletion, and climate change. The EPA has recognized, however, that there are existing regulatory or non-regulatory programs that are specifically designed to address these issues, and the EPA continues to believe in general that the impacts of VOC exemptions on environmental endpoints other than O_3 formation can be adequately addressed by these programs. The VOC exemption policy is intended to facilitate attainment of the O_3 National Ambient Air Quality Standards (NAAQS), and VOC exemption decisions will continue to be based primarily on consideration of a compound's contribution to O_3 formation. However, if the EPA determines that a particular VOC exemption is likely to result in a significant increase in the use of a compound and that the increased use would pose a significant risk to human health or the environment that would not be addressed adequately by existing programs or policies, then the EPA may exercise its judgment accordingly in deciding whether to grant an exemption.

The EPA has provided the foregoing discussion of its VOC exemption policies as background for its assessment of the petition to list HCFO-1224yd(z) as an exempt compound and its proposed action to grant the petition. However, the EPA is not reopening the 2005 Interim Guidance or other aspects of its VOC exemption policy in this proposed rule and is not seeking comment on these issues.

B. Petition To List HCFO-1224yd(Z) as an Exempt Compound

The AGC Chemicals Americas, Inc. (''AGC'') submitted a petition to the EPA on July 29, 2020, requesting that (Z)-1-chloro-2,3,3,3-tetrafluoropropene (also known as HCFO-1224yd(Z); CAS number 111512–60–8) be exempted from the regulatory definition of VOC. The petition stated that HCFO-1224yd(Z) has low reactivity (*i.e.,* 0.052 ± 0.011g of O_3/g of HCFO-1224yd(Z))

[1] Interim Guidance on Control of Volatile Organic Compounds in Ozone State Implementation Plans, 2005, US Environmental Protection Agency, Document Number 05–18015 (70 FR 54046). And could be found at this link: *https://www.govinfo.gov/content/pkg/FR-2005-09-13/pdf/05-18015.pdf.*

compared to the MIR of ethane (0.28 g O_3/g). The petitioner indicated that HCFO-1224yd(Z) may be used in refrigeration which uses a turbo-type refrigerator, a binary generator, a heat recovery heat pump, etc. As a refrigerant, this compound will not be generally emitted into the atmosphere on a continuous basis in significant amounts. Refrigerators will be initially charged and then serviced with HCFO-1224yd(Z) with minimal losses of refrigerant to the atmosphere over time, and they will be subject to EPA's regulations related to servicing and ''venting.'' HCFO-1224yd(Z) has been approved by EPA through its Significant New Alternatives Policy (SNAP) program as an acceptable substitute for use in new and retrofitted centrifugal chillers, positive displacement chillers and industrial process refrigeration.[2]

AGC has developed HCFO-1224yd(Z) to support reductions in emissions of greenhouse gases (GHGs). The global warming potential (GWP) for HCFO-1224yd(Z) is 0.88 for a time horizon of 100 years. HCFO-1224yd(Z) is relatively short-lived in the atmosphere, with a lifetime of approximately 20 days. HCFO-1224yd(Z)'s ODP is almost zero (0.00023) and, leading to an environmental impact that is estimated to be low especially when compared to the existing alternatives (Tokuhashi et al., 2018). Hence, HCFO-1224yd(Z) can serve as a replacement for compounds in several centrifugal and positive displacement chillers such as ammonia absorption, carbon dioxide, and HFO-1336mzz(Z) among others with GWP ranging between zero and 630. For industrial process refrigeration, HCFO-1224yd(Z) has a GWP lower than or comparable to that of acceptable existing substitutes for new or retrofit equipment with GWP ranging between zero and 14,800.

Toxicity of HCFO-1224yd(Z) is comparable to or lower than that of other available substitutes in the same end uses. The toxicity risks are evaluated through the SNAP program but can also be minimized through the application of recommended guidance in the Occupational Alliance for Risk Science's Workplace Environmental Exposure Level (OARS WEEL), the American Society of Heating, Refrigerating and Air-Conditioning Engineers safety standards 15 (ASHARE 15) and other industry standards, as well as the safety data sheet (SDS) and other safety precautions related to refrigeration and air conditioning industry.

To support its petition, AGC provided a document on ground-level atmospheric ozone formation potential from the reactivity of HCFO-1224yd(Z) with the hydroxyl OH based on calculations using SARPC-11 atmospheric chemical mechanism.[3] AGC's supplemental technical report supplied a MIR of HCFO-1224yd(Z) of 0.052 ± 0.011 g O_3/g HCFO-1224yd(Z) on the mass-based MIR scale. This reactivity is significantly lower than that of ethane (0.29 ± 0.07 g O_3/g ethane). The report also addressed uncertainties around the MIR value calculated and stipulated that the relative impact on ozone formation will be small when compared to variability in atmospheric conditions. The report raised a warning around the chemical mechanism used to predict ozone formation potential to caution about the need to test whether the predicted value can be observed in an environmental chamber experiment. The petition did not include a value for the rate constant k_{OH} for the gas-phase reaction with OH radicals.

To address the potential for stratospheric O_3 impacts, the petitioner specified that, because the atmospheric lifetime of HCFO-1224yd(Z) due to loss by OH reaction was estimated to be relatively short, even though HCFO-1224yd(Z) contains chlorine, it is not expected to contribute to the depletion of the stratospheric O_3 layer more than other alternatives listed acceptable by EPA's SNAP program (USEPA, 2019).

III. The EPA's Assessment of the Petition

The EPA is proposing to respond to the petition to revise the EPA's regulatory definition of VOC for exemption of HCFO-1224yd(Z). This action is based on consideration of the compound's low contribution to tropospheric O_3 and the low likelihood of risk to human health or the environment, including stratospheric O_3 depletion, toxicity, and climate change. Additional information on these topics is provided in the following sections.

A. Contribution to Tropospheric Ozone Formation

The rate constant k_{OH} for the gas-phase reaction with OH radicals is measured to be (5.84 ± 0.030) 10^{-13} cm^3/molecule-sec at ~298 degrees Kelvin (K) (Tokuhashi *et al.,* 2018). This k_{OH} is more than twice the k_{OH} of ethane (2.4×10^{-13} cm^3/molecule-sec at ~298 K; Atkinson *et al.,* 2006) even when uncertainty is considered and, therefore, suggests that it is more reactive than ethane. In most cases, chemicals with high k_{OH} values also have high MIR values, but the products that are formed here in subsequent reactions are expected to be polyfluorinated compounds, which do not contribute to O_3 formation (Osterstrom *et al.,* 2017). In the case of HCFO-1224yd(Z), while the k_{OH} is relatively high, the calculated maximum incremental reactivity MIR is very low when compared to that of ethane based on Carter (2020), provided by the petitioner, and reviewed by EPA.

Carter (2020) estimates that HCFO-1224yd(Z) has a MIR value of 0.052 ± 0.011 g O_3/g VOC versus 0.29 ± 0.07 g O_3/g VOC for ethane. Therefore, the EPA considers HCFO-1224yd(Z) to be negligibly reactive and eligible for VOC-exempt status following the Agency's long-standing policy that compounds should so qualify where either reactivity metric (k_{OH} expressed on a molar basis or MIR expressed on a mass basis) indicates that the compound is less reactive than ethane. While the overall atmospheric reactivity of HCFO-1224yd(Z) was not studied in an experimental smog chamber, the chemical mechanism derived from other chamber studies (Carter, 2011) was used to model the complete formation of O_3 for an entire single day under realistic atmospheric conditions by Carter (2020). The EPA has assessed the Carter study provided by the petitioner and believes the calculated MIR value is reliable.[4]

Table 2 presents three reactivity metrics for HCFO-1224yd(Z) as they compare to ethane.

[2] 84 FR 64765 (Nov. 25, 2019): *https://www.federalregister.gov/documents/2019/11/25/2019-25412/protection-of-stratospheric-ozone-determination-35-for-significant-new-alternatives-policy-program.*

[3] Carter, W. P. L. 2020. Estimation of the ground-level atmospheric ozone formation potential of isomers of 1-chloro-2,3,3,3-tetrafluoro-1-propene, HFCO-1224YD(Z), Report to AGC Chemicals Americas Company, Exton, PA, USA.

[4] Supporting memo is included in the docket.

TABLE 2—REACTIVITIES OF ETHANE AND HCFO-1224yd(Z)

Compound	k_{OH} (cm^3/molecule-sec)	Maximum incremental reactivity (MIR) (g O_3/mole VOC)	Maximum incremental reactivity (MIR) (g O_3/g VOC)
Ethane	2.4×10^{-13}	8.4	0.28 ± 0.07
HCFO-1224yd(Z)	$(5.84 \pm 0.030) \times 10^{-13}$	7.7	0.052 ± 0.011

Notes:
k_{OH} value at 298 K for ethane is from Atkinson *et al.* (2006; page 3626).
k_{OH} value at 300 K for HCFO-1224yd(Z) is from Tokuhashi *et al.,* 2018 (table 1).
Mass-based MIR value (g O_3/g VOC) of ethane is from Carter (2011).
Mass-based MIR value (g O_3/g VOC) of HCFO-1224yd(Z) is from Carter 2020.
Molar-based MIR (g O_3/mole VOC) values were calculated from the mass-based MIR (g O_3/g VOC) values using the number of moles per gram of the relevant organic compound.

The reaction rate of HCFO-1224yd(Z) with the OH radical (k_{OH}) has been measured to be $(5.84 \pm 0.030) \times 10^{-13}$ cm^3/molecule-sec (Tokuhashi *et al.,* 2018); other reactions with O_3 and the nitrate radical were negligibly small. The corresponding reaction rate of ethane with OH is 2.4×10^{-13} cm^3/molecule-sec (Atkinson *et al.,* 2006). The data in table 2 show that HCFO-1224yd(Z) has a higher k_{OH} value than ethane, meaning that it initially reacts more than twice as fast in the atmosphere as ethane. However, the resulting unsaturated fluorinated compounds in the atmosphere are short lived and react more slowly to form O_3 (Baasandorj *et al.,* 2011). The modeled reactivity based on the mechanism considered by Carter resulted in a very low maximum incremental reactivity on a mass basis. When compared to ethane, HCFO-1224yd(Z) has a MIR of 0.052 ± 0.011 g O_3/g VOC. Hence HCFO-1224yd(Z)'s MIR is less than the fifth of that of ethane at 0.28 ± 0.07 g O_3/g ethane. As shown in table 2, HCFO-1224yd(Z)'s MIR on a molar basis is also somewhat lower than that of ethane. Considering the uncertainty and variability in the MIR modeling, as described by Carter (2020), we are confident that the MIR of HCFO-1224yd(Z) is less than that of ethane.

A molecule of HCFO-1224yd(Z) is considerably less reactive than a molecule of ethane in terms of complete O_3-forming activity, as shown by the molar-based MIR (g O_3/mole VOC) values. Likewise, one gram of HCFO-1224yd(Z) has a lower capacity than one gram of ethane to form O_3 in terms of a mass-based MIR. Thus, following the 2005 Interim Guidance, the EPA finds HCFO-1224yd(Z) to be eligible for exemption from the regulatory definition of VOC based on both the molar- and mass-based MIR.

B. Potential Impacts on Other Environmental Endpoints

The EPA's decision to exempt HCFO-1224yd(Z) from the regulatory definition of VOC is based on our findings above. However, as noted in the 2005 Interim Guidance, the EPA reserves the right to exercise its judgment in certain cases where an exemption is likely to result in a significant increase in the use of a compound and a subsequent significantly increased risk to human health or the environment. In this case, the EPA does not find that exemption of HCFO-1224yd(Z) would result in an increase of risk to human health or the environment, regarding stratospheric O_3 depletion, toxicity, and climate change. More information on these topics is provided in the following sections.

1. Contribution to Stratospheric Ozone Depletion

The SNAP program is the EPA's program to evaluate and regulate substitutes for end-uses historically using O_3-depleting chemicals. Under section 612(c) of the CAA, the EPA is required to identify and publish lists of acceptable and unacceptable substitutes for class I or class II O_3-depleting substances. Per the SNAP program findings, the ODP of HCFO-1224yd(Z) is zero, which is significantly less than the ODPs for the [ozone depleting substances] ODS subject to the phase out of production and consumption under regulations issued under sections 601–607 of the CAA and consistent with the Montreal Protocol on Substances that Deplete the Ozone Layer. The SNAP program has listed HCFO-1224yd(Z) as an acceptable substitute for chillers and other industrial process refrigeration end-uses provided in 84 FR 64765, November 25, 2019 (USEPA, 2019).

HCFO-1224yd(Z) is unlikely to contribute to the depletion of the stratospheric O_3 layer. The O_3 depletion potential (ODP) of HCFO-1224yd(Z) is expected to be negligible based on several lines of evidence (Tokuhashi *et al.,* 2018; Guo *et al.,* 2019). Because HCFO-1224yd(Z)'s atmospheric lifetime is short (20 days according to Tokuhashi *et al.,* 2018) compared to the timescale for mixing within the troposphere, it will decay before it has a chance to reach the stratosphere and, thus, will not participate in O_3 destruction (Guo *et al.,* 2019).

2. Toxicity

Based on screening assessments of the health and environmental risks of HCFO-1224yd(Z), the SNAP program expected that users will be able to use the compound without significantly greater health risks than presented using other available substitutes for the same end uses (USEPA, 2019).

The EPA anticipates that HCFO-1224yd(Z) will be used consistent with the recommendations specified in the manufacturer's SDS (AGC, 2017). According to the SDS, potential health effects from inhalation of HCFO-1224yd(Z) include drowsiness or dizziness, irritation of the skin or eyes, or frostbite. These potential health effects are common to many refrigerants. However, HCFO-1224yd(Z) could cause asphyxiation if air is displaced by vapors in a confined space. The Workplace Environmental Exposure Limit (WEEL) committee of the Occupational Alliance for Risk Science (OARS) reviewed available animal toxicity data and recommends a WEEL for the workplace of 1000 parts per million (ppm) (6700 mg/m^3) [5] time-weighted average (TWA) for an 8-hour workday, as later published in 2019 in *Toxicology and Industrial Health* (''(Z)-I-Chloro-2,3,3,3-tetrafluoropropene,'' 2020).[6] This WEEL was derived based

[5] *Occupational Alliance for Risk Science (OARS–WEELs)*– HCFO-1224yd(Z)), *2017: https://www.tera.org/OARS/PDF_documents/09_hcfo-1224yd(z)-weel-document-final-2017.pdf.*

[6] (''(Z)-I-Chloro-2,3,3,3-tetrafluoropropene (HCFO-1224yd(Z)) (2017). (2019). Toxicology and Industrial Health, 36(5), 305–309. *https://doi.org/10.1177/0748233720930548.*

on a 4-week, GLP-compliant inhalation toxicity study in rats (AGC, 2016), based on the point of departure a NOAEL of 40,000 ppm. This was also the NOAEL for the developmental toxicity study where developmental effects were only observed in female rats. The EPA expects that users will be able to meet the WEEL and address potential health risks by following requirements and recommendations in the SDS and other safety precautions common to the refrigeration and air conditioning industry.

HCFO-1224yd(Z) is not regulated as a hazardous air pollutant (HAP) under title I of the CAA. Also, it is not listed as a toxic chemical under section 313 of the Emergency Planning and Community Right-to-Know Act (EPCRA).

The Toxic Substances Control Act (TSCA) gives the EPA authority, among other things, to evaluate and, if necessary, address risks of injury to health or the environment from new chemical substances before such substances may be manufactured (including imported). Section 5 of TSCA requires manufacturers and importers to notify the EPA before manufacturing a new chemical substance or manufacturing or processing any chemical substance for a use which the Administrator has determined is a significant new use. When EPA receives such notice, it assesses whether sufficient information is available to permit a reasoned evaluation of the health and environmental effects of the substance or use and whether manufacturing, processing, distribution in commerce, use, or disposal of the substance (or any combination of such activities) presents, may present, or is not likely to present an unreasonable risk. Based on its review of a premanufacture notice (PMN) for HCFO-1224yd(Z), the EPA signed a consent order under TSCA section 5(e) to protect against an unreasonable risk of injury to health or the environment. EPA also subsequently issued a Significant New Use Rule (SNUR) under TSCA that requires submission of a Significant New Use Notice (SNUN) to the EPA at least 90 days before manufacturing or processing of HCFO-1224yd(Z) for any significant new use. The required notification will provide the EPA with the opportunity to evaluate any intended significant new use before it occurs and, if necessary, to issue orders to address any potential unreasonable risk to human health or the environment.

HCFO-1224yd(Z) is one of the class of substances generally referred to as per- and polyfluoroalkyl substances (PFAS). Many PFAS compounds represent a public health concern due to their toxicity and persistence in the environment. As a class, they are also highly varied, and variations in structure may result in (yet unknown) differences in environmental mobility and toxicity. The agency's ongoing work addressing PFAS does not currently address HCFO-1224yd(Z) specifically; however, the exposure limits and SNAP screening assessment noted above give us confidence that the use of this compound will not pose an unreasonable risk to human health. EPA also believes that the impacts of PFAS will be adequately addressed by regulatory and non-regulatory programs specifically designed to address those impacts.[7]

3. Contribution to Climate Change

The Intergovernmental Panel on Climate Change (IPCC) Fifth Assessment Report (IPCC AR5) does not provide an estimate for HCFO-1224yd(Z)'s global warming potential (GWP).[8] The HCFO-1224yd(Z) GWP on a 100-year time horizon was calculated to be 5.4 in one study by Tokuhashi *et al.* (2018), but the same study reported an experimental chamber value of 0.88 and a lifetime of 20 days. This is consistent with the Scientific Assessment of Ozone Depletion by the chemical sciences laboratory (NOAA, 2022) where the GWP was found to be smaller than one under all reactivity efficiencies and recommended adjustments. These authors also calculated an inflated radiation or IR spectrum from a theoretical model using density functional theory (DFT) for HCFO-1224yd(Z). That calculation gives a GWP of 5.4. While the theoretical value differs substantially on a percentage basis from the measured value, the GWP based on the experimental measurement is expected to be the more accurate given the large uncertainties in the calculated molecular model which tend to be unknown and high. Either value is 1–2 orders of magnitude lower than the GWP for the refrigerant(s) that HCFO-1224yd(Z) is designed to replace. HCFO-1224yd(Z) has a GWP below one indicating that it has less radiating impact than that of CO_2 over a 100-year time period (GWP_{100}). Species with double bonds assembled in the Intergovernmental Panel on Climate Change Fifth Assessment Report (table 8.A.1) show lower GWP than species without a double bond. According to the SNAP rule, HCFO-1224yd(Z)'s GWP is smaller than one and is comparable to or lower than those of some of the substitutes such as used in new chillers, ammonia absorption, carbon dioxide (CO_2), and hydro-fluoro-olefin (HFO–1336mzz(Z)), and for new and retrofit chillers with GWPs ranging from 0 to 630. (USEPA, 2019). Both the calculated and the observed values of HCFO-1224yd(Z)'s GWP are lower than that of ethane determined to be 10.2.[9]

C. Conclusions

The EPA finds that HCFO-1224yd(Z) is negligibly reactive with respect to its contribution to tropospheric O_3 formation and, thus, may be exempted from the EPA's definition of VOC in 40 CFR 51.100(s). HCFO-1224yd(Z) has been listed as acceptable for use in new and retrofitted centrifugal chillers, positive displacement chillers and industrial process refrigeration under the SNAP program (USEPA, 2019). The EPA has also determined that exemption of HCFO-1224yd(Z) from the regulatory definition of VOC will not result in an increase of risk to human health and the environment, and, to the extent that use of this compound does have impacts on other environmental endpoints, those impacts are adequately managed by existing programs. For example, HCFO-1224yd(Z) has a similar or lower stratospheric O_3 depletion potential than available substitutes in those end-uses, and the toxicity risk from using HCFO-1224yd(Z) is not significantly greater than the risk from using other available alternatives for the same uses. The EPA has concluded that non-tropospheric O_3-related risks associated with potential increased use of HCFO-1224yd(Z) are adequately managed by SNAP. The EPA does not expect significant use of HCFO-1224yd(Z) in applications not covered by the SNAP program. To the extent that

[7] Interim Guidance on Control of Volatile Organic Compounds in Ozone State Implementation Plans, 2005, US Environmental Protection Agency, Document Number 05–18015 (70 FR 54046). And could be found at this link: *https://www.govinfo.gov/content/pkg/FR-2005-09-13/pdf/05-18015.pdf.*

[8] IPCC, 2013: Climate Change 2013: Chapter 8, Myhre, G., D. Shindell, F.-M. Bréon, W. Collins, J. Fuglestvedt, J. Huang, D. Koch, J.-F. Lamarque, D. Lee, B. Mendoza, T. Nakajima, A. Robock, G. Stephens, T. Takemura and H. Zhang, 2013: Anthropogenic and Natural Radiative Forcing. In: Climate Change 2013: The Physical Science Basis. Contribution of Working Group I to the Fifth Assessment Report of the Intergovernmental Panel on Climate Change [Stocker, T.F., D. Qin, G.-K. Plattner, M. Tignor, S.K. Allen, J. Boschung, A. Nauels, Y. Xia, V. Bex and P.M. Midgley (eds.)]. Cambridge University Press, Cambridge, United Kingdom and New York, NY, USA. *https://www.ipcc.ch/site/assets/uploads/2018/02/WG1AR5_Chapter08_FINAL.pdf.*

[9] Lifetimes, direct and indirect radiative forcing, and global warming potentials of ethane (C2H6), propane (C3H8), and butane (C4H10): *https://rmets.onlinelibrary.wiley.com/doi/full/10.1002/asl.804.*

the compound is used in other applications not already reviewed under SNAP or under the New Chemicals Program under TSCA, the SNUR in place under TSCA requires that any significant new use of a chemical be reported to the EPA using a SNUN. Any significant new use of HCFO-1224yd(Z) would, thus, need to be evaluated by the EPA, and the EPA will continually review the availability of acceptable substitute chemicals under the SNAP program.

IV. Proposed Action

The EPA is responding to the petition by proposing to revise its regulatory definition of VOC at 40 CFR 51.100(s) to add HCFO-1224yd(Z) to the list of compounds that are exempt from the regulatory definition of VOC because it is less reactive than ethane based on a comparison of mass-based MIR and molar-based MIR metrics and is, therefore, considered negligibly reactive. As a result of this action, if an entity uses or produces this compound and is subject to the EPA regulations limiting the use of VOC in a product, limiting the VOC emissions from a facility, or otherwise controlling the use of VOC for purposes related to attaining the O_3 NAAQS, this compound will not be counted as a VOC in determining whether these regulatory obligations have been met. This action would affect whether this compound is considered a VOC for State regulatory purposes to reduce O_3 formation, if a State relies on the EPA's regulatory definition of VOC. States are not bound to exclude from control as a VOC those compounds that the EPA has found to be negligibly reactive. However, no State may take credit for controlling this compound in its O_3 control strategy. Consequently, reductions in emissions for this compound will not be considered or counted in determining whether States have met the rate of progress requirements for VOC in State Implementation Plans or in demonstrating attainment of the O_3 NAAQS.

V. Statutory and Executive Order Reviews

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

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 14094: Modernizing Regulatory Review

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

B. Paperwork Reduction Act (PRA)

This action does not impose an information collection burden under the PRA. It does not contain any recordkeeping or reporting requirements.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This action removes HCFO-1224yd(Z) from the regulatory definition of VOC and, thereby, relieves manufacturers, distributers, and users of the compound from tropospheric O_3 requirements to control emissions of the compound.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any State, local or Tribal governments, or the private sector.

E. Executive Order 13132: Federalism

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

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

This action does not have Tribal implications, as specified in Executive Order 13175. This proposed rule removes HCFO-1224yd(Z) from the regulatory definition of VOC and, thereby, relieves manufacturers, distributers, and users from tropospheric O_3 requirements to control emissions of the compound. Thus, Executive Order 13175 does not apply to this action.

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

Executive Order 13045 directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045, because it is not economically significant as defined in Executive Order 12866, and because the EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. Our assessment is consistent with the SNAP finding that the conditional use of this chemical will guarantee the reduction of exposure risks to the general population particularly the most sensitive population (*e.g.,* children). Since HCFO-1224yd(Z) is utilized in specific industrial applications where children are not present and dissipates quickly (*e.g.,* lifetime of 22 days) with short-lived end products, there is no exposure or disproportionate risk to children. This action removes HCFO-1224yd(Z) from the regulatory definition of VOC and, thereby, relieves manufacturers, distributers, and users from tropospheric O_3 requirements to control emissions of the compound.

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

The EPA believes that the human health and environmental conditions that exist prior to this action do not result in disproportionate and adverse effects on communities with EJ concerns. As we found no data available to support the opposite, we addressed the human health and environmental risks by this proposed action to the greatest ability feasible. This action was developed in accordance with agency guidance on environmental justice.

The EPA believes that this action in not likely to result in new disproportionate and adverse effects on communities with environmental justice concerns. This action removes HCFO-1224yd(Z) from the regulatory definition

of VOC and, thereby, relieves manufacturers, distributers, and users of the compound from tropospheric O_3 requirements to control emissions of the compound. It will in fact help States focus on more photochemically reactive chemicals preventing more formation of Ozone and consequently more adverse related health and environmental effects.

K. Judicial Review

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 District of Columbia Circuit Court within 60 days from the date the proposed action is published in the **Federal Register**. Filing a petition for review by the Administrator of this proposed action 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 must be filed and shall not postpone the effectiveness of such action. Thus, any petitions for review of this action related to the exemption of HCFO-1224yd(Z) from the regulatory definition of VOC must be filed in the Court of Appeals for the District of Columbia Circuit within 60 days from the date proposed action is published in the **Federal Register**.

VII. References

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List of Subjects in 40 CFR Part 51

Environmental protection, Administrative practice and procedure, Air pollution control, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Michael S. Regan,

Administrator.

For reasons stated in the preamble, title 40, chapter I of the Code of Federal Regulations is proposed to be amended as follows:

PART 51—REQUIREMENTS FOR PREPARATION, ADOPTION, AND SUBMITTAL OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 51 continues to read as follows:

Authority: 23 U.S.C. 101; 42 U.S.C. 7401–7671q.

Subpart F—Procedural Requirements

■ 2. Section 51.100 is amended by revising paragraph (s)(1) introductory text to read as follows:

§ 51.100 Definitions.

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(s) * * *

(1) This includes any such organic compound other than the following, which have been determined to have negligible photochemical reactivity: methane; ethane; methylene chloride (dichloromethane); 1,1,1-trichloroethane (methyl chloroform); 1,1,2-trichloro-1,2,2-trifluoroethane (CFC–113); trichlorofluoromethane (CFC–11); dichlorodifluoromethane (CFC–12); chlorodifluoromethane (HCFC–22); trifluoromethane (HFC–23); 1,2-dichloro 1,1,2,2-tetrafluoroethane (CFC–114); chloropentafluoroethane (CFC–115); 1,1,1-trifluoro 2,2-dichloroethane (HCFC–123); 1,1,1,2-tetrafluoroethane (HFC–134a); 1,1-dichloro 1-fluoroethane (HCFC–141b); 1-chloro 1,1-difluoroethane (HCFC–142b); 2-chloro-1,1,1,2-tetrafluoroethane (HCFC–124); pentafluoroethane (HFC–125); 1,1,2,2-tetrafluoroethane (HFC–134); 1,1,1-trifluoroethane (HFC–143a); 1,1-difluoroethane (HFC–152a); parachlorobenzotrifluoride (PCBTF); cyclic, branched, or linear completely methylated siloxanes; acetone; perchloroethylene (tetrachloroethylene); 3,3-dichloro-1,1,1,2,2-pentafluoropropane (HCFC–225ca); 1,3-dichloro-1,1,2,2,3-pentafluoropropane (HCFC–225cb); 1,1,1,2,3,4,4,5,5,5-decafluoropentane (HFC 43–10mee); difluoromethane (HFC–32); ethylfluoride (HFC–161); 1,1,1,3,3,3-hexafluoropropane (HFC–236fa); 1,1,2,2,3-pentafluoropropane (HFC–245ca); 1,1,2,3,3-pentafluoropropane (HFC–245ea); 1,1,1,2,3-pentafluoropropane (HFC–245eb); 1,1,1,3,3-pentafluoropropane (HFC–245fa); 1,1,1,2,3,3-hexafluoropropane (HFC–236ea); 1,1,1,3,3-pentafluorobutane (HFC–365mfc); chlorofluoromethane (HCFC–31); 1 chloro-1-fluoroethane (HCFC–151a); 1,2-dichloro-1,1,2-trifluoroethane (HCFC–123a); 1,1,1,2,2,3,3,4,4-nonafluoro-4-methoxy-butane ($C_4F_9OCH_3$ or HFE–7100); 2-(difluoromethoxymethyl)-1,1,1,2,3,3,3-heptafluoropropane ($(CF_3)_2CFCF_2OCH_3$); 1-ethoxy-1,1,2,2,3,3,4,4,4-nonafluorobutane ($C_4F_9OC_2H_5$ or HFE–7200); 2-(ethoxydifluoromethyl)-1,1,1,2,3,3,3-heptafluoropropane ($(CF_3)_2CFCF_2OC_2H_5$); methyl acetate; 1,1,1,2,2,3,3-heptafluoro-3-methoxy-propane (n-C3F7OCH3, HFE–7000); 3-ethoxy- 1,1,1,2,3,4,4,5,5,6,6,6-dodecafluoro-2-(trifluoromethyl) hexane (HFE–7500); 1,1,1,2,3,3,3-heptafluoropropane (HFC 227ea); methyl formate (HCOOCH3); 1,1,1,2,2,3,4,5,5,5-decafluoro-3-methoxy-4-trifluoromethyl-pentane (HFE–7300); propylene carbonate; dimethyl carbonate; *trans*-1,3,3,3-tetrafluoropropene; HCF_2OCF_2H (HFE–134); $HCF_2OCF_2OCF_2H$ (HFE–236cal2); $HCF_2OCF_2CF_2OCF_2H$ (HFE–338pcc13); $HCF_2OCF_2OCF_2CF_2OCF_2H$ (H-Galden 1040x or H-Galden ZT 130 (or 150 or 180)); *trans* 1-chloro-3,3,3-trifluoroprop-1-ene; 2,3,3,3-tetrafluoropropene; 2-amino-2-methyl-1-propanol; t-butyl acetate; 1,1,2,2- Tetrafluoro -1-(2,2,2-trifluoroethoxy) ethane; *cis*-1,1,1,4,4,4-hexafluorobut-2-ene (HFO–1336mzz-Z); (Z)-1-chloro-2,3,3,3-tetrafluoropropene (HCFO-1224yd(Z)); and perfluorocarbon compounds which fall into these classes:

* * * * *

[FR Doc. 2024–25971 Filed 11–8–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2024–0059; FRL–11682–09–OCSPP]

Receipt of a Pesticide Petition Filed for Residues of Pesticide Chemicals in or on Various Commodities (September 2024)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petition and request for comment.

SUMMARY: This document announces the Agency's receipt of an initial filing of a pesticide petition requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before December 12, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2024–0059, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Madison H. Le, Biopesticides and Pollution Prevention Division (BPPD) (7511M), main telephone number: (202) 566–1400, email address: *BPPDFRNotices@epa.gov;* or Charles Smith, Registration Division (RD) (7505T), main telephone number: (202) 566–1030, email address: *RDFRNotices@epa.gov.* The mailing address for each contact person is Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/comments.html.*

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing receipt of a pesticide petition filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking public comment on the request before responding to the petitioner. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petition described in this document contains data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the pesticide petition. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition that is the subject of this document, prepared by the petitioner, is included in a docket EPA has created for this rulemaking. The docket for this petition is available at *https://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

A. Notice of Filing—Amended Tolerances for Non-Inerts

PP 1E8952. EPA–HQ–OPP–2021–0789. BASF Corporation, 26 Davis Drive, Research Triangle Park, North Carolina 27709, requests to amend the tolerances in 40 CFR 180.473 for residues of the herbicide glufosinate-ammonium, including its metabolites and degradates. Compliance with the tolerance levels specified below is to be determined by measuring the sum of glufosinate-ammonium (butanoic acid, 2-amino-4-(hydroxymethylphosphinyl)-monoammonium salt), and its metabolites, 2-acetamido-4-methylphosphinico-butanoic acid and 3-methylphosphinico-propionic acid, expressed as 2-amino-4-(hydroxymethylphosphinyl) butanoic acid equivalents in or on the following raw agricultural plant commodities: By amending tolerance in or on rice, grain from 1.0 parts per million (ppm) to 0.9 ppm, and by removing tolerance on rice, hull at 2.0 ppm. The analytical methods for crops matrices involve water extraction, filtration and addition of an isotopically labeled internal standard followed by solid phase extraction. Quantitation is by high performance liquid chromatography-electrospray ionization/tandem mass spectrometry

(LC/MS/MS) is used to measure and evaluate the chemical glufosinate-ammonium. *Contact:* RD.

B. Notice of Filing—New Tolerance Exemptions for Non-Inerts (Except PIPS)

1. *PP 3F9093.* EPA–HQ–OPP–2024–0429. Sinon Corporation, 1F., No. 101, Nanrong Road Dadu District, RC–43245 Taichung, Taiwan (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192), requests to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of the fungicide and bactericide, Bacillus velezensis strain CL3 in or on all food commodities. The petitioner believes no analytical method is needed because an exemption from the requirement of a tolerance is being proposed. *Contact:* BPPD.

2. *PP 4F9139.* EPA–HQ–OPP–2024–0427. Aphea.Bio NV, Technologiepark 21, 9052 Gent, Belgium (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192), requests to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of the fungicide Streptomyces griseofuscus strain M1A1 in or on all food commodities. The petitioner believes no analytical method is needed because an exemption from the requirement of a tolerance is being proposed. *Contact:* BPPD.

3. *PP* 0F8850. EPA–HQ–OPP–2024–0426. VPTox LLC, on behalf of Draslovka Services Pty Ltd., 21320 Sweet Clover Place, Ashburn VA 20147, requests to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of the insecticide, Ethyl formate in or on all food commodities. The petitioner believes no analytical method is needed because both ethyl formate and formic acid are naturally found in many commodities at very low levels and the fumigation of the commodities does not result in residue levels higher than background in those commodities. *Contact:* BPPD.

4. *PP* 4F9139. EPA–HQ–OPP–2024–0427. Aphea.Bio NV, Technologiepark 21, 9052 Gent, Belgium (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192), requests to establish an exemption from the requirement of a tolerance in 40 CFR part 180 for residues of the fungicide *Streptomyces griseofuscus* strain M1A1 in or on all food commodities. The petitioner believes no analytical method is needed because an exemption from the requirement of a tolerance is being proposed. *Contact:* BPPD.

(Authority: 21 U.S.C. 346a.)

Dated: October 11, 2024.

Kimberly Smith,

Acting Director, Information Technology and Resources Management Division, Office of Program Programs.

[FR Doc. 2024–25764 Filed 11–8–24; 8:45 am]

BILLING CODE 6560–50–P

Notices

Federal Register

Vol. 89, No. 218

Tuesday, November 12, 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 COMMERCE

Census Bureau

U.S. Census Bureau Tribal Consultation; Virtual Public Meeting

AGENCY: Census Bureau, Department of Commerce.

ACTION: Notice of virtual public meeting

SUMMARY: The U.S. Census Bureau (Census Bureau) will conduct two virtual Tribal consultations on updating the race/ethnicity code list for the American Community Survey and the 2030 Census on December 11, 2024, and January 15, 2025. The two virtual Tribal consultation webinars will reflect the Census Bureau's continuous commitment to strengthen government-to-government relationships with federally recognized Tribes. The Census Bureau's procedures for outreach, notice, and consultation ensure involvement of Tribes, to the extent practicable and permitted by law, before making decisions or implementing policies, rules, or programs that affect federally recognized Tribal governments. These meetings are open to citizens of federally and State recognized Tribes by invitation.

DATES: The Census Bureau will conduct two virtual Tribal consultations; the first on Wednesday, December 11, 2024, from 3 p.m. to 4:30 p.m. ET and the second on Wednesday, January 15, 2025, from 3 p.m. to 4:30 p.m. ET. Any questions or topics to be considered in the Tribal consultation meetings must be received in writing via email by December 2, 2024.

FOR FURTHER INFORMATION CONTACT: Dee Alexander, Tribal Affairs Coordinator, Office of Congressional and Intergovernmental Affairs, Intergovernmental Affairs Office, U.S. Census Bureau, Washington, DC 20233; telephone (301) 763–9335; (202) 407–6635 or email at *Dee.A.Alexander@census.gov* or *ocia.tao@census.gov.*

SUPPLEMENTARY INFORMATION: *Meeting Information:* The Census Bureau Tribal consultation webinar meetings will be held via the WebEx platform at the following presentation link:

Wednesday, December 11, 2024, 3 p.m.–4:30 p.m. ET

Register link: https://uscensus.webex.com/weblink/register/r489540f73a388fe3c4c9f6b9bbd3f648.

Date and time: Wednesday, January 15, 2025, 3 p.m.–4:30 p.m. ET.

Register link: https://uscensus.webex.com/weblink/register/ree1ade98a8ed634b2754ef6209796141.

Once you register as an attendee, you will receive an email with login information, or the option to join via phone only.

Submit your comments by email. Send comments to: *Dee.A.Alexander@census.gov* or *OCIA.TAO@census.gov.*

The Census Bureau is planning two national webinars to be held on December 11, 2024, and January 15, 2025, with federally and State recognized Tribes, which will provide a forum for Tribes to learn about its Race/Ethnicity Coding Improvement Project and provide feedback. The Race/Ethnicity Coding Improvement Project provides an opportunity for Tribes to provide feedback on how detailed race and/or ethnicity and American Indian or Alaska Native populations will be coded in the American Community Survey (ACS) and the 2030 Census. The Census Bureau aims to enhance and improve the code list that was used in the 2020 Census and is currently used in the ACS to ensure that detailed race and/or ethnicity and Tribal responses are accurately coded and tabulated in future data collections.

The webinars will provide information on how to interpret and understand the code list and its impact on the data Tribes receive. Tribal leaders will have the opportunity to provide feedback on alternative terms, abbreviations, or in-language terms that individuals may use to identify themselves as a citizen of their Tribes and any groups that may be missing or misclassified in the code list. We are providing Tribes for their review the proposed code list and **Federal Register** Notice with background information about this project. The Census Bureau is seeking feedback from Tribal governments on the following questions:

1. Are there any groups missing from the proposed code list? If so, please identify them and suggest how the groups should be classified and why.

2. Are any groups on the proposed code list misclassified? If so, please identify them and suggest an alternative classification or indicate if the term should be removed.

3. Are there alternative terms, abbreviations, or in-language terms people may use to identify with a specific group that should be added to the proposed code list? If so, please identify them and suggest a classification.

In accordance with Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, issued November 6, 2000, the Census Bureau has adhered to its Tribal consultation policy by seeking the input of Tribal governments in the planning and implementation of the ACS and the 2030 Census with the goal of ensuring the most accurate counts and data for the American Indian or Alaska Native population. In that regard, the Census Bureau is seeking comments on the proposed race/ethnicity code list: *https://www2.census.gov/programs-surveys/demo/2030-race-and-or-ethnicity-code-list/.*

Tribes will have until February 5, 2025, to review the proposed updates to the code list and provide input.

Robert L. Santos, Director, Census Bureau, approved the publication of this notice in the **Federal Register**.

Dated: October 28, 2024.

Shannon Wink,

Program Analyst, Policy Coordination Office, U.S. Census Bureau.

[FR Doc. 2024–26172 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Services Surveys: BE–30, Quarterly Survey of Ocean Freight Revenues and Foreign Expenses of U.S. Carriers, and the BE–37, Quarterly Survey of U.S. Airline Operators' Foreign Revenues and Expenses

The Department of Commerce will submit the following information collection request to the Office of

Management and Budget (OMB) for review and clearance, in accordance with the Paperwork Reduction Act of 1995 (PRA) on or after the date of publication of this notice. We invite 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. Public comments were previously requested via the **Federal Register** on June 28, 2024, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Economic Analysis, Department of Commerce.

Title: Quarterly Survey of Ocean Freight Revenues and Foreign Expenses of U.S. Carriers, and Quarterly Survey of U.S. Airline Operators' Foreign Revenues and Expenses.

OMB Control Number: 0608–0011.

Form Number(s): BE–30 and BE–37.

Type of Request: Regular submission.

Estimated Number of BE–30 Respondents: 200 annually (50 filed each quarter; 48 reporting mandatory data, and 2 that would file exemption claims or voluntary responses).

Estimated Number of BE–37 Respondents: 120 annually (30 filed each quarter; 28 reporting mandatory data, and 2 that would file an exemption claim or voluntary response).

Estimated Time per Response: For the BE–30, 4 hours is the average for those reporting mandatory data and one hour is the average for those filing an exemption claim or voluntary responses. For the BE–37, 5 hours is the average for those reporting mandatory data and one hour is the average for those filing an exemption claim or voluntary responses. For the BE–30 and BE–37 surveys, hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 1,344 (776 for the BE–30; 568 for the BE–37).

Needs and Uses: The data are needed to monitor U.S. trade in transport services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the trade in transport services component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

Affected Public: Business or other for-profit organizations.

Frequency: Quarterly.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0608–0011.

Sheleen Dumas,

Departmental PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–26166 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Services Surveys: BE–9, Quarterly Survey of Foreign Airline Operators' Revenues and Expenses in the United States

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance, in accordance with the Paperwork Reduction Act of 1995 (PRA) on or after the date of publication of this notice. We invite 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. Public comments were previously requested via the **Federal Register** on May 16, 2024, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Economic Analysis, Department of Commerce.

Title: Quarterly Survey of Foreign Airline Operators' Revenues and Expenses in the United States.

OMB Control Number: 0608–0068.

Form Number(s): BE–9.

Type of Request: Regular submission.

Estimated Number of Respondents: 500 annually (125 filed each quarter; 115 reporting mandatory data, and 10 that would file exemption claims or voluntary responses).

Estimated Time per Response: 6 hours is the average for the 115 respondents filing mandatory data and 1 hour for those filing an exemption claim or voluntary response. Hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 2,800.

Needs and Uses: The data are needed to monitor U.S. trade in transport services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the trade in transport services component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

Affected Public: Business or other for-profit organizations.

Frequency: Quarterly.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0608–0068.

Sheleen Dumas,

Departmental PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–26169 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Services Surveys: BE–185, Quarterly Survey of Financial Services Transactions Between U.S. Financial Services Providers and Foreign Persons

The Department of Commerce will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance, in accordance with the Paperwork Reduction Act of 1995 (PRA) on or after the date of publication of this notice. We invite 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. Public comments were previously requested via the **Federal Register** on August 5, 2024, during a 60-day comment period. This notice allows for an additional 30 days for public comments.

Agency: Bureau of Economic Analysis, Department of Commerce.

Title: Quarterly Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons.

OMB Control Number: 0608–0065.

Form Number(s): BE–185.

Type of Request: Regular submission.

Estimated Number of Respondents: 2,860 annually (715 filed each quarter; 580 reporting mandatory data, and 135 that would file exemption claims or voluntary responses).

Estimated Time per Response: 10 hours is the average for the 715 respondents filing mandatory data and 1 hour for those filing an exemption claim or voluntary response. Hours may vary considerably among respondents because of differences in company size and complexity.

Estimated Total Annual Burden Hours: 23,740.

Needs and Uses: The data are needed to monitor U.S. trade in financial services, to analyze the impact of these cross-border services on the U.S. and foreign economies, to compile and improve the U.S. economic accounts, to support U.S. commercial policy on trade in services, to conduct trade promotion, and to improve the ability of U.S. businesses to identify and evaluate market opportunities. The data are used in estimating the trade in financial services component of the U.S. international transactions accounts (ITAs) and national income and product accounts (NIPAs).

Affected Public: Business or other for-profit organizations.

Frequency: Quarterly.

Respondent's Obligation: Mandatory.

Legal Authority: International Investment and Trade in Services Survey Act (Pub. L. 94–472, 22 U.S.C. 3101–3108, as amended).

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the collection or the OMB Control Number 0608–0065.

Sheleen Dumas,

Departmental PRA Clearance Officer, Office of the Under Secretary of Economic Affairs, Commerce Department.

[FR Doc. 2024–26165 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–06–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–714–001]

Phosphate Fertilizers From the Kingdom of Morocco: Final Results of Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that OCP S.A. (OCP), a producer/exporter of phosphate fertilizers from the Kingdom of Morocco (Morocco), received countervailable subsidies during the period of review (POR), January 1, 2022, through December 31, 2022.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Jaron Moore or Faris Montgomery, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–3640 or (202) 482–1537, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the preliminary results of this administrative review on May 2, 2024.[1] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On August 1, 2024, Commerce extended the deadline for the final results of this review to no later than November 5, 2024.[3]

For a summary of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[4] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

We conducted this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by this order are phosphate fertilizers. For a complete description of the scope of this order, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

The issues raised by parties in this administrative review are addressed in the Issues and Decision Memorandum. A list of the issues addressed in the Issues and Decision Memorandum is provided in the appendix to this notice.

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding the *Preliminary Results,* we made certain revisions to

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[1] *See Phosphate Fertilizers from the Kingdom of Morocco: Preliminary Results of the Countervailing Duty Administrative Review, 2022,* 89 FR 35800 (May 2, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See* Memorandum, ''Extension of Deadline for the Final Results of Countervailing Duty Administrative Review,'' dated August 1, 2024.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Phosphate Fertilizers from the Kingdom of Morocco; 2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

the subsidy calculations for OCP. These changes are explained in the Issues and Decision Memorandum.

Final Results of Administrative Review

In accordance with 19 CFR 351.221(b)(4)(i), we calculated an individual net countervailable subsidy rate for OCP. Commerce determines that, during the POR, the net countervailable subsidy rate for the company under review is as follows:

Company	Subsidy rate (percent ad valorem)
OCP S.A.[5]	16.81

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rate

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for the above-listed company at the applicable *ad valorem* assessment rate. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed with the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Rates

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amount shown for OCP on shipments of the subject merchandise entered, or withdrawn from warehouse for consumption, on or after the date of publication of the final results of this administrative review. The cash deposit requirement, effective upon the publication of the final results of this review, shall remain in effect until further notice.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Subsidies Valuation
V. Analysis of Programs
VI. Discussion of the Issues
- Comment 1: Whether Commerce Can Seek Information Regarding Previously Investigated Programs That Commerce Found Conferred No Benefit and ''Other Assistance'' Provided by the GOM
- Comment 2A: Whether Commerce Should Revise the Phosphate Rock Benchmark for the Provision of Phosphate Mining Rights for Less Than Adequate Remuneration (LTAR) Program
- Comment 2B: Whether Commerce Should Include Headquarters (HQ), Support, and Debt Costs in the Costs of Producing Phosphate Rock for the Benchmark for the Provision of Phosphate Mining Rights for LTAR Program
- Comment 2C: Whether Commerce Should Revise the Methodology for the Calculation of OCP's Profit Rate Used in its Valuation of OCP's Phosphate Rock
- Comment 3A: Whether Certain of OCP's Land Purchases Provided a Financial Contribution from the GOM
- Comment 3B: Whether the Provision of Land for LTAR is Specific
- Comment 3C: Whether Commerce Should Include Certain Land Transactions in the Benchmark Calculation for the Provision of Land for LTAR
- Comment 3D: Whether Commerce Should Include OCP's Land Transactions Subject to Ongoing Judicial Proceedings in the Benefit Calculation for the Provision of Land for LTAR
- Comment 3E: Whether Commerce Should Correct Arithmetical Errors in the Provision of Land for LTAR Calculation of Benefit
- Comment 4: Whether Commerce Should Include Transactions from Countries with Free Trade Agreements (FTAs) with Morocco in OCP's Benefit Calculation for the Customs Duty Exemptions for Capital Goods, Machinery, and Equipment Program
- Comment 5: Whether the Provision of Port Services and Infrastructure for LTAR Program Provided a Countervailable Benefit to OCP During the POR
- Comment 6: Whether Marsa Maroc's Provision of Port and Vessel Services is Consistent with Market Principles
- Comment 7: Whether Commerce Should Make Certain Changes to its Cash Deposit Instructions

VII. Recommendation

[FR Doc. 2024–26178 Filed 11–8–24; 8:45 am]

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[5] Commerce has found the following companies to be cross-owned with OCP S.A.: Jorf Fertilizers Company I; Jorf Fertilizers Company II; Jorf Fertilizers Company III; Jorf Fertilizers Company IV; Jorf Fertilizers Company V; and OCP Nutricrops S.A.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–106]

Wooden Cabinet and Vanities and Components Thereof From the People's Republic of China: Final Results and Partial Rescission of the Antidumping Duty Administrative Review; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that and The Ancientree Cabinet Co., Ltd. (Ancientree) and Jiangsu Weisen Houseware Co., Ltd. (Weisen) did not make sales of wooden cabinets and vanities and components thereof (cabinets) at prices below normal value during the period of review (POR) April 1, 2022, through March 31, 2023.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Garry Kasparov or Hermes Pinilla, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1397 or (202) 482–3477, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 2, 2024, Commerce published in the **Federal Register** the *Preliminary Results* of the antidumping duty administrative review and invited interested parties to comment.[1] On July

[1] *See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of*

Continued

22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On August 8, 2024, Commerce extended the deadline for issuing the final results in this review to November 5, 2024.[3]

For a complete description of the events that occurred since Commerce published the *Preliminary Results, see* the Issues and Decision Memorandum.[4] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [5]

The products covered by this *Order* are wooden cabinets and vanities For full description of the scope of the *Order, see* the Issues and Decision Memorandum.

Partial Rescission of Review

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of an antidumping duty order when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.[6] Normally, upon completion of an administrative review, the suspended entries are liquidated at the antidumping duty assessment rate calculated for the review period.[7] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that Commerce can instruct CBP to liquidate at the antidumping duty assessment rate calculated for the review period.[8] Commerce found during this administrative review that, for certain companies listed in the in the *Initiation Notice,* there were no reviewable entries during the POR.[9] As a result, in the absence of suspended entries of subject merchandise during the POR, we are hereby rescinding this administrative review for certain companies listed in appendix IV of this notice, in accordance with 19 CFR 351.213(d)(3).

Analysis of Comments Received

All issues raised in the parties' briefs are addressed in the Issues and Decision Memorandum. A list of the issues addressed is included as appendix I to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes From the Preliminary Results

Based on our review and analysis of the comments received, we made changes to the *Preliminary Results.* For a more detailed discussion of the issues raised by parties, *see* the Issues and Decision Memorandum.[10]

Rates for Non-Examined Separate Rate Respondents

Commerce determines that 18 companies, not individually examined, are eligible for separate rates in this administrative review.[11] The Act and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate rate respondents which Commerce did not examine individually in an administrative review. For the final results of this review, Commerce determined the estimated dumping margins for Ancientree and Weisen to be zero. For the reasons explained in the Issues and Decision Memorandum, we are assigning this rate to the non-examined respondents which qualify for a separate rate in this review.[12]

China-Wide Entity

As stated in the *Preliminary Results,* because no party requested a review of the China-wide entity is not under review and the China-wide entity's rate, *i.e.,* 251.64 percent, is not subject to change.[13] Commerce considers all other companies, listed in appendix III of this notice, for which a review was requested, and which did not demonstrate separate rate eligibility, to be part of the China-wide entity, including Jiangsu Sunwell Cabinetry Co., Ltd.

Final Results of Administrative Review

Commerce determines that the following estimated weighted-average dumping margin exists for the administrative review covering the period April 1, 2022, through March 31, 2023:

Exporter	Weighted-average dumping margin (percent)
Jiangsu Weisen Houseware Co., Ltd	0.00
The Ancientree Cabinet Co., Ltd	0.00
Non-Selected Companies Under Review Receiving a Separate Rate [14]	0.00

China: Preliminary Results, Preliminary Determination of No Shipments, and Partial Rescission of the Antidumping Duty Administrative Review; 2022–2023, 89 FR 35785 (May 2, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See* Memorandum, ''Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated August 8, 2024.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] *See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Antidumping Duty Order,* 85 FR 22126 (April 21, 2020) (*Order*).

[6] *See, e.g., Dioctyl Terephthalate from the Republic of Korea: Rescission of Antidumping Administrative Review; 2021–2022,* 88 FR 24758 (April 24, 2023); *see also Certain Carbon and Alloy Steel Cut-to Length Plate from the Federal Republic of Germany: Recission of Antidumping Administrative Review; 2020–2021,* 88 FR 4157 (January 24, 2023); and *Lightweight Thermal Paper from Japan: Rescission of Antidumping Administrative Review; 2022–2023,* 89 FR 18373 (March 13, 2024).

[7] *See* 19 CFR 351.212(b)(1).

[8] *See* 19 CFR 351.213(d)(3).

[9] *See* Commerce's Memorandum, ''U.S. Customs and Border Protection (CBP) Data release,'' dated June 20, 2023.

[10] *See* Issues and Decision Memorandum.

[11] *See* Appendix II.

[12] *See* Issues and Decision Memorandum at Comment 4.

[13] *See Preliminary Results,* 89 FR 35785.

Disclosure

Normally, Commerce discloses to interested parties the calculations of the final results of an administrative review within five days of a public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because we have made no changes to Ancientree's and Weisen's margin calculations from the *Preliminary Results,* there are no calculations to disclose.

Assessment

Pursuant to section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b)(1), Commerce has determined, and U.S. Customs and Border Protections (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. Pursuant to 19 CFR 351.212(b)(1), for Ancientree, and Weisen, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales and the total entered value of the sales. Where an importer-specific assessment rate is zero or *de minimis* (*i.e.,* less than 0.5 percent), the entries by that importer will be liquidated without regard to antidumping duties.

For all non-selected separate rate applicants subject to this review, we will instruct CBP to liquidate all entries of subject merchandise that entered the United States during the POR at the average of the rates calculated for Ancientree and Weisen as listed above.[15] For entries of subject merchandise during the POR produced by Ancientree and Weisen for which they did not know their merchandise was destined for the United States, we intend to instruct CBP to liquidate such entries at the China-wide rate if there is no rate for the intermediate company or companies involved in the transaction.

For the companies for which the review is rescinded, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the rate as entered. For all other companies, we will instruct CBP to apply the antidumping duty assessment rate of the China-wide entity, 251.64 percent, to all entries of subject merchandise exported by these companies.[16]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies subject to this review will be the rate established in these final results of the review; (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding in which they were reviewed; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be equal to the weighted-average dumping margin for the China-wide entity (*i.e.,* 251.64 percent); and (4) for all non-Chinese exporters of subject merchandise which have not received their own separate rate, the cash deposit rate will be the rate applicable to the Chinese exporter(s) that supplied that non-Chinese exporter.[17] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Certification

Following the publication of this notice, the importer, or the importer's agent, must continue to submit any required certifications to CBP as part of the entry process by uploading them into the document imaging system in CBP's Automated Commercial Environment at the time of entry summary filing. Consistent with CBP's procedures, importers shall also identify entries required to have certifications by using importers' additional declaration (record 54) AD/CVD Certification Designation (type code 06) when filing entry summary.[18]

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties has occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of countervailing duties.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5) and 19 CFR 351.213(h)(2).

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Changes from the *Preliminary Results*
V. Discussion of the Issues

[14] *See* Appendix II.

[15] *See* Issues and Decision Memorandum at Comment 4.

[16] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021 (June 12, 2023) (''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a Separate Rate Application or Certification, as described below.'').

[17] *See Order,* 85 FR at 22126.

[18] *See* Cargo System Messaging Service #59384253, dated 02/12/2024; *see also,* Announcing an Importer's Additional Declaration in the Automated Commercial Environment Specific to Antidumping/Countervailing Duty Certifications, 89 FR 7372 (February 2, 2024).

Comment 1: Whether Commerce Should Rely on Adverse Facts Available (AFA) to Determine a Margin for Ancientree
Comment 2: Surrogate Country Selection
Comment 3: Whether Commerce Should Find That Jiangsu Sunwell Cabinetry Co., Ltd. (Sunwell) Has Rebutted the Presumption of Government Control.
Comment 4: Whether Commerce Should Revise the Calculation of the Separate Rate in the Final Results.
Comment 5: Whether Commerce Should Rescind the Review for All Companies That Have No Unliquidated Type 03 Entries as Reflected in the U.S. Customs and Border Protection (CBP) Data.
Comment 6: Whether Commerce Should Determine Jiangsu Xiangsheng Bedtime Furniture Co., Ltd. (Bedtime) Has No Shipments.
VI. Recommendation

Appendix II

Non-Selected Companies Under Review Receiving a Separate Rate

1. Fujian Dushi Wooden Industry Co., Ltd.
2. Fujian Leifeng Cabinetry Co., Ltd.
3. Fuzhou CBM Imp & Exp Co., Ltd.
4. Goldenhome Living Co., Ltd.
5. Honsoar New Building Material Co., Ltd.
6. Jiangsu Beichen Wood Co., Ltd.
7. KM Cabinetry Co., Ltd.
8. Nantong Aershin Cabinets Co., Ltd.
9. Qingdao Shousheng Industry Co., Ltd.
10. Senke Manufacturing Company
11. Shanghai Zifeng International Trading Co., Ltd.
12. Shouguang Fushi Wood Co., Ltd.
13. Taishan Hongxiang Trading Co., Ltd.
14. Taishan Oversea Trading Co., Ltd.
15. Taizhou Overseas Int'l Ltd.
16. Xiamen Adler Cabinetry Co., Ltd.
17. Xiamen Golden Huanan Imp & Exp Co., Ltd.
18. Yixing Pengjia Technology Co., Ltd. (formally known as Yixing Pengjia Cabinetry Co., Ltd.)

Appendix III

Companies Determined To Be Part of the China-Wide Entity

1. Deqing Meisheng Import and Export Co., Ltd.
2. Fujian Senyi Kitchen Cabinet Co., Ltd.
3. Fuzhou Hauster Kitchen Cabinet Manufacturing Co., Ltd.
4. Fuzhou Pyrashine Trading Co., Ltd.
5. Jiang Su Rongxin Import and Export Co., Ltd.
6. Jiangsu Sunwell Cabinetry Co., Ltd.
7. Jiangsu Xiangsheng Bedtime Furniture Co., Ltd.
8. Linshu Meibang Furniture Co., Ltd.
9. Linyi Bomei Furniture Co., Ltd.
10. Qufu Xinyu Furniture Co., Ltd.
11. Shanghai Beautystar Cabinetry Co., Ltd.
12. Shanghai Zifeng Industries Development Co., Ltd.
13. Shenzhen Pengchengzhirong Trade Co., Ltd.
14. Xiamen Got Cheer Co., Ltd.
15. Yichun Dongmeng Wood Co., Ltd.
16. Yindu Kitchen Equipment Co., Ltd.
17. ZBOM Cabinets Co., Ltd.
18. Zaozhuang New Sharp Import & Export Trading Co., Ltd.
19. Zhongshan KM Cabinetry Co., Ltd.

Appendix IV

Companies for Which the Review Is Rescinded

1. Anhui Xinyuanda Cupboard Co., Ltd.
2. Changyi Zhengzheng Woodwork Co.,
3. Dalian Hualing Wood Co., Ltd.
4. Dalian Meisen Woodworking Co., Ltd.
5. Dongguan Ri Sheng Home Furnishing Articles Co., Ltd.
6. Guangzhou Nuolande Import and Export Co., Ltd.
7. Hangzhou Hoca Kitchen & Bath Products Co., Ltd.
8. Jiang Su Rongxin Wood Industry Co., Ltd. (Formerly known as Jiang Su Rongxin Cabinets Ltd.)
9. Kunshan Baiyulan Furniture Co., Ltd.
10. Linyi Kaipu Furniture Co., Ltd.
11. Morewood Cabinetry Co., Ltd.
12. Pizhou Ouyme Import & Export Trade Co., Ltd.
13. Quanzhou Ample Furnishings Co., Ltd.
14. Shandong Jinhua Wood Co., Ltd.
15. Shandong Longsen Woods Co., Ltd.
16. Sheen Lead International Trading (Shanghai) Co., Ltd.
17. Suzhou Siemo Wood Import & Export Co., Ltd.
18. Tech Forest Cabinetry Co., Ltd.
19. Weifang Fuxing Wood Co., Ltd.
20. Weifang Yuanlin Woodware Co., Ltd.
21. Weihai Jarlin Cabinetry Manufacture Co., Ltd.
22. Xuzhou Yihe Wood Co., Ltd.
23. Zhangzhou OCA Furniture Co., Ltd.
24. Zhongshan NU Furniture Co., Ltd.
25. Zhoushan For-Strong Wood Co.

[FR Doc. 2024–26174 Filed 11–8–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–918]

Steel Wire Garment Hangers From the People's Republic of China: Final Results of the Expedited Third Sunset Review of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of this expedited sunset review, the U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty (AD) order on steel wire garment hangers (steel hangers) from the People's Republic of China (China) would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Kabir Archuletta, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2953.

SUPPLEMENTARY INFORMATION:

Background

On October 6, 2008, Commerce published the AD *Order* on steel hangers from China.[1] On July 1, 2024, Commerce published the notice of initiation of the five-year sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On July 10, 2024, Commerce received a notice of intent to participate in this review from M&B Metal Products Company, Inc. (the domestic interested party) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested party claimed interested party status under section 771(9)(C) of the Act as a manufacturer, producer, or wholesaler of a domestic like product in the United States.

On July 18, 2024, the domestic interested party provided a timely substantive response for this review within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive responses from any other interested parties, nor was a hearing requested. On August 21, 2024, Commerce notified the U.S. International Trade Commission (ITC) that it did not receive an adequate substantive response from respondent interested parties.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), Commerce conducted an expedited (120-day) sunset review of this *Order.* On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[6] The deadline for the final results is now November 5, 2024.

Scope of the Order

The merchandise subject to this *Order* is steel hangers. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[7]

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[1] *See Notice of Antidumping Duty Order: Steel Wire Garment Hangers from the People's Republic of China,* 73 FR 58111 (October 6, 2008) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 89 FR 54435 (July 1, 2024).

[3] *See* Domestic Interested Party's Letter, ''Notice of Intent to Participate,'' dated July 10, 2024.

[4] *See* Domestic Interested Party's Letter, ''Substantive Response to Notice of Initiation,'' dated July 18, 2024.

[5] *See* Commerce's Letter, ''Sunset Review for July 2024,'' dated August 21, 2024.

[6] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited

Analysis of Comments Received

All issues raised in this review, including the likelihood of continuation or recurrence of dumping in the event of revocation and the magnitude of the margins likely to prevail if the *Order* were revoked, are addressed in the accompanying Issues and Decision Memorandum.[8] A list of topics discussed in the Issues and Decision Memorandum is included as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the antidumping duty order on steel hangers from China would be likely to lead to the continuation or recurrence of dumping, and that the magnitude of the margins likely to prevail would be weighted-average dumping margins up to 187.25 percent.

Administrative Protective Order (APO)

This notice serves as the only reminder to interested parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these final results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2) and 19 CFR 351.221(c)(5)(ii).

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Margins Likely to Prevail
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2024–26177 Filed 11–8–24; 8:45 am]

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Third Sunset Review of the Antidumping Duty Order on Certain Steel Wire Garment Hangers from the People's Republic of China'' (Issues and Decisions Memorandum), dated concurrently with these results and hereby adopted by this notice.

[8] *Id.*

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–054]

Certain Aluminum Foil From the People's Republic of China: Final Results of Countervailing Duty Administrative; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that countervailable subsidies were provided to certain exporters/producers of certain aluminum foil (aluminum foil) from the People's Republic of China (China) during the period of review (POR) January 1, 2022, through December 31, 2022.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Natasia Harrison or Harrison Tanchuck, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1240 or (202) 482–7421, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 2, 2024, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** and invited comments from interested parties.[1] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On July 26, 2024, Commerce extended the deadline for issuing these final results to November 5, 2024.[3] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[4]

Scope of the Order [5]

The product covered by the scope of the *Order* is aluminum foil from China. A full description of the scope of the *Order* is contained in the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised by the interested parties in their case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of topics discussed in the Issues and Decision Memorandum is provided in Appendix I to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on our analysis of comments from interested parties and the evidence on the record, we revised the calculation of the net countervailable subsidy rates for Hangzhou Five Star

[1] *See Certain Aluminum Foil from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review and Rescission of Review, in Part; 2022,* 89 FR 35790 (May 2, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] Commerce extended the time period for the final results to 180 days after the publication date of the *Preliminary Results* (*i.e.,* October 29, 2024). However, because Commerce tolled certain deadlines in this administrative review by seven days, the deadline is now November 5, 2024. *See* Memorandum, ''Extension of Deadline for Final Results of Countervailing Duty Administrative Review, 2022,'' dated July 26, 2024.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Certain Aluminum Foil from the People's Republic of China; 2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] *See Certain Aluminum Foil from the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 83 FR 17360 (April 19, 2018); *see also Certain Aluminum Foil from the People's Republic of China: Notice of Court Decision Not in Harmony With the Amended Final Determination in the Countervailing Duty Investigation, and Notice of Amended Final Determination and Amended Countervailing Duty Order,* 85 FR 47730 (August 6, 2020) (collectively, *Order*).

Aluminium Co., Ltd. (Five Star) and Jiangsu Zhongji Lamination Materials Co., (HK) Limited (Zhongji HK). In addition, we have also revised the rate applicable to companies not selected for individual review. For a discussion of these changes, *see* the Issues and Decision Memorandum.

Methodology

Commerce conducted this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, we find that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[6] For a complete description of the methodology underlying all of Commerce's conclusions, including our reliance, in part, on facts otherwise available, including adverse facts available, pursuant to sections 776(a) and (b) of the Act, *see* the Issues and Decision Memorandum.

Companies Not Selected for Individual Review

The statute and Commerce's regulations do not directly address the establishment of rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides the basis for calculating the all-others rate in an investigation. Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate an all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters and/or producers individually examined, excluding any rates that are zero, *de minimis,* or based entirely on facts available.

There are 18 companies for which a review was requested and not rescinded, and which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent. In this review, the preliminary rates calculated for Five Star and Zhongji HK are above *de minimis* and not based entirely on facts available. Therefore, we are applying to the non-selected companies the simple average of the net subsidy rates calculated for Five Star and Zhongji HK.[7]

Final Results of Review

We determine the following net countervailable subsidy rates exist for the period January 1, 2022, through December 31, 2022:

Company	Subsidy rate (percent ad valorem)
Hangzhou Five Star Aluminium Co., Ltd.[8]	29.90
Jiangsu Zhongji Lamination Materials Co., (HK) Limited[9]	[10] 22.35
Non-Selected Companies Under Review[11]	[12] 27.50

Disclosure

Commerce intends to disclose calculations and analysis performed for the final results of review within five days after the date of publication of this notice in the **Federal Register** in accordance with 19 CFR 351.224(b).

Cash Deposit Requirements

In accordance with section 751(a)(1) of the Act, Commerce also intends to instruct U.S. Customs and Border Protection (CBP) to collect cash deposits of estimated countervailing duties in the amounts shown above for the above-listed companies with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of these final results of review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, effective upon publication of these final results, shall remain in effect until further notice.

Assessment Requirements

In accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce has determined, and CBP shall assess, countervailing duties on all appropriate

[6] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[7] With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted-average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53663 (September 1, 2010).

[8] Commerce finds the following companies to be to be cross-owned with Five Star: Jiangsu Dingsheng New Materials Joint-Stock Co., Ltd. (Jiangsu Dingsheng), Dingsheng Aluminium Industries (Hong Kong) Trading Co., Limited or Dingsheng Aluminium Industries (Hong Kong) Trading Co., Ltd. (Dingsheng HK), Hangzhou Dingsheng Import & Export Co., Ltd. or Hangzhou Dingsheng Import and Export Co., Ltd. (Dingsheng IE), Hangzhou Teemful Aluminium Co., Ltd. (Teemful), Inner Mongolia Liansheng New Energy Material Co., Ltd. or Inner Mongolia Liansheng New Energy Material Joint-Stock Co., Ltd. (Liansheng), Inner Mongolia Liansheng New Energy Material Co., Ltd. or Inner Mongolia Xinxing New Material Co., Ltd. (Xinxing), Hangzou Dingsheng Industrial Group Co., Ltd. (Dingsheng Group), Hangzhou Dingcheng Aluminum Co., Ltd. (Dingcheng); Luoyang Longding Aluminium Co., Ltd. (Longding); Walson (HK) Trading Co., Limited (Walson HK); Dingheng New Materials Co., Ltd. (Dingheng) and Thai Ding Li New Materials Co., Ltd. (Ding Li), (collectively, Dingsheng Respondents). Longding, Walson HK, Dingheng and Ding Li were listed separately in the *Initiation Notice. See* Dingsheng Respondents' Letter, ''Hangzhou Five Star Affiliation Response,'' dated August 25, 2023 (Dingsheng Respondents AQR) at Exhibit A.1.

[9] As discussed in the *Preliminary Results,* Commerce finds the following companies to be to be cross-owned with Zhongji HK: Jiangsu Zhongji Lamination Materials Co., Ltd. (Zhongji) (FKA Jiangsu Zhongji Lamination Materials Co., Ltd.); Jiangsu Huafeng Aluminium Industry Co., Ltd. (Jiangsu Huafeng); Shantou Wanshun New Material Group Co., Ltd. (Shantou Wanshun) (FKA Shantou Wanshun Package Material Stock Co., Ltd.); Anhui Zhongji Battery Foil Sci&Tech Co., Ltd. (Anhui Zhongji) (FKA Anhui Maximum Aluminium Industries Company Limited); and Sichuan Wanshun Zhongji Aluminium Industry Co., Ltd. (Sichuan Wanshun). Anhui Zhongji, Anhui Maximum Aluminium Industries Company Limited, Jiangsu Huafeng, Zhongji, and Shantou Wanshun Package Material Stock Co., Ltd. were listed separately in the *Initiation Notice.*

[10] This net countervailable *ad valorem* subsidy rate reflects an EVA. *See* Issues and Decision Memorandum at Comment 3.

[11] *See* Appendix II for a list of the non-selected companies under review.

[12] The non-selected company rate reflects Five Star's *ad valorem* net countervailable subsidy rate and Zhongji HK's *ad valorem* net countervailable subsidy rate without the EVA. *See* Issues and Decision Memorandum at 4 and Comment 3.

entries covered by this review, for the above-listed companies at the applicable *ad valorem* assessment rates listed. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

The final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Non-Selected Companies Under Review
V. Subsidies Valuation
VI. Use of Facts Otherwise Available and Application of Adverse Inferences
VII. Analysis of Programs
VIII. Discussion of the Issues
Comment 1: Whether Commerce Should Continue to Make an Adverse Inference to Find that the Mandatory Respondents Benefited from the Export Buyer's Credit Program (EBCP)
Comment 2: Whether Commerce Should Revise its Application of the Trading Company Methodology for Jiangsu Zhongji Lamination Materials Co., (HK) Ltd. (Zhongji HK)
Comment 3: Whether Commerce Should Grant Jiangsu Zhongji Lamination Materials Co., Ltd. (Zhongji) an Entered Value Adjustment (EVA)
Comment 4: Whether Commerce Should Include Non-Production Income and Commission Expenses in Zhongji's Total Sales Denominator
Comment 5: Whether Commerce Should Adjust the Aluminum Plate and/or Sheet and Strip Benchmark for the Zhongji Respondents [13]
Comment 6: Whether Commerce Should Include Warehouse Storage Fees in the Benchmark for the Government Provision of Primary Aluminum for Less Than Adequate Remuneration (LTAR)
Comment 7: Whether Commerce Should Adjust the Calculation of the Zhongji Respondents' Inland Freight Used in the Primary Aluminum Benchmark
Comment 8: Whether Commerce Should Include Certain Purchases Disclosed at Verification to calculate Anhui Zhongji's Benefit from the Government Provision of Primary Aluminum for LTAR
Comment 9: Whether Commerce Should Revise the Dingsheng Respondents' Intercompany Sales
Comment 10: Whether Commerce Should Adjust the Primary Aluminum, Aluminum Sheet and Coal Benchmarks for the Dingsheng Respondents
Comment 11: Whether Commerce Should Include London Metal Exchange (LME) Data in the Calculation of the Primary Aluminum Benchmarks for the Dingsheng Respondents
Comment 12: Whether Commerce Should Adjust the Ocean Freight Benchmarks for the Dingsheng Respondents
Comment 13: Whether Commerce Should Revise the Dingsheng Respondents' Benefit Calculations for Income Tax Deductions for Research and Development (R&D) Expenses Under the Enterprise Income Tax Law (EITL)
Comment 14: Whether Commerce Should Adjust Dingsheng Respondents' Benefit Calculation for the Government Provision of Electricity for LTAR
Comment 15: Whether Commerce Should Revise Inner Mongolia Liansheng New Energy Material Joint-Stock Co., Ltd.'s (Liansheng's) Benefit Calculation for Certain Government Grants
IX. Recommendation

Appendix II

Non-Selected Companies Under Review

1. Alcha International Holdings Limited
2. Baotou Alcha Aluminum Co., Ltd.
3. Gränges Aluminum (Shanghai) Co., Ltd.
4. Guangxi Baise Xinghe Aluminum Industry Co., Ltd.
5. Hunan Suntown Marketing Limited
6. Jiangyin Dolphin Pack Ltd. Co.
7. Luoyang Longding Aluminium Industries Co., Ltd.
8. Shandong Yuanrui Metal Material Co., Ltd.
9. Shanghai Huafon Aluminium Corporation
10. Shanghai Shenhuo Aluminium Foil Co., Ltd.
11. Shanghai Shenyan Packaging Materials Co., Ltd.
12. SNTO International Trade Limited
13. Suntown Technology Group Corporation Limited
14. Xiamen Xiashun Aluminium Foil Co. Ltd.
15. Yangtai Jintai International Trade Co., Ltd.
16. Yantai Donghai Aluminum Co., Ltd.
17. Yinbang Clad Material Co., Ltd.
18. Zhejiang Zhongjin Aluminum Industry Co., Ltd.

[13] The Zhongji Respondents include Zhongji HK, Zhongji, Jiangsu Huafeng Aluminium Industry Co., Ltd. (Jiangsu Huafeng), Shantou Wanshun New Material Group Co., Ltd. (Shantou Wanshun), Anhui Zhongji Battery Foil Sci&Tech Co., Ltd. (Anhui Zhongji), and Sichuan Wanshun Zhongji Aluminium Industry Co., Ltd. (Sichuan Wanshun).

[FR Doc. 2024–26168 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

United States-Mexico-Canada Agreement (USMCA), Article 10.12: Binational Panel Review: Notice of Request for Panel Review

AGENCY: United States Section, USMCA Secretariat, International Trade Administration, Department of Commerce.

ACTION: Notice of USMCA Request for Panel Review.

SUMMARY: A Request for Panel Review was filed on behalf of the Coalition for Fair Mexican Exports of Aluminum Extrusions with the United States Section of the USMCA Secretariat on November 1, 2024, pursuant to USMCA Article 10.12. Panel Review was requested of the U.S. Department of Commerce's Final Results in the matter of Aluminum Extrusions from Mexico: Final Affirmative Determination of Sales at Less than Fair Value. The USMCA Secretariat has assigned case number USA–MEX–2024–10.12–05 to this request.

FOR FURTHER INFORMATION CONTACT: Vidya Desai, United States Secretary, USMCA Secretariat, Room 2061, 1401 Constitution Avenue NW, Washington, DC 20230, 202–482–5438.

SUPPLEMENTARY INFORMATION: The final determination was published in the **Federal Register** on October 3, 2024 (89 FR 80463).

Article 10.12 of Chapter 10 of USMCA provides a dispute settlement mechanism involving trade remedy determinations issued by the Government of the United States, the Government of Canada, and the Government of Mexico. Following a Request for Panel Review, a Binational Panel is composed to review the trade remedy determination being challenged and issue a binding Panel Decision. There are established USMCA *Rules of Procedure for Article 10.12 (Binational Panel Reviews),* which were adopted by the three governments for panels requested pursuant to Article 10.12(2) of USMCA which requires Requests for

Panel Review to be published in accordance with Rule 40. For the complete Rules, please see *https://can-mex-usa-sec.org/secretariat/agreement-accord-acuerdo/usmca-aceum-tmec/rules-regles-reglas/article-article-articulo_10_12.aspx?lang=eng.*

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 44 no later than 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is December 2, 2024);

(b) A Party, an investigating authority or other interested person who does not file a Complaint but who intends to participate in the panel review shall file a Notice of Appearance in accordance with Rule 45 no later than 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is December 16, 2024);

(c) The panel review will be limited to the allegations of error of fact or law, including challenges to the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and to the procedural and substantive defenses raised in the panel review.

Dated: November 5, 2024.

Vidya Desai,

United States Secretary, USMCA Secretariat.

[FR Doc. 2024–26105 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–GT–P

DEPARTMENT OF COMMERCE

International Trade Administration

United States-Mexico-Canada Agreement (USMCA), Article 10.12: Binational Panel Review: Notice of Request for Panel Review

AGENCY: United States Section, USMCA Secretariat, International Trade Administration, Department of Commerce.

ACTION: Notice of USMCA Request for Panel Review.

SUMMARY: A Request for Panel Review was filed on behalf of the Coalition for Fair Mexican Exports of Aluminum Extrusions with the United States Section of the USMCA Secretariat on November 1, 2024, pursuant to USMCA Article 10.12. Panel Review was requested of the U.S. Department of Commerce's Final Results in the matter of Aluminum Extrusions from Mexico: Final Affirmative Countervailing Duty Determination. The USMCA Secretariat has assigned case number USA–MEX–2024–10.12–04 to this request.

FOR FURTHER INFORMATION CONTACT: Vidya Desai, United States Secretary, USMCA Secretariat, Room 2061, 1401 Constitution Avenue NW, Washington, DC 20230, 202–482–5438.

SUPPLEMENTARY INFORMATION: The final determination was published in the **Federal Register** on October 3, 2024 (89 FR 80496).

Article 10.12 of chapter 10 of USMCA provides a dispute settlement mechanism involving trade remedy determinations issued by the Government of the United States, the Government of Canada, and the Government of Mexico. Following a Request for Panel Review, a Binational Panel is composed to review the trade remedy determination being challenged and issue a binding Panel Decision. There are established USMCA *Rules of Procedure for Article 10.12 (Binational Panel Reviews),* which were adopted by the three governments for panels requested pursuant to Article 10.12(2) of USMCA which requires Requests for Panel Review to be published in accordance with Rule 40. For the complete Rules, please see *https://can-mex-usa-sec.org/secretariat/agreement-accord-acuerdo/usmca-aceum-tmec/rules-regles-reglas/article-article-articulo_10_12.aspx?lang=eng.*

The Rules provide that:

(a) A Party or interested person may challenge the final determination in whole or in part by filing a Complaint in accordance with Rule 44 no later than 30 days after the filing of the first Request for Panel Review (the deadline for filing a Complaint is December 2, 2024);

(b) A Party, an investigating authority or other interested person who does not file a Complaint but who intends to participate in the panel review shall file a Notice of Appearance in accordance with Rule 45 no later than 45 days after the filing of the first Request for Panel Review (the deadline for filing a Notice of Appearance is December 16, 2024);

(c) The panel review will be limited to the allegations of error of fact or law, including challenges to the jurisdiction of the investigating authority, that are set out in the Complaints filed in the panel review and to the procedural and substantive defenses raised in the panel review.

Dated: November 5, 2024.

Vidya Desai,

United States Secretary, USMCA Secretariat.

[FR Doc. 2024–26102 Filed 11–8–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–821–825]

Phosphate Fertilizers From the Russian Federation: Final Results of Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Joint Stock Company Apatit (JSC Apatit), a producer/exporter of phosphate fertilizers from the Russian Federation (Russia), received countervailable subsidies during the period of review (POR), January 1, 2022, through December 31, 2022.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Shane Subler or William Horn, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–6241 or (202) 482–4868, respectively.

SUPPLEMENTARY INFORMATION:

Background

Commerce published the preliminary results of this administrative review on May 4, 2024.[1] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On August 13, 2024, Commerce extended the deadline for the final results of this administrative review until November 5, 2024.[3] For a description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[4] We conducted this review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

[1] *See Phosphate Fertilizers from the Russian Federation: Preliminary Results and Partial Rescission of the Countervailing Duty Administrative Review; 2022,* 89 FR 35794 (May 4, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See* Memorandum, ''Extension of Deadline for Final Results of Countervailing Duty Administrative Review,'' dated August 13, 2024.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Phosphate Fertilizers from the Russian Federation; 2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

Scope of the Order [5]

The products covered by this *Order* are phosphate fertilizers. For a complete description of the scope of this *Order, see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in interested parties' case briefs are addressed in the Issues and Decision Memorandum accompanying this notice. A list of the issues raised by parties, and to which Commerce responded in the Issues and Decision Memorandum, is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding the *Preliminary Results,* and for the reasons explained in the Issues and Decision Memorandum, we made certain revisions to the subsidy calculations for JSC Apatit. These changes are explained in the Issues and Decision Memorandum.

Final Results of Administrative Review

In accordance with 19 CFR 351.221(b)(4)(i), we calculated an individual net countervailable subsidy rate for JSC Apatit. Commerce determines that, during the POR, the net countervailable subsidy rate for the company under review is as follows:

Company	Subsidy rate (percent ad valorem)
Joint Stock Company Apatit [6]	18.21

Disclosure

Commerce intends to disclose the calculations performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rate

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries of subject merchandise in accordance with the final results of this review, for the above-listed company at the applicable *ad valorem* assessment rate. We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed with the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Rates

In accordance with section 751(a)(1) of the Act, Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amount shown for JSC Apatit on shipments of the subject merchandise entered, or withdrawn from warehouse for consumption on or after the date of publication of the final results of this administrative review. For all nonreviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate The cash deposit requirement, effective upon the publication of the final results of this review, shall remain in effect until further notice.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

These final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Use of Facts Otherwise Available and Adverse Inferences
V. Subsidies Valuation
VI. Analysis of Programs
VII. Discussion of the Issues
Provision of Mining Rights for Less Than Adequate Remuneration (LTAR)
  Comment 1a: Whether Commerce Selected a Benchmark Reflective of Prevailing Market Conditions and Consistent with Market Principles
  Comment 1b: Whether Eurostat Data Are the Most Representative Benchmark Data Available to Commerce
  Comment 1c: Whether Commerce Should Expand Its Selected Data to Calculate a More Representative Benchmark If It Continues to Use Global Trade Atlas (GTA) Data
  Comment 1d: Whether Commerce Should Include All Exports from South Africa in Its Benchmark
  Comment 1e: Whether Commerce Should Account for Additional Expenses Incurred in the Production and Sale of Phosphate Rock When Calculating a Profit Ratio
  Comment 1f: Whether Commerce Should Countervail Mining Licenses Obtained Prior to the April 1, 2002, Cut-Off Date
Provision of Natural Gas for LTAR
  Comment 2a: Whether Commerce Should Reject Kazakh Export Data as a Natural Gas Benchmark and Use European International Energy Agency (IEA) Data Instead
  Comment 2b: Whether Commerce Should Countervail JSC Apatit's Natural Gas Purchases from Independent Suppliers
  Comment 2c: Whether the Provision of Natural Gas is Specific
Other Program-Specific Issues
  Comment 3: Whether Commerce Properly Determined that the Vologda Region's Support of Industrial Development (SID) Program Is *De Facto* Specific
  Comment 4: Whether Commerce Erred in Its Selection of a Benchmark for One of JSC Apatit's Loans Under the Corporate Competitiveness Improvement Program (CCIP)
VIII. Recommendation

[FR Doc. 2024–26179 Filed 11–8–24; 8:45 am]

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[5] *See Phosphate Fertilizers from the Kingdom of Morocco and the Russian Federation: Countervailing Duty Orders,* 86 FR 18037 (April 7, 2021) (*Order*).

[6] As discussed in the *Preliminary Results* PDM, Commerce finds the following companies to be cross-owned with JSC Apatit: PhosAgro Public Joint Stock Company; Limited Liability Company PhosAgro-Region; Limited Liability Company PhosAgro-Belgorod; Limited Liability Company PhosAgro-Don; Limited Liability Company PhosAgro-Kuban; Limited Liability Company PhosAgro-Lipetsk; Limited Liability Company PhosAgro-Kursk; Limited Liability Company PhosAgro-Orel; Limited Liability Company PhosAgro-Stavropol; Limited Liability Company PhosAgro-Volga; Limited Liability Company PhosAgro-SeveroZapad; Limited Liability Company PhosAgro-Tambov; and Limited Liability Company PhosAgro-Sibir. *See Preliminary Results* PDM at 7–8.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–107]

Wooden Cabinets and Vanities and Components Thereof From the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that certain producers and exporters of wooden cabinets and vanities and components thereof (wooden cabinets) from the People's Republic of China (China) received countervailable subsidies during the period of review (POR) January 1, 2022, through December 31, 2022.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Michael Romani or Suresh Maniam, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0198 or (202) 482–1603, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 2, 2024, Commerce published the *Preliminary Results* of this administrative review in the **Federal Register** and invited comments from interested parties.[1] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[2] Commerce conducted this review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the *Order* are wooden cabinets from China. For a full description of the scope of the order, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised by the interested parties in their case and rebuttal briefs are addressed in the Issues and Decision Memorandum. The topics discussed and the issues raised by parties to which we responded in the Issues and Decision Memorandum are listed in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov*. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx*.

Changes Since the Preliminary Results

Based on our analysis of comments received from interested parties, we made changes to the net countervailable subsidy rates for The Ancientree Cabinet Co., Ltd. (Ancientree) and Yixing Pengjia Cabinetry Co., Ltd. (Pengjia). For a discussion of these changes, *see* the Issues and Decision Memorandum.

Methodology

Commerce conducted this administrative review in accordance with section 751(a)(1)(A) the Act. For each of the subsidy programs found to be countervailable, we determine that there is a subsidy, *i.e.,* a government-provided financial contribution that gives rise to a benefit to the recipient, and that the subsidy is specific.[3] In making this final determination, Commerce relied, in part, on facts otherwise available, including with an adverse inference, pursuant to sections 776(a) and (b) of the Act. For a full description of the methodology underlying all of Commerce's conclusions, *see* the Issues and Decision Memorandum.

Companies Not Selected for Individual Review

The statute and Commerce's regulations do not address the establishment of a rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides the basis for calculating the all others rate in an investigation. Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate the all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters and producers individually investigated, excluding any zero or *de minimis* countervailable subsidy rates, and any rates determined entirely on the basis of facts available.

There are seven companies for which a review was requested and not rescinded, and which were not selected as mandatory respondents or found to be cross-owned with a mandatory respondent. In this review, the rates for Ancientree and Pengjia were above *de minimis* and not based entirely on facts available. Therefore, we are applying to the non-selected companies the average of the net subsidy rates calculated for Ancientree and Pengjia, which we calculated using the publicly-ranged sales data submitted by Ancientree and Pengjia.[4]

Final Results of Administrative Review

Commerce determines that the following net countervailable subsidy rates exist for the period January 1, 2022, through December 31, 2022:

[1] *See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Preliminary Results and Partial Rescission of Countervailing Duty Administrative Review; 2022,* 89 FR 35782 (May 2, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum.

[2] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Countervailing Duty Administrative Review of Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China; 2022,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[3] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[4] With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated subsidy rates calculated for the examined respondents; (B) a simple average of the estimated subsidy rates calculated for the examined respondents; and (C) a weighted average of the estimated subsidy rates calculated for the examined respondents using each company's publicly-ranged U.S. sale quantities for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an order in Part,* 75 FR 53661, 53663 (September 1, 2010).

[5] This company was formerly known as Yixing Pengjia Cabinetry Co., Ltd. *See* Pengjia's Letter ''Section III,'' dated January 4, 2024, at 2 and Exhibit 5.1.

[6] Commerce previously found Shanghai Beautystar Cabinetry Co., Ltd. to be a cross-owned affiliate with Jiangsu Sunwell Cabinetry Co Ltd. *See Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Preliminary Results of Countervailing Duty Administrative Review, Rescission of Administrative Review in Part, and Intent To Rescind in Part; 2021,* 88 FR 29084 (May 5, 2023), and accompanying Preliminary Decision Memorandum at 33, unchanged in *Wooden Cabinets and Vanities and Components Thereof from the People's Republic of China: Final Results and Partial Recission of Countervailing Duty Administrative Review,* 2021, 88 FR 76732 (November 7, 2023).

[7] This rate is based on the rate for the respondents that were selected for individual review, excluding

Producer/exporter	Subsidy rate (percent ad valorem)
The Ancientree Cabinet Co., Ltd	11.99
Yixing Pengjia Technology Co., Ltd [5]	0.92
Jiangsu Sunwell Cabinetry Co Ltd [6]	163.46
Taizhou Overseas Trading Company Ltd	163.46
Taishan Oversea Trading Company Ltd	163.46
Review-Specific Average Rate Applicable to the Following Companies [7]	
Fujian Dushi Wooden Industry Co., Ltd	10.92
Fuzhou CBM Import & Export Co., Ltd	10.92
KM Cabinetry Co., Ltd	10.92
Nantong Aershin Cabinet Co., Ltd	10.92
Shouguang Fushi Wood Co., Ltd	10.92
Weifang Fuxing Wood Co., Ltd	10.92
Xiamen Adler Cabinetry Co., Ltd	10.92

Disclosure

Commerce intends to disclose the calculations and analysis performed for these final results of review within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment

In accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

In accordance with section 751(a)(1) and (a)(2)(C) of the Act, Commerce also intends to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown above for the companies listed above for shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of these final results of review. For all non-reviewed firms, we will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the all-others rate or the most recent company-specific rate applicable to the company, as appropriate. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Certification

Following the publication of this notice, the importer, or the importer's agent, must continue to submit any required certifications to CBP as part of the entry process by uploading them into the document imaging system in CBP's Automated Commercial Environment at the time of entry summary filing. Consistent with CBP's procedures, importers shall also identify entries required to have certifications by using importers' additional declaration (record 54) AD/CVD Certification Designation (type code 06) when filing entry summary.[8]

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

Notification to Interested Parties

The final results are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(5).

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Non-Selected Companies Under Review
V. Subsidies Valuation
VI. Use of Facts Otherwise Available and Application of Adverse Inferences
VII. Analysis of Programs
VIII. Discussion of Issues
- Comment 1: Whether Commerce Should Calculate a Land Purchase Benefit for Jiangsu Yunru
- Comment 2: Whether Commerce Should Apply Adverse Facts Available (AFA) to the Export Buyer's Credit (EBC) Program for Ancientree
- Comment 3: Whether Commerce Should Revise the Calculation of the Benchmark Interest Applied to Ancientree's Policy Loans
- Comment 4: Whether Commerce should Rely on Freightos Data in its Ocean Freight Benchmarks
- Comment 5: Whether Commerce should Exclude Pengjia's Sales that Are Not Related to Productive Activities
- Comment 6: Whether Species Specific Sawnwood Benchmarks are Appropriate
- Comment 7: Whether Commerce Should Continue to Countervail the Provision of Certain Inputs for LTAR Based on AFA
- Comment 8: Whether Commerce Should Revise the Calculation of the Benefit for the Provision of Electricity for LTAR Program for Ancientree
- Comment 9: Whether Commerce Should Apply AFA to the Provision of Electricity for LTAR
- Comment 10: Whether Commerce Should Apply AFA to the Provision of Water for LTAR

rates that are zero, *de minimis,* or based entirely on facts available. *See* section 705(c)(5)(A) of the Act.

[8] *See* Cargo System Messaging Service #59384253, dated 02/12/2024; *see also Announcing an Importer's Additional Declaration in the Automated Commercial Environment Specific to Antidumping/Countervailing Duty Certifications,* 89 FR 7372 (February 2, 2024).

Comment 11: Whether *Income Tax Reductions under Article 28 of the Enterprise Income Tax* is Specific
Comment 12: Whether It is Appropriate to Consider Other Subsidies
IX. Recommendation

[FR Doc. 2024–26175 Filed 11–8–24; 8:45 am]
BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–821, C–560–813]

Certain Hot-Rolled Carbon Steel Flat Products From India and Indonesia: Final Results of the Expedited Fourth Sunset Reviews of the Countervailing Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) orders on certain hot-rolled carbon steel flat products (hot-rolled steel) from India and Indonesia would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of the Sunset Reviews'' section of this notice.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Peter Zukowski, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0189.

SUPPLEMENTARY INFORMATION:

Background

On December 3, 2001, Commerce published the *Orders* on hot-rolled steel from India and Indonesia.[1] On July 1, 2024, Commerce published the notice of initiation of the fourth five-year (sunset) reviews of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] From July 15 through July 16, 2024, Commerce received notices of intent to participate from Cleveland-Cliffs Inc.,[3] Nucor Corporation,[4] United States Steel Corporation,[5] Steel Dynamics, Inc., and SSAB Enterprises, LLC[6] (collectively, the domestic interested parties), within the deadline specified in 19 CFR 351.218(d)(1)(i). Each of the domestic interested parties claimed interested party status under section 771(9)(C) of the Act and 19 CFR 351.102(b)(29)(v) as producers of the domestic like product.

On July 31, 2024, Commerce received adequate substantive responses from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[7] Commerce did not receive a substantive response from any other interested party to this proceeding. On August 21, 2024, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[8] As a result, Commerce conducted expedited (120-day) sunset reviews of the *Orders,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)(2) and (C)(2).

On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[9] The deadline for these final results is now November 5, 2024.

Scope of the Orders

The merchandise covered by the *Orders* is certain hot-rolled carbon steel flat products from India and Indonesia. For a complete description of the scope of the *Orders, see* the Issues and Decision Memorandum.[10]

Analysis of Comments Received

A complete discussion of all issues raised in these sunset reviews, including the likelihood of continuation or recurrence of subsidization in the event of revocation of the *Orders* and the countervailable subsidy rates likely to prevail if the *Orders* were to be revoked, is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov.* In addition, complete versions of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Reviews

Pursuant to sections 751(c) and 752(b) of the Act, Commerce determines that revocation of the CVD orders on hot-rolled steel from India would be likely to lead to continuation or recurrence of a countervailable subsidies at the following net countervailable subsidy rates:

Producers/exporters	Net countervailable subsidy rate (percent ad valorem)
Essar Steel Limited	336.62
Ispat Industries Limited	360.23
Steel Authority of India Limited	346.61
Tata Iron and Steel Company Limited	337.51
All Others	344.44

[1] *See Notice of Amended Final Determination and Notice of Countervailing Duty Orders: Certain Hot-Rolled Carbon Steel Flat Products from India and Indonesia,* 66 FR 60198 (December 3, 2001) (*Orders*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 89 FR 54435 (July 1, 2024).

[3] *See* Cleveland-Cliffs Inc.'s Letter, ''Notice of Intent to Participate in Sunset Reviews,'' dated July 15, 2024.

[4] *See* Nucor Corporation's Letters, ''Hot-Rolled Carbon Steel Flat Products from India: Notice of Intent to Participate in Sunset Review,'' dated July 15, 2024; and ''Hot-Rolled Carbon Steel Flat Products from Indonesia: Notice of Intent to Participate in Sunset Review,'' dated July 15, 2024.

[5] *See* United States Steel Corporation's Letter, ''Notice of Intent to Participate,'' dated July 16, 2024.

[6] *See* Steel Dynamics, Inc. and SSAB Enterprises, LLC's Letters, ''Certain Hot-Rolled Carbon Steel Flat Products from India: Notice of Intent to Participate,'' dated July 16, 2024; and ''Certain Hot-Rolled Carbon Steel Flat Products from Indonesia: Notice of Intent to Participate,'' dated July 16, 2024.

[7] *See* Domestic Interested Parties' Letter, ''Domestic Industry Substantive Response,'' dated July 31, 2024.

[8] 8 *See* Commerce's Letter, ''Sunset Reviews for July 2024,'' dated August 21, 2024.

[9] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[10] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Fourth Sunset Reviews of the Countervailing Duty Orders on Certain Hot-Rolled Carbon Steel Flat Products from India and Indonesia,'' dated concurrently with, and adopted by, this notice.

Pursuant to sections 751(c) and 752(b) of the Act, Commerce determines that revocation of the CVD order on hot-rolled steel from Indonesia would be likely to lead to continuation or recurrence of a countervailable subsidies at the following net countervailable subsidy rates:

Producers/exporters	Net countervailable subsidy rate (percent ad valorem)
P.T. Krakatau Steel	10.21
All Others	10.21

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Orders*
IV. History of the *Orders*
V. Legal Framework
VI. Discussion of the Issues
1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
2. Net Countervailable Subsidy Rates Likely to Prevail
3. Nature of the Subsidies
VII. Final Results of Sunset Reviews
VIII. Recommendation

[FR Doc. 2024–26120 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–917]

Laminated Woven Sacks From the People's Republic of China: Final Results of the Third Expedited Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on laminated woven sacks from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of the Sunset Review'' section of this notice.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, 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) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On August 7, 2008, Commerce published the order on laminated woven sacks from China.[1] On July 1, 2024, Commerce published the notice of initiation of the third sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On July 12, 2024, Commerce received a notice of intent to participate from the Laminated Woven Sacks Fair Trade Coalition [3] (the domestic interested party), within the deadline specified in 19 CFR 351.218(d)(1)(i).[4] The domestic interested party claimed interested party status under section 771(9)(C) of the Act and 19 CFR 351.102(b)(29) as U.S. manufacturers of laminated woven sacks.

On July 31, 2024, Commerce received an adequate substantive response from the domestic interested party within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[5] Commerce did not receive a substantive response from any government or respondent interested party to this proceeding. On August 21, 2024, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from respondent interested parties.[6] As a result, Commerce conducted an expedited (120-day) sunset review of the *Order,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)(2) and (C)(2).

Scope of the Order

The merchandise covered by this *Order* is laminated woven sacks. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.[7]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of subsidization in the event of revocation of the *Order* and the countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is provided in the Issues and Decision Memorandum. A list of the topics

[1] *See Laminated Woven Sacks from the People's Republic of China: Countervailing Duty Order,* 78 FR 39256 (August 7, 2008) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 89 FR 54335 (July 1, 2024).

[3] The Laminated Woven Sacks Fair Trade Coalition consists of Polytex Fibers LLC and ProAmpac Holdings Inc.

[4] *See* Domestic Interested Party's Letter, ''Third Five-Year (''Sunset'') Review of Countervailing Duty Order on Laminated Woven Sacks from the People's Republic of China: Domestic Interested Parties Notice of Intent to Participate,'' dated July 12, 2024.

[5] *See* Domestic Interested Party's Letter, ''Third Five-Year (''Sunset'') Review of Countervailing Duty Order on Laminated Woven Sacks from the People's Republic of China: Domestic Interested Parties Substantive Response,'' dated July 31, 2024.

[6] *See* Commerce's Letter, ''Sunset Reviews for July 2024,'' dated August 21, 2024.

[7] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Sunset Review of the Countervailing Duty Order on Laminated Woven Sacks from China,'' dated concurrently with and adopted by this notice (Issues and Decision Memorandum).

discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(b) of the Act, Commerce determines that revocation of the *Order* would likely lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Producers/exporters	Subsidy rate (percent ad valorem)
Zibo Aifudi Plastic Packaging Co., Ltd.	83.34
Han Shing Chemical Co., Ltd.	277.54
Ningbo Yong Feng Packaging Co., Ltd.	277.54
Shandong Shougang Jianyuan Chun Co., Ltd./Shandong Longxing Plastic Products Company Ltd.	398.62
Shandong Qilu Plastic Fabric Group, Ltd.	358.20
All-Others	280.65

Administrative Protective Order

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
  2. Net Countervailable Subsidy Rates Likely to Prevail
  3. Nature of the Subsidies
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2024–26180 Filed 11–8–24; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–549–818]

Certain Hot-Rolled Carbon Steel Flat Products from Thailand: Final Results of Expedited Fourth Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on certain hot-rolled carbon steel flat products (hot-rolled steel) from Thailand would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Thomas Cloyd, 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) 482–1246.

SUPPLEMENTARY INFORMATION:

Background

On December 3, 2001, Commerce published the CVD order on hot-rolled steel from Thailand.[1] On July 1, 2024, Commerce published the notice of initiation of the fourth five-year sunset review of the *Order,* pursuant to section 751(c)(2) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.218(c).[2] On July 15, 2024, and July 16, 2024, Cleveland-Cliffs Inc., Nucor Corporation, Steel Dynamics, Inc., SSAB Enterprises, LLC, and U.S. Steel Corporation (collectively, the domestic interested parties) filed timely notices of intent to participate in accordance with 19 CFR 351.218(d)(1).[3] The domestic interested parties claim interested party status under section 771(9)(C) of the Act, as producers of a domestic like product in the United States. Commerce received a substantive response from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive response from the Royal Thai Government (RTG) or any other interested party in this proceeding.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), we determined that the respondent interested parties did not provide an adequate response to the notice of initiation and, therefore, Commerce conducted an expedited (120-day) sunset review of the *Order.*

Scope of the Order

The product covered by the *Order* is hot-rolled steel from Thailand. For a complete description of the scope of the

[1] *See Notice of Countervailing Duty Order: Certain Hot-Rolled Carbon Steel Flat Products from Thailand,* 66 FR 60197 (December 3, 2001) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 89 FR 54435 (July 1, 2024).

[3] *See* Cleveland-Cliffs Inc.'s Letter, ''Notice of Intent to Participate in Sunset Reviews,'' dated July 15, 2024; *see also* Nucor Corporation's Letter, ''Notice of Intent to Participate in Sunset Review,'' dated July 15, 2024; *see also* United States Steel Corporation's Letter, ''Notice of Intent to Participate,'' dated July 16, 2024; *see also* Steel Dynamics, Inc. and SSAB Enterprises, LLC's Letter, ''Notice of Intent to Participate,'' dated July 16, 2024.

[4] *See* Domestic Interested Parties' Letter, ''Domestic Industry Substantive Response,'' dated July 31, 2024.

[5] *See* Commerce's Letter, ''Sunset Reviews for July 2024,'' dated August 21, 2024; *see also* 19 CFR 351.218(e)(1)(ii)(B)(2); and 19 CFR 351.218 (e)(1)(ii)(C)(2).

Order, see the Issues and Decision Memorandum.[6]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum. A list of topics discussed in the Issues and Decision Memorandum is included in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via the Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c)(1) and 752(b) of the Act, we determine that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Company	Subsidy rate (percent ad valorem)
Steel Industries Public Co. Ltd. (SSI)	2.38
All Others	2.38

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305(a). Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing the final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
  2. Net Countervailable Subsidy Rates Likely to Prevail
  3. Nature of the Subsidy
VI. Final Results of Review
VII. Recommendation

[FR Doc. 2024–26143 Filed 11–8–24; 8:45 am]
BILLING CODE 3510–DS–P

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Fourth Expedited Five-Year Sunset Review of the Countervailing Duty Order on Certain Hot-Rolled Carbon Steel Flat Products from Thailand,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[1] *See Sodium Nitrite from the People's Republic of China: Countervailing Duty Order,* 73 FR 50595 (August 27, 2008) (*Order*).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–926]

Sodium Nitrite From the People's Republic of China: Final Results of Expedited Third Sunset Reviews of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on sodium nitrite from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Mark Hoadley, 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) 482–3148.

SUPPLEMENTARY INFORMATION:

Background

On August 27, 2008, Commerce published the CVD order on sodium nitrite from China.[1] On July 1, 2024, Commerce published the notice of initiation of the third five-year sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On July 10, 2024, Commerce received a timely notice of intent to participate from Chemtrade Chemicals US LLC (domestic interested party) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested party claimed interested party status under section 771(9)(C) of the Act and 19 CFR 351.102(b)(29)(v), as a domestic producer of sodium nitrite.

Commerce received a substantive response from the domestic interested party within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no substantive response from the Government of China or any other interested party in this proceeding.[5] As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), we determined that the respondent interested parties did not provide an adequate response to the notice of initiation and, therefore, Commerce conducted an expedited (120-day) sunset review of the *Order.*

Scope of the Order

The product covered by the *Order* is sodium nitrite from China. For a complete description of the scope of the

[2] *See Initiation of Five-Year (Sunset) Reviews,* 89 FR 54435 (July 1, 2024).

[3] *See* Domestic Interested Party's Letter, ''Sodium Nitrite from China: Notice of Intent to Participate,'' dated July 10, 2024.

[4] *See* Domestic Interested Party's Letter, ''Sodium Nitrite from Germany and China: Substantive Response to Notice of Initiation of Five-Year (Sunset) Reviews of the Antidumping Duty Orders on Imports from China and Germany and the Countervailing Duty Order on Imports from China,'' dated July 31, 2024.

[5] *See* Commerce's Letter, ''Sunset Reviews for February 2024,'' dated March 22, 2024; *see also* 19 CFR 351.218(e)(1)(ii)(B)(2); and 19 CFR 351.218 (e)(1)(ii)(C)(2).

Order, see the Issues and Decision Memorandum.[6]

Analysis of Comments Received

All issues raised in this sunset review are addressed in the Issues and Decision Memorandum. A list of topics discussed in the Issues and Decision Memorandum is included in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via the Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Reviews

Pursuant to sections 751(c)(1) and 752(b) of the Act, we determine that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Company	Subsidy rate (percent)
Shanxi Jiaocheng Hongxing Chemical Co., Ltd	169.01
Tianjin Soda Plant Tianjin Port Free Trade Zone Pan Bohai International Trading Co., Ltd	169.01
All Others	169.01

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under an APO in accordance with 19 CFR 351.305(a). Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing the final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
  2. Net Countervailable Subsidy Rates Likely to Prevail
  3. Nature of the Subsidies
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2024–26122 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited Third Sunset Review of the Countervailing Duty Order on Sodium Nitrite from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–087]

Steel Propane Cylinders From the People's Republic of China: Final Results of the Expedited First Sunset Review of the Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) finds that revocation of the countervailing duty (CVD) order on steel propane cylinders from the People's Republic of China (China) would be likely to lead to continuation or recurrence of countervailable subsidies at the levels indicated in the ''Final Results of the Sunset Review'' section of this notice.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Peter Zukowski, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0189.

SUPPLEMENTARY INFORMATION:

Background

On August 15, 2019, Commerce published the *Order* on steel propane cylinders from China.[1] On July 1, 2024, Commerce published the notice of initiation of the first sunset review of the *Order,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).[2] On July 16, 2024, Commerce received a notice of intent to participate from Worthington Enterprises (the domestic interested party), within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested party claimed interested party status under section 771(9)(C) of the Act as a U.S. producer engaged in the production of steel propane cylinders in the United States.

On July 30, 2024, Commerce received an adequate substantive response from the domestic interested party within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] Commerce did not receive a substantive response from any government or respondent interested party to this proceeding. On August 21, 2024, Commerce notified the U.S. International Trade Commission that it did not receive an adequate substantive response from any respondent interested party.[5] As a result, Commerce conducted an expedited (120-day) sunset review of the *Order,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)(2) and (C)(2).

Scope of the Order

The merchandise covered by this *Order* is steel propane cylinders from China. For a complete description of the

[1] *See Steel Propane Cyinders from the People's Republic of China: Countervailing Duty Order, 84 FR 41700* (August 15, 2019) (*Order*).

[2] *See Initiation of Five-Year (Sunset) Reviews*, 89 FR 54435 (July 1, 2024).

[3] *See* Domestic Interested Party's Letter, ''Domestic Industry's Notice of Intent to Participate,'' dated July 16, 2024.

[4] *See* Domestic Interested Party's Letter, ''Domestic Industry's Substantive Response,'' dated July 30, 2024.

[5] *See* Memorandum, ''Case Number Correction on 50 Day Letter,'' dated October 15, 2024, at attachment.

scope of the *Order, see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

A complete discussion of all issues raised in this sunset review, including the likelihood of continuation or recurrence of subsidization in the event of revocation of the *Order* and the countervailable subsidy rates likely to prevail if the *Order* were to be revoked, is provided in the Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is attached as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov*. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Review

Pursuant to sections 751(c) and 752(b) of the Act, we determine that revocation of the *Order* would be likely to lead to continuation or recurrence of countervailable subsidies at the following net countervailable subsidy rates:

Producers/exporters	Net countervailable subsidy rate (percent ad valorem)
Guangzhou Lion Cylinders Co. Ltd	142.37
Hubei Daly LPG Cylinder Manufacturer Co. Ltd	142.37
Shandong Huanri Group Co. Ltd	37.91
Taishan Machinery Factory Ltd	142.37
TPA Metals and Machinery (SZ) Co. Ltd	142.37
Wuyi Xilinde Machinery Manufacture Co., Ltd	142.37
Zhejiang Jucheng Steel Cylinder Co., Ltd	142.37
All Others	37.91

Administrative Protective Order (APO)

This notice serves as the only reminder to parties subject to an APO of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act, and 19 CFR 351.218.

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. History of the *Order*
V. Legal Framework
VI. Discussion of the Issues
1. Likelihood of Continuation or Recurrence of a Countervailable Subsidy
2. Net Countervailable Subsidy Rates Likely to Prevail
3. Nature of the Subsidies
VII. Final Results of Sunset Review
VIII. Recommendation

[FR Doc. 2024–26121 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979, C–570–980]

Antidumping and Countervailing Duty Orders on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Notice of Amended Final Affirmative Determination of Circumvention Pursuant to Settlement Agreement

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Pursuant to a settlement agreement with Red Sun Energy Long An Company Limited (Red Sun), the U.S. Department of Commerce (Commerce) is amending its final affirmative determination that Vietnamese Cells and Modules are circumventing the antidumping duty (AD) and countervailing duty (CVD) orders on crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells and modules), from the People's Republic of China (China).

DATES: Applicable November 12, 2024.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Expedited First Sunset Review of the Countervailing Duty Order on Steel Propane Cylinders from the People's Republic of China,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

FOR FURTHER INFORMATION CONTACT: Howard Smith, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5193.

SUPPLEMENTARY INFORMATION:

Background

On August 23, 2023, Commerce published its final affirmative determinations of circumvention of the AD and CVD orders on solar cells and modules from China.[1] In the *Final Circumvention Determinations,* Commerce based its decision regarding Red Sun [2] on adverse facts available (AFA) and, with the exception of the ''Applicable Entries'' certification, precluded importers and exporters from using the certifications that Commerce developed in the circumvention inquiry with respect to Red Sun's solar cells and modules.[3]

Following publication of the *Final Circumvention Determinations,* Red Sun filed a lawsuit with the U.S. Court of International Trade (CIT) challenging Commerce's determination to apply AFA to Red Sun and preclude certain certifications from being used with respect to entries of Red Sun's solar cells and modules. On October 29, 2024, the United States and Red Sun entered into an agreement to settle and resolve all claims raised in Red Sun's complaint. Pursuant to the terms of the settlement and the stipulation for entry of judgment, Commerce is removing Red Sun from the list of companies in Appendix II of the *Final Circumvention Determinations* for which parties may not file the certifications that are in Appendix VI of the *Final Circumvention Determinations.* The CIT issued its order of judgment by stipulation on November 1, 2024.[4]

Consistent with the settlement agreement and the November 1, 2024, order of judgment by stipulation, Commerce will notify U.S. Customs and Border Protection (CBP) that it has removed Red Sun from the list of companies for which parties may not file the certifications that are in Appendix VI of the *Final Circumvention Determinations.* Specifically, Commerce will instruct CBP that importers and exporters are permitted to use the certifications that are in Appendix VI of the *Final Circumvention Determinations* with respect to Red Sun's inquiry merchandise that is entered into the United States, or withdrawn from warehouse, for consumption, on or after April 1, 2022, the date of initiation of the circumvention inquiry.

Specifically, for Red Sun's inquiry merchandise that was entered into the United States, or withdrawn from warehouse, for consumption during the period April 1, 2022, through the date that is two weeks after publication of this notice of amended final determinations in the **Federal Register**, where the entry has not been liquidated (and entries for which liquidation has not become final), importers should complete, sign, and date the Appendix VI importer certification, if applicable, and exporters should complete, sign, and date the Appendix VI exporter certification, if applicable, and provide a copy of the exporter certification to the importer, no later than 45 days after the date of publication of this notice of amended final determinations in the **Federal Register**. Importers and exporters each have the option to complete an Appendix VI certification covering multiple entries, individual Appendix VI certifications for each entry, or a combination thereof.

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, it 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.

For Red Sun's inquiry merchandise that was entered into the United States, or withdrawn from warehouse, for consumption, after the date that is two weeks after publication of this notice of amended final determinations in the **Federal Register**, the importer should complete, sign, and date the Appendix VI importer certification, if applicable, on, or prior to, the date of the entry summary, and the exporter should complete, sign, and date the Appendix VI exporter certification, if applicable, and provide a copy of the exporter certification to the importer, on, or prior to, the date of shipment.

Notification to Interested Parties

We are issuing, and publishing notice of, this amended determination in accordance with section 516a(e) of the Tariff Act of 1930, as amended.

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2024–26141 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Antidumping and Countervailing Duty Orders on Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Final Scope Determination and Final Affirmative Determinations of Circumvention With Respect to Cambodia, Malaysia, Thailand, and Vietnam,* 88 FR 57419 (August 23, 2023) (*Final Circumvention Determinations*).

[2] In the circumvention inquiry, Commerce referred to the company as Red Sun Energy Co., Ltd. *See* Red Sun's Letter ''Request for a Public Hearing'' dated January 6, 2023, at 1 (''. . . Red Sun Energy Long An Co., Ltd. (also known as, Red Sun Energy Co., Ltd.) . . .'').

[3] See *Final Circumvention Determinations,* 88 FR 57420–21 and Appendix II.

[4] *See* Order of Judgment by Stipulation, ECF No. 47, CIT No. 23–00229 (November 1, 2024).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–028]

Antidumping Duty Order on Hydrofluorocarbon Blends From the People's Republic of China: Final Negative Determination of Circumvention With Respect to R–410B From Mexico

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that imports of R–410B from Mexico, which are completed in Mexico using components originating in the People's Republic of China (China), and further processed in the United States, as specified below, are not circumventing the antidumping duty (AD) order on hydrofluorocarbon (HFC) blends from China.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Ashley Cossaart, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0462.

SUPPLEMENTARY INFORMATION:

Background

On July 2, 2024, Commerce published in the **Federal Register** its *Preliminary Determination* that imports of R–410B completed in Mexico using Chinese-origin HFC components and subsequently exported from Mexico to the United States are not circumventing the *Order* and invited interested parties to comment.[1] On July 22, 2024,

[1] *See Antidumping Duty Order on Hydrofluorocarbon Blends from the People's Republic of China: Preliminary Negative Determination of Circumvention With Respect to R–410B from Mexico,* 89 FR 54768 (July 2, 2024),

Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On August 12, 2024, Commerce postponed the deadline to issue the final determination in this circumvention inquiry by 65 days, until November 5, 2024.[3] We received timely-filed case and rebuttal briefs from IGas Holdings, Inc. and the petitioner.[4]

For a summary of events that occurred since the *Preliminary Determination,* as well as a full discussion of the issues raised by parties for consideration in the final determination, *see* the Issues and Decision Memorandum.[5] The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Scope of the Order [6]

The products subject to the *Order* are HFC blends from China. For a complete description of the scope of the *Order, see* the Issues and Decision Memorandum.

Merchandise Subject to the Circumvention Inquiry

This circumvention inquiry covers imports of R–410B from Mexico, which are completed in Mexico using China-origin HFC components and further processed in the United States (inquiry merchandise).

Methodology

Commerce conducted this circumvention inquiry in accordance with section 781(a) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.226. We made no changes to our methodology in the final determination. Therefore, for a complete description of the methodology underlying this circumvention inquiry, *see* the *Preliminary Determination.*

Analysis of Comments Received

All issues raised in this inquiry are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as an appendix. Based on our analysis of the comments received, we made no changes to the *Preliminary Determination.*

Final Circumvention Determination

Pursuant to section 781(a) of the Act, Commerce determines that R–410B from Mexico, completed in Mexico using HFC components from China, that is further processed in the United States, is not circumventing the *Order.* As a result, in accordance with section 781(a) of the Act, we determine that the inquiry merchandise should not be included within the scope of the *Order.*

Suspension of Liquidation and Cash Deposit Requirements

Pursuant to 19 CFR 351.226(l)(4), Commerce will order U.S. Customs and Border Protection to terminate the suspension of liquidation and refund cash deposits for any imports of inquiry merchandise that are suspended pursuant to this circumvention inquiry.

Administrative Protective Order

This notice will serve as the only reminder to all parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

This determination is issued and published in accordance with section 781(a) of the Act and 19 CFR 351.226(g)(2).

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of the Issues
Comment 1: Whether Commerce Should Continue to Reach a Negative Determination
Comment 2: Whether to Impose an End-Use Certification Requirement for Future Imports
Comment 3: Whether to Require IGas Holdings, Inc. (IGas Holdings) to Certify That it is Not Reblending or Reselling R–410B from Mexico
V. Recommendation

[FR Doc. 2024–26176 Filed 11–8–24; 8:45 am]

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(*Preliminary Determination*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See* Memorandum, ''Extension of Final Determination in Circumvention Inquiry,'' dated August 12, 2024.

[4] The petitioner is the American HFC Coalition, which consists of individual members Arkema, Inc., The Chemours Company FC LLC, Honeywell International Inc., and Mexichem Fluor Inc.

[5] *See* Memorandum, ''Issues and Decision Memorandum for the Circumvention Inquiry of the Antidumping Duty Order on Hydrofluorocarbon Blends from the People's Republic of China with Respect to Imports of R–410B from Mexico,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[6] *See Hydrofluorocarbon Blends from the People's Republic of China: Antidumping Duty Order,* 81 FR 55436 (August 19, 2016) (*Order*).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–533–820; A–560–812; A–570–865; A–583–835; A–549–817; A–823–811]

Certain Hot-Rolled Carbon Steel Flat Products from India, Indonesia, the People's Republic of China, Taiwan, Thailand, and Ukraine: Final Results of Expedited Fourth Sunset Reviews of the Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of these expedited sunset reviews, the U.S. Department of Commerce (Commerce) finds that revocation of the antidumping duty orders on certain hot-rolled carbon steel flat products from India, Indonesia, the People's Republic of China (China), Taiwan, Thailand, and Ukraine would be likely to lead to continuation or recurrence of dumping. The magnitude of the dumping margins likely to prevail are indicated in the ''Final Results of Sunset Review'' section of this notice.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Yang Jin Chun, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone (202) 482–5760.

SUPPLEMENTARY INFORMATION:

Background

In 2001, Commerce published in the **Federal Register** the orders with respect to certain hot-rolled carbon steel flat products from India, Indonesia, China, Taiwan, Thailand, and Ukraine.[1] On

[1] *See Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Certain Hot-Rolled Carbon Steel Flat Products from India,* 66 FR 60194 (December 3, 2001); *Antidumping Duty Order: Certain Hot-Rolled Carbon Steel Flat Products from Indonesia,* 66 FR 60192 (December 3, 2001); *Notice of Antidumping Duty Order: Certain Hot Rolled*

Continued

July 1, 2024, Commerce published the notice of initiation of the fourth sunset reviews of the *Orders* on certain hot-rolled carbon steel flat products from India, Indonesia, China, Taiwan, Thailand, and Ukraine, in accordance with section 751(c) of the Tariff Act of 1930, as amended (the Act).[2]

On July 15, 2024, Commerce received notices of intent to participate in these sunset reviews from Nucor Corporation; Cleveland-Cliffs Inc; United States Steel Corporation; SSAB Enterprises LLC; and Steel Dynamics, Inc. (collectively, the domestic interested parties) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] The domestic interested parties claimed interested party status under section 771(9)(C) of the Act, as manufacturers, producers, or wholesalers of a domestic like product in the United States. On July 31, 2024, Commerce received complete substantive responses to the *Initiation Notice* from the domestic interested parties within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] Commerce received no substantive responses from respondent interested parties. As a result, Commerce conducted the expedited (120-day) sunset reviews of these *Orders* in accordance with section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2). On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[5] The current deadline for these final results of sunset reviews is November 5, 2024.

Scope of the Orders

The merchandise subject to the *Orders* is certain hot-rolled carbon steel flat products. For a complete description of the products covered, *see* the Issues and Decision Memorandum.[6]

Analysis of Comments Received

All issues raised in these sunset reviews, including the likelihood of continuation or recurrence of dumping in the event of revocation of the *Orders* and the magnitude of the margins of dumping likely to prevail if the *Orders* were to be revoked, are addressed in the accompanying Issues and Decision Memorandum. A list of the topics discussed in the Issues and Decision Memorandum is included in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Final Results of Sunset Reviews

Pursuant to sections 751(c)(1) and 752(c)(1) and (3) of the Act, Commerce determines that revocation of the *Orders* would likely lead to continuation or recurrence of dumping. We determine that the magnitude of the dumping margins likely to prevail are up to the following percents:

Country	Weighted-average dumping margin (percent)
India	44.40
Indonesia	47.86
China	90.83
Taiwan	29.14
Thailand	20.30
Ukraine	90.33

Administrative Protective Order

This notice serves as the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

We are issuing and publishing these results and notice in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2) and 19 CFR 351.221(c)(5)(ii).

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Orders*
IV. History of the *Orders*
V. Legal Framework
VI. Discussion of the Issues
  1. Likelihood of Continuation or Recurrence of Dumping
  2. Magnitude of the Dumping Margins Likely to Prevail
VII. Final Results of Sunset Reviews
VIII. Recommendation

[FR Doc. 2024–26142 Filed 11–8–24; 8:45 am]

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Carbon Steel Flat Products from the People's Republic of China, 66 FR 59561 (November 29, 2001); *Notice of Antidumping Duty Order; Certain Hot-Rolled Carbon Steel Flat Products from Taiwan,* 66 FR 59563 (November 29, 2001); *Antidumping Duty Order: Certain Hot-Rolled Carbon Steel Flat Products from Thailand,* 66 FR 59562 (November 29, 2001); and *Antidumping Duty Order: Certain Hot-Rolled Carbon Steel Flat Products from Ukraine,* 66 FR 59559 (November 29, 2001) (collectively, *Orders*).

[2] *See Initiation of Five-Year (Sunset) Reviews,* 89 FR 54435 (July 1, 2024) (*Initiation Notice*).

[3] *See* Cleveland-Cliffs Inc.'s Letter, ''Notice of Intent to Participate in Sunset Reviews,'' dated July 15, 2024, Nucor Corporation's Letter, ''Notice of Intent to Participate in Sunset Reviews,'' dated July 15, 2024, United States Steel Corporation's Letter, ''Notice of Intent to Participate,'' dated July 16, 2024, and SSAB Enterprises LLC; and Steel Dynamics, Inc.'s Letter, ''Notice of Intent to Participate,'' dated July 16, 2024.

[4] *See* Domestic Interested Parties' Letters, ''Substantive Response'' dated July 31, 2024.

[5] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[6] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of Expedited Fourth Sunset Reviews of the Antidumping Duty Orders on Certain Hot-Rolled Carbon Steel Flat Products from India, Indonesia, the People's Republic of China, Taiwan, Thailand, and Ukraine,'' dated concurrently with and hereby adopted by this notice.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–053]

Certain Aluminum Foil From People's Republic of China: Final Results of Antidumping Duty Administrative Review, Final Determination of No Shipments, and Rescission of Review, in Part; 2022–2023

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that certain producers and/or exporters made sales of certain aluminum foil (aluminum foil) at less than normal value during the period of review (POR), April 1, 2022, through March 31, 2023. Additionally, Commerce is rescinding this administrative review with respect to one company.

DATES: Applicable November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Michael J. Heaney, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4475.

SUPPLEMENTARY INFORMATION:

Background

On May 2, 2024, Commerce published the *Preliminary Results* and invited interested parties to comment.[1] On July 22, 2024, Commerce tolled certain deadlines in this administrative proceeding by seven days.[2] On August 9, 2024, we extended the deadline for these final results until November 5, 2024.[3] For a full summary of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[4] Commerce conducted this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [5]

The merchandise covered by the *Order* is aluminum foil from China. For a complete description of the scope, *see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum and are listed in Appendix I. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be found at *https://access.trade.gov/public/FRNotices ListLayout.aspx.*

Rescission of Review, in Part

In the *Preliminary Results,* Commerce preliminarily determined that SK Global America, Inc. (SK Global) was not eligible for a separate rate because it was not a producer or exporter of subject merchandise.[6] However, because SK Global is located in the United States,[7] we find that an administrative review should not have been initiated for SK Global. Accordingly, we are rescinding this review with respect to SK Global.[8]

Changes From the Preliminary Results

Based on our analysis of the comments received from interested parties, we made certain changes to the margin calculations for: (1) Dingsheng Aluminium Industries (Hong Kong) Trading Co., Limited (Dingsheng Aluminium Industries (Hong Kong) Trading Co., Ltd.); Hangzhou Dingsheng Import & Export Co., Ltd. (Hangzhou Dingsheng Import and Export Co., Ltd.); Hangzhou Five Star Aluminium Co., Ltd.; Hangzhou Teemful Aluminium Co., Ltd.; Inner Mongolia Liansheng New Energy Material Co., Ltd.; and Inner Mongolia Xinxing New Energy Material Co., Ltd. (collectively, Dingsheng); and (2) Jiangsu Zhongji Lamination Materials Co., (HK) Limited, Jiangsu Zhongji Lamination Materials Stock Co., Ltd., Jiangsu Huafeng Aluminium Industry Co., Ltd., Jiangsu Zhongji Lamination Materials Co., Ltd. (collectively Zhongji).[9] Additionally, we made changes to the separate rate eligibility determination for Lotte Aluminium Co., Ltd. (Lotte).[10] For a discussion of these changes, *see* the Issues and Decision Memorandum.

Final Determination of No Shipments

In the *Preliminary Results,* we preliminarily determined that Anhui Zhongji Battery Foil Science & Technology Co., Ltd. (Anhui Zhongji), Anhui Maximum Aluminum Industries Company Ltd. (Anhui Maximum), Manakin Industries, LLC (Manakin), and Xiamen Xiashun Aluminium Foil Co., Ltd. (Xiashun) did not have any shipments of subject merchandise to the United States during the POR. We received no information to contradict this determination. Therefore, we continue to find that Anhui Zhongji, Anhui Maximum, Manakin, and Xiashun had no shipments of subject merchandise during the POR and will issue appropriate liquidation instructions that are consistent with our ''automatic assessment'' clarification for these final results.

Separate Rates

In the *Preliminary Results,* we determined that the following companies demonstrated their eligibility for a separate rate: (1) Dingsheng; (2) Zhongji; (3) Dong-IL Aluminium Co., Ltd. (Dong-IL); (4) Dongwon Systems Corp. (Dongwon); (5) Eastern Valley Co., Ltd. (Eastern Valley); (6) Granges Aluminum (Shanghai) Co., Ltd. (Granges Aluminum); (7) Shanghai Shenyan Packaging Materials Co., Ltd. (Shanghai Shenyan); (8) Suzhou Manakin Aluminum Processing Technology Co., Ltd. (Suzhou Manakin Aluminum); and (9) Suzhou Manakin Trading Co., Ltd. (Suzhou Manakin Trading).[11] For these final results, we continue to determine that the companies listed above are eligible for a separate rate, and that 15 companies [12] are ineligible for a separate rate. Additionally, for these final results, we also find that Lotte is eligible for a separate rate.[13]

The China-Wide Entity

In accordance with Commerce's policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the China-wide entity.[14] Because no party requested a review of the China-wide entity, and Commerce did not self-initiate a review of the entity, the China-wide entity is not under review, and the weighted-average dumping margin for the China-wide entity (*i.e.,* 105.80 percent) is not subject to change.[15] Because 15 companies did not demonstrate their eligibility for a separate rate, we continue to determine the 15 companies to be part of the China-wide entity, and they will be subject to the China-wide entity rate.[16]

[1] *See Certain Aluminum Foil from People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review, Partial Rescission of Antidumping Duty Administrative Review, and Preliminary Determination of No Shipments; 2022–2023,* 89 FR 35801 (May 2, 2024) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Tolling of Deadlines for Antidumping and Countervailing Duty Proceedings,'' dated July 22, 2024.

[3] *See* Memorandum, ''Extension of Time Limit for Final Results of Antidumping Duty Administrative Review, 2022–2023,'' dated August 9, 2024.

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Antidumping Duty Administrative Review of Certain Aluminum Foil from the People's Republic of China; 2022–2023,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] *See Certain Aluminum Foil from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 83 FR 17362 (April 19, 2018) (*Order*).

[6] *See Preliminary Results* PDM at 12.

[7] *See* SK Global America, Inc.'s Letter, ''Separate Rate Application,'' dated July 31, 2023.

[8] *See* Issues and Decision Memorandum at Comment 11.

[9] *See* Memorandum, ''Dingsheng Final Results Analysis Memorandum,'' dated concurrently with this memorandum.

[10] In the *Preliminary Results,* we stated that we were rescinding the administrative review with respect to Lotte because all requests for review had been withdrawn. *See Preliminary Results,* 89 FR at 35802. However, all requests for review of Lotte were not withdrawn; therefore, Lotte is still under review, and we have considered its separate rate eligibility for these final results.

[11] *See Preliminary Results* PDM at the ''Separate Rate Determinations'' section for more details.

[12] *See* Appendix II of this notice for a complete listing of these companies.

[13] *See* Issues and Decision Memorandum at Comment 10.

[14] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963, 65969–70 (November 4, 2013).

[15] *See Order,* 84 FR at 2814.

[16] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 38021 (June 12, 2023); *see also Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 51271 (August 3, 2023) (which included a previously omitted company, ''Manakin Industries, LLC,'' as a

Continued

For a listing of these companies, *see* Appendix II of this notice.

Final Results of Administrative Review

We determine that the following estimated weighted-average dumping margins exist for the period April 1, 2022, through March 31, 2023:[17]

Exporter	Weighted-average dumping margin (percent)
Dingsheng Aluminium Industries (Hong Kong) Trading Co., Limited (Dingsheng Aluminium Industries (Hong Kong) Trading Co., Ltd.)/Hangzhou Dingsheng Import & Export Co., Ltd. (Hangzhou Dingsheng Import and Export Co., Ltd.)/Hangzhou Five Star Aluminium Co., Ltd./Hangzhou Teemful Aluminium Co., Ltd./Inner Mongolia Liansheng New Energy Material Co./Inner Mongolia Xinxing New Energy Material Co., Ltd	60.61
Jiangsu Zhongji Lamination Materials Co., (HK) Limited/Jiangsu Zhongji Lamination Materials Stock Co., Ltd./Jiangsu Huafeng Aluminium Industry Co., Ltd./Jiangsu Zhongji Lamination Materials Co., Ltd	75.65
Dong-IL Aluminium Co., Ltd	63.25
Dongwon Systems Corp	63.25
Eastern Valley Co., Ltd	63.25
Granges Aluminum (Shanghai) Co., Ltd	63.25
Lotte Aluminium Co., Ltd	63.25
Shanghai Shenyan Packaging Materials Co., Ltd	63.25
Suzhou Manakin Aluminum Processing Technology Co., Ltd	63.25
Suzhou Manakin Trading Co., Ltd	63.25

Disclosure

Pursuant to 19 CFR 351.224(b), we intend to disclose to parties in this proceeding the calculations performed for these final results within five days of the publication of this notice in the **Federal Register**.

Assessment Rates

Commerce has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries in this review, in accordance with section 751(a)(2)(C) of the Act and 19 CFR 351.212(b). We intend to issue assessment instructions to CBP no earlier than 35 days after the date of publication of these final results in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Where Dingsheng and Zhongji reported reliable entered values, we calculated importer- (or customer-) specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer).[18] Where Commerce calculated a weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to that party by the total sales quantity associated with those transactions, Commerce will direct CBP to assess importer- (or customer-) specific assessment rates based on the resulting per-unit rates.[19] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is greater than *de minimis* (*i.e.,* 0.50 percent), Commerce will instruct CBP to collect the appropriate duties at the time of liquidation.[20] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[21]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) for subject merchandise exported by the companies listed above that have separate rates, the cash deposit rate will be the rate established in these final results of review for each exporter as listed above; (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the relevant entries during this review

respondent in this administrative review), stating ''All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below.''

[17] Commerce calculated the rate for non-reviewed respondents using a weighted average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's publicly ranged values for the merchandise under consideration. With two respondents under examination, Commerce normally calculates: (A) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents; (B) a simple average of the estimated weighted-average dumping margins calculated for the examined respondents; and (C) a weighted-average of the estimated weighted-average dumping margins calculated for the examined respondents using each company's publicly ranged U.S. sales values for the merchandise under consideration. Commerce then compares (B) and (C) to (A) and selects the rate closest to (A) as the most appropriate rate for all other producers and exporters. *See, e.g., Ball Bearings and Parts Thereof from France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews, Final Results of Changed-Circumstances Review, and Revocation of an Order in Part,* 75 FR 53661, 53662 (September 1, 2010), and accompanying Issues and Decision Memorandum at Comment 1. As complete publicly ranged sales data were available, Commerce based the all-others rate on the publicly ranged sales data of the mandatory respondents. For a complete analysis of the data, *see* the Non-Reviewed Respondents Calculation Memorandum.

[18] *See* 19 CFR 351.212(b)(1).

[19] *Id.*

[20] *Id.*

[21] *See* 19 CFR 351.106(c)(2).

period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of the countervailing duties.

Administrative Protective Order (APO)

This notice also serves as a reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

These final results of review are issued and published in accordance with sections 751(a) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: November 5, 2024.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Changes to the *Preliminary Results*
V. Discussion of the Issues
  Comment 1: Selection of Surrogate Country
  Comment 2: Surrogate Value (SV) for Dingsheng's Self-Produced Recycled Scrap Input and its By-Product Recycled Aluminum
  Comment 3: Calculation of Zhongji's Factors of Production (FOPs)
  Comment 4: Zhongji's Freight and Movement Distance
  Comment 5: Dingsheng's Freight Costs and Processing Costs in Thailand
  Comment 6: SV for Electricity
  Comment 7: Deduct Additional Expenses Reported for Certain U.S. Sales
  Comment 8: Export-Contingent Countervailing Duty (CVD) Offset
  Comment 9: Double Remedies Adjustment
  Comment 10: Separate Rate for Lotte
  Comment 11: Separate Rate for SK Global America, Inc. (SK Global)
VI. Recommendation

Appendix II

Companies Determined To Be Part of the China-Wide Entity

1. Alcha International Holdings Limited
2. Aluminum Corporation of China Limited
3. Dingheng New Materials Co., Ltd.
4. Henan Mingtai Al. Industrial
5. Hunan Suntown Marketing Limited
6. Jiangsu Dingsheng New Materials Joint-Stock Co., Ltd.
7. SAM–A Aluminum Co., Ltd.
8. Shandong Nanshan Aluminum Co., Ltd.
9. Shanghai Huafon Aluminium Corporation
10. Shanghai Shenhuo Aluminium Foil Co., Ltd
11. Shanghai Sunho Aluminum Foil Co., Ltd.
12. Suntown Technology Group Corporation Limited (Suntown Technology Group Co., Ltd.)
13. Walson (HK) Trading Co., Limited
14. Yinbang Clad Materials Co., Ltd.
15. Zhejiang Yongjie Aluminum Co., Ltd.

[FR Doc. 2024–26167 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–DS–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; Office of Marine and Aviation Operations: Occupational Health, Safety, and Readiness Forms

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 January 13, 2025.

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 0648–0824 in the subject line of your comments. 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 OMAO Policy Program, NOAA, 1315 East West Highway, Silver Spring, MD 20910, MaryBeth Ryan, *omao.policy@noaa.gov* or by phone: 202–656–8310.

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a request for a revision to an approved collection of information.

The National Oceanic and Atmospheric Administration's (NOAA) Office of Marine and Aviation Operations (OMAO) manages and operates NOAA's fleet of 15 research and survey ships and nine specialized environmental data-collecting aircraft. Comprised of civilians and officers of the NOAA Commissioned Officer Corps, OMAO also manages the NOAA Diving Program, NOAA Small Boat Program, and NOAA Uncrewed Systems Operations Center.

The research and survey ships operated, managed, and maintained by OMAO comprise the largest fleet of federal research ships in the nation. Ranging from large oceanographic research vessels capable of exploring the world's deepest ocean, to smaller ships responsible for charting the shallow bays and inlets of the United States, the fleet supports a wide range of marine activities including fisheries surveys, nautical charting, and ocean and climate studies.

NOAA aircraft operate throughout the world providing a wide range of capabilities including hurricane reconnaissance and research, marine mammal and fisheries assessment, and coastal mapping. NOAA aircraft carry scientists and specialized instrument packages to conduct research for NOAA's missions.

Housed within the NOAA Office of Marine and Aviation Operations and staffed by the U.S. Public Health Service (USPHS) Commissioned Corps officers, the Office of Health Services (OHS) is charged with directly supporting all personnel within the National Oceanic and Atmospheric Administration (NOAA).

NOAA medical officers work to maximize deployment readiness and minimize medically related disruptions to fleet, aircraft, and diving operations. OHS programs assess and promote mental and physical readiness within their operational medical discipline. Given the austere and geographically remote operational environments OHS supports, our officers are also responsible for preventing and containing disease in operational environments as subject matter experts in travel medicine. The forms contained in this collection will be used to make medical readiness recommendations for

individuals and to key leadership in operational environments.

The NOAA Health Services Questionnaire NF 57–10–01 is being revised to include supportive questions to document previous sailing dates and clarifying medical information within NF 57–10–01 to ensure OMAO has a complete medical history for all personnel aboard NOAA vessels.

II. Method of Collection

The primary method of collection is electronic, although some hard copies may be mailed or faxed.

III. Data

OMB Control Number: 0648–0824.

Form Number(s): Medical: 57–10–01, 57–10–02, 57–10–05. Safety: 57–17–02, 57–17–09. Small Boat: 57–19–04.

Type of Review: Regular submission [revision to an approved information collection].

Affected Public: Individuals using OMAO platforms and facilities.

Estimated Number of Respondents: 1,515.

Estimated Time per Response: Response time varies based on the form. Forms may take as little as 5 minutes to complete or as long as 30 minutes.

Estimated Total Annual Burden Hours: 537 hours.

Estimated Total Annual Cost to Public: $0. Although some forms may be mailed or faxed, they account for only a handful of submissions annually.

Respondent's Obligation: Required to Obtain or Retain Benefits.

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,

Departmental PRA Clearance Officer, Office of the Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2024–25591 Filed 11–8–24; 8:45 am]

BILLING CODE 3510–12–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–0P]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.*

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–0P.

Dated: November 6, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P

DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

October 19, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 23-0P. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 18-19 of June 26, 2018.

Sincerely,

James A. Hursch
Director

Enclosure:
1. Transmittal

BILLING CODE 6001–FR–C

Transmittal No. 23–0P

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Purchaser:* Government of Spain
(ii) *Sec. 36(b)(1), AECA Transmittal No.:* 18–19
Date: June 26, 2018
Implementing Agency: Navy
(iii) *Description:* On June 26, 2018, Congress was notified by Congressional certification transmittal number 18–19, of the possible sale, under Section 36(b)(1) of the Arms Export Control Act, of five (5) AEGIS Weapons Systems (AWS) MK7, six (6) shipsets Digital Signal Processing, five (5) shipsets AWS Computing Infrastructure MARK 1 MOD 0, five (5) shipsets Operational Readiness Test Systems (ORTS), five (5) shipsets MK 99 MOD 14 Fire Control System, five (5) shipsets MK 41 Baseline VII Vertical Launching Systems (VLS), two (2) All-Up-Round MK 54 Mod 0 lightweight torpedoes, twenty (20) Standard Missile 2 (SM–2) Block IIIB missiles and MK 13 canisters with AN/DKT–71 warhead compatible telemeter. Also included was one (1) S4 AWS computer program, five (5) shipsets Ultra High Frequency (UHF) Satellite Communications (SATCOM), five (5) shipsets AN/SRQ–4 radio terminal sets, five (5) shipsets ordnance handling equipment, five (5) shipsets Selective Availability Anti-Spoofing Modules (SAASM), five (5) shipsets aviation handling and support equipment, five (5) shipsets AN/SLQ–24E Torpedo countermeasures systems, five (5) shipsets LM04 Thru-Hull XBT Launcher and test canisters, one (1) shipset MK 36 MOD 6 Decoy Launching System, five (5) shipsets Link Level COMSEC (LLC) 7M for LINK 22, five (5) shipsets Maintenance Assist Module (MAM) cabinets, five (5) shipsets technical documentation, five (5) shipsets installation support material, special purpose test equipment, system engineering, technical services, on-site vendor assistance, spare parts, systems training, foreign liaison office and staging services necessary to support ship construction and delivery, spare and repair parts, tools and test equipment, support equipment, repair and return support, personnel training

and training equipment, publications and technical documentation, U.S. Government and contractor engineering and logistics support services, and other related elements of logistic and program support. The estimated total cost was $860.4 million. Major Defense Equipment (MDE) constituted $324.4 million of this total.

On June 15, 2020, Congress was notified by Congressional certification transmittal number 20–0G of an additional MDE sale of thirty (30) All-Up-Round MK 54 Lightweight Torpedoes (LWT). The following non-MDE items were also included: MK 54 LWT expendables; MK 54 turnaround kits; MK 54 containers; one (1) MK–695 Torpedo Systems Test Set (TSTS); support equipment including fire control modification platforms and spare parts; torpedo spare parts; training; publications; software; U.S. Government and contractor engineering, technical, and logistics support services and other related elements of logistics and program support. The addition of these items resulted in a net increase in MDE cost of $45 million, resulting in a revised MDE cost of $369.4 million. The total estimated case value increased to $940.4 million.

On June 8, 2022, Congress was notified by Congressional certification transmittal number 22–0G of the MDE replacement of the previously notified two (2) All Up Round MK 54 Mod 0 LWTs with two (2) Exercise MK 54 Mod 0 LWTs. Also included was additional Engineering Technical Assistance for redesign of Radar Signal Processing Group configuration and updates to International Aegis Fire Control Loop design; shipsets of SAASM units and associated spares; COMSEC equipment for use between test sites; and removal of one (1) shipset MK 36 Mod 6 Decoy Launching System. The MDE total value remained $369.4 million; however, the non-MDE estimated value increased from $571 million to $810.6 million. The total estimated case value increased to $1.18 billion.

On February 27, 2023, Congress was notified by Congressional certification transmittal number 22–0W of the MDE inclusion of up to an additional sixty-two (62) SM–2 Block IIIB missiles in tactical and telemetered configurations. Also included were MK 13 canisters; spare parts and associated containers; personal training and training equipment; publications and technical data; U.S. Government and contractor technical assistance; and other related elements of logistics and program support. The addition of these items resulted in a net increase in MDE value of $260 million, resulting in a revised MDE value of $629.4 million. The non-MDE estimated value increased from $810.6 million to $850.6 million. The total estimated case value increased by $300 million to $1.48 billion.

This transmittal notifies: 1) the MDE inclusion of an additional one hundred-ten (110) MK 54 Mod 0 Lightweight Torpedoes (LWT) in the form of conversion kits for the Spanish Navy's MK 46 LWTs; and 2) the replacement of the previously notified additional up to sixty-two (62) SM–2 Block IIIB missiles with up to sixty-two (62) SM–2 Block IIIC missiles. Also included are MK 54 LWT expendables; MK 54 turnaround kits; MK 54 containers; torpedo spare parts; training; logistics support services; air launch accessories; and unclassified and classified publications. The estimated total value of the new items is $181 million. The value of the new MDE items constitutes $75 million of this total, resulting in a revised MDE value of $704.4 million. The estimated non-MDE value will increase by $106 million to $956.6 million. The total estimated case value will increase by $181 million to $1.661 billion.

(iv) *Significance:* The inclusion of this MDE represents an increase in capability over what was previously notified. The proposed amendment will support Spain's Anti-Submarine Warfare (ASW) capability by providing 50 MK 54 Conversion Kits for use with surface ships and 60 Conversion Kits for use on helicopters.

(v) *Justification:* This proposed sale will support the foreign policy and national security of the U.S. by improving the security of a North Atlantic Treaty Organization (NATO) Ally, which is an important force for political stability and economic progress in Europe. It is vital to the U.S. national interest to assist Spain in developing and maintaining a strong and ready self-defense capability.

(vi) *Sensitivity of Technology:*

The SM–2 Block IIIC Active Missile maximizes existing SM–6 Block I active and SM–2 semi-active missile technology to deliver a low cost, medium range dual mode active/semi-active missile. Improvements to the Guidance Section, communications plate and steering control section are planned to address obsolescence.

The Sensitivity of Technology Statement contained in the original notification applies to additional items reported here.

The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

(vii) *Date Report Delivered to Congress:* October 19, 2023

[FR Doc. 2024–26155 Filed 11–8–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Charter Renewal of Department of Defense Federal Advisory Committees—United States Military Academy Board of Visitors, United States Naval Academy Board of Visitors, and Board of Visitors of the United States Air Force Academy

AGENCY: Department of Defense (DoD).

ACTION: Charter renewal of Federal advisory committees.

SUMMARY: The DoD is publishing this notice to announce that it is renewing the charters for the United States Military Academy Board of Visitors, the United States Naval Academy Board of Visitors, and the Board of Visitors of the U.S. Air Force Academy; hereafter referred to as ''the Military Service Academy Boards of Visitors.''

FOR FURTHER INFORMATION CONTACT: Jim Freeman, DoD Advisory Committee Management Officer at *james.d.freeman4.civ@mail.mil,* 703–697–1142.

SUPPLEMENTARY INFORMATION: The charters for the Military Service Academy Boards of Visitors are being renewed in accordance with chapter 10 of title 5, United States Code (U.S.C.) (commonly known as ''the Federal Advisory Committee Act'' or ''FACA''), and 41 Code of **Federal Register** (CFR) 102–3.50(a). The charters and contact information for the Military Service Academy Boards of Visitors Designated Federal Officers (DFO) can be found at *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.*

The mission/scope for the Military Service Academy Boards of Visitors along with its membership requirements are described in 10 U.S.C. 7455, 8468, and 9455. Members of the Military Service Academy Boards of Visitors who are not full-time or permanent part-time Federal civilian officers or employees, or active-duty members of the Uniformed Services are appointed as experts or consultants, pursuant to 5 U.S.C. 3109, to serve as special government employee members. Members of the Military Service Academy Boards of Visitors who are full-time or permanent part-time Federal civilian officers or employees, or active-duty members of the Uniformed Services are designated pursuant to 41

CFR 102–3.130(a), to serve as regular government employee members.

The public or interested organizations may submit written statements about the mission and functions of the Military Service Academy Boards of Visitors. Written statements shall be submitted to the respective DFO and may be submitted at any time or in response to the stated agenda of an announced meeting of a Military Service Academy Boards of Visitors. The respective DFO shall ensure that all written statements are provided to their respective membership for their consideration.

Dated: November 5, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–26106 Filed 11–8–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Renewal of Department of Defense Federal Advisory Committees—Defense Advisory Committee for the Prevention of Sexual Misconduct

AGENCY: Department of Defense (DoD).

ACTION: Renewal of Federal advisory committee.

SUMMARY: The DoD is publishing this notice to announce that it is renewing the Defense Advisory Committee for the Prevention of Sexual Misconduct (DAC–PSM).

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of Defense, 703–697–1142.

SUPPLEMENTARY INFORMATION: The DAC–PSM is being renewed in accordance with chapter 10 of title 5, United States Code (U.S.C.) (commonly referred to as the ''Federal Advisory Committee Act'' or ''FACA'') and 41 Code of Federal Regulations (CFR) chapter 102–3.55(a)(4). The charter and contact information for the DAC–PSM's Designated Federal Officer (DFO) are found at *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.*

Pursuant to subsection 550B(c)(1) of the National Defense Authorization Act for Fiscal Year 2020 (''the NDAA for FY 2020''), the DAC–PSM shall provide independent recommendations on the prevention of sexual assault (including rape, forcible sodomy, other sexual assault, and other sexual misconduct including behaviors on the sexual assault continuum of harm) involving members of the Armed Forces and the policies, programs and practices of each Military Department, each Armed Force, and each Military Service Academy for the prevention of sexual assault. Pursuant to section 535 of the NDAA for FY 2021, ''Military Service Academy'' includes the United States Coast Guard Academy.

In accordance with subsection 550B(b)(1) of the NDAA for FY 2020, the DAC–PSM shall consist of not more than 20 members, appointed, or designated by the Secretary of Defense from among individuals who have expertise appropriate for the work of the DAC–PSM, including at least one individual with each expertise as follows: a. The prevention of sexual assault and behaviors on the sexual assault continuum of harm; b. Adverse behaviors, including the prevention of suicide and the prevention of substance abuse; c. The change of culture of large organizations; or d. Implementation science.

In accordance with subsection 550B(b)(2) of the NDAA for FY 2020, individuals appointed or designated to the DAC–PSM may include individuals with experience in sexual assault prevention efforts of institutions of higher education, public health officials, and such other individuals as the Secretary of Defense considers appropriate. As further described in subsection 550B(b)(3) of the NDAA for FY 2020, no active-duty member of the Armed Forces, as defined by 10 U.S.C. 101(a)(4), shall be appointed or designated as a DAC–PSM member.

DAC–PSM members who are not full-time or permanent part-time Federal civilian officers or employees, or active-duty members of the Uniformed Services, shall be appointed as experts or consultants pursuant to 5 U.S.C. 3109 to serve as special government employee members. DAC–PSM members who are full-time or permanent part-time Federal civilian officers or employees, or active-duty members of the Uniformed Services (excluding the Armed Forces), shall be designated pursuant to 41 CFR 102–3.130(a) to serve as regular government employee members. The DoD Appointing Authority shall appoint the DAC–PSM's leadership from among the membership previously approved to serve on the DAC–PSM in accordance with DoD policy and procedures, for a term of service of one-to-two years, with annual renewal, which shall not exceed the member's approved DAC–PSM appointment or designation.

DAC–PSM members are appointed or designated to exercise their own best judgment on behalf of the DoD, without representing any particular points of view, and to discuss and deliberate in a manner that is free from conflicts of interest. Except for reimbursement of official DAC–PSM-related travel and per diem, DAC–PSM members serve without compensation.

The public or interested organizations may submit written statements to the DAC–PSM about the DAC–PSM's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the DAC–PSM. All written statements shall be submitted to the DFO for the DAC–PSM, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: November 5, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2024–26101 Filed 11–8–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 22–68]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.*

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 22–68, Policy Justification, and Sensitivity of Technology.

Dated: November 6, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P

DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

October 23, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 22-68, concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of the United Kingdom for defense articles and services estimated to cost $957.4 million. We will issue a news release to notify the public of this proposed sale upon delivery of this letter to your office.

Sincerely,

James A. Hursch
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 6001–FR–C

Transmittal No. 22–68

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of the United Kingdom

(ii) *Total Estimated Value:*

Major Defense Equipment *	$950.2 million
Other	$ 7.2 million
Total	$957.4 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Three thousand (3,000) Joint Air-to-Ground Missiles (JAGM), AGM–179A

Non-MDE:

Also included are dummy missiles; technical assistance; publications; integration support; and other related elements of logistics and program support.

(iv) *Military Department:* Army (UK–B–WVD)

(v) *Prior Related Cases, if any:* UK–B–WSO, UK–B–WTX

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None known at this time

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* October 23, 2023

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

United Kingdom—Joint Air-to-Ground Missiles (JAGM)

The Government of the United Kingdom has requested to buy three thousand (3,000) JAGM, AGM–179A. Also included are dummy missiles; technical assistance; publications; integration support; and other related elements of logistics and program support. The total estimated program cost is $957.4 million.

This proposed sale will support the foreign policy goals and national security objectives of the United States (U.S.) by improving the security of a NATO Ally that is a force for political stability and economic progress in Europe.

The proposed sale will improve the United Kingdom's capability to meet current and future threats. The United Kingdom will use the enhanced capability to strengthen its homeland defense and deter regional threats. The United Kingdom will have no difficulty absorbing this equipment and services into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be the Lockheed Martin Corporation, Orlando, FL. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any U.S. Government or contractor representatives to the United Kingdom.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 22–68

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The JAGM all up round (AUR), designated AGM–179A, is an Air-to-Ground Missile (AGM) consisting of a HELLFIRE Romeo (AGM–114R) back-end (*i.e.,* propulsion, warhead, and control sections) mated to a newly designed dual-mode Guidance Section (GS). The dual-mode GS is a combination of Millimeter Wave (MMW) and Semi-Active Laser (SAL) sensors co-axially aligned on a steerable gimbal. The combination of MMW and SAL sensors provide improved Precision Point and Fire-and-Forget capabilities onto a single munition. This combination allows targeting capability against fast moving and stationary targets in countermeasure and/or a battlefield intensive environment, and in low cloud ceiling and adverse weather.

2. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that the United Kingdom can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of the United Kingdom.

[FR Doc. 2024–26154 Filed 11–8–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–0R]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.*

SUPPLEMENTARY INFORMATION: This 36(b)(5)(C) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–0R.

Dated: November 6, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P

DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

October 23, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(5)(C) of the Arms Export Control Act (AECA), as amended, we are forwarding Transmittal No. 23-0R. This notification relates to enhancements or upgrades from the level of sensitivity of technology or capability described in the Section 36(b)(1) AECA certification 20-51 of August 26, 2020.

Sincerely,

James A. Hursch
Director

Enclosure:
1. Transmittal

BILLING CODE 6001–FR–C

Transmittal No. 23–0R

REPORT OF ENHANCEMENT OR UPGRADE OF SENSITIVITY OF TECHNOLOGY OR CAPABILITY (SEC. 36(B)(5)(C), AECA)

(i) *Prospective Purchaser:* Government of the United Kingdom

(ii) *Sec. 36(b)(1), AECA Transmittal No.:* 20–51

Date: August 26, 2020

Military Department: Army

(iii) *Description:* On August 26, 2020, Congress was notified by Congressional certification transmittal number 20–51, of the possible sale, under Section 36(b)(1) of the Arms Export Control Act, of three hundred ninety-five (395) AGM–114R2 Hellfire missiles. Also included was technical assistance, publications, integration support, and other related elements of logistics and program support. The estimated total cost was $46 million. Major Defense Equipment (MDE) constituted $42 million of this total.

This transmittal notifies the inclusion of an additional up to one thousand six hundred five (1,605) AGM–114R2 Hellfire missiles (MDE). Also included are publications, integrated support, and technical assistance. The estimated value of the new MDE items is $216 million, and the estimated value of the new non-MDE items is $20 million. The revised estimated total MDE value is $258 million, and the revised total case value is $282 million.

(iv) *Significance:* The proposed sale will improve the United Kingdom's capability to meet current and future threats by replacing unserviceable and expiring missiles to allow continued efficient operations alongside U.S. forces.

(v) *Justification:* This proposed sale will support the foreign policy goals and national security objectives of the United States by improving the security of a NATO Ally that is a force for political stability and economic progress in Europe.

(vi) *Sensitivity of Technology:* The Sensitivity of Technology Statement contained in the original notification applies to items reported here.

The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

(vii) *Date Report Delivered to Congress:* October 23, 2023

[FR Doc. 2024–26156 Filed 11–8–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–74]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.*

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–74, Policy Justification, and Sensitivity of Technology.

Dated: November 6, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P

DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

October 23, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 23-74, concerning the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Finland for defense articles and services estimated to cost $500 million. We will issue a news release to notify the public of this proposed sale upon delivery of this letter to your office.

Sincerely,

James A. Hursch
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 6001–FR–C

Transmittal No. 23–74

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Finland

(ii) *Total Estimated Value:*

Major Defense Equipment *	$370 million
Other	$130 million
TOTAL	$500 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:*

Major Defense Equipment (MDE):

Up to one hundred fifty (150) AGM-88G Advanced Anti-Radiation Guided Missiles-Extended Range (AARGM-ERs)

Non-MDE:

Also included are Dummy Air Training Missiles (DATM); missile containers; software; training; support equipment; spare and repair parts; publications and technical documentation; transportation; U.S. Government and contractor engineering; technical and logistical support services; and other related elements of logistics and program support.

(iv) *Military Department:* Navy (FI-P-AAW)

(v) *Prior Related Cases, if any:* None

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None known at this time

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* October 23, 2023

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Finland—Advanced Anti-Radiation Guided Missiles-Extended Range (AARGM-ER)

The Government of Finland has requested to buy up to one hundred fifty (150) AGM-88G Advanced Anti-Radiation Guided Missiles-Extended Range (AARGM-ERs). Also included are DATM; missile containers; software; training; support equipment; spare and repair parts; publications and technical documentation; transportation; U.S. Government and contractor engineering; technical and logistical support services; and other related elements of logistics and program support. The estimated total cost is $500 million.

This proposed sale will support the foreign policy and national security of the United States (U.S.) by improving the security of a NATO Ally that is an important force for political stability and economic progress in Europe.

The proposed sale will improve Finland's capability to meet current and future threats by strengthening its self-defense capabilities and ensuring interoperability with U.S. and other allied forces. Finland will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Northrop Grumman Systems, Falls Church, VA. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require the assignment of any additional U.S. Government or contractor representatives to Finland.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 23–74

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AGM-88G Advanced Anti-Radiation Guided Missile Extended Range (AARGM-ER) is a medium-range air-to-ground missile employed for Suppression and/or Destruction of Enemy Air Defenses. The AARGM-ER system is an upgrade to the AARGM, which is an upgrade to the AGM-88 High-Speed Anti-Radiation Missile system. The AARGM-ER incorporates hardware and software modifications to improve AGM-88E AARGM capabilities to extend the range, increase survivability, and enhance effectiveness against future threats.

2. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that Finland can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Finland.

[FR Doc. 2024–26158 Filed 11–8–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 23–58]

Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense (DoD).

ACTION: Arms sales notice.

SUMMARY: The DoD is publishing the unclassified text of an arms sales notification.

FOR FURTHER INFORMATION CONTACT: Pamela Young at (703) 953–6092, *pamela.a.young14.civ@mail.mil,* or *dsca.ncr.rsrcmgmt.list.cns-mbx@mail.mil.*

SUPPLEMENTARY INFORMATION: This 36(b)(1) arms sales notification is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996. The following is a copy of a letter to the Speaker of the House of Representatives with attached Transmittal 23–58, Policy Justification, and Sensitivity of Technology.

Dated: November 6, 2024.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

BILLING CODE 6001–FR–P

DEFENSE SECURITY COOPERATION AGENCY
2800 Defense Pentagon
Washington, DC 20301-2800

October 4, 2023

The Honorable Kevin McCarthy
Speaker of the House
U.S. House of Representatives
H-209, The Capitol
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 23-58, concerning the Army's proposed Letter(s) of Offer and Acceptance to the Government of Spain for defense articles and services estimated to cost $2.8 billion. We will issue a news release to notify the public of this proposed sale upon delivery of this letter to your office.

Sincerely,

James A. Hursch
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology

BILLING CODE 6001–FR–C

Transmittal No. 23–58

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Spain

(ii) *Total Estimated Value:*

Major Defense Equipment *	$1.7 billion
Other	$1.1 billion
Total	$2.8 billion

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* The Government of Spain has requested to buy four (4) PATRIOT Configuration-3+ Modernized Fire Units consisting of:

Major Defense Equipment (MDE):
- Fifty-one (51) PATRIOT Advanced Capability (PAC) 3 Missile Segment Enhanced (MSE) Missiles (includes one (1) Fly-to-Buy Missile)
- Twenty-four (24) PATRIOT M903 Launch Stations
- Four (4) AN/MPQ–65 Radar Sets
- Four (4) AN/MSQ–132 Engagement Control Stations
- Two (2) Information Coordination Central (ICC)
- Eight (8) Antenna Mast Groups
- Four (4) Electrical Power Plants
- Four (4) Energy Power Units

Non-MDE:
- Also included is communications equipment; tools and test equipment; range and test programs; support equipment and services comprising Skids kits,

telemetry kits, generators, publications, and technical documentation; training equipment; spare and repair parts; repair and return; personnel training; New Equipment Training (NET); Technical Assistance Field Team (TAFT) support; Flight Test Support and Targets; United States (U.S.) Government and contractor technical assistance, engineering, and logistics support services; Systems Integration and Checkout (SICO) and Battalion Demonstration; field office support; and other related elements of logistics and program support.

(iv) *Military Department:* Army (SP–B–WBS)

(v) *Prior Related Cases, if any:* SP–B–WBM

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* October 4, 2023

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Spain—PATRIOT Configuration-3+ Modernized Fire Units

The Government of Spain has requested to buy four (4) PATRIOT Configuration-3+ Modernized Fire Units consisting of: fifty-one (51) PATRIOT Advanced Capability (PAC) 3 Missile Segment Enhanced (MSE) missiles (includes one (1) Fly-to-Buy missile); twenty-four (24) PATRIOT M903 launch stations; four (4) AN/MPQ–65 radar sets; four (4) AN/MSQ–132 Engagement Control Stations; two (2) Information Coordination Central (ICC); eight (8) Antenna Mast Groups; four (4) Electrical Power Plants; and four (4) Energy Power Units. Also included is communications equipment; tools and test equipment; range and test programs; support equipment and services comprising Skids kits, telemetry kits, generators, publications, and technical documentation; training equipment; spare and repair parts; Repair and Return; personnel training; New Equipment Training (NET); Technical Assistance Field Team (TAFT) support; Flight Test Support and Targets; U.S. Government and contractor technical assistance, engineering, and logistics support services; Systems Integration and Checkout (SICO) and Battalion Demonstration; field office support; and other related elements of logistics and program support. The estimated total cost is $2.8 billion.

This proposed sale will support the foreign policy and national security of the U.S. by improving the security of a NATO ally which is an important force for political stability and economic progress in Europe.

The proposed sale of the PATRIOT missile system will improve Spain's missile defense capability, increase the defensive capabilities of its military, and support its goal of improving national and territorial defense and interoperability with U.S. and NATO forces. Spain will use the PATRIOT to defend its territorial integrity and for regional stability. Spain will have no difficulty absorbing this equipment into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractors will be Raytheon Corporation, Tewksbury, MA, and Lockheed Martin, Dallas, TX. There are no known offset agreements in connection with this potential sale.

Implementation of this proposed sale will require U.S. Government and contractor representatives to travel to Spain for an extended period for system checkout, training, and technical and logistics support.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 23–58

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The PATRIOT Advanced Capability (PAC) 3 Missile Segment Enhanced missile is a small, highly agile, kinetic kill interceptor for defense against tactical ballistic missiles, cruise missiles, and air-breathing threats. The MSE variant of the PAC–3 missile represents the next generation in hit-to-kill interceptors and provides expanded battlespace against evolving threats. The PAC–3 MSE improves upon the original PAC–3 capability with a higher performance solid rocket motor, modified lethality enhancer, more responsive control surfaces, upgraded guidance software, and insensitive munitions improvements.

2. M903 launcher stations are capable of launching the entire family of PATRIOT missiles. All new U.S. launchers are M903 configuration.

3. The highest level of classification of defense articles, components, and services included in this potential sale is SECRET.

4. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

5. A determination has been made that the Government of Spain can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

6. All defense articles and services listed in this transmittal have been authorized for release and export to Spain.

[FR Doc. 2024–26157 Filed 11–8–24; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2024–SCC–0109]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; High School and Beyond 2022 (HS&B:22) First Follow-Up Field Test Data Collection

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before December 12, 2024.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information

Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carrie Clarady, (202) 245–6347.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: High School and Beyond 2022 (HS&B:22) First Follow-up Field Test Data Collection.

OMB Control Number: 1850–0944.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 16,167.

Total Estimated Number of Annual Burden Hours: 32,891.

Abstract: The High School and Beyond Longitudinal Study of 2022 (HS&B:22) is the sixth in a series of longitudinal studies at the high school level conducted by the National Center for Education Statistics (NCES), within the Institute of Education Sciences (IES) of the U.S. Department of Education. HS&B:22 is following a nationally representative sample of ninth grade students from the start of high school in the fall of 2022 to the spring of 2026 when most will be in twelfth grade. The sample will be freshened in 2026 to create a nationally representative sample of twelfth-grade students. A high school transcript collection and additional follow-up data collections beyond high school are also planned.

A field test was conducted in fall 2019 and the first follow-up field test (F1FT) is planned for spring 2024 in preparation for the spring 2026 first follow-up full-scale study (F1FS). This submission is to request approval to conduct the HS&B:22 F1FT collection in the spring of 2024. OMB provided approval for F1FT sampling, tracking, and recruitment in March 2021 (OMB# 1850–0944 v.9).

Part A of this submission presents information on the basic design of HS&B:22. Part B discusses the statistical methods employed. Part C presents justification for the questionnaire content. Appendix A provides the communication materials to be used during state, school district, school, student, and parent F1FT recruitment and data collection activities. Appendix B provides the first follow-up field test data collection instruments.

Dated: November 6, 2024.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2024–26135 Filed 11–8–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Applications for New Awards; Research Training Programs in the Education Sciences

AGENCY: Institute of Education Sciences, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for new awards for fiscal year (FY) 2025 for the Research Training Programs in the Education Sciences Grant Program.

DATES:

Application Package Available: November 14, 2024.

Deadline for Transmittal of Applications: March 7, 2025.

ADDRESSES: For the addresses for obtaining and submitting an application, please refer to our Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at *www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.*

FOR FURTHER INFORMATION CONTACT: Jennifer Schellinger. Telephone: 202–987–0765.

Email: Jennifer.Schellinger@ed.gov.

If you are deaf, hard of hearing, or have a speech disability and wish to access telecommunications relay services, please dial 7–1–1.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

I. Funding Opportunity Description

Purpose of Program: Through the Research Training Programs in the Education Sciences Grant Program, IES aims to prepare individuals to conduct rigorous and relevant education research that advances knowledge within the field and addresses issues important to education policymakers and practitioners.

Assistance Listing Number: 84.305B.

OMB Control Number: 4040–0001.

Competition

The IES National Center for Education Research (NCER) is announcing one competition:

Research Training Programs in the Education Sciences (ALN 84.305B). Under this competition, NCER will consider only applications that address one of the following topics:

- Early Career Development and Mentoring Program for Education Research
- Pathways to the Education Sciences Training Program
  - IES will not accept FY 2025 Pathways Training Program applications that include institutions that received an FY 2021 Pathways Training grant award or served as a partner institution on an FY 2021 Pathways Training grant award.
- Predoctoral Interdisciplinary Research Training Program in the Education Sciences
  - IES will not accept FY 2025 Predoctoral Training Program applications from institutions that received an FY 2020 Predoctoral Training grant award.
- Methods Training for Education Researchers

Application Submission

You may submit one or more than one application to the IES FY 2025 Research Training Programs in the Education Sciences competition so long as you meet the following requirements.

- An institution may submit multiple applications to the Early Career Development and Mentoring Program so long as the Principal Investigator (PI) is different for each application and there is no overlap in mentors.
- An institution may not be the applicant or the partner on more than one application to the Pathways Training Program.
- An institution may not submit an application to the Pathways Training Program, or be a partner on an application, if it is the grantee or partner on an FY 2021 Pathways Training grant award.

• An institution may not submit more than one application to the Predoctoral Training Program.

• An institution may not submit an application to the Predoctoral Training Program if it received an FY 2020 Predoctoral Training grant award.

• An institution may submit multiple applications to the Methods Training Program so long as the applications are substantively different from one another and have no overlap in key personnel.

For the programs that permit multiple applications under the conditions described above, if an institution submits multiple applications that violate any of those conditions, IES will determine whether and which applications will be accepted for review and/or will be eligible for funding. If you submit the same or similar application to IES and to another funding entity within or external to the Department and receive funding for the non-IES application prior to IES scientific peer review of applications, you must withdraw the same or similar application submitted to IES, or IES may otherwise determine you are ineligible to receive an award. If reviews are happening concurrently, IES staff will consult with the other potential funder to determine the degree of overlap and which entity will provide funding if both applications are being considered for funding.

Exemption from Proposed Rulemaking: Under section 191 of the Education Sciences Reform Act, 20 U.S.C. 9581, IES is not subject to section 437(d) of the General Education Provisions Act, 20 U.S.C. 1232(d), and is therefore not required to offer interested parties the opportunity to comment on matters relating to grants.

Program Authority: 20 U.S.C. 9501 *et seq.*

Note: Projects will be awarded and must be operated in a manner consistent with the nondiscrimination requirements contained in Federal civil rights laws.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 77, 81, 82, 84, 86, 97, 98, and 99. In addition, the regulations in 34 CFR part 75 are applicable, except for the provisions in 34 CFR 75.100, 75.101(b), 75.102, 75.103, 75.105, 75.200, 75.201, 75.209, 75.210, 75.211, 75.217(a)–(c), 75.219, 75.220, 75.221, 75.222, 75.230, 75.250, and 75.708. (b) The Office of Management and Budget (OMB) Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Guidance for Federal Financial Assistance in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

Note: The open licensing requirement in 2 CFR 3474.20 does not apply to this competition.

Note: As of October 1, 2024, grant applicants must follow the provisions in the OMB Guidance for Federal Financial Assistance (89 FR 30046, April 22, 2024) when preparing an application. For more information about these regulations please visit: *https://www.cfo.gov/resources-coffa/uniform-guidance/.*

II. Award Information

Types of Awards: Discretionary grants and cooperative agreements.

Fiscal Information: Although Congress has not yet enacted an appropriation for FY 2025, IES is inviting applications for this competition now so that applicants can have adequate time to prepare their applications. The actual level of funding, if any, depends on final congressional action. IES may announce additional competitions later in FY 2025.

Estimated Range of Awards: The size of the awards will depend on the scope of the projects proposed. The estimated range of awards varies by topic:

• $200,000 to $400,000 (total) for the Early Career Development and Mentoring Program for Education Research.

• $800,000 to $1,700,000 (total) for the Pathways Training Program.

• $3,000,000 to $5,000,000 (total) for the Predoctoral Interdisciplinary Research Training Program in the Education Sciences.

• $400,000 to $800,000 (total) for the Methods Training Program.

Maximum Award: The maximum award amount for each topic is set out in the NCER Request for Applications (RFA).

For all IES competitions, applications must include budgets no higher than the relevant maximum award as set out in the relevant RFA. IES will not make an award exceeding the maximum award amount as set out in the relevant RFA.

Estimated Number of Awards: The number of awards made under each topic will depend on the quality of the applications received for that topic and the availability of funds. IES anticipates making between 5 and 10 awards under each topic, except for the Methods Training for Education Sciences topic. IES anticipates making between 3 and 5 awards under the Methods Training topic.

Note: The Department is not bound by any estimates in this notice.

Project Period: The maximum project period varies by topic as follows:

• 4 years for the Early Career Development and Mentoring Program for Education Research.

• 5 years for the Pathways Training Program.

• 5 years for the Predoctoral Interdisciplinary Research Training Program in the Education Sciences.

• 3 years for the Methods Training Program.

III. Eligibility Information

1. *Eligible Applicants:* For the Pathways to the Education Sciences topic, the applicant must either be:

• A minority-serving institution [1] (MSI) located in the territorial United States that confers bachelor's or master's degrees in academic fields relevant to education; or

• An academic institution located in the territorial United States that confers bachelor's or master's degrees in academic fields relevant to education and that partners with an eligible MSI. Any member of the partnership may serve as the grantee.

An institution may not submit an application to the Pathways Training Program, or be a partner on an application, if it is the grantee or partner on an FY 2021 Pathways Training grant award.

For Predoctoral Interdisciplinary Research Training Program in the Education Sciences, the applicant must be an academic institution located in the territorial United States that confers doctoral degrees in academic fields relevant to education. An institution may not submit an application to the Predoctoral Training Program if it received an FY 2020 Predoctoral Training grant award.

For Early Career Development and Mentoring Program for Education Research and Methods Training for Education Researchers, applicants that have the ability and capacity to conduct scientifically valid research are eligible to apply. Eligible applicants include, but are not limited to, nonprofit and for-

[1] For the purpose of this competition, institutions included on the Office of Postsecondary Education's FY 2024 Eligibility Matrix lists of Title III and Title V eligible institutions will be considered MSIs. For more information, see *https://www2.ed.gov/about/offices/list/ope/idues/eligibility.html#el-inst.* Institutions eligible only for the Department's Title III Part A Strengthening Institutions Program (SIP) are not considered MSIs for the purposes of this competition unless they also meet the eligibility requirement for a specific MSI category.

profit organizations and public and private agencies and institutions of higher education, such as colleges and universities.

2. a. *Cost Sharing or Matching:* This competition does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* These programs use an unrestricted indirect cost rate. For more information regarding indirect costs, or to obtain a negotiated indirect cost rate, please see *www2.ed.gov/about/offices/list/ocfo/intro.html.*

3. *Subgrantees:* Under 34 CFR 75.708(b) and (c) a grantee under this competition may award subgrants—to directly carry out project activities described in its application—to the following types of entities: nonprofit and for-profit organizations and public and private agencies and institutions of higher education. The grantee may award subgrants to entities it has identified in an approved application.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to follow the Common Instructions for Applicants to Department of Education Discretionary Grant Programs, published in the **Federal Register** on December 7, 2022 (87 FR 75045) and available at *https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs,* which contain requirements and information on how to submit an application.

2. *Other Information:* Information regarding program and application requirements for the competition can be found in the currently available IES Application Submission Guide and in the RFA, which will be available on or before November 14, 2024, on the IES website at: *https://ies.ed.gov/funding/.* The application packages for this competition will also be available on or before November 14, 2024.

3. *Content and Form of Application Submission:* Requirements concerning the content of an application are contained in the RFA for the specific competition. The forms that must be submitted are in the application package for the specific competition.

4. *Submission Dates and Times:* The deadline date for transmittal of applications is March 7, 2025.

We do not consider an application that does not comply with the deadline requirements.

5. *Intergovernmental Review:* This competition is not subject to Executive Order 12372 and the regulations in 34 CFR part 79.

6. *Funding Restrictions:* We reference regulations outlining funding restrictions in the *Applicable Regulations* section of this notice.

V. Application Review Information

1. *Selection Criteria:* For all of its grant competitions, IES uses selection criteria based on a peer review process that has been approved by the National Board for Education Sciences. The Peer Review Procedures for Grant Applications can be found on the IES website at Office of Science—Peer Review of Grant Applications (*ed.gov*).

For the 84.305B competition, Early Career Development and Mentoring, peer reviewers will evaluate the significance of the application, the quality of the research plan, the quality of the career development plan, the qualifications and experience of the personnel, the resources of the applicant to support the proposed activities, and the quality of the engagement and dissemination plan. These criteria are described in greater detail in the RFA.

For the other training topics competed in this notice, peer reviewers will evaluate the significance of the application, the quality of the research training plan, the qualifications and experience of the personnel, the resources of the applicant to support the proposed activities, and the quality of the engagement and dissemination plan. These criteria are described in greater detail in the RFA.

2. *Review and Selection Process:* We remind potential applicants that in reviewing applications in any discretionary grant competition, IES may consider, under 34 CFR 75.217(d)(3), the past performance of the applicant in carrying out a previous award, such as the applicant's use of funds, achievement of project objectives, compliance with the IES policy regarding public access to research, and compliance with grant conditions. IES may also consider whether the applicant failed to submit a timely performance report or submitted a report of unacceptable quality.

In addition, in making a competitive grant award, IES requires various assurances including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23). Also, IES requires all key personnel on a grant award to have a persistent identifier, such as ORCID iD (Open Researcher and Contributor Identification; *https://orcid.org/*) in place before an award will be made.

3. *Risk Assessment and Specific Conditions:* Consistent with 2 CFR 200.206, before awarding grants under this competition, the Department conducts a review of the risks posed by applicants. Under 2 CFR 200.208, IES may impose specific conditions and, under 2 CFR 3474.10, in appropriate circumstances, high-risk conditions on a grant if the applicant or grantee is not financially stable; has a history of unsatisfactory performance; has a financial or other management system that does not meet the standards in 2 CFR part 200, subpart D; has not fulfilled the conditions of a prior grant; or is otherwise not responsible.

4. *Integrity and Performance System:* If you are selected under this competition to receive an award that over the course of the project period may exceed the simplified acquisition threshold (currently $250,000), under 2 CFR 200.206(a)(2) we must make a judgment about your integrity, business ethics, and record of performance under Federal awards—that is, the risk posed by you as an applicant—before we make an award. In doing so, we must consider any information about you that is in the integrity and performance system (currently referred to as the Federal Awardee Performance and Integrity Information System (FAPIIS)), accessible through the System for Award Management. You may review and comment on any information about yourself that a Federal agency previously entered and that is currently in FAPIIS.

Please note that, if the total value of your currently active grants, cooperative agreements, and procurement contracts from the Federal Government exceeds $10,000,000, the reporting requirements in 2 CFR part 200, Appendix XII, require you to report certain integrity information to FAPIIS semiannually. Please review the requirements in 2 CFR part 200, Appendix XII, if this grant plus all the other Federal funds you receive exceed $10,000,000.

VI. Award Administration Information

1. *Award Notices:* If your application is successful, we notify your U.S. Representative and U.S. Senators and send you a Grant Award Notification (GAN); or we may send you an email containing a link to access an electronic version of your GAN. We also may notify you informally.

If your application is not evaluated or not selected for funding, we notify you.

2. *Administrative and National Policy Requirements:* We identify administrative and national policy

requirements in the application package and reference these and other requirements in the *Applicable Regulations* section of this notice.

We reference the regulations outlining the terms and conditions of an award in the *Applicable Regulations* section of this notice and include these and other specific conditions in the GAN. The GAN also incorporates your approved application as part of your binding commitments under the grant.

3. *Grant Administration:* Applicants should budget for an annual meeting of up to three days for project directors to be held in Washington, DC.

4. *Reporting:* (a) If you apply for a grant under a competition announced in this notice, you must ensure that you have in place the necessary processes and systems to comply with the reporting requirements in 2 CFR part 170 should you receive funding under the competition. This does not apply if you have an exception under 2 CFR 170.110(b).

(b) At the end of your project period, you must submit a final performance report, including financial information, as directed by IES. If you receive a multiyear award, you must submit an annual performance report that provides the most current performance and financial expenditure information as directed by IES under 34 CFR 75.118. IES may also require more frequent performance reports under 34 CFR 75.720(c). For specific requirements on reporting, please go to *www.ed.gov/fund/grant/apply/appforms/appforms.html.*

5. *Performance Measures:* To evaluate the overall success of its education research grant programs, IES annually assesses the percentage of projects that result in peer-reviewed publications and the number of IES-supported interventions with evidence of efficacy in improving learner education outcomes. School readiness outcomes include pre-reading, reading, pre-writing, early mathematics, early science, and social-emotional skills that prepare young children for school. Student academic outcomes include learning and achievement in academic content areas, such as reading, writing, math, and science, as well as outcomes that reflect students' successful progression through the education system, such as course and grade completion; high school graduation; and postsecondary enrollment, progress, and completion. Social and behavioral competencies include social and emotional skills, attitudes, and behaviors that are important to academic and post-academic success. Employment and earnings outcomes include hours of employment, job stability, and wages and benefits, and may be measured in addition to student academic outcomes.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, IES considers, among other things: whether a grantee has made substantial progress in achieving the goals and objectives of the project; whether the grantee has expended funds in a manner that is consistent with its approved application and budget; whether a grantee is in compliance with the IES policy regarding public access to research; and if IES has established performance measurement requirements, whether the grantee has made substantial progress in achieving the performance targets in the grantee's approved application.

In making a continuation award, IES also considers whether the grantee is operating in compliance with the assurances in its approved application, including those applicable to Federal civil rights laws that prohibit discrimination in programs or activities receiving Federal financial assistance from the Department (34 CFR 100.4, 104.5, 106.4, 108.8, and 110.23).

VII. Other Information

Accessible Format: On request to the program contact person listed in **FOR FURTHER INFORMATION CONTACT**, as well as in the relevant RFA and application package, individuals with disabilities can obtain this document and a copy of the RFA 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 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.

Matthew Soldner,

Acting Director, Institute of Education Sciences.

[FR Doc. 2024–26104 Filed 11–8–24; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

International Energy Agency Meetings

AGENCY: Department of Energy.

ACTION: Notice of meetings.

SUMMARY: The Industry Advisory Board (IAB) to the International Energy Agency (IEA) will meet on November 19, 20, 21, 2024, as a hybrid meeting via webinar and in person, in connection with a joint meeting of the IEA's Standing Group on Emergency Questions (SEQ) and the IEA's Standing Group on the Oil Market (SOM) which is scheduled at the same time via webinar.

DATES: November 19, 20, 21, 2024.

ADDRESSES: The location details of the SEQ and SOM webinar meeting are under the control of the IEA Secretariat, located at 9 rue de la Fédération, 75015 Paris, France. The in person meeting will take place at IEA Headquarters, 9 rue de la Fédération, 75015 Paris, France.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Reilly, Assistant General Counsel for International and National Security Programs, Department of Energy, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–5000.

SUPPLEMENTARY INFORMATION: In accordance with section 252(c)(1)(A)(i) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(i)) (EPCA), the following notice of meetings is provided:

A meeting of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held in person and via webinar at the IEA Headquarters, 9 rue de la Fédération, 75015 Paris, commencing at 9:30 a.m., Paris time, on November 19, 2024 and again on November 21, 2024. The purpose of this notice is to permit attendance by representatives of U.S. company members of the IAB at a meeting of the IEA's ERE 2024 Emergency Response Exercise, which is scheduled to be held at the same location on November 19, 2024; and a meeting of the IEA's Standing Group on Emergency Questions (SEQ), which is scheduled to be held at the same location in person

and via webinar on November 21, 2024. The IAB will also hold an online preparatory meeting among company representatives at 2:00 p.m. Paris time on November 14, 2024. The agenda for this preparatory meeting is to review the agendas for the upcoming ERE 2024, SEQ, and SEQ/SOM meetings on November 19–21, 2024.

The agenda of the ERE 2024 meeting is under the control of the IEA. It is expected that the IEA will adopt the following agenda:

1. ERE 2024—Welcome and Opening
2. Emergency response fundamentals
   —IEA oil emergency mechanisms
   —Current oil market risks
   —The importance of communication during a crisis
   —Key assessment factors
3. Crisis scenario discussion
   —Break-out groups
   —Plenary discussion, reports from each team
   —Conclusions of the day

The agenda of the SEQ meeting is under the control of the SEQ. It is expected that the SEQ will adopt the following agenda:

Closed SEQ Session—IEA Member Countries Only
1. Adoption of the Agenda
2. Approval of the Summary Record of the 179th SEQ meeting
3. Stockholding Levels of IEA Member Countries
4. Report on Data Task Force (DTF)
5. ERE 2024—Initial Impressions
6. Proposal on Institutional Structure for Energy Security
7. Mid-term Review of Belgium
8. Emergency and Security Review of Sweden
9. Mid-term Review of Hungary
10. Industry Advisory Board Update
11. Any Other Business
   Schedule of ERRs for 2024/25
   Schedule of SEQ & SOM Meetings for 2025:
   —25–27 March 2025 (tentative)
   —24–26 June 2025 (tentative)
   —18–20 November 2025 (tentative)

A meeting of the Industry Advisory Board (IAB) to the International Energy Agency (IEA) will be held in person and via webinar at the IEA Headquarters, 9 rue de la Fédération, 75015 Paris, commencing at 9:30 a.m., Paris time, on November 20, 2024. The purpose of this notice is to permit attendance by representatives of U.S. company members of the IAB at a joint meeting of the IEA's Standing Group on Emergency Questions (SEQ) and the IEA's Standing Group on the Oil Market (SOM), which is scheduled to be held at the same location in person and via webinar at the same time.

The agenda of the meeting is under the control of the SEQ and the SOM. It is expected that the SEQ and the SOM will adopt the following agenda

Welcome by the Chair
1. Adoption of the Agenda
2. Approval of Summary Record of meeting of 18 June 2024
3. Update on the Current Oil Market Situation
4. European Fuels Outlook—Update on product supply modelling
5. Reports on Recent Oil Market and Policy Developments in IEA member countries
6. Global Hydrogen Review
7. Gas Market Update
8. Renewables Markets Update—Outlook for sustainable fuels
9. World Energy Outlook
10. Energy Technology Perspectives
11. Shipping Update
12. Update on oil data issues in member and non-member countries
13. Update on plans for Summit on the Future of Energy Security
13. Any other business:
Date of next SOM/SEQ meetings: 25–27 March 2025

As provided in section 252(c)(1)(A)(ii) of the Energy Policy and Conservation Act (42 U.S.C. 6272(c)(1)(A)(ii)), the meetings of the IAB are open to representatives of members of the IAB and their counsel; representatives of members of the IEA's Standing Group on Emergency Questions and the IEA's Standing Group on the Oil Markets; representatives of the Departments of Energy, Justice, and State, the Federal Trade Commission, the General Accounting Office, Committees of Congress, the IEA, and the European Commission; and invitees of the IAB, the SEQ, the SOM, or the IEA.

Signing Authority: This document of the Department of Energy was signed on November 6, 2024, by Thomas Reilly, Assistant General Counsel for International and National Security Programs, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 6, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–26147 Filed 11–8–24; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[P–2232–887]

Duke Energy Carolinas, LLC; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Amendment of license to replace gantry cranes with fixed hoists at the Oxford dam.

b. *Project No.:* 2232–887.

c. *Date Filed:* May 3, 2024.

d. *Applicant:* Duke Energy Carolinas, LLC.

e. *Name of Project:* Catawba-Wateree Hydroelectric Project.

f. *Location:* The Oxford development includes Lake Hickory and is located on the Catawba River in Alexander and Catawba counties, North Carolina.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791 (a)–825(r).

h. *Applicant Contact:* Mr. Jeffrey G. Lineberger, Director of Water Strategy and Hydro Licensing, Duke Energy, Mail Code EC–12Q, 526 South Church Street, Charlotte, NC 28202, (704) 382–5942.

i. *FERC Contact:* Mr. Steven Sachs, (202) 502–8666, *Steven.Sachs@ferc.gov.*

j. Deadline for filing comments, motions to intervene, and protests: December 5, 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, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room

1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. The first page of any filing should include the docket number P–2232–887. Comments emailed to Commission staff are not part of the Commission record.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The applicant requests an amendment of license to replace the two mobile gantry cranes used to operate the ten spillway gates at the Oxford dam with ten fixed hoists mounted on a steel superstructure. The applicant also proposes to widen the spillway pier that is nearest the powerhouse, remove a catwalk along the upstream side of the spillway, reinstall the catwalk along the downstream side of the spillway, and install lighting to illuminate a new upper-level catwalk and the relocated lower-level catwalk. The applicant expects construction to take place from March 2025 through the spring of 2028, during which it would keep at least six spillway gates operational at any time. The applicant does not propose to make any changes to Lake Hickory elevations or releases from the dam during or following construction.

l. *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.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. 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.

o. 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.

p. 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: November 5, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–26145 Filed 11–8–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. Each filing may be viewed on the Commission's website at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket Nos.	File date	Presenter or requester
Prohibited:		
1. ER24–2172–000	10–24–2024	FERC Staff.[1]
Exempt:		
1. ER24–2172–000	10–31–2024	Senator Katie Fry Hester.
2. ER24–2172–000, AD24–11–000	11–1–2024	FERC Staff.[2]

[1] Written statement dated 10/16/2024 from Cole Muller, Executive VP of Strategic Ventures Talen Energy Corporation.
[2] Letter from Glenn Davis, Director of Virginia Department of Energy forwarding comments of Virginia State Governor Glenn Youngkin.

Dated: November 5, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–26148 Filed 11–8–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC24–118–000.
Applicants: Shady Hills Power Company, L.L.C.
Description: Response to 10/03/2024, Shady Hills Power Company, L.L.C. request for additional information for Application for Authorization Under Section 203 of the Federal Power Act.
Filed Date: 10/30/24.
Accession Number: 20241030–5283.
Comment Date: 5 p.m. ET 11/20/24.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG25–24–000.
Applicants: 50LW 8me LLC.
Description: 50LW 8me LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.
Filed Date: 11/4/24.
Accession Number: 20241104–5204.
Comment Date: 5 p.m. ET 11/25/24.

Docket Numbers: EG25–25–000.
Applicants: Bluebird Solar LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Status of Bluebird Solar LLC.
Filed Date: 11/5/24.
Accession Number: 20241105–5196.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: EG25–26–000.
Applicants: Seven Flags BESS, LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator Self-Certification of Seven Flags BESS, LLC.
Filed Date: 11/5/24.
Accession Number: 20241105–5199.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: EG25–27–000.
Applicants: Tierra Seca BESS, LLC.
Description: Tierra Seca BESS, LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.
Filed Date: 11/5/24.
Accession Number: 20241105–5201.
Comment Date: 5 p.m. ET 11/26/24.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER13–1992–032; ER23–1120–001; ER24–136–004; ER10–3125–019; ER10–2211–010; ER10–3319–021; ER10–3100–018; ER10–3109–016; ER13–1991–032.
Applicants: Desert Sunlight 250, LLC, Washington County Power, LLC, MPC Generating, LLC, Astoria Energy II LLC, Vandolah Power Company, L.L.C., AL Sandersville, LLC, Sunlight Storage II, LLC, Nevada Cogeneration Associates #1, Desert Sunlight 300, LLC.
Description: Notice of Change in Status of AL Sandersville, LLC, et al.
Filed Date: 10/31/24.
Accession Number: 20241031–5408.
Comment Date: 5 p.m. ET 11/21/24.

Docket Numbers: ER20–1608–003; ER20–1610–005; ER22–1065–005; ER22–1085–002; ER22–2622–004; ER23–842–003; ER23–843–003; ER23–1497–003; ER23–1595–004; ER23–2066–002; ER24–1336–001; ER11–4475–016; ER10–2535–014; ER10–2534–010; ER10–2532–020; ER10–2531–013; ER10–2530–007; ER10–2529–009; ER10–2528–007; ER10–2400–018; ER10–1821–023; ER10–2527–012.
Applicants: Allegheny Ridge Wind Farm, LLC, Goshen Phase II LLC, Blue Canyon Windpower LLC, Aragonne Wind LLC, Buena Vista Energy, LLC, Caprock Wind LLC, Cedar Creek Wind Energy, LLC, Crescent Ridge LLC, Kumeyaay Wind LLC, Mendota Hills, LLC, Rockland Wind Farm LLC, White Wing Ranch North, LLC, Antelope Valley BESS, LLC, LRE Energy Services, LLC, GSG Wind, LLC, Oak Trail Solar, LLC, Big Plain Solar, LLC, Chaparral Springs, LLC, Panorama Wind, LLC, Rabbitbrush Solar, LLC, Lone Tree Wind, LLC, Mountain Breeze Wind, LLC.
Description: Notice of Non-Material Change in Status of Allegheny Ridge Wind Farm, LLC, et al.
Filed Date: 10/31/24.
Accession Number: 20241031–5405.
Comment Date: 5 p.m. ET 11/21/24.

Docket Numbers: ER24–817–003; ER23–2404–004; ER24–1287–001; ER24–1288–001; ER24–1804–002.
Applicants: Clearwater Wind III, LLC, Washington County Solar, LLC, Wadley Solar, LLC, Bronco Plains Wind II, LLC, Babbitt Ranch Energy Center, LLC.
Description: Notice of Change in Status of Babbitt Ranch Energy Center, LLC et al.
Filed Date: 10/31/24.
Accession Number: 20241031–5406.
Comment Date: 5 p.m. ET 11/21/24.

Docket Numbers: ER24–1804–001; ER10–1852–097; ER10–1951–071; ER11–4462–095; ER17–838–069.
Applicants: NextEra Energy Marketing, LLC, NEPM II, LLC, NextEra Energy Services Massachusetts, LLC, Florida Power & Light Company, Clearwater Wind III, LLC.
Description: Notice of Change in Status of Clearwater Wind III, LLC et al.
Filed Date: 10/31/24.
Accession Number: 20241031–5404.
Comment Date: 5 p.m. ET 11/21/24.

Docket Numbers: ER24–2806–000.
Applicants: Prosperity Wind, LLC.
Description: Response to August 19, 2024, Deficiency Letter of Prosperity Wind, LLC.
Filed Date: 11/4/24.
Accession Number: 20241104–5214.
Comment Date: 5 p.m. ET 11/14/24.

Docket Numbers: ER24–3065–002.
Applicants: Prairie Center Energy LLC.
Description: Tariff Amendment: Supplement to Petition for Market-Based Rate Authorization to be effective 10/28/2024.
Filed Date: 11/5/24.
Accession Number: 20241105–5182.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–360–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to WMPA; Service Agreement No. 5729; AF1–021 to be effective 1/5/2025.
Filed Date: 11/5/24.
Accession Number: 20241105–5024.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–361–000.
Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to WMPA, Service Agreement No. 5694; AF1–022 to be effective 1/5/2025.
Filed Date: 11/5/24.
Accession Number: 20241105–5036.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–362–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, SA No. 6307 and ICSA, SA No. 6308; Queue No. AD2–093 to be effective 1/5/2025.
Filed Date: 11/5/24.
Accession Number: 20241105–5040.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–363–000.
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: PowerSouth NITSA Amendment, (Add McVay-Scyrene Temporary DP) to be effective 11/4/2024.
Filed Date: 11/5/24.
Accession Number: 20241105–5041.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–364–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendments to ISA/ICSA, Service Agreement Nos. 6681/6682; AD2–092 to be effective 1/5/2025.
Filed Date: 11/5/24.
Accession Number: 20241105–5050.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–365–000.
Applicants: NorthWestern Corporation.
Description: Tariff Amendment: Cancellation of SA 944—Beartooth Electric Coop., Inc. to be effective 11/6/2024.
Filed Date: 11/5/24.
Accession Number: 20241105–5070.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–366–000.
Applicants: Tucson Electric Power Company.
Description: § 205(d) Rate Filing: Third Amended and Restated Rate Schedule 246 to be effective 11/6/2024.
Filed Date: 11/5/24.
Accession Number: 20241105–5073.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–367–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to WMPA, SA No. 5591; Queue No. AE2–054 (amend) to be effective 1/5/2025.
Filed Date: 11/5/24.
Accession Number: 20241105–5076.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–368–000.
Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2024–11–05_SA 4387 Ameren-USA–SWPA IOA) (DE–PM75–24SW000896) to be effective 1/1/2025.
Filed Date: 11/5/24.
Accession Number: 20241105–5097.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–369–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Original GIA, SA No. 7392; Project Identifier AF2–234 to be effective 10/6/2024.
Filed Date: 11/5/24.
Accession Number: 20241105–5132.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–370–000.
Applicants: Midcontinent Independent System Operator, Inc., American Transmission Company LLC.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2024–11–05_SA 4249 ATC-Vista Sands Solar 1st Rev E&P) (J2185 J2107 J2099) to be effective 1/5/2025.
Filed Date: 11/5/24.
Accession Number: 20241105–5145.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–371–000.
Applicants: Duke Energy Carolinas, LLC.
Description: § 205(d) Rate Filing: DEC-EnergyUnited Revised NITSA SA No. 366 to be effective 12/1/2024.
Filed Date: 11/5/24.
Accession Number: 20241105–5151.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–372–000.
Applicants: Public Service Company of Colorado.
Description: Tariff Amendment: 2024–11–01—PSC—FRMS—GI–2014–6—LGIA Amnd 3—458—NOC to be effective 11/6/2024.
Filed Date: 11/5/24.
Accession Number: 20241105–5171.
Comment Date: 5 p.m. ET 11/26/24

Docket Numbers: ER25–373–000.
Applicants: Public Service Company of Colorado.
Description: Tariff Amendment: 2024–11–01—PSC–GI–2014–6–FRMS-Surplus LGIA-Amnd 2–584–0.2.0 NOC to be effective 11/6/2024.
Filed Date: 11/5/24.
Accession Number: 20241105–5173.
Comment Date: 5 p.m. ET 11/26/24.

Docket Numbers: ER25–374–000.
Applicants: Westlands Transmission Project Owner, LLC.
Description: Baseline eTariff Filing: Notice of Succession & Amended TSAs, etc. to be effective 12/31/9998.
Filed Date: 11/5/24.
Accession Number: 20241105–5188.
Comment Date: 5 p.m. ET 11/26/24.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD25–1–000.
Applicants: North American Electric Reliability Corporation.
Description: Petition of the North American Electric Reliability Corporation for Approval of a New Term ''Inverter-Based Resource'' used in NERC Reliability Standards.
Filed Date: 11/4/24.
Accession Number: 20241104–5219.
Comment Date: 5 p.m. ET 12/4/24.

Docket Numbers: RD25–2–000.
Applicants: North American Electric Reliability Corporation.
Description: Petition of the North American Electric Reliability Corporation for Approval of Proposed Disturbance Monitoring Reliability Standards PRC–028–1 and PRC–002–5.
Filed Date: 11/4/24.
Accession Number: 20241104–5220.
Comment Date: 5 p.m. ET 12/4/24.

Docket Numbers: RD25–3–000.
Applicants: North American Electric Reliability Corporation.
Description: Petition of the North American Electric Reliability Corporation for Approval of Proposed Reliability Standard PRC–030–1.
Filed Date: 11/4/24.
Accession Number: 20241104–5221.
Comment Date: 5 p.m. ET 12/4/24.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For

other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: November 5, 2024.

Carlos D. Clay,

Acting Deputy Secretary.

[FR Doc. 2024–26149 Filed 11–8–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP24–93–000]

Venice Gathering System, LLC; Notice of Scoping Period Requesting Comments on Environmental Issues for the Proposed Venice Gathering System Pipeline Abandonment Project

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental document, that will discuss the environmental impacts of the Venice Gathering System Pipeline Abandonment Project involving construction and operation of facilities by Venice Gathering System, LLC (VGS) in Plaquemines Parish, Louisiana. The Commission will use this environmental document in its decision-making process to determine whether the project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies regarding the project. As part of the National Environmental Policy Act (NEPA) review process, the Commission takes into account concerns the public may have about proposals and the environmental impacts that could result from its action whenever it considers the issuance of an authorizing Order. This gathering of public input is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the environmental document on the important environmental issues. Additional information about the Commission's NEPA process is described below in the NEPA Process and Environmental Document section of this notice.

By this notice, the Commission requests public comments on the scope of issues to address in the environmental document. To ensure that your comments are timely and properly recorded, please submit your comments so that the Commission receives them in Washington, DC on or before 5:00 p.m. Eastern Time on December 5, 2024. Comments may be submitted in written form. Further details on how to submit comments are provided in the Public Participation section of this notice.

Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the environmental document. Commission staff will consider all written comments during the preparation of the environmental document.

If you submitted comments on this project to the Commission before the opening of this docket on March 12, 2024, you will need to file those comments in Docket No. CP24–93–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

Public Participation

There are three methods you can use to submit your comments to the Commission. Please carefully follow these instructions so that your comments are properly recorded. The Commission encourages electronic filing of comments and has staff available to assist you at (866) 208–3676 or *FercOnlineSupport@ferc.gov.*

(1) You can file your comments electronically using the eComment feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. Using eComment is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the eFiling feature, which is located on the Commission's website (*www.ferc.gov*) under the link to FERC Online. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; a comment on a particular project is considered a ''Comment on a Filing''; or

(3) You can file a paper copy of your comments by mailing them to the Commission. Be sure to reference the project docket number (CP24–93–000) on your letter. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Additionally, the Commission offers a free service called eSubscription which makes it easy to stay informed of all issuances and submittals regarding the dockets/projects to which you subscribe. These instant email notifications are the fastest way to receive notification and provide a link to the document files which can reduce the amount of time you spend researching proceedings. Go to *https://www.ferc.gov/ferc-online/overview* to register for eSubscription.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, 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.*

Summary of the Proposed Project

VGS proposes to abandon certain onshore and offshore facilities comprising the Venice Gathering System located onshore in the state of Louisiana and offshore in state and federal waters in the Gulf of Mexico. Specifically, VGS proposes to abandon in-place a total of approximately 121.5 miles of 8-inch to 26-inch-diameter pipeline extending south of Venice Energy Services Company LLC's natural gas processing plant in Plaquemines Parish, Louisiana to offshore federal waters in the Gulf of Mexico in South Timbalier. Block 151 and West Delta Blocks 41 and 72.

The general location of the project facilities is shown in appendix 1.[1]

Land Requirements for Construction

Onshore project activities would be entirely within the existing Targa Terminal where approximately 100 feet of aboveground interconnection pipeline and associated valves would be abandoned by removal. As the pipeline and valves to be removed are aboveground, no ground disturbance would be required.

Approximately 20.4 miles of pipeline to be abandoned is within the coastal zone of Louisiana state waters; however, no ground disturbance in these areas is proposed. Abandonment in-place of the remaining 101.1 miles of pipeline would require a total of approximately 0.1 acre of seafloor disturbance within the existing right-of-way to allow for access to the pipeline via jetting for cutting and plugging at each end.

NEPA Process and the Environmental Document

Any environmental document issued by the Commission will discuss impacts that could occur as a result of the construction and operation of the proposed project under the relevant general resource areas:

- Geology, soils, and sediments;
- water resources and wetlands;
- vegetation and wildlife;
- threatened and endangered species;
- cultural resources;
- land use;
- environmental justice;
- air quality and noise; and
- reliability and safety.

Commission staff will also evaluate reasonable alternatives to the proposed project or portions of the project and make recommendations on how to lessen or avoid impacts on the various resource areas. Your comments will help Commission staff identify and focus on the issues that might have an effect on the human environment and potentially eliminate others from further study and discussion in the environmental document.

Following this scoping period, Commission staff will determine whether to prepare an Environmental Assessment (EA) or an Environmental Impact Statement (EIS). The EA or the EIS will present Commission staff's independent analysis of the issues. If Commission staff prepares an EA, a *Notice of Schedule for the Preparation of an Environmental Assessment* will be issued. The EA may be issued for an allotted public comment period. The Commission would consider timely comments on the EA before making its decision regarding the proposed project. If Commission staff prepares an EIS, a *Notice of Intent to Prepare an EIS/ Notice of Schedule* will be issued, which will open up an additional comment period. Staff will then prepare a draft EIS which will be issued for public comment. Commission staff will consider all timely comments received during the comment period on the draft EIS and revise the document, as necessary, before issuing a final EIS. Any EA or draft and final EIS will be available in electronic format in the public record through eLibrary[2] and the Commission's natural gas environmental documents web page (*https://www.ferc.gov/industries-data/ natural-gas/environment/ environmental-documents*). If eSubscribed, you will receive instant email notification when the environmental document is issued.

With this notice, the Commission is asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate in the preparation of the environmental document.[3] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultation Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, the Commission is using this notice to initiate consultation with the applicable State Historic Preservation Office(s), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project's potential effects on historic properties.[4] The environmental document for this project will document findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list Federal, State, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project and includes a mailing address with their comments. Commission staff will update the environmental mailing list as the analysis proceeds to ensure that Commission notices related to this environmental review are sent to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

If you need to make changes to your name/address, or if you would like to remove your name from the mailing list, please complete one of the following steps:

(1) Send an email to *GasProjectAddressChange@ferc.gov* stating your request. You must include the docket number CP24–93–000 in your request. If you are requesting a change to your address, please be sure to include your name and the correct address. If you are requesting to delete your address from the mailing list, please include your name and address as it appeared on this notice. This email address is unable to accept comments.

OR

(2) Return the attached ''Mailing List Update Form'' (appendix 2).

Additional Information

Additional information about the project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the eLibrary link. Click on the eLibrary link, click on ''General Search'' and enter the docket number in the ''Docket Number'' field. Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at *FercOnlineSupport@ferc.gov* or (866) 208–3676, or for TTY, contact (202) 502–8659. The eLibrary link also provides access to the texts of all formal documents issued by the Commission,

[1] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of the appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary''. For instructions on connecting to eLibrary, refer to the last page of this notice. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

[2] For instructions on connecting to eLibrary, refer to the last page of this notice.

[3] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at title 40, Code of Federal Regulations, § 1501.8.

[4] The Advisory Council on Historic Preservation's regulations are at title 36, Code of Federal Regulations, part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

such as orders, notices, and rulemakings.

Public sessions or site visits will be posted on the Commission's calendar located at *https://www.ferc.gov/news-events/events* along with other related information.

Dated: November 5, 2024.

Debbie-Anne A. Reese,

Secretary.

[FR Doc. 2024–26140 Filed 11–8–24; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Southwestern Power Administration

Integrated System Power Rates

AGENCY: Southwestern Power Administration, DOE.

ACTION: Notice of proposed rate.

SUMMARY: Southwestern Power Administration (Southwestern) proposes to revise the existing Integrated System rate schedules to meet the identified average annual revenue need of $237,821,129, an increase of $44,230,649 (22.8 percent), effective April 1, 2025, through September 30, 2027. Interested persons may review the proposed rate and supporting studies on Southwestern's website, request to participate in a public forum, and submit comments. Southwestern will evaluate all comments received in this process.

DATES: A consultation and comment period will begin November 12, 2024 and end February 10, 2025. Written comments are due on or before February 10, 2025. If requested, a public information and comment forum (Forum) will be held on December 18, 2024, at 9:00 a.m. to no later than 12:00 p.m. Central Standard Time (CST). The Forum will be conducted via Microsoft Teams. Persons desiring to attend the Forum should notify Southwestern by December 11, 2024, at 11:59 p.m. CST, so that a list of Forum participants can be prepared. Requests to attend the Forum should be sent via email to *swparates@swpa.gov* should include the individual's name, address, phone number, entity (if any) they represent, and email address. Persons desiring to speak at the Forum should specify this in their notification to Southwestern; others may speak if time permits.

If Southwestern does not receive a request for a Forum, the Forum will not be held. If a Forum is requested, the Microsoft Teams meeting information will be posted to Southwestern's website.

ADDRESSES: Written comments should be submitted to: Fritha Ohlson, Senior Vice President, Chief Operating Officer, Office of Corporate Operations, Southwestern Power Administration, U.S. Department of Energy, One West Third Street, Tulsa, Oklahoma 74103 or emailed to *swparates@swpa.gov.*

FOR FURTHER INFORMATION CONTACT: Ashley Corker, Director, Division of Resources and Rates, Southwestern Power Administration, U.S. Department of Energy, One West Third Street, Tulsa, Oklahoma 74103, (918) 595–6682, *ashley.corker@swpa.gov.*

SUPPLEMENTARY INFORMATION: Southwestern markets power from 24 multi-purpose reservoir projects with hydroelectric power facilities constructed and operated by the Corps. These projects are located in Arkansas, Missouri, Oklahoma, and Texas. Southwestern's marketing area includes these states plus Kansas and Louisiana. The costs associated with 22 of these 24 hydropower projects are repaid with revenues received under the Integrated System rates. These rates also cover the costs of Southwestern's transmission facilities that consist of 1,381 miles of high-voltage transmission lines, 27 substations, and 46 microwave and VHF radio sites.

On September 30, 2013, the Deputy Secretary of Energy, via Rate Order No. SWPA–66, placed Southwestern's Integrated System rate schedules (P–13, NFTS–13, and EE–13) into effect until September 30, 2017. Subsequently, rate schedule NFTS–13 was renamed to NFTS–13A and rate schedule P–13 was renamed to P–13A and then later to P–13B, in each case with no revenue adjustment.[1] Additionally, all three rate schedules have been extended with no revenue adjustment.[2] Most recently, the Southwestern Administrator extended rate schedules P–13B, NFTS–13A, and EE–13, via Rate Order No. SWPA–85, through September 30, 2025.

The guidelines for preparation of power repayment studies are included in DOE Order No. RA 6120.2, ''Power Marketing Administration Financial Reporting.'' In simple terms, the rate process works as follows. First, Southwestern conducts a Power Repayment Study to determine whether its current revenues are sufficient for Southwestern to meet its repayment obligations. If a revenue shortfall (or surplus) is indicated, Southwestern conducts a revised Power Repayment Study to determine the level of revenue needed. If the revenue change needed to meet Southwestern's repayment obligations is within a small margin of Agency discretion, Southwestern will finalize the Power Repayment Studies for that year and Southwestern's rates will not be adjusted. This is what occurred annually for Southwestern's Integrated System Rates from 2013 until 2023.

If, however, Southwestern's annual Power Repayment Studies indicate a revenue shortfall (or surplus) outside of that small margin of Agency discretion, Southwestern must then engage in a Rate Design Study to inform the Administrator as to what the new proposed rates should be in order to generate the needed revenue. This is what occurred in 2023.

Unlike previous years, Southwestern's 2023 Power Repayment Studies indicated the need for a revenue increase that was substantial enough to impact Southwestern's ability to meet its repayment obligations. The 2023 Power Repayment Studies indicated the need for an increase of $44,230,649 in average annual revenue. Southwestern then engaged in a Rate Design Study to develop rates necessary to generate this additional revenue. The resulting rates are described in the chart.

Part of the total additional revenue identified by the Power Repayment Studies is a need to increase revenues specifically for purchased power and wheeling. The Purchased Power & Wheeling Adder (PPWA) produces revenues which are segregated to cover the cost of power purchased to meet contractual obligations. The PPWA is established to reflect revenues required to meet Southwestern's purchased power and wheeling needs on an average annual basis. The PPWA rate will increase to reflect the increasing average cost of purchasing power over the period as well as the cost of firm transmission to wheel power and energy from two projects, Blakely Mountain and DeGray, from MISO into Southwestern's system. Revenue from the sale of excess energy from Blakely Mountain and DeGray will offset the increase in purchased power and wheeling cost. The Administrator's authority to adjust the PPWA at her or his discretion with the Purchased Power & Wheeling Adder Adjustment (PPWAA) will remain in force.[3] The PPWAA is limited to two adjustments per year not to exceed a total of ±8.7 mills per kilowatt-hour per year. The PPWA will increase to $0.0087 per kilowatt-hour and the PPWAA will

[1] Rate Order Nos. SWPA–71 (January 1, 2017), SWPA–73 (July 15, 2017), SWPA–80 (July 15, 2023)

[2] Rate Order Nos. SWPA–72 (September 13, 2017), SWPA–74 (September 22, 2019), SWPA–77 (August 30, 2021), SWPA–81 (September 20, 2023).

[3] See 138 FERC ¶ 62,199 (2012).

decrease to $0.00 per kilowatt-hour when the proposed rate schedules take effect.

Additionally, the Capacity Overrun and Energy Overrun penalties in the proposed Hydro Peaking Power rate schedule have been updated to be formula rates, which are the greater of the penalties as included in P–13B, or the applicable day-ahead locational marginal price. This change is to ensure that penalties are sufficient to cover the financial impact of unauthorized capacity and energy overruns. The Excess Energy rate schedule has also been converted to a formula rate based on the applicable market rates at the time of sale, rather than a set rate as in EE–13. Like EE–13, the proposed Excess Energy rate schedule does not include a transmission component, as transmission service will be the sole responsibility of the entity purchasing excess energy.

Below is a comparison of the existing and proposed Integrated System rates:

	Existing	Proposed	Change	
	P–13B	P–23	Dollars	Percent
Hydro Peaking Power				
Energy:				
Peaking Energy	$0.0094 /kWh	$0.0128 /kWh	$0.0034	36.2
Supplemental Peaking Energy	$0.0094 /kWh	$0.0128 /kWh	0.0034	36.2
Purchased Power & Wheeling	$0.0059 /kWh	$0.0087 /kWh	0.0028	47.5
Administrator's Discretionary Adder Adjustment—Annual Limit.	+/−$0.0059 /kWh	+/−$0.0087 /kWh	0.0028	47.5
Capacity:				
Grid or 138–161 kV	$4.50 /kW/Mo	$5.30 /kW/Mo	0.80	17.8
Regulation & Frequency Response	$0.07 /kW/Mo	$0.0208 /kW/Mo	(0.0492)	−70.3
Operational Reserves—Spinning	$0.0146 /kW/Mo	$0.0208 /kW/Mo	0.0062	42.5
Operational Reserves—Supplemental	$0.0146 /kW/Mo	$0.0208 /kW/Mo	0.0062	42.5
Energy Imbalance	$0.0 /kW/Mo	$0.0 /kW/Mo	0.0	0.0
Regulation Purchased Adder (load within SWPA BAA)	prorated share of total energy cost.	prorated share of total energy cost.	N/A	N/A
Transformation Service 69 kV & less (applied to usage, not reservation).	$0.46 /kW/Mo	$0.86 /kW/Mo	0.4000	87.0
Non-Federal Transmission & Interconnection Facilities Service				
	NFTS–13A	NFS–23	Dollars	Percent
Firm Point-to-Point Capacity	$1.48 /kW/Mo	$1.15 /kW/Mo	($0.33)	−22.3
Non-Firm Point-to-Point Capacity (80 percent of Firm Point-to-Point).	$1.184 /kW/Mo	$0.92 /kW/Mo	(0.26)	−22.3
Network Integration	$1.48 /kW/Mo	$1.15 /kW/Mo	(0.33)	−22.3
Interconnection Facilities	$1.48 /kW/Mo	$1.15 /kW/Mo	(0.33)	−22.3
Transformation Service 69 kV & less (applied to usage, not reservation).	$0.46 /kW/Mo	$0.86 /kW/Mo	0.40	87.0
Scheduling, System Control, & Dispatch	$0.09 /kW/Mo	$0.17 /kW/Mo	0.08	88.9
Reactive Supply & Voltage Control	$0.04 /kW/Mo	$0.10 /kW/Mo	0.06	150.0
Regulation & Frequency Response	$0.07 /kW/Mo	$0.0208 /kW/Mo	(0.0492)	−70.3
Operational Reserves—Spinning	$0.0146 /kW/Mo	$0.0208 /kW/Mo	0.0062	42.5
Operational Reserves—Supplemental	$0.0146 /kW/Mo	$0.0208 /kW/Mo	0.0062	42.5
Energy Imbalance	$0.0 /kW/Mo	$0.0 /kW/Mo	0.0	0.0
Regulation Purchased Adder (load within SWPA BAA)	prorated share of total energy cost.	prorated share of total energy cost.	N/A	N/A
Excess Energy				
	EE–13	EE–23	Dollars	Percent
Excess Energy	$0.0094 /kWh	formula rate	N/A	N/A

Public Participation

The procedures for public participation are found at title 10, part 903, subpart A of the Code of Federal Regulations (10 CFR part 903). This proposed action is considered a ''Major Rate Adjustment,'' as defined by 10 CFR 903.2(d). As such, in accordance with 10 CFR 903.14, the public consultation and comment period is 90 days. In accordance with 10 CFR 903.15(a) and 903.16(a), Southwestern will hold a Forum for this proposed rate adjustment if requested. Southwestern will review and consider all timely public comments at the conclusion of the consultation and comment period and adjust the proposal as appropriate. The Integrated System rate schedules will then be approved on an interim basis.

Legal Authority

By Delegation Order No. S1–DEL–RATES–2016, effective November 19, 2016, the Secretary of Energy delegated: (1) the authority to develop power and transmission rates to Southwestern's Administrator; (2) the authority to confirm, approve, and place such rates into effect on an interim basis to the Deputy Secretary of Energy; and (3) the authority to confirm, approve, and place into effect on a final basis, or to remand or disapprove such rates, to FERC. By Delegation Order No. S1–DEL–S3–2024, effective August 30, 2024, the Secretary of Energy also delegated the authority to confirm, approve, and place such rates into effect on an interim basis to the

Under Secretary for Infrastructure. By Redelegation Order No. S3–DEL–SWPA1–2023, effective April 10, 2023, the Under Secretary for Infrastructure redelegated the authority to confirm, approve, and place such rates into effect on an interim basis to the Administrator, Southwestern.

Availability of Information

The 2023 Integrated System Power Repayment Studies and the associated Rate Design Study as well as the proposed Integrated System rate schedules are available on Southwestern's website at: *https://www.energy.gov/swpa/rate-schedule-actions.* At the conclusion of the consultation and comment period, Southwestern will post all comments received at the same website location. If a Forum is held, the transcript of the Forum and any other documents introduced during the Forum will also be made available on Southwestern's website.

Environmental Impact

Southwestern is in the process of determining whether an environmental assessment or an environmental impact statement should be prepared or if this action can be categorically excluded from those requirements.[4]

Determination Under Executive Order 12866

Southwestern has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Signing Authority

This document of the Department of Energy was signed on November 6, 2024, by Mike Wech, Administrator for Southwestern Power Administration, pursuant to delegated authority from the Secretary of Energy. That document, with the original signature and date, is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE **Federal Register** Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of DOE. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 6, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–26144 Filed 11–8–24; 8:45 am]

BILLING CODE 6450–01–P

[4] In compliance with the National Environmental Policy Act (NEPA) of 1969, as amended, 42 U.S.C. 4321 through 4347; the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500 through 1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021)

DEPARTMENT OF ENERGY

Western Area Power Administration

Final 2028 Parker-Davis Project Power Marketing Plan and Call for Resource Pool Applications

AGENCY: Western Area Power Administration, Department of Energy (DOE).

ACTION: Notice of final plan and call for resource pool applications.

SUMMARY: The Department of Energy (DOE), Western Area Power Administration (WAPA), Desert Southwest Region (DSW), announces its Final 2028 Parker-Davis Project (P–DP) Power Marketing Plan (Final 2028 Plan) and issues a Call for Resource Pool Applications. This notice responds to comments received on the Proposed 2028 P–DP Power Marketing Plan (Proposed 2028 Plan). The Final 2028 Plan specifies the terms and conditions under which WAPA will market power from P–DP from October 1, 2028, through September 30, 2048. WAPA will offer new contracts for the sale of power to existing contractors and create a resource pool for potential new applicants. Entities who wish to apply for a new allocation of power from WAPA, and who meet the criteria defined in the Final 2028 Plan, must submit a formal application using the Applicant Profile Data (APD) form and must meet the Eligibility Criteria and Allocation Criteria described herein. The General Criteria and Contract Principles set forth in the Final 2028 Plan will apply to new allottees and existing contractors. This Final 2028 Plan supersedes all previous marketing plans for P–DP.

DATES: The Final 2028 Plan will become effective December 12, 2024 to make power allocations and complete the other processes necessary to begin providing service on October 1, 2028. Resource pool applications must be received on or before 5:00 p.m., Mountain Standard Time (MST), on January 31, 2025. WAPA will accept applications using the APD form by email or by certified mail (or its equivalent). Applications sent by regular mail will be accepted if postmarked before January 31, 2025, and received no later than February 5, 2025. WAPA will not consider applications unless they are received by the prescribed dates.

ADDRESSES: Preference entities interested in applying for an allocation of WAPA power may complete the APD form available at *https://www.wapa.gov/about-wapa/regions/dsw/pdpremarketing/* and mail the signed and dated APD form to Ms. Jennifer Henn, Power Marketing Advisor, Desert Southwest Region, Western Area Power Administration, P.O. Box 6457, Phoenix, AZ 85005–6457. APD application forms with an electronic signature (e-signature) may be emailed to *pdp-remarketing@wapa.gov.* If an electronic signature is not available, the signed APD form may be scanned and emailed to the address above, faxed to (602) 605–4663, or mailed it to the address above. All APD forms must be received by WAPA within the time required in the **DATES** section, herein. WAPA will publish a notice of Proposed 2028 Allocations in the **Federal Register** after evaluating all applications.

FOR FURTHER INFORMATION CONTACT: Jennifer Henn, Power Marketing Advisor, Desert Southwest Region, Western Area Power Administration, (602) 605–2572 or email: *pdp-remarketing@wapa.gov.* Information on development of the Final 2028 Plan can be found at *https://www.wapa.gov/about-wapa/regions/dsw/pdpremarketing/.*

SUPPLEMENTARY INFORMATION:

Development of the Final 2028 Plan

P–DP power facilities include Davis Dam, with its current total operating capacity of 255,000 kilowatts (kW) for P–DP and expected increase of approximately 3,750 kW from the rewind of Unit 3, and Parker Dam, with 60,000 kW of operating capacity allotted to P–DP and 60,000 kW allotted to Metropolitan Water District of Southern California. Both dams are owned and operated by the Bureau of Reclamation (Reclamation). WAPA owns and operates approximately 1,500 miles of high voltage transmission lines and 45 substations throughout Arizona, California, and Nevada to facilitate delivery of P–DP power in those three states.

On September 30, 2028, WAPA's existing long-term sales contracts for P–DP power will expire. WAPA began developing the Final 2028 Plan with a series of informal public information meetings for existing and new potential contractors. These meetings helped

WAPA identify pertinent issues to address in the Proposed 2028 Plan. WAPA subsequently published its Proposed 2028 Plan (1) to define the products and services WAPA will offer, and (2) to determine the criteria for marketing and allocating power from October 1, 2028, through September 30, 2048 (89 FR 43841). WAPA held a public information forum on June 20, 2024, to present the Proposed 2028 Plan and answer questions. On July 19, 2024, WAPA held a public comment forum to receive verbal comments. WAPA accepted written comments from the public through the end of the consultation and comment period on August 19, 2024. This notice sets forth WAPA's Final 2028 Plan and responds to comments received on the Proposed 2028 Plan.

Based on comments received, WAPA will: (1) apply the Energy Planning and Management Program (EPAMP) Power Marketing Initiative (PMI) regulations, set forth at 10 CFR 905.30 through 10 CFR 905.37, to the P–DP remarketing effort; (2) extend 98 percent of marketable capacity to existing contractors for a term of 20 years; and (3) use the remaining two percent of marketable capacity for the creation of a resource pool. WAPA will make allocations from the resource pool to eligible preference contractors using the Eligibility Criteria and Allocation Criteria for Resource Pool Allocations described in this notice and under the Final 2028 Plan. The Final 2028 Plan also sets forth General Criteria and Contract Principles that will apply to new allottees and existing contractors. This Final 2028 Plan supersedes all previous marketing plans for this project.

Responses to Comments Received on the Notice of Proposed Plan

During the public consultation and comment period, WAPA received nine letters commenting on the Proposed 2028 Plan. The letters are available on WAPA's website at *https://www.wapa.gov/about-wapa/regions/dsw/pdpremarketing/*. Six contractors and interested stakeholder representatives commented during the July 19, 2024, public comment forum. Transcripts from the public meetings are also available on WAPA's website. In addition, multiple parties requested clarification on the Proposed 2028 Plan during the 90-day public consultation and comment period. WAPA provided clarifying responses to these questions during the consultation and comment period. These responses remain available on WAPA's website at the address above and are not included below.

The following is a summary of the comments received during the consultation and comment period, and WAPA's responses to those comments. Comments are grouped by subject and paraphrased for brevity.

I. Marketing Plan Term

Comment: Two commenters supported the 20-year contract term for the forthcoming marketing period. WAPA received no comments objecting to the 20-year term.

Response: WAPA appreciates the support. The Final 2028 Plan provides for the marketing of P–DP power from October 1, 2028, through September 30, 2048.

II. Products and Services—Quarterly Energy

Background: WAPA proposed to offer energy amounts for three-month periods (''Quarterly Energy'') based on Reclamation's 24-month generation projection studies (''24-Month Study''), which are released every month.

Comment: Three commenters generally supported WAPA's proposed operational changes in response to challenging hydrology and WAPA's efforts to reduce purchase power activities, as such activities had led to accumulated deficits.

Response: WAPA appreciates the support to change the energy delivery methodology. The Final 2028 Plan will align energy deliveries with actual hydropower generation, thereby decreasing the amount of energy WAPA will have to purchase, reducing financial burdens on contractors, and promoting rate stability.

Comment: Two commenters recommended WAPA consider leaving the majority of the details concerning the implementation of the new operational strategy, such as the final process and operational changes related to estimating, committing, and scheduling the hydropower resource, in the contract and Metering and Scheduling Instructions (MSI), rather than including these details in the Final 2028 Plan to allow the most flexibility to amend agreements as conditions change.

Response: WAPA agrees more detailed terms and conditions regarding Quarterly Energy, Optional Energy, Excess Energy, changes to generation forecasts, minimum scheduling requirements, and other products or services will be addressed, as appropriate, in electric service contracts or MSI, which will be incorporated into such contracts as an attachment. WAPA has added additional language to the Final 2028 Plan to align with this recommendation.

Comment: One commenter expressed concern that WAPA is adopting a Quarterly Energy methodology while simultaneously creating a new resource pool. The commenter further stated that creating a Quarterly Energy methodology admits that the P–DP resource cannot sustain the energy deliveries associated with the allocated capacity.

Response: P–DP's fixed contractual obligation methodology for energy delivery imposed financial burdens on contractors in the existing marketing period. As a result, existing contractors have experienced increased P–DP power rates and incurred deficits for purchase power and wheeling (PPW) expenses. WAPA developed the Final 2028 Plan to provide energy deliveries based on actual generation and to reduce such deficits. WAPA believes the Final 2028 Plan constitutes a balanced approach between maximizing the ongoing value of the P–DP resource to existing contractors and encouraging widespread use with a two-percent resource pool.

Comment: One commenter noted that aligning P–DP energy deliveries with the July 2024, 24-Month Study would have resulted in a 17 percent megawatt hour (MWh) average potential reduction over a 12-month period, with the largest reductions occurring during the highest demand and highest price summer peaking months. This commenter requested that WAPA develop a policy to support full availability of P–DP generation capacity during summer from 3–10 p.m. MST when demand is at its highest and solar resources are waning. The commenter also requested operational measures to make generation available during system emergencies or forecasted peak days so that WAPA may have substantial operational flexibility to support regional reliability.

Response: Thank you for this recommendation. WAPA and Reclamation already collaborate to optimize P–DP generation. WAPA will continue those efforts and will approach Reclamation about options to further optimize the resource.

Additionally, the Final 2028 Plan provides for Optional Energy in which a contractor may elect for WAPA to purchase energy on behalf of the contractor to supplement available P–DP energy, up to the contractor's Contract Rate of Delivery (CROD). This product may help contractors meet their energy requirements during high demand hours.

Comment: One commenter expressed concern that Quarterly Energy will affect existing metering and scheduling instructions with its scheduling agent. This entity requested WAPA coordinate with its scheduling agent to ensure any energy delivery changes meet with the agent's approval.

Response: A contractor's entitlement to Quarterly Energy will not be contingent upon approval of a scheduling agent. WAPA is willing to work with the scheduling agent for this contractor, and other contractors as requested, to coordinate Quarterly Energy deliveries.

Comment: Comments expressed support for structuring the P–DP contract more like WAPA's Colorado River Storage Project (CRSP) contracts, with a small replacement power budget to help control future rates. The commenters strongly supported these changes, as they will help mitigate the rate impacts contractors are seeing with the reduction of generation at the dams.

Response: WAPA appreciates the support. Aligning energy deliveries with forecasted generation will mitigate rate impacts and significantly reduce the P–DP purchase power costs.

III. Products and Services—Optional Energy

Comment: One commenter supported the concept of Optional Energy and requested that WAPA develop a plan to meet the commenter's requirements using Optional Energy while minimizing energy purchase costs.

Response: WAPA appreciates the support. WAPA will work with the contractor to provide assistance as requested.

IV. Products and Services—Contractor Use of Transmission

Background: WAPA will allow contractors to use transmission capacity, reserved for delivery of their P–DP firm electric service (FES) allocation, for contractor-owned or contractor-purchased resources. Transmission capacity used for such energy must not exceed a contractor's CROD. As clarified during the public information forum, usage of transmission capacity will be comparable to service under WAPA's Open Access Transmission Tariff (OATT).

Comment: Three commenters supported WAPA's transmission proposal, with one commenter stating that the use of transmission up to CROD is consistent with the use of transmission facilities in other marketing areas.

Response: WAPA appreciates the support.

Comment: One commenter noted that reference to WAPA's OATT suggests divergency from WAPA's traditional practice of pairing an allocation of power with firm transmission rights over WAPA transmission facilities for the delivery of power. WAPA was asked to clarify that such transmission rights remain tied to the allocation and are not severable. Furthermore, the commenter stated the allusion to WAPA's OATT should be clarified to state that firm power customers are not required to separately reserve transmission pursuant to WAPA's OATT. The commenter stated that while WAPA may market transmission capacity excess for the mission of delivering preference power pursuant to the terms and conditions set forth in its safe harbor OATT, the use of transmission capacity associated with the P–DP allocation should remain within WAPA's organic authorities and outside the purview of the Federal Energy Regulatory Commission.

Response: WAPA will continue to utilize existing transmission capacity to deliver energy associated with a contractor's P–DP allocation. Under the Final 2028 Plan, transmission capacity not used by WAPA to deliver a contractor's P–DP allocation will be made available for contractors to deliver contractor-owned or contractor-purchased resources. Contractors will not be required to separately reserve transmission to deliver P–DP energy. When a contractor requests transmission service for contractor-owned or contractor-purchased resources on a transmission path other than that reserved for delivery of P–DP energy, WAPA will study the transmission system to determine availability, comparable to the OATT process for redirecting point-to-point transmission rights.

Comment: A commenter stated that WAPA's decision to create a new resource pool should be delayed until contractors fully understand the impact of how the transmission rights up to CROD are delineated and understood by the contractors.

Response: Transmission capacity used for delivery of contractor-owned or contractor-purchased resources must not exceed a contractor's CROD, regardless of the creation of a resource pool.

V. Application of PMI and Creation of Resource Pool

Background: WAPA proposed to apply the principles of the PMI (10 CFR 905.30–905.37) to P–DP for the forthcoming marketing period. This included a proposal to extend 98 percent of P–DP marketable capacity to existing contractors' CROD and creation of a single, one-time, two-percent resource pool of marketable capacity for new allottees.

Comment: Eight entities provided comments on this proposal. One entity supported the proposal to encourage widespread use. One entity requested a larger resource pool. Two entities opposed creating a resource pool at this time. Four entities preferred no resource pool but supported the small two-percent resource pool to accommodate widespread use. Two of these entities specifically supported WAPA's application of the PMI principles to ensure current contractors continue to receive a substantial amount of their resource. One entity noted its preference that WAPA not create a resource pool, but stated WAPA's proposal of a small, one-time, resource pool appears to be a reasonable compromise to ensure that existing contractors continue to receive most of their existing resources.

Response: WAPA appreciates the feedback.

Comment: One entity opposed using PMI principles because of the significant reduction WAPA is proposing for energy deliveries, along with the impact the capacity reduction may have on this entity's current crediting arrangement.

Response: Application of PMI provides WAPA with a framework for extending a significant portion of existing marketable capacity to existing contractors while also encouraging widespread use. Entities without a Federal hydropower allocation may exist within the P–DP marketing area, and WAPA intends to provide those entities with an opportunity to apply.

The two-percent resource pool will be largely offset by the anticipated addition of capacity from the Davis Dam Unit 3 rewind. Creating a resource pool during drought conditions further reduces energy deliveries to existing contractors. For that reason, WAPA determined to establish a modest resource pool.

WAPA has decided to apply the PMI formula to extend existing contractors' allocation for the Final 2028 Plan consistent with the Proposed 2028 Plan. WAPA recognizes the impact of reducing allocations for existing Tribal contractors with benefit crediting arrangements and is willing to coordinate with scheduling agents, as requested by contractors.

Comment: One commenter opposed reducing existing allocations and recommended creating the resource pool from the additional capacity expected from the rewind of Davis Dam Unit 3 to preserve existing allocations.

The commenter further stated that WAPA markets power consistent with sound business principles and therefore must weigh the benefit of creating small allocations (one kW) versus the cost that may be incurred if existing crediting arrangements are impacted by the withdrawal.

Response: WAPA appreciates the alternative idea. However, WAPA believes that the PMI formula, established through an extensive public process and commonly applied by WAPA in marketing plans across its territory, remains an effective methodology in the context of P–DP. WAPA recognizes the impact of reducing allocations for existing contractors with benefit crediting arrangements and is willing to coordinate with scheduling agents, as requested by contractors.

WAPA recognizes that small allocations may not be cost effective for every potential new contractor because associated energy is currently less than optimal. Each potential contractor will need to evaluate the cost effectiveness of the resource before entering into a contract with WAPA.

WAPA believes its decision to apply PMI and the other components of its Final 2028 Plan are in accordance with its statutory obligation to offer the lowest possible rates consistent with sound business principles.

Comment: A commenter that is not an existing P–DP contractor, but is located in the P–DP marketing area, requested that the resource pool be formed from a larger percentage of current allocations because if numerous or large preference entities apply, it would create an inequity between earlier applying parties who would keep 98 percent of their allocations, and later applying preference entities who would have to share two percent of the project's surplus power.

Response: WAPA interprets this commenter's reference to ''surplus power'' to mean marketable resource from the resource pool. WAPA is sensitive to the current hydrological conditions that exist in the Colorado River Basin. Under the existing P–DP marketing plan, energy allocations are a fixed seasonal amount for the length of contracts, regardless of hydroelectric generation (49 FR 50582, 50587; 68 FR 23709). Due to challenging hydrological conditions in the Colorado River Basin, this methodology imposed financial burdens on existing contractors during the current marketing period, as WAPA has been required to purchase significant amounts of power to meet contractors' firm energy requirements. For the Final 2028 Plan, WAPA will eliminate this methodology and instead offer energy amounts based on hydroelectric generation forecasts. A WAPA analysis using Reclamation's July 2024, 24-Month Study showed an approximate 17 percent reduction to energy deliveries to existing contractors over a 12-month period, with an even greater impact in the summer months when energy in the Southwest is needed most. This analysis was included in WAPA's responses to clarifying questions and can be found on WAPA's website at *https://www.wapa.gov/about-wapa/regions/dsw/pdpremarketing/.*

WAPA had to find a balance between encouraging widespread use and providing valuable energy deliveries. The two-percent resource pool would be largely offset by an anticipated increase in capacity resulting from the rewind of Davis Dam Unit 3. However, that additional capacity will not increase energy deliveries during current hydrological conditions. Because WAPA is sensitive to concerns over challenging hydrological conditions and reduced energy deliveries, it is extending 98 percent of marketable capacity to existing contractors in the Final 2028 Plan. WAPA believes a modest, two-percent resource pool is still a reasonable means of encouraging widespread use.

Comment: One commenter opposed the creation of a resource pool stating that with the loss of roughly 25 percent of energy deliveries since the execution of the last contracts, there is little additional energy for a new resource pool. The commenter stated the impacts to the creation of a new resource pool need to be assessed, and further stated that WAPA is asking existing contractors to make additional sacrifices at a point in time in which DSW has been unable to meet the CROD. The commenter stated that although WAPA indicates that capacity allocations for new contractors will be made from new capacity associated with a turbine rewind, there is an absence of associated energy for a new allocation.

Response: WAPA concurs that challenging hydrological conditions have reduced the energy output of P–DP generators since 2008. To clarify the comment, during the current marketing period, as P–DP energy production decreased, WAPA maintained CROD and associated energy through market purchases. As a result, existing contractors experienced rate increases, but no decrease in energy deliveries. As part of the Final 2028 Plan, contractors will be entitled to energy deliveries based on their pro rata share of projected hydrogeneration. WAPA recognizes the two-percent resource pool impacts existing contractors' CROD and resulting energy delivery. WAPA balanced the marketing of a limited and valuable resource with its obligation to encourage widespread use of the Federal resource. Given recent hydrology, and knowing that potential new contractors may exist, WAPA has decided to create a modest, two-percent resource pool, which some commenters have indicated is small. Marketable capacity is expected to increase with the addition of approximately 3,750 kW from the Davis Dam Unit 3 rewind, which will largely offset the capacity set aside for the resource pool. Energy deliveries are directly attributable to water releases and are constrained by the current hydrological conditions. WAPA assessed the impacts of creating a resource pool, along with changes using the Quarterly Energy methodology. The results are posted on WAPA's website as part of its responses to clarifying questions and show potential P–DP Quarterly Energy projections by contractor, including with the two-percent resource pool, using July 2024, 24-Month Study data.

Comment: A commenter opposed creation of the resource pool at this time because it argued that adopting the Quarterly Energy methodology while simultaneously proposing a new resource pool presents a conflict. According to the commenter, the creation of a Quarterly Energy methodology admits that the P–DP resource cannot sustain the energy deliveries associated with the allocated capacity.

Response: Given challenging hydrology, WAPA designed the Quarterly Energy product to achieve alignment with actual generation and to address the significant costs of purchase power. WAPA chose a modest resource pool size to reflect the reduction in hydrogeneration while encouraging widespread use.

Comment: A commenter explained it opposes creation of a resource pool based on WAPA eliminating the current off peak requirements and instead requiring minimum schedule requirements to coincide with water deliveries. The commenter stated this could lead to purchases at times when the resource is out of the market and at a point in time when it would not be as economic to the contractors to receive the power. With potential loss of value against the decision to create a new resource pool, this commenter suggested that WAPA refrain from creating the new resource pool until the actual impacts associated with the new scheduling regime have been disclosed and discussed with the contractors.

Response: WAPA does not believe there is a direct correlation between the decision to establish a resource pool and minimum scheduling requirements. Furthermore, it is not feasible to delay the resource pool determination.

WAPA is developing a tool to optimize scheduling requirements to reduce WAPA's purchase power requirements and minimize energy sales in low load hours. The tool will create minimum requirements that are based on actual limitations around the resource. The process to develop the tool will take time, but WAPA believes having a collaborative approach and providing contractors the opportunity to help shape the results will provide the best possible outcome. Prior to the execution of contracts for the 2028–2048 marketing period, WAPA will provide examples of methods being considered, seek feedback from existing contractors and potential new allottees, and select which option provides the greatest flexibility and achieves the goals identified in the Final 2028 Plan. Minimum scheduling requirements will be included in the MSI.

Comment: A commenter opposed creation of a resource pool because if WAPA is eliminating the scheduling flexibility and requiring contractors to purchase power at times when it is not economic, WAPA is not following its principle to set rates at the lowest possible rate consistent with sound business principles. The commenter states WAPA is allocating capacity, resources, and energy to new contractors at a time when WAPA does not have the full resources to meet contract rates of delivery, thus creating a situation in which existing allottees are being deprived of the value of the resource. To the extent that WAPA reduces energy allocations, the commenter stated contractors with longstanding allocations are forced to seek higher-cost replacement energy, and the record to date does not explain how promoting widespread use ensures that the power is sold at the lowest possible cost. The commenter also stated that the **Federal Register** notice fails to reconcile this proposed departure from the longstanding policy of keeping rates as low as possible, consistent with sound business principles, with an increased dilution of the resource under the guise of promoting widespread use of the power.

Response: WAPA believes that by changing the minimum scheduling requirements and developing the Quarterly Energy product, WAPA will be marketing power in alignment with its obligation to provide the lowest possible rates consistent with sound business principles, especially given the challenging hydrological conditions in the Colorado River Basin and the agency's obligation to encourage widespread use. Extending the benefit of Federal hydropower to new potential contractors who do not have an existing Federal hydropower allocation encourages widespread use with minimal impact to WAPA's rates.

Comment: A commenter provided further reasoning for opposing the resource pool at this time because there needs to be an understanding in terms of the flexibility of the transmission rights up to CROD, and decisions on creating a new resource pool should also be held until the customers fully understand the impact of how the transmission rights up to CROD are delineated and understood by the customers.

Response: WAPA has defined the transmission use it intends to provide to contractors. WAPA discerns no reason to delay its determination to create a resource pool.

Comment: A commenter noted that the impact from the creation of the resource pool is isolated to those contractors who are not Priority Use Power (PUP) contractors, and the new resource pool would not reduce capacity or energy deliveries to contractors who receive PUP. The commenter did not oppose any change to allocations for PUP or any change in those operations for PUP contractors.

Response: A portion of P–DP capacity and energy is first reserved for PUP requirements and remaining marketable capacity is marketed by WAPA as FES. Therefore, PUP capacity and energy allocations will not be reduced with the creation of the resource pool as part of the Final 2028 Plan.

VI. Eligibility Criteria for Resource Pool Allocations

Background: Qualified applicants must not have an existing allocation of Federal power or be a member of a parent entity that has an allocation of Federal power.

Comment: WAPA received comments in support of limiting resource pool eligibility to those who do not have other Federal hydropower allocations.

Response: WAPA appreciates the support.

Comment: WAPA received comments from three entities requesting that the eligibility criteria be changed to allow those with existing Boulder Canyon Project (BCP) and/or CRSP Federal hydropower allocations to be eligible for a P–DP allocation from the 2028 resource pool.

Response: WAPA chose to create a two-percent resource pool at a time when drought is already reducing P–DP energy production. Existing contractors have experienced rate increases and PPW deficits because P–DP generation could not meet contractual requirements. WAPA determined that limiting eligibility for resource pool allocations to those entities that do not already have a Federal power allocation is an appropriate means of encouraging widespread use, while the modest size of the resource pool also recognizes the strains on the P–DP resource and existing contractors.

Comment: One commenter requested WAPA consider adjusting the proposed eligibility criteria language to ''Qualified applicants must not have a *significant* allocation of Federal power . . .'' to not disqualify small electric utilities that currently receive a small BCP Federal power allocation from being considered as a 2028 P–DP qualified applicant.

Response: Given that Federal hydropower is a finite resource in the Southwest, WAPA considers all allocations to be beneficial and significant. In WAPA's view, determining a threshold at which an allocation is ''significant'' is not possible, and could not be accomplished in an equitable manner. WAPA's policy is to encourage widespread use of P–DP power at the lowest rates possible consistent with sound business principles. Adhering to the proposal to limit the resource pool eligibility to those entities without an existing Federal power allocation accomplishes both goals.

Comment: A commenter noted that WAPA is proposing that its resource pool allocations be returned to existing contractors if enough new preference customers are not found. The commenter requested that WAPA should reconsider this option and allow for additional qualified applicants that may have a small share of existing Federal power resources to be considered in lieu of returning the unused allocation pool back to the existing P–DP contractors.

Response: As discussed previously, WAPA considers all allocations to be beneficial and significant. WAPA created the two-percent resource pool to encourage widespread use at a time when it is experiencing challenging hydrological conditions. Granting resource pool allocations to entities that already have a Federal power allocation does not encourage widespread use to the same extent as making allocations to entities without an existing allocation. Returning the resource pool power to existing P–DP contractors if new

preference contractors are not found recognizes the resource strains on existing contractors. WAPA's decision is also consistent with the framework set forth in the PMI, which provides, ''[i]f power is reserved for new customers but not allocated, or resources are offered but not placed under contract, this power will be offered on a pro rata basis to customers that contributed to the resource pool through application of the extension formula in [10 CFR] 905.33.'' 10 CFR 905.32(e)(1).

Comment: One commenter asked if it is a new requirement that qualified applicants must not have an existing allocation of Federal power or be a member of a parent entity that has an allocation of Federal power. Two commenters noted that at least one of WAPA's current FES allocation contractors obtained Federal power from more than one Federal source. A commenter located in the P–DP marketing area with a CRSP allocation stated that this eligibility requirement seems to be an inequity and a bias against later applying preference customers, as well as a violation of the widespread use mandate.

Response: WAPA's eligibility criterion is not new. The EPAMP Final Rule, published October 20, 1995, provided a framework for the marketing of power while also allowing for project-specific approaches to be used during future proceeding and marketing plan development. The Final Rule noted, ''[i]n the past, [WAPA] has allowed preference entities to receive power from more than one project when marketing areas overlap. Given the significant new customer load that exists in portions of [WAPA]'s service territory, [WAPA] is not willing to continue this policy on a [WAPA]-wide basis. On this issue, [WAPA] will retain the flexibility set forth in the proposed Program. An existing customer will not be eligible to receive power from a resource pool unless [WAPA] provides otherwise on a project-specific basis. Comments on the eligibility of existing customers to receive resource pool power will be accepted as part of the project-specific public process'' (60 FR 54151, 54163).

Given the hydrological conditions impacting P–DP generation, it is prudent for WAPA to maintain that existing Federal power contractors will not be eligible to receive P–DP power from the resource pool.

Comment: One commenter requested that if there are fewer applicants than can equitably use the resource pool, then the unallocated power be shared among all customers.

Response: WAPA interprets this comment to mean that unallocated power be shared among all resource pool applicants and existing contractors. WAPA has wide discretion to balance relative amounts of load being served by Federal hydropower as part of establishing the resource pool. WAPA's goal is to find applicants that meet the eligibility criteria up to the two percent.

Comment: A Tribe with an existing CRSP Federal hydropower allocation commented that it considers its ability to receive allocations and Federal hydropower resources (generation and transmission systems) to be trust resource under the DOE definitions and related to the construction of Coolidge Dam. Although the Tribe has a CRSP allocation, it requested the ability to apply for an allocation of P–DP power as well.

Response: WAPA's power marketing authority is defined by Reclamation law, which grants the agency-wide discretion as to who and under what terms it will contract for the sale of Federal power. While WAPA will create a modest resource pool to encourage widespread use, it also chose to limit applicant eligibility for the resource pool because P–DP energy has been limited in recent years due to drought conditions. WAPA believes expanding resource pool eligibility to entities already holding a Federal power allocation would not encourage widespread use given current conditions.

Although there is no federal legislation requiring WAPA to expand its eligibility criteria to make the Tribe eligible for a P–DP resource pool allocation, WAPA notes the San Carlos Irrigation Project, owned and operated by the Department of Interior, Bureau of Indian Affairs, is an existing P–DP contractor and is required by Federal law to provide power to the Tribe.[1] WAPA values its relationships with tribal preference customers and understands the challenges the Tribe faces in obtaining affordable electric service. WAPA is willing to further collaborate with the Tribe and the Bureau of Indian Affairs in addressing these challenges.

VII. General Criteria and Contract Principles—Minimum Scheduling Requirements

Background: P–DP contractors will have a new minimum scheduling requirement that aligns with Reclamation's generation schedule and how energy is scheduled within the Western Interconnection. Please also see comments and responses under *V. Application of PMI and Creation of Resource Pool* regarding implementing minimum scheduling requirements at the same time as creating a resource pool.

Comment: One commenter noted that the details regarding minimum scheduling requirements are unclear and requested WAPA ensure that changes are coordinated with its scheduling agent and are acceptable to all parties.

Response: WAPA will collaboratively develop the minimum scheduling requirements tool with contractors and is willing to coordinate changes with scheduling agents, as requested by contractors.

Comment: A commenter supported changing minimum scheduling requirements to provide scheduling flexibility, reduce purchase power costs, and minimize sales in low load hours. The commenter questioned how changing minimum scheduling requirements to meet water requirements will affect schedules and noted that it appears that this impact has not been fully examined by DSW personnel. The commenter stated that removing the 25 percent off peak minimum could improve resource availability but remains uncertain as to how that change will benefit contractors. The commenter asks WAPA to improve transparency regarding scheduling requirements and operational needs.

Response: WAPA is developing a tool to identify contractor minimum schedules needed to meet Reclamation water release requirements. When P–DP contractors schedule less energy than Reclamation generates, WAPA may need to sell P–DP energy to balance hourly loads and resources. WAPA intends to produce an hourly minimum schedule each month for each contractor. The change will benefit P–DP contractors by reducing sales of short-term surplus energy when such energy could have been delivered to P–DP contractors and will decrease potential WAPA purchases in more expensive hours to replace generation that was sold. Selling generation and replacing it with purchases in more expensive hours increases the purchase power requirement for the project. Consequently, there is a direct relationship between potential scheduling flexibility and the need for purchase power. WAPA intends to collaborate with contractors when identifying levels of purchase power to align with contractors' preference for scheduling flexibility.

Comment: A commenter stated that the proposal does not indicate any

[1] *See* Act of March 7, 1928, 45 Stat. 200, 210–212.

limits to the amount of off peak power that would have to be required and could lead to a further diminishment of the value of the P–DP resource by eliminating scheduling flexibility and requiring contractors to purchase power at times when it is non-economic.

Response: P–DP generation is based on Reclamation water release requirements. WAPA will continue to coordinate with Reclamation to optimize generation timing and intends to work out a collaborative solution with contractors during negotiations of electric service contracts and the MSI. WAPA received requests specifically asking WAPA to reserve the details of operational changes to the MSI and contracts.

Comment: A commenter requested WAPA confirm that, although the scheduling may evolve to a more dynamic model, WAPA will provide suitable advance notice for contractors to schedule the resource for maximum benefit.

Response: WAPA agrees that it is beneficial for all parties to receive suitable advance notice for scheduling parameters. Minimum scheduling requirements will be included in the MSI.

Comment: One commenter stated that as WAPA reserves the right to enter exchange transmission service and other related agreements, such reservation of authorities should also include WAPA's discretion to manage its interconnection queue to meet these objectives.

Response: Thank you for this recommendation.

Comment: One commenter acknowledged that P–DP generation is based on Reclamation water orders and asked, to the extent possible, for increased flexibility to provide peak shaving in the summer and to avoid competing with solar resources.

Response: WAPA appreciates the recommendation. WAPA acknowledges that the energy market has changed with the increase in solar resources and there are times when P–DP energy is more valuable to contractors. WAPA will continue to stay engaged in the energy market and will collaborate with Reclamation to optimize generation dispatch within water release requirements.

VIII. General Criteria and Contract Principles—Renewable Energy Certificates

Background: Renewable energy certificates (RECs) associated with P–DP power will be made available to contractors and may be sold or transferred to third parties, provided such sale or transfer is consistent with WAPA policy and documented in electric service contracts. As stated in the responses to clarifying questions posted on WAPA's website, it is WAPA's intention that P–DP RECs will be made available to contractors with similar flexibility offered to BCP contractors; however, the end result for P–DP will need to be consistent with WAPA policy.

Comment: Two commenters supported WAPA's RECs proposal and requested WAPA to make its RECs policy available as soon as practicable and before P–DP contract negotiations.

Response: WAPA is currently working on changing its RECs policy and is attempting to achieve resolution as soon as possible.

Comment: One commenter strongly supported WAPA's RECs proposal to help mitigate rate impacts from generation reductions. WAPA was asked to consider using similar language as that used in the BCP contracts when drafting P–DP RECs language to ensure contractors receive the ''environmental benefits'' of hydropower.

Response: WAPA appreciates this recommendation and agrees that language from the BCP electric service contracts may be appropriate for use in the P–DP contracts, consistent with WAPA policy and project-specific legal authorities.

IX. General Criteria and Contract Principles—Undepreciated Replacement Advances

Background: Consistent with the current P–DP Advancement of Funds contract, new allottees would be required to reimburse existing contractors for undepreciated replacement advances, to the extent existing contractors' allocations are reduced as a result of creating the resource pool.

Comment: WAPA received comments from three entities supporting the requirement for new allottees to reimburse existing contractors for undepreciated replacement advances. Additionally, commenters stated it is imperative that potential new allottees understand that a P–DP allocation includes responsibility for their portion of the undepreciated replacement advances and understanding how the deferred purchase power repayments could impact their future rates. The commenters noted these issues could severely change a potential new contractor's decision to sign the contract, especially benefit crediting contractors.

Response: WAPA appreciates the supportive comments. It is accurate that new potential allottees need to consider all costs associated with a P–DP allocation, including their share of undepreciated replacement advances. WAPA agrees that it is prudent for new allottees to evaluate the costs and value associated with a P–DP allocation, especially if a bill crediting or benefit crediting partnership will be required. WAPA would like to clarify that, as stated in its proposal and in the Final 2028 Plan, deficits incurred during the current marketing period will not be passed through to new allottees in the forthcoming marketing period. Such deficits include purchase power deficits.

X. General Criteria and Contract Principles—Deficit Repayment

Background: Deficits for costs incurred during a previous marketing period will not be passed through to new allottees.

Comment: One commenter stated that a portion of the current period deficit should be repaid by future potential allottees under the new resource pool since purchase power expenses were accumulated in connection with the rewind at Davis Dam and purchase power costs related to that outage should not be solely borne by the existing allottees.

Response: PPW deficits were incurred from fiscal years 2018–2023 when challenging hydrological conditions were experienced at the same time as numerous variables affecting the energy market, resulting in higher than anticipated P–DP purchase power costs. New potential contractors will have a different energy product than existing contractors, and WAPA's ability to level PPW costs in rates does not mean that future contractors should pay for annual expenses from the prior marketing period.

It is accurate that the Davis Dam Unit 3 rewind requires a unit outage and results in reduced capacity during the current marketing period. However, there is not a reduction to energy resulting from the outage because Reclamation dispatches the same amount of generation to maintain water releases. The impact to existing contractors is not an overall reduction in energy, but is from the timing of purchases, to the extent WAPA needs to buy power due to capacity shortages in higher priced hours. Existing contractors will experience the benefit of WAPA retaining the additional capacity for the remainder of the current marketing period and that additional capacity could help defer power purchases in high demand hours. To quantify the estimated PPW costs associated with this Davis Dam Unit 3

outage, WAPA would need to conduct a post-hoc analysis to determine when WAPA may or may not have purchased or sold power in various hours. Such analysis would be speculative and hypothetical. Therefore, WAPA believes that a balanced approach is to not pass such outage-related PPW expenses onto potential new contractors, but rather WAPA may use the unallocated, additional capacity from the rewind for the remainder of the current marketing period to help offset PPW expenses incurred during maintenance on the unit, thereby benefitting existing contractors.

XI. Changes in the Electric Utility Industry

Comment: Two commenters noted expansion of markets in the West and requested WAPA to include contract language to protect the value of P–DP to enable WAPA's contractors to use the resource in current and future energy markets. Some of the examples provided in which WAPA has worked with contractors included use of RECs, dynamic signals, and pseudo-ties. The commenters requested language to allow technical solutions for changing market dynamics in the future.

Response: WAPA appreciates this comment. WAPA will work with contractors to include language in contracts to protect the value of contractors' Federal hydropower resources in the event WAPA joins a market.

Comment: A Tribe requested government-to-government consultation if WAPA continues forward with participation in SPP.

Response: WAPA interprets this comment's reference to SPP as the Southwest Power Pool (SPP). WAPA appreciates this request and comment. Currently, DSW does not intend to participate in the SPP regional transmission organization or expand current market participation with SPP. DSW will engage in government-to-government consultation in the event changes to current market participation are contemplated.

XII. Additional Comments

Comment: Commenters expressed appreciation for the effort and careful thought that WAPA put into this process; WAPA's effort to preserve the existing contractors' allocations and provide a more workable construct for future rates; WAPA's deliberate approach to the 2028 marketing plan; and WAPA recognizing the impact of drought on hydropower generation.

Response: WAPA appreciates the support and engagement throughout this process.

Summary of Revisions to the Proposed Plan

WAPA revised the Proposed 2028 Plan as a result of the comments received during the consultation and comment period and public forums. Revisions have been made to define the intent of the marketing plan more clearly; the revisions do not alter the substance of the original proposal. The revisions are summarized as follows:

WAPA was asked to clarify the meaning of ''prescheduling'' regarding prescheduling timetables for Quarterly Energy, Optional Energy, and generation forecast changes to Quarterly Energy. WAPA provided a response to this clarifying question on its website during the consultation and comment period. WAPA modified references to ''prescheduling'' in the Proposed 2028 Plan to ''day-ahead prescheduling'' in the Final 2028 Plan for enhanced clarity.

In response to recommendations that WAPA leave the majority of details concerning the implementation of the new operational strategy, such as the final process and operational changes related to estimating, committing, and scheduling the hydropower resource, in the contract and MSI, WAPA has added language in the Final 2028 Plan to indicate that additional details will be addressed, as appropriate, in FES contracts or MSI, which will be incorporated into such contracts as an attachment.

The Proposed 2028 Plan stated that WAPA expected the addition of 3,750 kW of capacity resulting from the rewind of Davis Dam Unit 5. The unit number was incorrect; the rewind will occur at Davis Dam Unit 3. WAPA has made this correction in the Final 2028 Plan.

The Final 2028 Plan clarifies that ''approximately'' 3,750 kW of additional marketable capacity is expected to be available as a result of the rewind of Davis Dam Unit 3. The modification was necessary because the rewind is not yet complete, and the actual capacity gains from the rewind cannot be determined until the project is complete.

The Final 2028 Plan clarifies that WAPA will allow contractors to use transmission capacity, reserved for delivery of their P–DP FES allocation, for ''contractor-owned or contractor-purchased resources.'' The Proposed 2028 Plan used the term, ''contractor-owned or -purchased resources.''

The Final 2028 Plan also clarifies that transmission used for contractor-owned or contractor-purchased resources will only be available to contractors after minimum scheduling requirements for P–DP generation have been met.

Finally, the Final 2028 Plan fixes an error in the statutory citation for Section 9(c) of the Reclamation Project Act. The correct citation is 43 U.S.C. 485h(c).

Final 2028 Plan

The Final 2028 Plan provides new power marketing criteria for Parker-Davis Project (P–DP). The Final 2028 Plan addresses: (1) the power to be marketed after September 30, 2028, which is the termination date for all existing P–DP firm electric service (FES) contracts; (2) the general terms and conditions under which the power will be marketed starting on October 1, 2028, and going through September 30, 2048; and (3) the criteria to determine eligibility for allocations from the resource pool.

Within broad statutory guidelines and operational constraints of P–DP, WAPA has wide discretion as to whom and under what terms it will contract for the sale of Federal power, if preference is accorded to statutorily defined entities. WAPA markets power in a manner that will encourage the most widespread use at the lowest possible rates consistent with sound business principles. All products and services provided under this Final 2028 Plan will be subject to the operational requirements and constraints of the P–DP, transmission availability, purchase power limitations, and Federal authorities. WAPA will continue a collaborative process in implementing the terms set forth in this Final 2028 Plan.

I. Marketable Power Resource

The primary purpose of P–DP is water control and delivery. The water control system consists of storage reservoirs that provide daily, seasonal, and annual flow regulation. Power generated from these resources depends on hydrology and water operation requirements.

Some of the power generated by P–DP is reserved for priority use by the United States (herein referred to as ''Priority Use Power'' or ''PUP''). PUP is capacity and energy required for the development and operation of Reclamation projects as required by legislation (Reclamation project use power), and irrigation pumping on certain Indian lands. Reclamation project use power is defined to mean that capacity and energy for Reclamation projects in the Lower Colorado River Basin. The following is a list of facilities and projects for which Reclamation project use power is reserved: relift and drainage pumps;

construction campsites; the Yuma-Mesa Irrigation and Drainage District; Gila Project drainage pumps; Wellton-Mohawk Irrigation and Drainage District Plant Nos. 1, 2, and 3; and the Colorado River Front Work and Levee System. Power for irrigation pumping on certain Indian lands is defined to mean capacity and energy for use in irrigation pumping on Indian irrigation projects which are adjacent to the Lower Colorado River south of Davis Dam and north of the border between the United States and Mexico.

P–DP power in surplus to that reserved for PUP shall be reserved for allocation to existing contractors and a resource pool shall be offered to potential new contractors, consistent with applicable law and the terms and conditions provided herein. Power that is reserved as PUP, but not presently needed, also may be marketed to contractors as withdrawable power. Withdrawable power is power that can be withdrawn for Reclamation project use power and power for irrigation pumping on Indian lands, which shall have equal priority. When PUP is requested, WAPA will confirm that the power to be withdrawn will be used for the above specified purposes, and then will withdraw the necessary amount of PUP upon a two-year advance notice. Withdrawals of power will be made as requested and confirmed until the total amount of power reserved for priority use purposes is in use.

II. Products and Services

WAPA will market a fixed amount of capacity, referred to as Contract Rate of Delivery (CROD), for summer and winter seasons. WAPA will have at least 259,206 kW of marketable capacity in the summer and at least 198,337 kW of marketable capacity in the winter, beginning October 1, 2028, with an expected capacity increase of approximately 3,750 kW resulting from a rewind of Davis Dam Unit 3. The summer season for any calendar year is the seven-month period beginning the first day of P–DP's March billing period and continuing through the last day of its September billing period. The winter season is the five-month period beginning the first day of P–DP's October billing period and continuing through the last day of its February billing period in the next succeeding calendar year.

Under the existing P–DP marketing plan, energy allocations are a fixed seasonal amount for the length of customers' contracts and are equal to 3,441 kWh/kW, a 67 percent capacity factor, in the summer season, and 1,703 kWh/kW, a 47 percent capacity factor, in the winter season (49 FR 50582, 50587; 68 FR 23709). Due to challenging hydrological conditions in the Colorado River Basin, this methodology has imposed increasing financial burdens on contractors during the current marketing period, as WAPA has been required to purchase significant amounts of power to meet contractors' firm energy requirements. Accordingly, WAPA will eliminate this methodology and instead offer energy amounts for three-month periods (''Quarterly Energy'') based on Reclamation's 24-month generation projection studies (''24-Month Study''), which are released every month. The Quarterly Energy will be published for contractors by no later than the last day of August for October through December, the last day of November for January through March, the last day of February for April through June, and the last day of May for July through September, of each year during the marketing period. This will allow for energy deliveries to be aligned with actual generation. Under the Final 2028 Plan, available generation, less PUP (which will be fixed on the same terms as under the existing marketing plan), will be published for contractors in the form of Quarterly Energy based on a pro rata share of their seasonal CROD. Details for Quarterly Energy will be further outlined, as appropriate, in FES contracts or Metering and Scheduling Instructions (MSI), which will be incorporated into such contracts as an attachment.

WAPA will purchase energy on behalf of contractors to supplement projected hydropower generation (''Optional Energy''), if requested. Contractors must elect to purchase Optional Energy from WAPA no later than the day before day-ahead prescheduling takes place. The amount of Optional Energy requested, combined with the contractor's monthly energy entitlement pursuant to its Quarterly Energy, must not exceed the contractor's CROD scheduled at a hundred percent capacity factor (contractor's CROD multiplied by twenty-four hours multiplied by the number of days in the month). An estimated monthly price for Optional Energy will be published by WAPA at least quarterly but may be revised and re-published as conditions dictate. The actual costs associated with Optional Energy purchased by WAPA will be passed through to the contractor who elects to receive it. Details for Optional Energy will be further outlined, as appropriate, in FES contracts or MSI, which will be incorporated into such contracts as an attachment.

There may be instances, after Quarterly Energy has been published, that Reclamation makes significant reductions to generation projections. For example, sustained periods of precipitation and/or run off from water sources other than the Colorado River can result in water being stored in Lake Mead for later use, thereby reducing P–DP generation. To minimize power purchases resulting from these situations, WAPA will revise contractors' monthly energy entitlements when significant generation reductions occur after Quarterly Energy has been published. A significant reduction in generation will occur when dollars associated with projected purchase power requirements needed to maintain the Quarterly Energy for a particular month exceed dollars associated with that month's portion of WAPA's Annual Purchase Power Projection. The Annual Purchase Power Projection is an annual estimate of what power WAPA will purchase in the upcoming fiscal year, from October 1 through September 30. Currently, WAPA's Annual Purchase Power Projection is used as a component of the P–DP firm electric service (FES) rate. When such significant reductions occur, WAPA will publish contractors' revised energy for the month using the reduced generation projections. Revised energy will continue to be based on a pro rata share of contractors' CROD and will be effective no later than one day prior to day-ahead prescheduling. Contractors may request that WAPA purchase Optional Energy on their behalf per the terms described above to obtain energy following a revision.

WAPA will designate the portion of projected annual generation exceeding a kWh calculation of all projected marketable capacity (including PUP) multiplied by a 67 percent capacity factor in the summer season and 47 percent capacity factor in the winter season as ''Excess Energy.'' If the current 24-Month Study generation projection for a year exceeds the result of the capacity factor calculation described above, energy exceeding that calculation (Excess Energy) will be distributed to all contractors and PUP recipients based on a pro rata share of their seasonal CROD. Excess Energy will be distributed to contractors monthly and included as an addition to each contractor's Quarterly Energy. Excess Energy will be subject to the same rate and payment requirements as other available P–DP hydropower. The 24-Month Study yearly projections could show Excess Energy at the beginning of a year, but such Excess Energy may not remain at originally projected levels for the full year. Excess Energy distributed

in part of a year may be subject to adjustment in subsequent months if the 24-Month Study yearly generation projection drops below the Excess Energy threshold later that year. WAPA will establish procedures for designating and adjusting Excess Energy in MSI, which will be incorporated into the electric service contracts, to minimize subsequent energy adjustments as much as possible. Additional details for Excess Energy will be outlined, as appropriate, in FES contracts or MSI.

WAPA also will allow contractors to use transmission capacity, reserved for delivery of their P–DP FES allocation, for contractor-owned or contractor-purchased resources, after hourly minimum scheduling requirements have been met. Transmission capacity used for such energy must not exceed a contractor's CROD.

III. Resource Extensions and Resource Pool Allocations

WAPA will apply the principles of the Power Marketing Initiative (PMI) (10 CFR 905.30 through 10 CFR 905.37) to P–DP for the forthcoming marketing period. WAPA will extend 98 percent of P–DP marketable resource as of September 30, 2028, to existing contractors' CROD, for an additional 20 years, from October 1, 2028, through September 30, 2048. The existing CROD for PUP contractors will remain unchanged. WAPA will establish a single, one-time resource pool of two percent of P–DP marketable capacity for new allottees. Energy associated with the new resource pool will be based on a pro rata share of the allottee's seasonal CROD and published in the form of Quarterly Energy. Specific terms and conditions governing the extensions and resource pool are described below.

A. Extension for Existing Contractors

WAPA will have at least 259,206 kW of marketable capacity in the summer and at least 198,337 kW of marketable capacity in the winter, beginning October 1, 2028. WAPA expects an addition of approximately 3,750 kW of capacity resulting from the rewind of Davis Dam Unit 3, anticipated to be available in July 2025 or earlier. The actual marketable capacity for the forthcoming marketing period will be adjusted to include the final Davis Dam Unit 3 capacity increase.

WAPA will extend existing contractors' allocations using the formula contained in the PMI: ''Customer Contract Rate of Delivery (CROD) today/total project CROD under contract today × project-specific percentage × marketable resource determined to be available at the time future resource extensions begin = CROD extended'' (10 CFR 905.33(a)). The creation of a resource pool will not affect PUP customers' CROD.

In the event any existing contractors forfeit or express an intention not to extend some or all of their allocations prior to October 1, 2028, such resources will be returned to the other existing contractors on a pro rata basis.

B. Resource Pool Allocations

WAPA will establish a resource pool by reserving a portion of the power available during the forthcoming marketing period for allocation to new, eligible preference entities, or returned to existing contractors if enough new preference contractors are not found. Allocations for the resource pool will be determined through a separate public process as described under Call for Resource Pool Applications herein.

The 2028 resource pool will consist of two percent of the marketable resources available beginning October 1, 2028. When reducing existing allocations to create the resource pool, WAPA will first take energy from existing contractors' withdrawable allocations up to the total reduction, when available. The remaining reductions will come from nonwithdrawable energy.

C. Eligibility Criteria for Resource Pool Allocations

WAPA will apply the following Eligibility Criteria to all applicants seeking a resource pool allocation under the new marketing plan.

1. Qualified applicants must meet the preference requirements under Section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)), as amended and supplemented.

2. Qualified applicants will be located within the P–DP marketing area that includes: (1) all of the drainage area considered tributary to the Colorado River below a point one mile downstream from the mouth of the Paria River (Lees Ferry); (2) the State of Arizona, excluding that portion lying in the Upper Colorado River Basin; (3) that portion of the State of New Mexico lying in the Lower Colorado River Basin and the independent Quemada Basin lying north of the San Francisco River drainage area; (4) those portions of the State of California lying in the Lower Colorado River Basin and in drainage basins of all streams draining into the Pacific Ocean south of Calleguas Creek; and (5) those parts of the States of California and Nevada in the Lahontan Basin including and lying south of the drainages of Mono Lake, Adobe Meadows, Owens Lake, Amargosa River, Dry Lakes, and all closed independent basins or other areas in southern Arizona not tributary to the Colorado River.

3. Qualified applicants must not have an existing allocation of Federal power or be a member of a parent entity that has an allocation of Federal power.

4. Qualified applicants, except Native American tribes, must be ready, willing, and able to receive and distribute or use power from WAPA. Ready, willing, and able means that the potential allottee has the facilities needed for the receipt of power or has made the necessary arrangements for transmission and/or distribution service; and the potential allottee's power supply contracts with third parties permit the delivery of WAPA power.

5. Qualified applicants that desire to purchase power from WAPA for resale to consumers, including cooperatives, public utility districts, public power districts and municipalities, must achieve electric utility status and have necessary arrangements for transmission and/or distribution service in place by January 31, 2028. Native American tribes are not subject to this requirement. Electric utility status means the applicant has responsibility to meet load growth, has a distribution system, and is ready, willing, and able to purchase P–DP Federal power from WAPA on a wholesale basis for resale to retail customers.

6. Qualified Native American applicants must be a Native American tribe as defined in the Indian Self Determination Act of 1975 (25 U.S.C. 5301, *et seq.,* as amended or supplemented).

7. Qualified applicants must apply in response to the Call for Resource Pool Applications, as described in the Call for Resource Pool Applications section herein. Completed applications must be received by WAPA within the time required in the **DATES** section.

D. Allocation Criteria for Resource Pool Allocations

WAPA will apply the following Allocation Criteria to all applicants seeking a resource pool allocation under the new marketing plan.

1. Allocations will be made in amounts as determined solely by WAPA in exercise of its discretion consistent with its governing authorities and considered to be in the best interest of the United States.

2. Allocations will be based on the applicant's load during the calendar year prior to the Call for Resource Pool Applications or the amount requested, whichever is less.

3. WAPA will base allocations made to Native American tribes on the actual

load experienced during the calendar year prior to the Call for Resource Pool Applications or the amount requested, whichever is less. WAPA may use estimated load values if actual load data is not available. WAPA will review and adjust, where necessary, inaccurate estimates received during the allocation process.

4. WAPA will consider allocations below 1,000 kW.

5. Qualified applicants seeking an allocation as an aggregated group must demonstrate to WAPA's satisfaction the existence of a contractual aggregation arrangement prior to WAPA's notice of final allocations. Members of an aggregated group must individually and collectively meet preference status and all other eligibility requirements. Qualified applicants aggregating their loads will be required to enter into a single firm power contract with WAPA, with the aggregated group entity as the contracting party.

6. An allottee will have the right to purchase power from WAPA only upon execution of an electric service contract between WAPA and the allottee, and satisfaction of all conditions in that contract.

IV. General Criteria and Contract Principles

WAPA will apply the following criteria and contract principles to all contracts executed under the new marketing plan:

A. Electric service contracts shall be executed no later than May 31, 2028, unless otherwise agreed to in writing by WAPA.

B. Contracts will include clauses specifying criteria that contractors must meet on a continuous basis to be eligible to receive electric service from WAPA.

C. All power supplied by WAPA will be delivered pursuant to MSI, which will be part of contractors' electric service contracts.

D. Contracts shall provide for WAPA to furnish electric service effective October 1, 2028, through September 30, 2048.

E. Contracts shall incorporate WAPA's standard provisions for electric service contracts, integrated resource plans, and General Power Contract Provisions, as determined by WAPA.

F. WAPA will adopt a new minimum scheduling requirement that aligns with Reclamation's generation schedule and how energy is scheduled within the Western Interconnection. WAPA intends for contractors to receive the maximum benefit of their resource allocations while accommodating the following goals: meeting Reclamation's water requirements; reducing purchase power and wheeling costs; and minimizing sales of energy in low load hours. WAPA will develop a tool that uses Reclamation's 24-Month Study data, the status of generators, water volumes and elevation, reduced water releases, hourly pricing and projected hourly load, and other relevant information to model and produce an optimized monthly capacity and monthly minimum energy requirement for each contractor. Prior to the execution of contracts for the 2028–2048 marketing period, WAPA will provide examples of methods being considered, seek feedback from existing contractors and potential new allottees, and select which option provides the greatest flexibility and achieves the goals identified herein. Minimum scheduling requirements will be included in the MSI.

G. WAPA may, as it deems reasonable and necessary, enter into other agreements such as: transmission service agreements, interchange agreements, reserve agreements, load regulation agreements, exchange agreements, maintenance and emergency service agreements, power pooling agreements, or other transactions.

H. P–DP will remain operationally integrated with the Boulder Canyon Project, subject to applicable operational restraints of the Bureau of Reclamation, applicable laws, and the other requirements of the marketing plan.

I. WAPA, at its discretion and sole determination, reserves the right to adjust the CROD on five years' written notice in response to changes in hydrology and river operations. Such adjustments will take place only after WAPA conducts a public process.

J. Renewable energy certificates associated with P–DP power will be made available to contractors and may be sold or transferred to third parties, provided such sale or transfer is consistent with WAPA policy and documented in electric service contracts.

K. Each entity is ultimately responsible for obtaining its own delivery or other arrangements to its load. Transmission service over the P–DP system will be provided in accordance with Part V of this Final 2028 Plan.

L. WAPA may develop rate schedules for services provided under the Final 2028 Plan. Such rates will be developed through a separate public process.

M. Contractors must pay all applicable rates and charges in the manner and within the time prescribed in the contract.

N. P–DP will remain financially segregated for the purposes of accounting and project repayment. Beginning June 1, 2005, and until the end of the repayment period for the Central Arizona Project, P–DP provides for surplus revenues by including the equivalent of 4½ mills per kWh in the rates charged to contractors in Arizona and by including the equivalent of 2½ mills per kWh in the rates charged to contractors in California and Nevada. After the repayment period for the Central Arizona Project, the equivalent of 2½ mills per kWh shall be included in the rate charged to all contractors in Arizona, Nevada, and California.

O. Consistent with the current P–DP Advancement of Funds contract, new allottees will be required to reimburse existing contractors for undepreciated replacement advances, to the extent existing contractors' allocations are reduced as a result of creating the resource pool. New allottees who receive an allocation will be required to prepay for service according to the applicable rate schedule and may participate in advance funding of WAPA's and Reclamation's operation and maintenance expenses, consistent with the existing Advancement of Funds contract, or an updated version of the contract that addresses the status of P–DP, as appropriate.

P. Deficits for costs incurred during a previous marketing period will not be passed through to new allottees.

V. Transmission Service

P–DP power will be delivered to designated points of delivery on WAPA's P–DP transmission system. Contractors must secure all necessary transmission service to deliver Federal power beyond WAPA's P–DP transmission system. WAPA may assist new contractors in obtaining third-party transmission arrangements for delivery of firm power allocated during the forthcoming marketing period. WAPA will determine the use of its transmission resources concurrently with further development of the products and services under this Final 2028 Plan. A list of designated delivery points will be provided on WAPA's website at *https://www.wapa.gov/about-wapa/regions/dsw/pdpremarketing/.* WAPA will market surplus transmission capacity on P–DP under WAPA's Open Access Transmission Tariff and other applicable arrangements.

Call for Resource Pool Applications

The Final 2028 Plan describes how WAPA will market its P–DP power resources beginning October 1, 2028, through September 30, 2048. As part of

the Final 2028 Plan, WAPA is creating a resource pool to offer two percent of P–DP's marketable power resource to qualified applicants. WAPA, at its discretion, will allocate the resource pool to selected applicants that meet the Eligibility Criteria and Allocation Criteria defined in the Final 2028 Plan. The process by which WAPA will make final allocation decisions and implement such allocations is outlined below.

I. Applications for Power

Through this **Federal Register** notice, WAPA formally requests applications from qualified preference entities seeking to purchase power from P–DP from October 1, 2028, through September 30, 2048. Existing contractors do not need to submit an application. All applicants must submit applications using the APD form so that WAPA has a uniform basis upon which to evaluate the applications. To be considered, applicants must meet the Eligibility Criteria and Allocation Criteria contained in the Final 2028 Plan and must submit a completed APD application form by the deadline specified in the **DATES** section. To ensure full consideration is given to all applicants, WAPA will not consider requests for power or applications submitted before publication of this **Federal Register** notice or after the deadlines specified in the **DATES** section.

A list of designated delivery points will be provided on WAPA's website at *https://www.wapa.gov/about-wapa/regions/dsw/pdpremarketing/.*

II. Applicant Profile Data

The APD form has been approved by the Office of Management and Budget under Control No. 1910–5136. Applications may be submitted by mail or email, as described in the **ADDRESSES** section. APD forms are available on WAPA's website at *https://www.wapa.gov/about-wapa/regions/dsw/pdpremarketing/* or by request to Jennifer Henn, Power Marketing Advisor, Desert Southwest Region, Western Area Power Administration, (602) 605–2572 or email: *pdp-remarketing@wapa.gov.* It is the applicant's responsibility to ensure it submits its application in a timely manner, so WAPA receives the applications before the date and time stated in the **DATES** section.

Applicants must provide all information requested on the APD form, if available and applicable. Please indicate if the requested information is not applicable or not available. WAPA may request, in writing, additional information from any applicant whose application is deficient. The applicant will have 10 business days from the date on WAPA's request to provide the information. In the event an applicant fails to provide all information to WAPA, the application will not be considered.

The information in the APD form should be answered as if prepared by the entity/organization seeking the allocation of Federal power.

The information collected under this process will not be part of a system of records covered by the Privacy Act and may be available under the Freedom of Information Act. If you are submitting any confidential or business sensitive information, please mark such information before submitting your application.

III. Recordkeeping Requirement

If WAPA accepts an application and the applicant receives an allocation of Federal power, the applicant must keep all information related to the APD for a period of 3 years after signing a contract for Federal power. There is no recordkeeping requirement for unsuccessful applicants who do not receive an allocation of Federal power.

WAPA has obtained Office of Management and Budget Clearance Number 1910–5136 for collection of the above information. The APD form is collected to enable WAPA to properly perform its function of marketing limited amounts of Federal hydropower. The data supplied will be used by WAPA to evaluate who will receive an allocation of Federal power.

IV. Contracting Process

After WAPA has evaluated the applications, WAPA will publish a notice of Proposed 2028 Allocations in the **Federal Register**. The public will have an opportunity to comment on the Proposed 2028 Allocations. After reviewing the comments, WAPA will publish a notice of Final 2028 Allocations in the **Federal Register**. WAPA will begin the contracting process with the new allottees after publishing final allocations in the **Federal Register**, tentatively scheduled for summer 2026. WAPA will offer a pro forma contract for power allocated under the Final 2028 Allocations. Allottees will be required to sign their electric service contract for WAPA to execute no later than May 31, 2028. Electric service contracts will be effective upon WAPA's signature, and service will begin on October 1, 2028, and continue through September 30, 2048.

Legal Authorities

WAPA developed the Final 2028 Plan and Call for Resource Pool Applications in accordance with its power marketing authorities pursuant to the Department of Energy Organization Act (42 U.S.C. 7101, *et seq.*); the Reclamation Act of June 17, 1902 (32 Stat. 388), as amended and supplemented by subsequent enactments, particularly section 9(c) of the Reclamation Project Act of 1939 (43 U.S.C. 485h(c)); and other acts specifically applicable to P–DP.

Procedural Requirements

Review Under the Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1980 (44 U.S.C. 3501, *et seq.*), WAPA has received approval from the Office of Management and Budget for the collection of customer information under control number 1910–5136.

Environmental Compliance

WAPA has determined this action fits within the following categorical exclusions listed in appendix B to subpart D of 10 CFR part 1021: B4.1 (Contracts, policies, and marketing and allocation plans for electric power) and B4.4 (Power marketing services and activities). Categorically excluded projects and activities do not require preparation of either an environmental impact statement or an environmental assessment.[2] A copy of the categorical exclusion determination is available on WAPA's website under the 2024 accordion menu at *www.wapa.gov/about-wapa/regions/dsw/environment.*

Determination Under Executive Order 12866

WAPA has an exemption from centralized regulatory review under Executive Order 12866; accordingly, no clearance of this notice by the Office of Management and Budget is required.

Signing Authority

This document of the Department of Energy was signed on October 30, 2024, by Tracey A. LeBeau, Administrator, Western Area Power Administration. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in

[2] The determination was done in compliance with NEPA (42 U.S.C. 4321 through 4347); the Council on Environmental Quality Regulations for implementing NEPA (40 CFR parts 1500 through 1508); and DOE NEPA Implementing Procedures and Guidelines (10 CFR part 1021).

electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 6, 2024.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2024–26162 Filed 11–8–24; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–12302–01–R5]

Charter Renewal for the Great Lakes Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of charter renewal for the Great Lakes Advisory Board.

SUMMARY: Notice is hereby given that the Environmental Protection Agency (EPA) has determined that, in accordance with the provisions of the Federal Advisory Committee Act (FACA), the EPA Great Lakes Advisory Board is a necessary committee which is in the public's interest. Accordingly, the Advisory Board will be renewed for an additional two-year period. The purpose of the Advisory Board is to provide advice and recommendations to the EPA Administrator through the Great Lakes National Program Manager on matters related to the Great Lakes Restoration Initiative and on domestic matters related to the implementation of the Great Lakes Water Quality Agreement. The Advisory Board's major objectives are to provide advice and recommendations on: Great Lakes protection and restoration activities; long term goals, objectives and priorities for Great Lakes protection and restoration; and other issues identified by the Great Lakes Interagency Task Force/Regional Working Group.

FOR FURTHER INFORMATION CONTACT: Alana Davicino, Designated Federal Officer, Great Lakes National Program Office, U.S. Environmental Protection Agency, 77 West Jackson Boulevard, (G–9J), Chicago, Illinois; telephone number: 312–886–2307, email address: *davicino.alana@epa.gov.*

Dated: November 5, 2024.

Debra Shore,

Regional Administrator, Region 5.

[FR Doc. 2024–26116 Filed 11–8–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2024–0058; FRL–11681–09–OCSPP]

Pesticide Product Registration; Receipt of Applications for New Active Ingredients—September 2024

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is hereby providing notice of receipt and opportunity to comment on these applications.

DATES: Comments must be received on or before December 12, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2024–0058, through the *Federal eRulemaking Portal* at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting and visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Madison H. Le, Biopesticides and Pollution Prevention Division (BPPD) (7511M), main telephone number: (202) 566–1400, email address: *BPPDFRNotices@epa.gov.* The mailing address for each contact person is Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001. As part of the mailing address, include the contact person's name, division, and mail code.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Registration Applications

EPA has received applications to register pesticide products containing active ingredients not included in any currently registered pesticide products. Pursuant to the provisions of FIFRA section 3(c)(4) (7 U.S.C. 136a(c)(4)), EPA is hereby providing notice of receipt and opportunity to comment on these applications. Notice of receipt of these applications does not imply a decision by the Agency on these applications. For actions being evaluated under EPA's public participation process for registration actions, there will be an additional opportunity for public comment on the proposed decisions. Please see EPA's public participation website for additional information on this process (*https://www.epa.gov/pesticide-registration/public-participation-process-registration-actions*).

Notice of Receipt—New Active Ingredients

1. *File Symbol:* 70552–G. *Docket ID number:* EPA–HQ–OPP–2024–0429. *Applicant:* Sinon Corporation, 1F., No. 101, Nanrong Road Dadu District, RC–43245 Taichung, Taiwan (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192). *Product name: Bacillus velezensis* strain CL3. *Active ingredient:* Fungicide and bactericide—*Bacillus velezensis* strain CL3 at

1.385%. *Proposed use:* For manufacturing into end-use pesticide products. *Contact:* BPPD.

2. *File Symbol:* 70552–U. *Docket ID number:* EPA–HQ–OPP–2024–0429. *Applicant:* Sinon Corporation, 1F., No. 101, Nanrong Road Dadu District, RC–43245 Taichung, Taiwan (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192). *Product name:* SINSMART. *Active ingredient:* Fungicide and bactericide—*Bacillus velezensis* strain CL3 at 1.385%. *Proposed use:* For commercial and residential use on crops. *Contact:* BPPD.

3. *File Symbol:* 92643–E. *Docket ID number:* EPA–HQ–OPP–2024–0428. *Applicant:* Verily Life Sciences, LLC, 269 East Grand Avenue, South San Francisco, CA 94080. *Product name:* DQB Males. *Active ingredient:* *Wolbachia pipientis w*AlbB contained in live adult *Culex quinquefasciatus* males. *Proposed use:* Microbial Biopesticide. *Contact:* BPPD.

4. *File Symbol:* 102919–E. *Docket ID number:* EPA–HQ–OPP–2024–0427. *Applicant:* Aphea.Bio NV, Technologiepark 21, 9052 Gent, Belgium (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192). *Product name:* Virtuosa. *Active ingredient:* Fungicide—*Streptomyces griseofuscus* strain M1A1 at 16.67%. *Proposed use:* For commercial use on fruit and vegetable crops. *Contact:* BPPD.

5. *File Symbol:* 102919–G. *Docket ID number:* EPA–HQ–OPP–2024–0427. *Applicant:* Aphea.Bio NV, Technologiepark 21, 9052 Gent, Belgium (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192). *Product name:* Valoria. *Active ingredient:* Fungicide—*Streptomyces griseofuscus* strain M1A1 at 8.75%. *Proposed use:* For commercial use on the cereals crop group. *Contact:* BPPD.

6. *File Symbol:* 102919–R. *Docket ID number:* EPA–HQ–OPP–2024–0427. *Applicant:* Aphea.Bio NV, Technologiepark 21, 9052 Gent, Belgium (c/o SciReg, Inc., 12733 Director's Loop, Woodbridge, VA 22192). *Product name:* M1A1 Technical Material. *Active ingredient:* Fungicide—*Streptomyces griseofuscus* strain M1A1 at 41.7%. *Proposed use:* For manufacturing into end-use products. *Contact:* BPPD.

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 6, 2024.

Kimberly Smith,

Acting Director, Information Technology and Resources Management Division, Office of Program Support.

[FR Doc. 2024–26170 Filed 11–8–24; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice: 2021–6023]

Agency Information Collection Activities: Submission to the Office of Management and Budget for Review and Approval; Comment Request; EIB 92–64, Application for Exporter Short Term Single Buyer Insurance

AGENCY: Export-Import Bank of the United States

ACTION: Notice of information collection; request for comment.

SUMMARY: The Export-Import Bank of the United States (EXIM), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

DATES: Comments must be received on or before January 13, 2025 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *www.regulations.gov* (EIB 92–64), by email *edward.coppola@exim.gov,* or by mail to Edward Coppola, Export-Import Bank of the United States, 811 Vermont Ave. NW, Washington, DC.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact Edward Coppola, *edward.coppola@exim.gov,* 202–565–3717.

SUPPLEMENTARY INFORMATION: The Application for Exporter Short Term Single Buyer Insurance form will be used by entities involved in the export of U.S. goods and services, to provide EXIM with the information necessary to obtain legislatively required assurance of repayment and fulfills other statutory requirements. Export-Import Bank customers will be able to submit this form on paper or electronically.

The application tool can be reviewed at: *https://img.exim.gov/s3fs-public/pub/pending/eib92-64_2025_508.pdf.*

Title and Form Number: EIB 92–64, Application for Exporter Short Term Single Buyer Insurance.

OMB Number: 3048–0018.

Type of Review: Regular.

Need and Use: The information requested enables the applicant to provide EXIM with the information necessary to obtain legislatively required assurance of repayment and fulfills other statutory requirements.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 310.

Estimated Time per Respondent: 1.51 hours.

Annual Burden Hours: 465 hours.

Frequency of Reporting of Use: As needed.

Dated: November 6, 2024.

Andrew Smith,

Records Officer.

[FR Doc. 2024–26163 Filed 11–8–24; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Thursday, November 14, 2024, 11:00 a.m.

PLACE: Hybrid Meeting: 1050 First Street NE, Washington, DC (12th Floor) and virtual.

NOTE: If you would like to virtually access the meeting, see the instructions below.

STATUS: This meeting will be open to the public. To access the meeting virtually, go to the Commission's website *www.fec.gov* and click on the banner to be taken to the meeting page.

MATTERS TO BE CONSIDERED:

REG 2024–06 (Request to Modify or Redact Contributor Info)—Draft Notice of Proposed Rulemaking

Jill Stein and Jill Stein for President 2024—Date of Ineligibility (LRA 1205)

REG 2024–08 (Untraceable Electronic Payment Methods)—Draft Notice of Availability

Management and Administrative Matters

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Individuals who plan to attend in person and who require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Secretary and Clerk, at (202) 694–1040 or *secretary@fec.gov,* at least 72 hours prior to the meeting date.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Laura E. Sinram,

Secretary and Clerk of the Commission.

[FR Doc. 2024–26295 Filed 11–7–24; 4:15 pm]

BILLING CODE 6715–01–P

FEDERAL MEDIATION AND CONCILIATION SERVICE

Intent To Request Revision From OMB of One Current Public Collection of Information: FMCS F–7 Notice

AGENCY: Federal Mediation and Conciliation Service (FMCS).

ACTION: 30-Day notice and request for comments.

SUMMARY: The Federal Mediation and Conciliation Service (FMCS) invites public comment on one current Information Collection Request (ICR), abstracted below, that we will submit to the Office of Management and Budget (OMB) for approval in compliance with the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The purpose of the collection is to facilitate a reporting requirement to FMCS by labor or management practitioners under the National Labor Relations Act (NLRA) in an effort to utilize federal mediation to prevent or minimize disruption to the community that could arise from a labor/management dispute.

DATES: Comments must be submitted on or before December 12, 2024.

ADDRESSES: You may submit comments, identified by the FMCS F–7 Notice, through one of the following methods:

- *Email: register@fmcs.gov;*
- *Mail:* Office of the General Counsel, One Independence Square, 250 E St. SW, Washington, DC 20427. Please note that at this time, mail is sometimes delayed. Therefore, we encourage emailed comments.

FOR FURTHER INFORMATION CONTACT: Karen Pierce, *kpierce@fmcs.gov,* (202) 302–6499.

SUPPLEMENTARY INFORMATION: A copy of the Agency's form, FMCS F–7 Notice, is available here.

I. 60-Day Comment Period

FMCS published a **Federal Register** notice, with a 60-day public comment period soliciting comments, of the following collection of information on September 6, 2024, 89 FR 72841. FMCS received no comments.

II. Request for Comments

FMCS solicits comments to:

i. Evaluate whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

ii. Enhance the accuracy of the agency's estimates of the burden of the proposed collection of information.

iii. Enhance the quality, utility, and clarity of the information to be collected.

iv. Minimize the burden of the collections of information on those who are to respond, including the use of appropriate automated, electronic collection technologies or other forms of information technology.

III. Information Collection Request

Agency: Federal Mediation and Conciliation Service.

Title: FMCS F–7 Notice.

OMB Number: 3076–0004.

Type of Request: Revision of a currently approved collection.

Affected Public: Private Sector to include farms and not-for-profit institutions.

Frequency: On occasion.

Burden: The total annual burden estimate is that FMCS will receive requests from approximately 25,000 respondents per year, one response per event. The form takes about 10 minutes to complete.

Information Collection Requirement

Purpose and Description of Data Collection

To facilitate a reporting requirement to FMCS by labor or management practitioners under the National Labor Relations Act (NLRA), 29 U.S.C. 158(d)(3), in an effort to utilize federal mediation to prevent or minimize disruption to the community that could arise from a labor/management dispute.

Use of Results

The Agency uses the collected information to contact the chief negotiators in the dispute to evaluate the progress of the negotiations and determine if mediation would be beneficial and monitor or become involved in the negotiations to possibly avoid or minimize disruption to the community. FMCS receive notices electronically through its public website.

IV. The Official Record

The official records are electronic records.

Dated: November 6, 2024.

Alisa Zimmerman,

Deputy General Counsel.

[FR Doc. 2024–26151 Filed 11–8–24; 8:45 am]

BILLING CODE 6732–01–P

FEDERAL RESERVE SYSTEM

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

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Ann E. Misback, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than December 12, 2024.

A. Federal Reserve Bank of Atlanta (Erien O. Terry, Assistant Vice President), 1000 Peachtree Street NE, Atlanta, Georgia 30309. Comments can also be sent electronically to *Applications.Comments@atl.frb.org:*

1. *First National Bancshares of Louisiana, Inc., Crowley, Louisiana;* to become a bank holding company by acquiring First National Bank of Louisiana, also of Crowley, Louisiana.

Board of Governors of the Federal Reserve System.

Erin Cayce,

Assistant Secretary of the Board.

[FR Doc. 2024–26164 Filed 11–8–24; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3459–FN]

Medicare and Medicaid Programs; Approval of Application by the American Association for Accreditation of Ambulatory Surgery Facilities, dba QUAD A, for Continued CMS-Approval of Its Ambulatory Surgical Center (ASC) Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice acknowledges the approval of an application by the American Association for Accreditation of Ambulatory Surgery Facilities, dba QUAD A, for continued recognition as a national accrediting organization for Ambulatory Surgical Centers that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable November 27, 2024, to November 27, 2029.

FOR FURTHER INFORMATION CONTACT:
Erin Imhoff, (410) 786–2337.
Joy Webb, (410) 786–1667.

SUPPLEMENTARY INFORMATION:

I. Background

Ambulatory Surgical Centers (ASCs) are distinct entities that operate exclusively for the purpose of furnishing outpatient surgical services to patients. Under the Medicare program, eligible beneficiaries may receive covered services from an ASC provided certain requirements are met. Section 1832(a)(2)(F)(i) of the Social Security Act (the Act) establishes distinct criteria for a facility seeking designation as an ASC. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 416 specify the conditions that an ASC must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for ASCs.

Generally, to enter into an agreement, an ASC must first be certified by a State survey agency (SA) as complying with the conditions or requirements set forth in part 416 of our Medicare regulations. Thereafter, the ASC is subject to regular surveys by an SA to determine whether it continues to meet these requirements.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by a Centers for Medicare & Medicaid Services (CMS) approved national accrediting organization (AO) that all applicable Medicare conditions are met or exceeded, we may deem that provider entity as having met the requirements. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary of the Department of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program may be deemed to meet the Medicare conditions. The AO applying for approval of its accreditation program under part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5.

QUAD A's current term of approval for its ASC program expires November 27, 2024.

II. Application Approval Process

Section 1865(a)(2) of the Act and our regulations at § 488.5 require that our findings concerning review and approval of an AO's requirements consider, among other factors, the applying AO's requirements for accreditation; survey procedures; resources for conducting required surveys; capacity to furnish information for use in enforcement activities; monitoring procedures for provider entities that were not in compliance with the conditions or requirements; and their ability to provide CMS with the necessary data for validation.

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

On June 13, 2024, we published a proposed notice in the **Federal Register** (89 FR 50330), announcing QUAD A's request for continued approval of its Medicare ASC accreditation program. In the June 13, 2024 proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of QUAD A's Medicare ASC accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An administrative review of QUAD A's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its ASC surveyors; (4) ability to investigate and respond appropriately to complaints against accredited ASCs; and (5) survey review and decision-making process for accreditation.
- The equivalency of QUAD A's standards for ASCs as compared with Medicare's Conditions for Coverage (CfCs) for ASCs.
- QUAD A's survey process to determine the following:

++ The composition of the survey team, surveyor qualifications, and the ability of the organization to provide continuing surveyor training.

++ The comparability of QUAD A's processes to those of State agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

++ QUAD A's processes and procedures for monitoring an ASC found out of compliance with QUAD A's program requirements. These monitoring procedures are used only when QUAD A identifies noncompliance. If noncompliance is identified through validation reviews or complaint surveys, the State survey agency monitors corrections as specified at § 488.9(c)(1).

++ QUAD A's capacity to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

++ QUAD A's capacity to provide CMS with electronic data and reports necessary for the effective validation and assessment of the organization's survey process.

++ The adequacy of QUAD A's staff and other resources, and its financial viability.

++ QUAD A's capacity to adequately fund required surveys.

++ QUAD A's policies with respect to whether surveys are announced or unannounced, to ensure that surveys are unannounced.

++ QUAD A's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ QUAD A's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as we may require (including corrective action plans).

IV. Analysis of and Responses to Public Comments on the Proposed Notice

In accordance with section 1865(a)(3)(A) of the Act, the June 13, 2024 proposed notice also solicited public comments regarding whether QUAD A's requirements met or exceeded the Medicare CfCs for ASCs. No public comments were received in response to our proposed notice.

V. Provisions of the Final Notice

A. Differences Between QUAD A's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared QUAD A's ASC accreditation requirements and survey process with the Medicare CfCs of parts 416, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of QUAD A's ASC application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, QUAD A has completed revising its standards and certification processes in order to do all of the following:

• Meet the standard's requirements of all of the following regulations:

++ Section 416.40, to ensure that ASCs comply with state licensure requirements.

++ Section 416.44(b)(2), to clarify that an AO may recommend a waiver of specific provisions of the Life Safety Code (LSC), which would result in unreasonable hardship upon an ASC, but only if the waiver will not adversely affect the health and safety of the patients.

We also reviewed QUAD A's comparable survey processes, which were conducted as described in section III. of this final notice, and yielded the following areas where, as of the date of this notice, QUAD A has completed revising its survey processes in order to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

++ Updating QUAD A's survey procedures to ensure all areas of the Health Care Facilities Code (HCFC) are surveyed and reflected in QUAD A's policies and surveyor guides.

++ Providing clarification to QUAD A's survey scheduling policies to explain the number of LSC surveyors required for survey teams at small, medium, and large ASCs.

++ Revising QUAD A policy to ensure surveyor qualifications include experience with the LSC and HCFC.

++ Providing additional surveyor training to ensure that LSC deficiency citations contain a sufficient level of detail and quantifiable information comparable to what is required by the CMS Principles of Documentation in Chapter 9 of the State Operations Manual.

++ Providing a process to ensure that any findings on the ASC surveyor infection control worksheet are cited appropriately in the final survey report.

++ Providing a process to ensure the appropriate sample of patient records, including open and closed records, is reviewed during surveys based on the ASC's case volume.

B. Term of Approval

Based on our review described in section III. and section V. of this final notice, we approve QUAD A as a national AO for ASCs that request participation in the Medicare program. The decision announced in this final notice is effective November 27, 2024 through November 27, 2029. In accordance with § 488.5(e)(2)(i) the term of the approval will not exceed 6 years.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–26124 Filed 11–8–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–3457–FN]

Medicare and Medicaid Programs; Approval of Application by Community Health Accreditation Partner (CHAP) Inc. for Continued CMS-Approval of Its Hospice Accreditation Program

AGENCY: Centers for Medicare & Medicaid Services, HHS.

ACTION: Notice.

SUMMARY: This notice acknowledges the approval of an application by Community Health Accreditation Partner Inc., for continued CMS-approval as a national accrediting organization for its hospice programs that wish to participate in the Medicare or Medicaid programs.

DATES: The decision announced in this notice is applicable November 20, 2024 through November 20, 2029.

FOR FURTHER INFORMATION CONTACT: Lillian Williams, (410) 786–8636. Erin Imhoff, (410) 786–2337.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services in a hospice provided certain requirements are met by the hospice. Section 1861(dd) of the Social Security Act (the Act) establishes distinct criteria for facilities seeking designation as a hospice. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 418 specify the conditions that a hospice must meet in order to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for hospices.

Generally, to enter into an agreement, a hospice must first be certified as complying with the conditions set forth in part 418 and recommended to the Centers for Medicare & Medicaid (CMS) for participation by a state survey agency. Thereafter, the hospice is

subject to periodic surveys by a state survey agency to determine whether it continues to meet these conditions. However, there is an alternative to certification surveys by state agencies. Accreditation by a nationally recognized Medicare accreditation program approved by CMS may substitute for both initial and ongoing state review.

Section 1865(a)(1) of the Act provides that, if the Secretary of the Department of Health and Human Services (the Secretary) finds that accreditation of a provider entity by an approved national accrediting organization (AO) meets or exceeds all applicable Medicare conditions, we may treat the provider entity as having met those conditions; that is, we may ''deem'' the provider entity to be in compliance. Accreditation by an AO is voluntary and is not required for Medicare participation.

If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national AO's approved program may be deemed to meet the Medicare conditions. A national AO applying for CMS approval of their accreditation program under 42 CFR part 488, subpart A, must provide CMS with reasonable assurance that the AO requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of AOs are set forth at § 488.5. Section 488.5(e)(2)(i) requires AOs to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. The Community Health Accreditation Partner's (CHAP'S) term of approval as a recognized accreditation program for its hospice accreditation program expires November 20, 2024.

II. Application Approval Process

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS-approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days after receiving a complete application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Provisions of the Proposed Notice

In the June 7, 2024, **Federal Register** (89 FR 48646), we published a proposed notice announcing CHAP's request for continued approval of its Medicare hospice accreditation program. In the June 7, 2024, proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and in our regulations at § 488.5, we conducted a review of CHAP's Medicare hospice accreditation application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- A virtual administrative review of CHAP's: (1) corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its hospice surveyors; (4) ability to investigate and respond appropriately to complaints against accredited hospices; and (5) survey review and decision-making process for accreditation.
- The comparison of CHAP's Medicare hospice accreditation program standards to our current Medicare hospice CoPs.
- A documentation review of CHAP's survey process to—

++ Determine the composition of the survey team, surveyor qualifications, and CHAP's ability to provide continuing surveyor training.

++ Compare CHAP's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited hospices.

++ Evaluate CHAP's procedures for monitoring hospices it has found to be out of compliance with CHAP's program requirements. (This pertains only to monitoring procedures when CHAP identifies non-compliance. If noncompliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c)).

++ Assess CHAP's ability to report deficiencies to the surveyed hospice and respond to the hospice's plan of correction in a timely manner.

++ Establish CHAP's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

++ Determine the adequacy of CHAP's staff and other resources.

++ Confirm CHAP's ability to provide adequate funding for performing required surveys.

++ Confirm CHAP's policies with respect to surveys being unannounced.

++ Confirm CHAP's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys or participate in accreditation decisions.

++ Obtain CHAP's agreement to provide CMS with a copy of the most current accreditation survey together with any other information related to the survey as CMS may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the June 7, 2024 proposed notice also solicited public comments regarding whether CHAP's requirements met or exceeded the Medicare CoPs for hospices. We received one comment, which was out of the scope of the proposed notice.

IV. Provisions of the Final Notice

A. Differences Between CHAP's Standards and Requirements for Accreditation and Medicare Conditions and Survey Requirements

We compared CHAP's hospice accreditation requirements and survey process with the Medicare CoPs of part 418, and the survey and certification process requirements of parts 488 and 489. Our review and evaluation of CHAP's hospice application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, CHAP has completed revising its standards and certification processes in order to meet the requirements at:

- Section 418.52(c)(5), to include reference to 45 CFR parts 160 and 164.
- Section 418.62(a), to include reference to § 418.114.
- Section 418.64(b)(2), to address the requirement that state law permits registered nurses to see, treat, and write orders for patients, then registered nurses may provide services to beneficiaries receiving hospice care.
- Section 418.64(c), to indicate that services are not only provided under the direction of a physician but also by a qualified social worker.
- Section 418.66(a)(3)(i) through (iv), to include all the requirements that are entailed in ''good faith efforts'' to hire nurses.
- Section 418.74(d), to address the requirement that if a hospice wishes to receive a 1-year extension, it must submit a request to CMS before the expiration of the waiver period and certify that conditions under which it originally requested the waiver have not changed since the initial waiver was granted.

• Section 418.76(k)(2), to address the requirement for instructions to be prepared by the interdisciplinary group.

• Section 418.104(c), to include reference to 45 CFR parts 160 and 164.

• Section 418.106(b)(1)(iii), to address this requirement to allow a physician assistant to order drugs in accordance with state scope of practice requirements and hospice policy.

• Section 418.110(d)(2), to address the regulatory Life Safety Code (LSC) waiver requirement.

• Section 418.110(d)(3), to address the requirement that the provisions of the adopted edition of the LSC do not apply in a State if we find that a fire and safety code imposed by State law adequately protects patients in hospices.

• Section 418.110(e)(2), to address the Health Care Facilities Code waiver allowance.

In addition to the standards review, we also reviewed CHAP's comparable survey processes, which were conducted as described in section III. of this notice, and yielded the following areas where, as of the date of this notice, CHAP has completed revising its survey processes to demonstrate that it uses survey processes that are comparable to state survey agency processes by:

• Revising CHAP's surveyor guide to include comparable guidance relating to situations that might require discontinuation or refusal to conduct exit conference activities or share with CMS additional materials that are used by CHAP hospice program surveyors.

• Revising CHAP's surveyor guidance to be comparable with Appendix M related to inpatient hospice care.

• Revising CHAP's surveyor guide to include comparable guidance on reviewing personnel records for training requirements.

• Revising CHAP's Hospice Accreditation Processes and resources to include the applicable sections of the Health Care Facilities Code (HCFC) and National Fire Protection Agency (NFPA 101) in accordance with § 418.110.

• Ensuring that all Hospice LSC surveyors have received comparable, adequate training or have sufficient experience to make them qualified to survey health care facilities to both the 2012 editions of LSC and HCFC, and 2013 edition of the Fire Safety Evaluation System NFPA 101A Fire Safety for Health Care Occupancies.

• Revising CHAP's survey process to require pre-survey preparation to include review of the 2012 editions of the LSC and HCFC.

• Revising CHAP's LSC Survey Checklist and LSC citation documentation process to ensure all applicable regulations, LSC/HCFC sections, and CHAP standards are referenced in the survey report and provide surveyor training, as necessary.

B. Term of Approval

Based on our review and observations described in section III. of this final notice, we approve CHAP as a national accreditation organization for hospices that request participation in the Medicare program, effective November 20, 2024 through November 20, 2029.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Vanessa Garcia, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Vanessa Garcia,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2024–26123 Filed 11–8–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0019]

Agency Information Collection Request; 60-Day Public Comment Request

AGENCY: Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before January 13, 2025.

ADDRESSES: Submit your comments to *sagal.musa@hhs.gov* or by calling (202) 205–2634.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 4040–0019–60D and project title for reference, to Sagal Musa, email: *sagal.musa@hhs.gov,* or call (202) 205–2634 the Reports Clearance Officer.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Project Abstract Summary.

Type of Collection: Extension.

OMB No. 4040–0019.

Abstract: The Project Abstract Summary form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Agencies may use Project Abstract Summary form for grant programs not required to collect all the data that is required on the SF–424 core data set and form. Project Abstract Summary form is used by organizations to apply for Federal financial assistance in the form of grants. This form is evaluated by Federal agencies as part of the overall grant application. This IC expires on February 28, 2025. *Grants.gov* seeks a three-year clearance of these collections.

ANNUALIZED BURDEN HOUR TABLE

Forms (if necessary)	Respondents (if necessary)	Number of respondents	Number of responses per respondents	Average burden per response	Total burden hours
Project Abstract Summary	Grant applicants	3,467	1	1	3,467
Total		3,467		1	3,467

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2024–26103 Filed 11–8–24; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business-Anti-Infective Therapeutics.

Date: December 4, 2024.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marcus Ferrone, Pharm.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–2371, *marcus.ferrone@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 23–064 P01 Review: Translational Research on Antiretrovirals and Methamphetamine in the CNS.

Date: December 4, 2024.

Time: 2:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Raul Rojas, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6185, Bethesda, MD 20892, (301) 451–6319, *rojasr@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Social and Community Influences Across the Lifecourse.

Date: December 5, 2024.

Time: 10:30 a.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Kate Fothergill, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3142, Bethesda, MD 20892, 301–435–1782, *fothergillke@mail.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–23–213: Interactive Digital Media Biomedical Science Resources for Pre-College Students and Teachers.

Date: December 6, 2024.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Marie-Jose Belanger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 6188, MSC 7804, Bethesda, MD 20892, 301–435–1267, *belangerm@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: November 5, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–26111 Filed 11–8–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory General Medical Sciences Council.

The meeting will be held as a virtual meeting and open to the public, as indicated below. Individuals who plan to view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should submit a request using the following link: *https://www.nigms.nih.gov/Pages/ContactUs.aspx* at least 5 days prior to the event. The open session will also be videocast, closed captioned, and can be accessed from the NIH Videocasting and Podcasting website (*http://videocast.nih.gov*).

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory General Medical Sciences Council.

Date: February 6, 2025.

Open: 9:30 a.m. to 12:30 p.m.

Agenda: For the discussion of program policies and issues; opening remarks; report of the Director, NIGMS; and other business of the Council.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Closed: 1:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Erica L. Brown, Ph.D., Director, Division of Extramural Activities, National Institute of General Medical Sciences, National Institutes of Health, Natcher Building, Room 2AN24C, Bethesda, MD 20892, 301–594–4499, *erica.brown@nih.gov.*

Members of the public are welcome to provide written comments by emailing *NIGMS_DEA_Mailbox@nigms.nih.gov* at least 3 days in advance of the meeting. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.nigms.nih.gov/About/Council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: November 5, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–26074 Filed 11–8–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious 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: Microbiology, Infectious Diseases and AIDS Initial Review Group; Acquired Immunodeficiency Syndrome Research Study Section Acquired Immunodeficiency Syndrome Research Study Section.

Date: December 6, 2024.

Time: 10:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3D32, Rockville, MD 20892 (Video Assisted Meeting).

Contact Person: Robert C. Unfer, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3D32, Rockville, MD 20892, (240) 669–5035, *robert.unfer@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 5, 2024

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–26110 Filed 11–8–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Data Use Certification for the NIH Brain Development Cohorts (NBDC), (National Institute on Drug Abuse)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The purpose of this revision is to clarify inclusion of the HBCD Study, to update data use terms and conditions, and to request a progress report statement at the time of renewal. Burden levels remain unchanged.

In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the National Institute on Drug Abuse (NIDA) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Elizabeth A. Hoffman, Associate Director, Division of Extramural Research, National Institute on Drug Abuse, 3WFN Room 09C75 MSC 6021, Gaithersburg, MD 20877, or call non-toll-free number (301) 594–2265 or Email your request, including your address to: *elizabeth.hoffman@nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Data Use Certification for the NIH BRAIN Development Cohorts (NBDC), (NIDA) 0925–0780, exp., date 10/31/2026 REVISION, National Institute on Drug Abuse (NIDA), National Institutes of Health (NIH).

Need and Use of Information Collection: The purpose of this proposal is to inform data requestors about terms and conditions for using data generated by the Adolescent Brain Cognitive Development (SM) (ABCD) Study and the Healthy Brain and Child Development (HBCD) Study, collectively known as the NIH Brain Development Cohorts (NBDC), and to obtain signed agreements from requestors and their institutional officials attesting to their commitment to abide by the data use terms and conditions. These include using data for research purposes; adhering to human subjects research requirements; not distributing the data to non-authorized users; minimizing risk of participant identifiability; using data ethically and responsibly; and keeping the data secure. Recipients must include a brief description of their research project and submit their signed data use agreements to the data repository to gain access to NBDC Study data. Recipients who plan to conduct research studies specifically on American Indian/Alaska Native (AI/AN) populations must submit an additional signed data use certification.

OMB approval is requested for 3 years. There are no costs to respondents

other than their time. The total estimated annualized burden hours are 2,000.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual burden hour
Individuals (standard DUC form)	1,800	1	1	1,800
Individuals (additional AI/AN DUC form when needed)	200	1	1	200
Total		2,000		2,000

Lanette A. Palmquist,

Project Clearance Liaison, National Institute on Drug Abuse, National Institutes of Health.

[FR Doc. 2024–26138 Filed 11–8–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Fogarty International Center; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Fogarty International Center Advisory Board.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The open session can be accessed from the Fogarty International Center website (*https://www.fic.nih.gov/About/Advisory/Pages/default.aspx*).

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: Fogarty International Center Advisory Board.

Date: February 10–11, 2025.

Closed: February 10, 2025, 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate the second level of grant applications.

Address: Fogarty International Center, National Institutes of Health, Lawton Chiles International House (Stone House), 16 Center Drive, Conference Room, Bethesda, MD 20892 (In-person and Virtual Meeting).

Open: February 11, 2025, 9:00 a.m. to 3:00 p.m.

Agenda: Update and discussion of current and planned Fogarty International Center activities.

Address: Fogarty International Center, National Institutes of Health, Lawton Chiles International House (Stone House), 16 Center Drive, Conference Room, Bethesda, MD 20892 (In-person and Virtual Meeting).

Meeting Access: https://www.fic.nih.gov/About/Advisory/Pages/default.aspx.

Contact Person: Kristen Weymouth, Executive Secretary, Fogarty International Center, 31 Center Drive, Room B2C02, Bethesda, MD 20892, 301–495–1415, *kristen.weymouth@nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Persons 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/campusaccess-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://www.fic.nih.gov/About/Advisory/Pages/default.aspx,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.106, Minority International Research Training Grant in the Biomedical and Behavioral Sciences; 93.154, Special International Postdoctoral Research Program in Acquired Immunodeficiency Syndrome; 93.168, International Cooperative Biodiversity Groups Program; 93.934, Fogarty International Research Collaboration Award; 93.989, Senior International Fellowship Awards Program, National Institutes of Health, HHS)

Dated: November 5, 2024.

Lauren A. Fleck,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–26112 Filed 11–8–24; 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 Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the 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 Diabetes and Digestive and Kidney Diseases Advisory Council.

Date: January 29–30, 2025.

Open: January 29, 2025, 8:30 a.m. to 12:00 p.m.

Agenda: Call to order; Announcements; Consideration of Summary Minutes for May 2024 Council, Future Council Dates; Report from the Director; Speakers; Concept Clearance.

Address: National Institutes of Health, Building 31, C Wing 6th Floor Conference Room, 31 Center Drive, Bethesda, MD 20892 (In-Person and Virtual Meeting).

Open: January 29, 2025, 1:00 p.m. to 2:30 p.m.

Agenda: KUH Open session.

Address: National Institutes of Health, Building 31, C Wing 6th Floor Conf. Room B (KUH), 31 Center Drive, Bethesda, MD 20892 (In-Person and Virtual Meeting).

Open: January 29, 2025, 1:00 p.m. to 2:15 p.m.

Agenda: DEM Open session.

Address: National Institutes of Health, Building 31, C Wing 6th Floor Conf. Room F&G (DEM), 31 Center Drive, Bethesda, MD 20892 (In-Person and Virtual Meeting).

Open: January 29, 2025, 1:00 p.m. to 2:30 p.m.

Agenda: DDN Open session.

Address: National Institutes of Health, Building 31, C Wing 6th Floor Conf. Room A (DDN), 31 Center Drive, Bethesda, MD 20892 (In-Person and Virtual Meeting).

Closed: January 29, 2025, 2:15 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Building 31, C Wing 6th Floor Conf. Room A (DDN), 31 Center Drive, Bethesda, MD 20892 (In-Person and Virtual Meeting).

Closed: January 29, 2025, 2:15 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Building 31, C Wing 6th Floor Conf. Room B (KUH), 31 Center Drive, Bethesda, MD 20892 (In-Person and Virtual Meeting).

Closed: January 29, 2025, 2:15 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Building 31, C Wing 6th Floor Conf. Room F&G (DEM), 31 Center Drive, Bethesda, MD 20892 (In-Person and Virtual Meeting).

Closed: January 29, 2025, 3:45 p.m. to 4:00 p.m.

Agenda: Reports of Subcommittees and Consideration of Applications.

Address: National Institutes of Health, Building 31, C Wing 6th Floor Conf. Room F&G, 31 Center Drive, Bethesda, MD 20892 (In-Person and Virtual Meeting).

Contact Person: Karl F. Malik, Ph.D., Director Division of Extramural Activities, National Institutes of Diabetes and Digestive and Kidney Diseases, 6707 Democracy Blvd., Room 7329, MSC 5452, Bethesda, MD 20892, (301) 594–4757, *malikk@niddk.nih.gov.*

Information is also available on the Institute's/Center's home page: *www.niddk.nih.gov/fund/divisions/DEA/Council/coundesc.htm.,* where an agenda and any additional information for the meeting will be posted when available.

(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: November 5, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–26073 Filed 11–8–24; 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 Review.

Date: December 11, 2024.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Thomas A. Tatham, Ph.D., Scientific Review Officer, National Institute of Diabetes and Digestive and Kidney, National Institute of Health, 6707 Democracy Boulevard, Rm. 7021, Bethesda, MD 20892–5452, (301) 594–3993, *tathamt@mail.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: November 5, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–26071 Filed 11–8–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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 Mental Health Special Emphasis Panel; NIMH HIV/AIDS Review (P30, R25, T32, K99).

Date: December 11, 2024.

Time: 11:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Meeting Format: Virtual Meeting.

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, 6001 Executive Blvd, Bethesda, MD 20892, 301–443–4525, email: *steinerr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: November 6, 2024.

Bruce A. George,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024–26139 Filed 11–8–24; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

[Docket No. TSA–2005–20118]

Intent To Request Extension From OMB of One Current Public Collection of Information: Maryland Three Airports: Enhanced Security Procedures for Operations at Certain Airports in the Washington, DC, Metropolitan Area Flight Restricted Zone

AGENCY: Transportation Security Administration, DHS.

ACTION: 60-Day notice.

SUMMARY: The Transportation Security Administration (TSA) invites public comment on one currently approved Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0029, that we will submit to OMB for an extension in compliance with the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. The collection is necessary to comply with a requirement for individuals to successfully complete a security threat assessment before operating an aircraft or serving as an airport security coordinator at one of the Maryland Three airports.

DATES: Send your comments by January 13, 2025.

ADDRESSES: Comments may be emailed to *TSAPRA@tsa.dhs.gov* or delivered to the TSA PRA Officer, Information Technology (IT), TSA–11, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6011.

FOR FURTHER INFORMATION CONTACT: Christina A. Walsh at the above address, or by telephone (571) 227–2062.

SUPPLEMENTARY INFORMATION:

Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation will be available at *https://www.reginfo.gov* upon its submission to OMB. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Information Collection Requirement

OMB Control Number 1652–0029; Maryland Three Airports: Enhanced Security Procedures for Operations at Certain Airports in the Washington, DC Metropolitan Area Flight Restricted Zone, 49 CFR part 1562. TSA's regulations impose requirements and security procedures on airport operators of three airports in the State of Maryland that are located within the Washington, DC, Metropolitan Area Flight Restricted Zone (Maryland Three Airports),[1] and on individuals operating aircraft to or from these airports. The information collected is used to determine compliance with 49 CFR part 1562, subpart A.

Part 1562, subpart A, allows an individual who is approved by TSA to operate an aircraft to or from one of the Maryland Three Airports or to serve as an airport security coordinator at one of these airports. In order to be approved, a pilot or airport security coordinator applicant is required to submit information and successfully complete a security threat assessment. As part of this threat assessment, the applicant must submit their fingerprints and undergo a criminal history records check and a check of Government terrorist watch lists and other databases to determine whether the individual poses, or is suspected of posing, a threat to transportation or national security. An applicant will not receive TSA's approval under this analysis if TSA determines or suspects the applicant of being a threat to national or transportation security.

Applicants can be fingerprinted at the Ronald Reagan Washington National Airport's badging office and any participating airport badging office or law enforcement office located nearby to the applicant's residence or place of work. Airport security coordinators and pilots must complete the applicable sections of TSA Form 418, which include but are not limited to the following: full name; Social Security number; date of birth; address; phone number and email; current and valid airman certificate or current and valid student pilot certificate; current medical certificate; a list of the make, model, and Federal Aviation Administration (FAA) aircraft registration number for each aircraft the pilot intends to operate at Maryland Three Airports; one form of Government-issued picture ID; the certificate of completion of the FAA DC Special Flight Rules Area training; and fingerprints. Although not required by the rule, TSA asks applicants to voluntarily provide an email address and emergency contact phone number to facilitate immediate communication that might be necessary when operating in the Flight Restricted Zone or helpful during the application process.

TSA also provides an option to submit certain documents for the application by email. For example, applicants no longer need to submit the required documentation to the FAA Flight Standards District Offices in-person, but may submit the information to TSA electronically at *mdthree@tsa.dhs.gov.* This option does not apply to fingerprints, which must continue to be collected in-person at the various locations.

TSA receives approximately 369 applications (366 pilots and 3 airport security coordinators) annually and estimates applicants spend approximately 5.75 hours to prepare and submit the information to TSA, which is a total annual burden of 2,121.75 hours.

Christina A. Walsh,

TSA Paperwork Reduction Act Officer, Information Technology.

[FR Doc. 2024–26072 Filed 11–8–24; 8:45 am]

BILLING CODE 9110–05–P

[1] The Maryland Three Airports are: College Park Airport, Potomac Airfield, and Washington Executive/Hyde Field. However, on November 30, 2022, Washington Executive/Hyde Field ceased operations following a bankruptcy sale of the airport property. Nevertheless, TSA will continue to use TSA Form 418 to collect the information as required by 49 CFR part 1562, subpart A.

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

RIN 1652–ZA18

TSA PreCheck® Application Program Fee

AGENCY: Transportation Security Administration, DHS.

ACTION: Notice.

SUMMARY: The Transportation Security Administration (TSA) administers the

TSA PreCheck® Application Program, in which individuals determined to be low-risk travelers may receive expedited airport security screening. To apply for TSA Precheck® eligibility, individuals submit biometric and biographic information that TSA uses to verify identity and conduct a security threat assessment and submit fees to cover the costs associated with the program. TSA announces in this Notice that, under certain circumstances, the membership renewal fee will be reduced by $11.25 due to changes related to the Federal Bureau of Investigation (FBI) fee for criminal history checks.

DATES: This notice is effective November 12, 2024.

FOR FURTHER INFORMATION CONTACT: Anne Walbridge, Transportation Security Administration, 6595 Springfield Center Drive, Springfield, VA 20598–6047; by phone at (240) 568–5372, or email at *TSAPrecheckEnrollment@tsa.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Availability of Notice Document

You can get an electronic copy using the internet by—

(1) Accessing the Government Printing Office's web page at *https://www.gpo.gov/fdsys/browse/collection.action?collectionCode=FR* to view the daily published **Federal Register** edition; or accessing the ''Search the **Federal Register** by Citation'' in the ''Related Resources'' column on the left, if you need to do a Simple or Advanced search for information, such as a type of document that crosses multiple agencies or dates; or

(2) Visiting TSA's Security Regulations web page at *https://www.tsa.gov* and accessing the link for ''Stakeholders'' at the top of the page, then the link ''Research Center'' in the left column.

In addition, copies are available by writing or calling the individual in the **FOR FURTHER INFORMATION CONTACT** section.

I. Background

A. Overview of TSA PreCheck® Application Program

The TSA PreCheck® Application Program is a voluntary, expedited security screening program connecting low-risk travelers departing from the United States with smarter security and a better air travel experience.[1] As of August 2024, there are approximately 20 million members in the TSA PreCheck® Application Program. Individuals enrolled in the TSA PreCheck® Application Program are eligible to receive expedited screening at U.S. airports. As explained in its Notice establishing the program,[2] membership in the TSA PreCheck® Application Program is within the sole discretion of TSA.

TSA established the TSA PreCheck® Application Program in December 2013 to expand access to expedited screening to individuals who voluntarily provide information that TSA uses to determine whether the traveler is low risk.[3] TSA uses biographic and biometric information the applicant provides to conduct a security threat assessment (STA) that includes review of criminal history, immigration, intelligence, and regulatory violation records. During the enrollment process, TSA requires applicants to present government-issued identity documents with a photo to prove their identity and that they are a U.S. person.

Following enrollment, TSA evaluates the information generated by the vetting process to determine whether the individual poses a low risk to transportation and national security. Once completed, the STA remains valid for 5 years, provided the individual continues to meet the eligibility standards. At the end of the 5-year term, individuals wishing to maintain their membership must renew it by completing a new STA and paying renewal fees.

If TSA determines that the applicant is low risk, TSA issues a Known Traveler Number (KTN)[4] that the individual enters when making flight reservations. Enrollment in the TSA PreCheck® Application Program and use of the associated KTN do not guarantee that an individual will receive expedited screening at airport security checkpoints. TSA retains an element of randomness to maintain unpredictability for security purposes, and travelers with valid KTNs may be selected for additional physical screening on occasion.

An individual is ineligible for a KTN and access to TSA PreCheck® expedited screening if TSA determines the individual poses a risk to transportation or national security; has committed certain criminal acts;[5] does not meet the immigration status standards;[6] has committed regulatory violations;[7] or is otherwise not a low-risk traveler. TSA notifies individuals who it determines are ineligible for a KTN or whose membership in the program is revoked, in writing, and they continue to undergo standard screening at airport security checkpoints.

B. Program Fees

TSA is required by law to collect a non-refundable fee to cover the costs of operating the TSA PreCheck® Application Program.[8] Collecting biographic and biometric information from applicants, conducting the STA, adjudicating the results of the STA, and managing the program[9] generate costs for TSA, the enrollment providers who TSA has selected to conduct enrollment, and the FBI who processes the fingerprint-based criminal history records check. Consistent with the statutory mandate, TSA established a fee structure for new TSA PreCheck® enrollments and renewals. The fee includes a TSA fee, an FBI fee, and an enrollment provider fee.

The TSA fee recovers TSA's costs to analyze the immigration, terrorism, criminal, and regulatory violation information generated in the vetting process to determine whether applicants meet all eligibility requirements; notify applicants of TSA's determination; issue KTNs to eligible individuals; conduct research and development for innovative improvements to enrollment, expedited screening, and overall airport experience; expand the TSA PreCheck®: Touchless Identity Solution;[10] and continue to monitor databases and information to confirm that members remain low risk. The current TSA fee is $42.75.[11]

The FBI fee covers the FBI's costs to compare fingerprints against the national criminal databases and return any results to TSA. This fee also

[1] For purpose of this document, the ''TSA PreCheck® Application Program'' refers to the DHS Trusted Traveler Program that TSA operates to determine if individuals are low-risk and may receive expedited screening. ''TSA PreCheck®'' refers to expedited screening provided by TSA.

[2] *See* Notice, 78 FR 72922 (Dec. 4, 2013).

[3] *Id.*

[4] The Known Traveler Number is a component of Secure Flight Passenger Data, which is defined in TSA Secure Flight regulations at 49 CFR 1560.3. *See also* the Secure Flight regulations at 49 CFR part 1560.

[5] *See* 49 CFR 1572.103 for the criminal standards that apply to TSA PreCheck® applicants.

[6] Individuals who apply for membership in the TSA PreCheck® Application Program must be U.S. citizens, U.S. Nationals, or Lawful Permanent Residents.

[7] For instance, an individual who interferes with security screening or brings a weapon to the security checkpoint would be deemed ineligible for TSA PreCheck® expedited screening and their membership in the program may be revoked.

[8] *See* sec. 540 of the DHS appropriations act of 2006, Public Law 109–90 (119 Stat. 2064, 2088–89, Oct. 18, 2005); 49 U.S.C. 114 (note).

[9] *Id.*

[10] For more information on the Touchless Identity Solution, visit *tsa.gov/digital-id.*

[11] If it is necessary to change this fee in the future, TSA will notify the public through publication of a Notice in the **Federal Register**.

includes subscription in the FBI Rap Back program, which provides TSA notification of any new criminal activity or information. The FBI determines when it is necessary to change its fee for this service and publishes a Notice of those changes in the **Federal Register**.[12] TSA ensures that the current FBI fee is collected during enrollment and transmitted to the FBI. The current FBI fee is $11.25.

The enrollment provider fee covers the cost of the vendor's enrollment products and services to include costs to establish and maintain enrollment centers; equip and staff the centers; develop and maintain the information technology infrastructure to securely collect and transmit applicant data; and administer these services. The enrollment provider collects this fee directly from the applicant during enrollment and retains it; TSA does not ingest, transfer, or retain the enrollment provider fee.

When the TSA PreCheck® Application Program launched in 2013, the enrollment provider fee was set via contract. TSA recompeted this contract in 2019. The contract was awarded to IDEMIA and set an updated enrollment provider fee. In 2018, Congress passed the *TSA Modernization Act*[13] requiring TSA to increase the number of enrollment providers in the TSA PreCheck® program. This legislation sought to add competition, capabilities, and options to the enrollment process and provides that TSA must select at least two additional enrollment vendors to conduct enrollment under Other Transaction Agreements (OTAs) with TSA. Unlike a contract, an OTA permits the vendor to establish its fees and the services it wishes to provide, rather than having them set by TSA, which increases the opportunity for options and services for the applicants. Applicants can choose an enrollment provider based on the services it provides in addition to TSA PreCheck® enrollment. Nothing in the OTA process prevents TSA and the FBI from receiving their respective fees. TSA entered into OTAs with IDEMIA,[14] Alclear, LLC and Telos Identity Management Solutions, LLC in 2020 to provide enrollment services for the TSA PreCheck® program. TSA maintains a list of the overall fees to enroll in TSA PreCheck®, by enrollment provider, at *www.tsa.gov/precheck.* These fees include the TSA fee, the FBI fee, and the enrollment provider fee.

II. Reduced Renewal Fee

In May 2021, TSA began subscribing TSA PreCheck® Application Program members in the FBI's Rap Back service.[15] The FBI currently charges $11.25 to process fingerprints for the criminal history records check and retain them in the FBI's Next Generation Identification system. The FBI then allows TSA to subscribe individuals in Rap Back at no additional cost. Currently, the FBI permits an individual seeking to renew TSA PreCheck® membership to remain subscribed in Rap Back if their STA has not expired and the enrollment provider remains the same. In these cases, the FBI does not charge the $11.25 FBI fee.

TSA's contract with IDEMIA requires this $11.25 savings to be passed on to the renewing individual. Providers operating under an OTA with TSA may, but are not required, to pass this savings on to the individual. As stated above, the OTA process permits the provider to set its fees and services, which applicants may take into account when choosing a provider.

TSA will continue to maintain a current listing of the overall fees for all enrollment and renewal options at *www.tsa.gov/precheck.*

Dated: October 30, 2024.

Stacey Fitzmaurice,

Executive Assistant Administrator, Operations Support.

[FR Doc. 2024–25701 Filed 11–8–24; 8:45 am]

BILLING CODE 9110–05–P

[12] *See https://www.federalregister.gov/documents/2022/08/04/2022-16668/fbis-criminal-justice-information-services-division-user-fee-schedule.*

[13] *TSA Modernization Act,* division K—title I of the FAA Reauthorization Act sec. 1937(f), Public Law 115–254, 132 Stat. 3186 (Oct. 5, 2018).

[14] IDEMIA has an OTA with TSA for the TSA PreCheck® Application Program and a contract for TSA enrollment, to include TSA PreCheck®.

[15] Rap Back is an optional service offered by the FBI that provides authorized users with the capability to subscribe an individual to receive notification of subsequent triggering information, such as a new criminal arrest or the disposition of an old arrest, involving that individual during the term of enrollment.

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0007]

Agency Information Collection Activities; Reinstatement, With Change, of a Previously Approved Collection for Which Approval Has Expired: Change of Address

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The purpose of this notice is to allow an additional 30 days for public comments.

DATES: Comments are encouraged and will be accepted until December 13, 2024.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be submitted via the Federal eRulemaking Portal website at *http://www.regulations.gov* under e-Docket ID number USCIS–2008–0018. All submissions received must include the OMB Control Number 1615–0007 in the body of the letter, the agency name and Docket ID USCIS–2008–0018.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number; comments are not accepted via telephone message.). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *http://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

The information collection notice was previously published in the **Federal Register** on August 16, 2024, at 89 FR 66733, allowing for a 60-day public comment period. USCIS received two comments in connection with the 60-day notice.

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2008–0018 in the search box. Comments must be submitted in English, or an English translation must be provided. The comments submitted to USCIS via this method are visible to the Office of Management and Budget and comply with the requirements of 5

CFR 1320.12(c). All submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Reinstatement, With Change, of a Previously Approved Collection For Which Approval Has Expired.

(2) *Title of the Form/Collection:* Change of Address.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* AR–11; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form AR–11, Change of Address, provides a standardized format for compliance with section 265(a) of the INA. Change of Address Online provides a standardized format for providing change of address information electronically.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection AR–11 is 83,470 and the estimated hour burden per response is 0.283 hours; the estimated total number of respondents for the information collection Change of Address Online is 1,631,876 and the estimated hour burden per response is 0.167 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 296,145 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $313,013.

Dated: November 5, 2024.

Jerry L. Rigdon,

Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security

[FR Doc. 2024–26126 Filed 11–8–24; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX24LR000F60100; OMB Control Number 1028–0053/Renewal]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Nonferrous Metals Surveys

AGENCY: U.S. Geological Survey, Department of the Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, and Federal regulations, the U.S. Geological Survey (USGS) is proposing to renew an Information Collection with revisions to add a currently OMB-exempt 'Battery Recycling' canvass (USGS Form 9–4147–A) and convert to OMB-exempt status the 'Alumina' (USGS Form 9–4055–A) and 'Pig Tin' (USGS Form 9–4090–M) canvasses.

DATES: Interested persons are invited to submit comments on or before January 13, 2025.

ADDRESSES: Send your comments on this Information Collection Request (ICR) by mail to U.S. Geological Survey, Information Collections Officer, 12201 Sunrise Valley Drive MS 159, Reston, VA 20192; or by email to *gs-info_collections@usgs.gov.* Please reference OMB Control Number 1028–0053 Nonferrous Metals Surveys in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Elizabeth S. Sangine by email at *escottsangine@usgs.gov,* or by telephone at 703–648–7720. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA, as part of our continuing effort to reduce paperwork and respondent burdens, we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provides the requested data in the desired format.

We are soliciting comments on the proposed ICR that is described below. We are especially interested in public comments addressing the following issues:

(1) is the collection necessary to the proper functions of the USGS minerals information mission; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how the USGS might enhance the quality, utility, and clarity of the information to be collected; and (5) how the USGS might minimize the burden of this collection on the respondents, including through the use 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 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 can ask us in your comment to withhold your PII from

public review, we cannot guarantee that we will be able to do so.

Abstract: Respondents to these forms supply the USGS with domestic production and consumption data for 22 ores, concentrates, and metals, some of which are considered strategic and critical, to assist in determining National Defense Stockpile goals. These data and derived information will be published as chapters in Minerals Yearbooks, monthly Mineral Industry Surveys, annual Mineral Commodity Summaries, and special publications for use by government agencies, Congressional offices, educational institutions, research organizations, financial institutions, consulting firms, industry, academia, and the general public. We will convert to OMB-exempt status the 'Alumina' (USGS Form 9–4055–A) and 'Pig Tin' (USGS Form 9–4090–M) canvasses because of a permanent reduction in the number of potential respondents.

Title of Collection: Nonferrous Metals Surveys.

OMB Control Number: 1028–0053.

Form Number: Various (26 USGS forms).

Type of Review: Renewal with revisions of a currently approved collection.

Respondents/Affected Public: Businesses or Other For-Profit Institutions: U.S. nonfuel minerals producers and consumers of nonferrous metals and related materials.

Total Estimated Number of Annual Respondents: 1,508.

Total Estimated Number of Annual Responses: 4,885.

Estimated Completion Time per Response: For each form, we will include an average burden time ranging from 20 minutes to 90 minutes.

Total Estimated Number of Annual Burden Hours: 3,616.

Respondent's Obligation: Voluntary.

Frequency of Collection: Monthly, Quarterly, or Annually.

Total Estimated Annual Non-hour Burden Cost: There are no ''non-hour cost'' burdens associated with this ICR.

An agency may not conduct or sponsor, nor is a person required to respond to, a collection of information unless it displays a currently valid OMB control number.

The authorities for this action are the PRA, the National Materials and Minerals Policy, Research and Development Act of 1980 (30 U.S.C. 1601 *et seq.*), the National Mining and Minerals Policy Act of 1970 (30 U.S.C. 21(a)), the Strategic and Critical Materials Stock Piling Act (50 U.S.C. 98 *et seq.*), and the Defense Production Act (50 U.S.C. 2061 *et seq.*).

Daniel Hayba,

Acting Director, National Minerals Information Center, U.S. Geological Survey.

[FR Doc. 2024–26160 Filed 11–8–24; 8:45 am]

BILLING CODE 4338–11–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[256A2100DD/AAKC001030/A0A51010.999900]

Proclaiming Certain Lands as Reservation for Snoqualmie Indian Tribe

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of reservation proclamation.

SUMMARY: This notice informs the public that the Assistant Secretary—Indian Affairs proclaimed approximately 68.17 acres, more or less, an addition to the reservation of the Snoqualmie Indian Tribe.

DATES: This proclamation was made on October 31, 2024.

FOR FURTHER INFORMATION CONTACT: Ms. Carla Clark, Bureau of Indian Affairs, Division of Real Estate Services, 1001 Indian School Road NW, Box #44, Albuquerque, New Mexico 87104, *carla.clark@bia.gov,* (505) 563–3132.

SUPPLEMENTARY INFORMATION: This notice is published in the exercise of authority delegated by the Secretary of the Interior to the Assistant Secretary—Indian Affairs by part 209 of the Departmental Manual.

A proclamation was issued according to the Act of June 18, 1934 (48 Stat. 984; 25 U.S.C. 5110) for the lands described below. The land was proclaimed to be the Snoqualmie Indian Tribe Reservation for Snoqualmie Indian Tribe in King County Washington.

Snoqualmie Indian Tribe Reservation for Snoqualmie Indian Tribe in King County Washington, Willamette Meridian King County, Washington, Legal Descriptions Containing 68.17 Acres, More or Less

130 T 1262

Parcel A

Beginning at a point on the South line of the Northwest quarter of section 31, Township 24 North, Range 8 east, W.M., 1741.29 feet South 88°51′11″ West of the Southeast corner of the Northwest corner of said Section 31;

Thence North 3°02′25″ West 627.28 feet of the South line of a 60 foot street;

Thence South 86°57′35″ West along said street 330.0 feet;

Thence South 3°02′25″ East 616.36 feet to the South line of said Northwest quarter of said Section 31;

Thence North 88°51′11″ East along said South line of said Northwest quarter of said Section 31, 330.18 feet to the Point of Beginning, in King County, Washington.

(Also known as Lot 4, Block 3, of the unrecorded Plat of SI View Acre Tracts)

Parcel B

That portion of the Northwest quarter of Section 31, Township 24 North, Range 8 East, W.M., in King County, Washington, described as follows:

Beginning at a point on the section line between Section 31. Township 24 North, Range 8 East, W.M., in King County, Washington and Section 36, Township 24 North, Range 8 East, W.M., in King County, Washington, 628.28 feet North 0°30′14″ West of the one-quarter corner between said Sections 31 and 36;

Thence North 86°57′35″ East 226.80 feet;

Thence North 3°02′25″ West 30.0 feet;

Thence North 86°57′35″ East 630 feet to the West line of Weathervane Lane Estates, according to the plat thereof recorded in Volume 88 of Plats, page 29, in King County, Washington;

Thence North 3°02′25″ West along said West line 660 feet;

Thence South 86°57′35″ West to the section line between Sections 31 and 36;

Thence South 0°30′14″ East along the section line 690.64 feet to the Point of Beginning; except that portion described as follows:

The West 256 feet in width of that portion of the Northwest quarter of Section 31, Township 24 North, Range 8 East, W.M., in King County, Washington, described as follows:

Beginning at a point on the section line between Section 31, Township 24 North, Range 8 East, W.M., in King County, Washington and Section 36, Township 24 North, Range 8 East, W.M., in King County, Washington, 628.28 feet North 0°30′14″ West of the one-quarter corner between said Sections 31 and 36;

Thence North 86°57′35″ East 226.80 feet;

Thence North 3°02′25″ West 30.0 feet;

Thence North 86°57′35″ East 374 feet to the True Point of Beginning;

Thence North 86°57′35″ East 586 feet to the west line of that certain tract of land described in deed recorded under Recording Number 3324383, King County Building Co., Grantor, to Ernest C. Crawford and Helen G. Crawford, his wife, Grantees;

Thence North 3°02′25″ West, 660 feet to a point North 86°5T35″ East 1098.74 feet and South 3°02′25″ East; 1305.79 feet from the Northwest corner of said Section 31;

Thence South 86°57′35″ West 586 feet;

Thence South 0°30′14″ East 660 feet to the True Point of Beginning.

(Also known as Lot 5, and the West 74 feet of Lot 4, Block 4, SI View Acre Tracts, according to the unrecorded plat thereof).

Situate in the County of King, State of Washington.

Parcel C

That portion of the South 265.14 feet of the North half of the Southeast quarter of the Northeast quarter of Section 36, Township 24 North, Range 7 East, W.M. in King County, Washington, lying Easterly of County Road;

Except the Northern Pacific Railway Spur Right-of-Way;

Situate in the County of King, State of Washington.

Parcel D

That portion of the North half of the Southeast quarter of the Northeast quarter of Section 36, Township 24 North, Range 7 East, W.M. in King County, Washington, lying Easterly of County Road;

Except the South 265.14 feet thereof;

And except the Northern Pacific Railway Spur Right of Way.

Situate in the County of King, State of Washington.

126 T 1002

Parcel A

That portion of the Southwest quarter of the Southeast quarter of Section 19, Township 24 North, Range 8 East, Williamette Meridian, in King County, Washington, lying Westerly of the Westerly margin of Tokul Road Southeast (also known as Adolph Weller County Road).

Parcel B

That portion of Government Lot 8 in Section 30, Township 24 North, Range 8 East, Williamette Meridian, in King County, Washington, lying Westerly of the Westerly margin of Tokul Road Southeast (also known as Adolph Weller County Road).

Parcel C

Lot B of City of Snoqualmie lot line adjustment No. 89004, recorded May 30, 1989 under Recording No. 8905300788, in King County, Washington;

Except that portion conveyed to the City of Snoqualmie, a Washington Municipal Corporation, as disclosed by statutory Warranty Deed, recorded June 30, 2005, under Recording No. 20050630001949.

Parcel D

That portion of the following described property lying East of the East margin of the right of way of State Road No. 2 (also known as SR 202), lying in Government Lots 2, 3 and 4, Section 19, Township 24 North, Range 8 East, Williamette Meridian, in King County, Washington, and being more particularly described as follows:

Beginning at the South quarter corner of said Section 19; thence along the East line Government Lot 3, North 0°29′50″ East a distance of 1,322.18 feet to the Northeast corner of said Lot 3;

Thence along the North line of said Lots 3 and 2 North 89°02′00″ West a distance of 2,290 feet, more or less, to the left bank of the Snoqualmie River;

Thence Northerly along said left bank of the river to the West line of said Section 19;

Thence along the West line of said Section 19, South 1°21′20″ West a distance of 1,660 feet, more or less, to the Southwest corner of said Section 19;

Thence along the South line of said Section 19, South 88°50′20″ East a distance of 377.16 feet;

Thence North 5°49′20″ West a distance of 44.19 feet; thence North 15°12′20″ East a distance of 56.04 feet;

Thence North 8°06′10″ West a distance of 198.73 feet;

Thence North 60°13′00″ West a distance of 120.23 feet;

Thence North 11°48′20″ East a distance of 208.86 feet;

Thence North 0°53′00″ East a distance of 213.90 feet;

Thence North 21°33′20″ West a distance of 45.59 feet;

Thence South 78°52′20″ East a distance of 489.80 feet;

Thence South 21°27′00″ West a distance of 184.22 feet;

Thence South 31°28′10″ East a distance of 89.19 feet;

Thence North 55°33′50″ East a distance of 630.43 feet;

Thence South 35°23′40″ East a distance of 1,054.95 feet to a point on the South line of the said section;

Thence along said South line South 88°50′20″ East a distance of 595.86 feet to the Point of Beginning.

Parcel E

A parcel of land in Government Lot 9 or Section 30, Township 24 North, Range 8 East, Williamette Meridian, in King County, Washington, and being more particularly described as follows:

Beginning at a point on the Southerly right of way line of Washington State Road No. 2, said point being South 0°22′10″ West along the North-South quarter section line a distance of 1,009.43 feet and North 41°21′10″ West along the Southerly road right of way line a distance of 628.33 feet from the North quarter corner of said Section 30;

Thence along the Southerly right of way line of State Road No. 2, North 41°21′10″ West a distance of 101.47 feet;

Thence along the arc of a 766.3 foot radius curve to the right, the chord of which bears North 31°15′10″ West a distance of 268.78 feet;

Thence North 21°09′10″ West a distance of 28.44 feet;

Thence leaving said Southerly right of way line South 66°47′30″ West a distance of 139.44 feet;

Thence South 35°12′40″ East a distance of 28.44 feet;

Thence South 10°11′00″ West a distance of 160.45 feet;

Thence South 16°14′30″ West a distance of 44.49 feet;

Thence South 48°49′30″ East a distance of 48.54 feet;

Thence South 67°25′50″ East a distance of 40.35 feet;

Thence North 72°16′30″ East a distance of 46.73 feet;

Thence South 89°03′20″ East a distance of 39.47 feet;

Thence South 63°46′10″ East a distance of 28.33 feet;

Thence South 49°59′20″ East a distance of 22.27 feet;

Thence South 83°07′20″ East a distance of 160.44 feet;

Thence South 48°38′50″ East a distance of 19.84 feet to the Point of Beginning.

Parcel F

Lot A of City of Snoqualmie lot line adjustment No. LLA–96–01, recorded September 30, 1996, under Recording No. 9609309004, in King County, Washington. more thoroughly described as follows:

A parcel of land located in the Southwest quarter of Section 19, Township 24 North, Range 8 East, Williamette Meridian, in King County, Washington;

More particularly described as follows:

Commencing at the South quarter corner of said Section 19, thence 88°50′20″. West along the South line of said section, a distance of 756.09 feet;

Thence North 10°9′40″ East, a distance of 148.30 feet to the True Point of Beginning;

Thence South 14°55′55″ West, a distance of 29.29 feet;

Thence North 60°38′05″ West, a distance of 18.73 feet to a point on a curve concaved to the Southeast and

having a radius of 55.03 feet, a radial line of said curve through said point bearing North 51°15′30″ West;

Thence Southwesterly along said curve through a central angle of 25°11′21″, an arc distance of 24.19 feet; thence South 63°46′21″ West, a distance of 16.50 feet; hence North 28°58′50″ West, a distance of 17.00 feet; thence North 77°08′4T West, a distance of 94.52 feet;

Thence North 292°34′42″ West, a distance of 94.52 feet to a point on a curve concaved to the South and having a radius of 299.27 feet, a radial line of said curve through said point bearing North 21°04′58″ West;

Thence easterly along said curve through a central angle of 18°56′12″, an arc distance of 98.91 feet;

Thence South 33°44′20″ East, a distance or 95.32 feet to the True Point of Beginning and containing 11.241 square feet, more or less.

The above described lands contain a total of 68.17 acres, more or less, which are subject to all valid rights, reservations, rights-of-way, and easements of record.

This proclamation does not affect title to the lands described above, nor does it affect any valid existing easements for public roads, highways, public utilities, railroads and pipelines, or any other valid easements or rights-of-way or reservations of record.

Bryan Newland,

Assistant Secretary—Indian Affairs.

[FR Doc. 2024–26183 Filed 11–8–24; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0038996; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: Turtle Bay Exploration Park, Redding, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), Turtle Bay Exploration Park (TBEP) intends to repatriate certain a cultural item that meets the definition of an object of cultural patrimony and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural item in this notice may occur on or after December 12, 2024.

ADDRESSES: Julia Cronin, Turtle Bay Exploration Park, 844 Sundial Bridge Drive, Redding, CA 96001, telephone (530) 242–3191, email *jcronin@turtlebay.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of Turtle Bay Exploration Park, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of one object of cultural patrimony has been requested for repatriation. The single Pomo basket is listed in museum records as a ''gift type'' and was acquired by the Redding Museum and Art Center (predecessor of TBEP) in 1981 as part of a donation from James ''Jim'' Dotta. Mr. Dotta was a local instructor at Shasta Community College in Redding, CA, an archaeologist, and heavily involved in the RMAC. He was also an avid collector of books, historical objects, artworks, and Indigenous Belongings. A handwritten note in the accession record states the basket was purchased from Mildred's Antiques for $25.00 in 1959, but no further provenance information is provided and it's not clear in which city, state, or country Mildred's Antiques operated.

Conservation records from April 1992 indicate dermestid damage was discovered on baskets stored near this Pomo basket. Therefore, treatment was conducted on this basket and others. In addition to freezer treatment, the basket was placed in an acid-free box with paradichlorobenzene suspended from the lid. Paradichlorobenzine is a fumigant insecticide used in mothballs and a deodorant in cleaners, sanitizers, and deodorizers. There is no documentation as to when the treatment was complete, but no chemical treatments have been used in Turtle Bay Collections since 2000.

Determinations

Turtle Bay Exploration Park has determined that:

- The one object of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.
- There is a reasonable connection between the cultural item described in this notice and the Sherwood Valley Rancheria of Pomo Indians of California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural item in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, Turtle Bay Exploration Park must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item are considered a single request and not competing requests. Turtle Bay Exploration Park is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26078 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0038999; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Rochester Museum & Science Center, Rochester, NY

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Rochester Museum & Science Center (RMSC) has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects

and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after December 12, 2024.

ADDRESSES: Kathryn Murano Santos, Rochester Museum & Science Center, 657 East Avenue, Rochester, NY 14607, telephone (585) 697–1929, email *kmurano@rmsc.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the RMSC, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, seven individuals removed from the Bennett Mound or Bennett Site (CA–SAC–16), Sacramento County, CA, have been identified. The seven lots of associated funerary objects are projectile points. On an unknown date prior to 1928, Albert Heath, a collector and dealer from Chicago, Illinois, obtained the individuals and associated funerary objects. They were purchased by RMSC from Albert Heath in March 1928. RMSC has no knowledge of any potentially hazardous substances used to treat the human remains or the associated funerary objects.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains and associated funerary objects described in this notice.

Determinations

The RMSC has determined that:

- The human remains described in this notice represent the physical remains of seven individuals of Native American ancestry.
- The seven objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a reasonable connection between the human remains and associated funerary objects described in this notice and the Buena Vista Rancheria of Me-Wuk Indians of California; California Valley Miwok Tribe, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Band of Miwuk Indians; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; Tuolumne Band of Me-Wuk Indians of the Tuolumne Rancheria of California; United Auburn Indian Community of the Auburn Rancheria of California; and the Wilton Rancheria, California.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the RMSC must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The RMSC is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26081 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0039005; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Gilcrease Museum, Tulsa, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Gilcrease Museum has completed an inventory of associated funerary objects and has determined that there is a cultural affiliation between the associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the associated funerary objects in this notice may occur on or after December 12, 2024.

ADDRESSES: Laura Bryant, Gilcrease Museum, 800 S Tucker Drive, Tulsa, OK 74104, telephone (918) 596–2747, email *laura-bryant@utulsa.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Gilcrease Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, associated funerary objects have been reasonably identified. The five associated funerary objects are four lots of shell beads and one lot of glass beads. These were removed likely in the early to mid-20th century from three sites in Sacramento County, CA: Johnson Mound, Hollister Mound, and Calhoun Mound. Thomas Gilcrease, founder of Gilcrease Museum, likely purchased these in the 1950s.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the associated funerary objects described in this notice.

Determinations

The Gilcrease Museum has determined that:

- The five objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a reasonable connection between the associated funerary objects described in this notice and the Ione Band of Miwok Indians of California and the Wilton Rancheria, California.

Requests for Repatriation

Written requests for repatriation of the associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the associated funerary objects in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the Gilcrease Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the associated funerary objects are considered a single request and not competing requests. The Gilcrease Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26087 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0038990; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) intends to repatriate certain cultural items that meet the definition of sacred objects and objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after December 12, 2024.

ADDRESSES: Deanna Byrd, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 384–0672, email *deannabyrd@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of 19 cultural items have been requested for repatriation. The 19 sacred objects/objects of cultural patrimony are one lot of baskets, one lot of faunal remains, one lot of twined bowls, one lot of lithic material, one dugout canoe and one lot of accompanying parts, one lot of gaming pieces, one lot of utensils, one stone maul, one salmon club, one lot of fishing implements including nets and net sinkers, one lot of fiber material, one dentalium box, one lot of pipes and cases, one lot of natural brushes, one lot of mush paddles, one lot of bone implements, one lot of unfinished regalia, and one lot of completed ceremonial regalia which includes headbands, moccasins, masks, dance caps, skirts, aprons, adornment items, and plumes. Grace Nicholson, Carroll S. Hartman, Mrs. Lee Hoffman, Dr. Alfred Louis Kroeber, Frederick H. Rindge, among others, collected and exchanged cultural items from several Yurok communities and villages from their expeditions along the Klamath River during the early to mid-20th century. The information available in PMAE records indicates that these 19 cultural items are culturally affiliated with the Yurok people.

Determinations

The PMAE has determined that:

- The 19 sacred objects/objects of cultural patrimony described in this notice are, according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization, specific ceremonial objects needed by a traditional Native American religious leader for present-day adherents to practice traditional Native American religion, and have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision).
- There is a reasonable connection between the cultural items described in this notice and the Elk Valley Rancheria, California; Resighini Rancheria, California; and the Yurok Tribe of the Yurok Reservation, California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26086 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0039002; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: Yale Peabody Museum, Yale University, New Haven, CT

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Yale

Peabody Museum, Yale University intends to repatriate certain cultural items that meet the definition of unassociated funerary objects and that have a cultural affiliation with the Indian Tribes in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after December 12, 2024.

ADDRESSES: Professor David Skelly, Director, Yale Peabody Museum, P.O. Box 208118, New Haven, CT 06520–8118, telephone (203) 432–3752, email *david.skelly@yale.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Yale Peabody Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of eight cultural items have been requested for repatriation. Circa 1915, the eight cultural items were removed from various burial contexts by Warren K. Moorehead, who is known to have conducted an extensive archaeological survey of Maine between 1912 and 1920. The cultural items were transferred to George Thompson before they were donated to the Yale Peabody Museum in 1926.

The two unassociated funerary objects are one spearhead and one plummet removed from Emerson Cemetery in Hancock County, ME.

The one unassociated funerary object is one spearhead removed from Hartford's Cemetery in Hancock County, ME.

The one unassociated funerary object is one lot of red ochre removed from Sullivan Falls Cemetery in Hancock County, ME.

The three unassociated funerary objects are three gouges removed from Stevens Cemetery in Knox County, ME.

The one unassociated funerary object is one gouge removed from Hathaway's Cemetery in Penobscot County, ME.

Determinations

The Yale Peabody Museum has determined that:

- The eight unassociated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.
- There is a reasonable connection between the cultural items described in this notice and the Houlton Band of Maliseet Indians; Mi'kmaq Nation (*previously* listed as Aroostook Band of Micmacs); Passamaquoddy Tribe; and the Penobscot Nation.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the Yale Peabody Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The Yale Peabody Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26090 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0039001; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: Wesleyan University, Middletown, CT

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), Wesleyan University intends to repatriate certain cultural items that meet the definition of unassociated funerary objects and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after December 12, 2024.

ADDRESSES: Wendi Field Murray, Wesleyan University (Archaeology & Anthropology Collections), 265 Church Street, Middletown, CT 06033, telephone (860) 685–2085, email *wmurray01@wesleyan.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of Wesleyan University and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of 257 cultural items have been requested for repatriation. The 257 unassociated funerary objects are shell ornaments and beads, stone mortars/vessels, bone tools, digging stick weights, a spherical stone object, a stone pendant, bifacial manos, stone pestles, stone weight/sinker, glass beads, cut shell with ochre, asphaltum skirt weights, shell fishhooks, a bird bone whistle, a stone plummet, stone knives, black chia seeds, and red ochre.

Dos Pueblos, CA

Sixty-four objects, including shell beads and ornaments and one stone pestle, were taken by Paul Schumacher from Dos Pueblos, CA in Santa Barbara County during the 1870s. They were all transferred from the Smithsonian Institution to Wesleyan's natural history museum in 1878.

Santa Barbara County, CA

One hundred-twenty objects originated in Santa Barbara County, CA. They include a stone vessel, a bone tool, asphaltum skirt weights, shell beads, a shell ornament, and an abalone fishhook blank taken by Paul Schumacher in the 1870s; a stone vessel, a digging stick weight, a stone sphere, bifacial manos, shell beads and ornaments, a stone plummet, and stone knives taken by Stephen Bowers in the 1870s; and black chia seeds ''from an Indian grave'' taken by Lt. George Montague Wheeler sometime prior to 1878. They were all transferred from the Smithsonian Institution to Wesleyan's natural history museum in 1878.

There are two additional objects from Santa Barbara County (a stone pestle and a stone tube pipe) taken by Schumacher and originally included in 1878 transfer paperwork (as well as a 1971 collections inventory) but were discovered to be missing by Wesleyan collections staff in 1999. It has not yet been found, but for future reference this object has the same provenance and cultural affiliation as the Schumacher-related objects listed above.

Santa Cruz Island, CA

Forty-one objects originated in Santa Cruz Island, CA. They include a stone pestle, and shell beads and ornaments taken by Paul Schumacher in the 1870s; and shell beads and ornaments, a shell fishhook, a bone tool, and a bird bone whistle taken by Stephen Bowers in the 1870s. Two of the shell ornaments are not definitively attributed to an individual collector in museum catalog records but are listed as being taken by ''Stephen Bowers OR Paul Schumacher.'' They were all transferred from the Smithsonian Institution to Wesleyan's natural history museum in 1878.

Santa Rosa Island, CA

Fifteen objects originated in Santa Rosa Island, CA. They include bone tools/implements, stone pestles, and shell beads and ornaments taken by Stephen Bowers in the 1870s. One of the objects (a string of beads) is not definitively attributed to an individual collector in museum catalog records but are listed as being taken by ''Stephen Bowers OR Paul Schumacher.'' They were all transferred from the Smithsonian Institution to Wesleyan's natural history museum in 1878.

There is one additional object from Santa Rosa Island (glass beads attributed to ''Indian graves'' in museum catalog records) taken by Bowers and originally included in 1878 transfer paperwork (as well as a 1971 collections inventory) but was discovered to be missing by Wesleyan collections staff in 1999. It has not yet been found, but for future reference this object has the same provenance and cultural affiliation as the Bowers-related objects listed above.

''San Rosa,'' CA

Two objects attributed to ''San Rosa, CA'' in Wesleyan's ethnology records include a polished stone plummet and stone weight/sinker. They were taken by John Waterman sometime prior to 1899, when Wesleyan acquired them. Based on Wesleyan's focus on collections from the Channel Islands during the late 19th century, as well as the museum's cataloging conventions for abbreviating ''Santa Rosa Island'' in our records to ''San Rosa,'' these objects are also presumably from Santa Rosa Island, and are consistent with the types of objects likely to be included in Chumash burials.

Santa Ynez, CA

Three objects originating in Santa Ynez, CA include bone tools and strung shell ornaments, were taken by Stephen Bowers in the 1870s. They were all transferred from the Smithsonian Institution to Wesleyan's natural history museum in 1878.

San Luis Obispo, CA

Two objects originating in San Luis Obispo, CA include two strings of shell beads taken by Dr. Hayes in the 1870s and transferred to Wesleyan via a transfer from the Smithsonian Institution in 1878.

Unknown CA, Likely Channel Islands

Three jars of red ochre are likely attributed to the Channel Islands and the collecting activities of Stephen Bowers in the 1870s. They are believed to have been transferred from the Smithsonian Institution to Wesleyan's natural history museum in 1878.

Unknown, California

Three objects, including glass beads and shell beads and ornaments, are from an unknown location in California, but are listed in museum records as being likely connected to the collecting activities of Stephen Bowers and/or Paul Schumacher in the 1870s. They were all likely transferred from the Smithsonian Institution to Wesleyan's natural history museum in 1878.

There is one additional object from California (a stone projectile point) taken by Bowers and originally included in 1878 transfer paperwork (as well as a 1971 collections inventory) but was discovered to be missing by Wesleyan collections staff in 1999. It has not yet been found, but for future reference this object has the same provenance and cultural affiliation as the Bowers-related objects listed above.

Both Stephen Bowers' and Paul Shumacher's collecting was prolific in the Channel Islands and other parts of California during the 1870s—both worked for the Smithsonian and were known to excavate Chumash burials. The looting of Native American burials figures prominently in the documentation of their work via reports and personal journals, making it likely that the items are from funerary contexts. They were initially delivered to the Smithsonian Institution, and in 1878, they were included in a large (Smithsonian) transfer of cultural objects originating in the Channel Islands and other parts of California to Wesleyan University's natural history museum.

For those objects from the Smithsonian attributed to Dr. Hayes and Lt. GM Wheeler, the nature of the objects, the known the timing of their taking, and their association with Wesleyan's bulk acquisition of CA funerary objects from the Smithsonian during the late 19th century make it likely that they are also unassociated funerary objects. Nothing is known about Jonathan Waterman, though the nature of the items suggests that they are likely funerary objects.

No cultural affiliation information was included in the records of the taking or the transfer, though their geographical origin and the well-documented cultural, historical, geographical, and linguistic connections between the claimants and the geographical areas in from which these were taken indicates a cultural affiliation with the Santa Ynez Band of Chumash Indians.

The presence of potentially hazardous substances (*i.e.,* pesticide residues) on these particular objects is unknown. In 2021, Wesleyan University discovered the presence of pesticide residue (arsenic) on one organic object from Samoa that was transferred from the Smithsonian in the 19th century, as well as several taxidermy specimens. This suggests the possibility that other objects in the collection may be contaminated (particularly those transferred from the Smithsonian, as the requested objects are). While pesticides were not typically applied to non-organic objects due to their inherent resilience to pest damage, the objects have potentially been intermingling with organic objects in a large ethnographic teaching collection since the 1870s, and possibly with natural

history specimens as well. To what extent Wesleyan staff attempted to mitigate cross-contamination when objects were stored or handled is unknown.

There is one documented instance of pest fumigation relating to the collections that dates to 1972–1973. This was to treat a silverfish infestation in underground storage rooms that held the museum's objects after it closed. The proposal was for the application of dichlorodiphenyltrichloroethane (DDT) to the floors, the placement of open containers of paradichlorobenzene (PDB) around the room, and the placement of a mildew-retarding insecticide inside the wraps of specimens. The specific contents of the room in which the chemicals were applied, and to what extent they were shielded from them, is unknown.

Determinations

Wesleyan University has determined that:

- The 257 unassociated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.
- There is a reasonable connection between the cultural items described in this notice and the Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, Wesleyan University must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. Wesleyan University is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26083 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0038989; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: The San Diego Archaeological Center, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the San Diego Archaeological Center has completed an inventory of associated funerary objects and has determined that there is a cultural affiliation between the associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the associated funerary objects in this notice may occur on or after December 12, 2024.

ADDRESSES: Stephanie Sandoval, Executive Director, The San Diego Archaeological Center, 16666 San Pasqual Valley Road, Escondido, CA 92027, telephone (760) 291–0370, email *sjsandoval@sandiegoarchaeology.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the San Diego Archaeological Center, and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, human remains representing at least one individual has been reasonably identified and a Notice of Inventory Completion was published in the **Federal Register** on October 7, 2008 (73 FR 58628). The 49 additional associated funerary objects related to these human remains are ceramic effigy, figurines, and pipe fragments; faunal bone bird talon; ground stone figurine fragment; crystals; ochre and hematite fragments. The site was excavated in 1989 by CRM firm ERC Environmental and Energy Services Co. as part of a cultural assessment program before development of the property. Artifacts were found and excavated in compliance with mitigation as required pursuant to the California Environmental Quality Act (CEQA). The site was described in the report as a village. The report does not reference an individual Native American monitor who served the project but refers to the assistance of Luiseño representatives from the Rincon reservation in the completion of the project. During the project, researchers met with three Rincon elders for an interview concerning several artifacts. The site report states that the site falls within the traditional Luiseño territory.

Cultural Affiliation

Based on the information available, cultural affiliation is reasonably identified by the geographical location or acquisition history of the associated funerary objects described in this notice.

Determinations

The San Diego Archaeological Center has determined that:

- The 49 associated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a reasonable connection between the associated funerary objects described in this notice and the La Jolla Band of Luiseno Indians; Pala Band of Mission Indians; Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California; Pechanga Band of Indians (*previously* listed as Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California); Rincon Band of Luiseno Mission Indians of the Rincon Reservation, California; Soboba Band of Luiseno Indians, California; and the Twenty-Nine Palms Band of Mission Indians of California.

Requests for Repatriation

Written requests for repatriation of the associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the associated funerary objects in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the San Diego Archaeological Center must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the associated funerary objects are considered a single request and not competing requests. The San Diego Archaeological Center is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26084 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0039000; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: Field Museum, Chicago, IL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Field Museum intends to repatriate a certain cultural item that meets the definition of an unassociated funerary object and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural item in this notice may occur on or after December 12, 2024.

ADDRESSES: June Carpenter, NAGPRA Director, Field Museum, 1400 S Lake Shore Drive, Chicago, IL 60605, telephone (312) 665–7820, email *jcarpenter@fieldmuseum.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Field Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of one cultural item has been requested for repatriation. The one unassociated funerary object is a burial kapa cloth (represented by Field Museum catalog number T2023.29.1). The kapa cloth was included in the book, *Specimens of Hawaiian Kapa* Vol. I, No. 31, published by D.R. Severson in 1979. The burial kapa cloth, from Severson's private collection, was removed from a burial cave on the Kona coast of the island of Hawaii at an unknown date. The Field Museum acquired the book from Samuel R. Rosenthal sometime between 1979 and 1983. No potentially hazardous substances are known to have been used to treat this item.

Determinations

The Field Museum has determined that:

- The one unassociated funerary object described in this notice is reasonably believed to have been placed intentionally with or near human remains, and is connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary object has been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.
- There is a reasonable connection between the cultural items described in this notice and the Na Hoa Aloha O Ka Pu'uhonua o Hōnaunau and the Office of Hawaiian Affairs.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural item in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the Field Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural item are considered a single request and not competing requests. The Field Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26082 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0039004; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Disposition: U.S. Army Corps of Engineers, Albuquerque District, Albuquerque, New Mexico

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Army Corps of Engineers, Albuquerque District intends to carry out the disposition of human remains removed from Federal or Tribal lands to the lineal descendants, Indian Tribe, or Native Hawaiian organization with priority for disposition in this notice.

DATES: Disposition of the human remains in this notice may occur on or after December 12, 2024. If no claim for disposition is received by November 12,

2025, the human remains in this notice will become unclaimed human remains.

ADDRESSES: Jeremy Decker, U.S. Army Corps of Engineers, Albuquerque District, 4101 Jefferson Plaza NE, Albuquerque, NM 87109, telephone (505) 342–3671, email *jeremy.t.decker@usace.army.mil.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the U.S. Army Corps of Engineers, Albuquerque District and additional information on the human remains or cultural items in this notice, including the results of consultation, can be found in the related records. The National Park Service is not responsible for the identifications in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, four individuals have been reasonably identified. No associated funerary objects are present. The individuals, including two adult females, and one adult male, along with 11 additional fragments from comingled or isolated contexts and representing, at a minimum, a fourth individual, were removed from the Leone Bluff site, 5LA1211, in Las Animas County, Colorado. Wave action associated with increased lake levels at Trinidad Reservoir in 1999 and 2000 contributed to a significant increase in slumping and erosion of cultural deposits at the site. As water levels fell, artifacts and human remains eroded from those deposits were scattered across the surface of a wave-cut terrace that surrounded the site. The remains were discovered on May 28, 2000. The remains were later collected on June 3–7, 2000, and the excavation of additional human remains exposed by receding water levels was conducted between August 7th and August 30th, 2000.

Determinations

U.S. Army Corps of Engineers, Albuquerque District, has determined that:

- The human remains described in this notice represent the physical remains of four individuals of Native American ancestry.
- The Jicarilla Apache Nation, New Mexico has priority for disposition of the human remains described in this notice.

Claims for Disposition

Written claims for disposition of the human remains in this notice must be sent to the appropriate official identified in this notice under **ADDRESSES**. If no claim for disposition is received by November 12, 2025, the human remains in this notice will become unclaimed human remains. Claims for disposition may be submitted by:

1. Any lineal descendant, Indian Tribe, or Native Hawaiian organization identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that they have priority for disposition.

Disposition of the human remains in this notice may occur on or after December 12, 2024. If competing claims for disposition are received, the U.S. Army Corps of Engineers, Albuquerque District, must determine the most appropriate claimant prior to disposition. Requests for joint disposition of the human remains are considered a single request and not competing requests. The U.S. Army Corps of Engineers, Albuquerque District is responsible for sending a copy of this notice to the lineal descendants, Indian Tribes, and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3002, and the implementing regulations, 43 CFR 10.7.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26088 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0038994; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Repatriation: San Francisco State University, NAGPRA Program, San Francisco, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the San Francisco State University (SF State) NAGPRA Program intends to repatriate certain cultural items that meet the definition of unassociated funerary objects or objects of cultural patrimony and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the cultural items in this notice may occur on or after December 12, 2024.

ADDRESSES: Elise Green, San Francisco State University NAGPRA Program, 1600 Holloway Avenue, San Francisco, CA 94132, telephone (415) 338–1381, email *egreen@sfsu.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the SF State NAGPRA Program, and additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

A total of 471 lots of cultural items have been requested for repatriation. The 471 lots of unassociated funerary objects are lithics, obsidian, sediment samples, beads, faunal remains, pestles, chert, steatite, and tools. These cultural items are from archaeological sites: CA–FRE–Yosemite, CA–FRE–Shaver Lake, CA–FRE–Huntington Lake Region, CA–Auberry–UNK, CA–Auberry–22, CA–Auberry–20, CA–Auberry–19, CA–Auberry–18, CA–Auberry–17, CA–Auberry–16, CA–Auberry–15, CA–Auberry–14, CA–Auberry–12, CA–Auberry–10, CA–Auberry–9, CA–Auberry–8, CA–Auberry–7, CA–Auberry–6, CA–Auberry–5, CA–Auberry–4, CA–Auberry–3, CA–Auberry–2, CA–Auberry–1, CA–FRE–2264, CA–FRE–2263, CA–FRE–492. The ''Auberry Burgess Collection'' was donated to SF State in October 1968 by Ray Burgess as a gift. The remainder of the archaeological sites are located near Shaver Lake in Fresno County.

It was once common practice by museums to use chemicals on cultural items to prevent deterioration by mold, insects, and moisture. To date, the SF State NAGPRA Program has no records documenting use of chemicals at our facilities, and we currently do not use chemicals on any cultural items. A former SF State professor, Dr. Michael Moratto, stated that staff used glues, polyvinyl acetate, and a solution called Glyptol to mend and stabilize cultural objects in the past. Prior non-invasive and non-destructive hazardous chemical tests conducted at the SF State NAGPRA Program repositories show arsenic, mercury, and/or lead in some storage containers, surfaces, and certain cultural items.

A total of seven cultural items are requested for repatriation. The seven objects of cultural patrimony include three seed beater baskets, one burden basket, two cradle boards, and one round basket. These baskets were donated to the Treganza Anthropology Museum (TAM) at San Francisco State University in the 1960s and 1970s. When the TAM closed in 2012, all the Native American items were transferred to the SF State NAGPRA Program.

It was once common practice by museums to use chemicals on cultural items to prevent deterioration by mold, insects, and moisture. To date, the SF State NAGPRA Program has no records documenting use of chemicals at our facilities, and we currently do not use chemicals on any cultural items. A former SF State professor, Dr. Michael Moratto, stated that staff used glues, polyvinyl acetate, and a solution called Glyptol to mend and stabilize cultural objects in the past. Prior non-invasive and non-destructive hazardous chemical tests conducted at the SF State NAGPRA Program repositories show arsenic, mercury, and/or lead in some storage containers, surfaces, and certain cultural items.

Determinations

The SF State NAGPRA Program has determined that:

- The seven objects of cultural patrimony described in this notice have ongoing historical, traditional, or cultural importance central to the Native American group, including any constituent sub-group (such as a band, clan, lineage, ceremonial society, or other subdivision), according to the Native American traditional knowledge of an Indian Tribe or Native Hawaiian organization.
- The 471 lots of unassociated funerary objects described in this notice are reasonably believed to have been placed intentionally with or near human remains, and are connected, either at the time of death or later as part of the death rite or ceremony of a Native American culture according to the Native American traditional knowledge of a lineal descendant, Indian Tribe, or Native Hawaiian organization. The unassociated funerary objects have been identified by a preponderance of the evidence as related to human remains, specific individuals, or families, or removed from a specific burial site or burial area of an individual or individuals with cultural affiliation to an Indian Tribe or Native Hawaiian organization.
- There is a reasonable connection between the cultural items described in this notice and Big Sandy Rancheria of Western Mono Indians of California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the SF State NAGPRA Program must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. The SF State NAGPRA Program is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3004 and the implementing regulations, 43 CFR 10.9.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26076 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0038995; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: California State University, Sacramento, Sacramento, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the California State University, Sacramento has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after December 12, 2024.

ADDRESSES: Dr. Mark R. Wheeler, Senior Advisor to President Luke Wood, California State University, Sacramento, 6000 J Street, Sacramento, CA 95819, telephone (916) 460–0490, email *mark.wheeler@csus.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the California State University, Sacramento, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, seven individuals have been identified from CA–TEH–600, located in the eastern-central portion of Tehama County, CA. The 26,582 associated funerary objects include baked clay objects; faunal and floral remains; flaked and ground stones; historic materials; modified bones, shells and stones; thermally altered rocks; geologic and soil samples; unmodified stones; quartz crystals; manuports; pigments; and various other materials. Of this number, at least 377 objects are currently missing from the collection. Sacramento State continues to look for any missing objects. The human remains and funerary objects were collected by individuals associated with the California State University, Sacramento in the 1970s. They have since been housed at the University under accession 81–40.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains and associated funerary objects described in this notice.

Determinations

The California State University, Sacramento has determined that:

- The human remains described in this notice represent the physical remains of seven individuals of Native American ancestry.
- The 26,582 objects described in this notice are reasonably believed to have been placed intentionally with or near individual human remains at the time of death or later as part of the death rite or ceremony.

• There is a connection between the human remains and associated funerary objects described in this notice and the Grindstone Indian Rancheria of Wintun-Wailaki Indians of California and the Paskenta Band of Nomlaki Indians of California.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains and associated funerary objects described in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the California State University, Sacramento must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The California State University, Sacramento is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26077 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0038997; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Museum of Us, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Museum of Us has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after December 12, 2024.

ADDRESSES: Carmen Mosley, NAGPRA Repatriation Manager, Museum of Us, 1350 El Prado, Balboa Park, San Diego, CA 92101, telephone (619) 239–2001 Ext. 42, email *cmosley@museumofus.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Museum of Us and additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Based on the information available, human remains representing, at least, one individual have been reasonably identified. No associated funerary objects are present. Between 1932–1933, human remains were gifted to George C. Hatch by an acquaintance while attending college in Massachusetts. According to Mr. Hatch, the acquaintance who gifted him the remans said that he had been at an ''Indian mound'' [location unknown] dig a year or so earlier and acquired the remains then. Mr. Hatch donated the remains to the San Diego Museum of Man (now Museum of Us) in November of 1982.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is reasonably identified by the geographical location or acquisition history of the human remains described in this notice.

Determinations

The Museum of Us has determined that:

• The human remains described in this notice represent the physical remains of one individual of Native American ancestry.

• There is a reasonable connection between the human remains described in this notice and the Eastern Band of Cherokee Indians and The Choctaw Nation of Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the Museum of Us must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The Museum of Us is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26079 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0038991; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intended Disposition Amendment: U.S. Department of the Interior, Bureau of Land Management, Colorado State Office, Canyons of the Ancients National Monument, Dolores, CO

AGENCY: National Park Service, Interior.

ACTION: Notice; amendment.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the U.S. Department of the Interior, Bureau of Land Management, Canyons of the Ancients National Monument has amended a notice of intended disposition published in the **Federal Register** on August 21, 2024. This notice amends the Indian Tribes with priority for disposition.

DATES: Disposition of the human remains in this notice may occur on or

after December 12, 2024. If no claim for disposition is received by November 12, 2025, the human remains in this notice will become unclaimed human remains.

ADDRESSES: Raymond O'Neil, Monument Manager, Canyons of the Ancients National Monument, 27501 Highway 184, Dolores, CO 81323, telephone (970) 882–5616, email *roneil@blm.gov.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Bureau of Land Management, and additional information on the human remains in this notice, including the results of consultation, can be found in the related records. The National Park Service is not responsible for the identifications in this notice.

Amendment

This notice amends the list of Indian Tribes with priority for disposition published in a notice of intended disposition in the **Federal Register** (89 FR 67656–67657, August 21, 2024). Disposition of the human remains in the original notice of intended disposition has not occurred.

Determinations

The Bureau of Land Management has determined that:

• The Hopi Tribe of Arizona; Ohkay Owingeh, New Mexico; Pueblo of Acoma, New Mexico; Pueblo de Cochiti, New Mexico; Pueblo of Isleta, New Mexico; Pueblo of Jemez, New Mexico; Pueblo of Laguna, New Mexico; Pueblo of Nambe, New Mexico; Pueblo of Picuris, New Mexico; Pueblo of Pojoaque, New Mexico; Pueblo of San Felipe, New Mexico; Pueblo de San Ildefonso, New Mexico; Pueblo of Sandia, New Mexico; Pueblo of Santa Ana, New Mexico; Pueblo of Santa Clara, New Mexico; Pueblo of Taos, New Mexico; Pueblo of Tesuque, New Mexico; Pueblo of Zia, New Mexico; Santo Domingo Pueblo; Ysleta del Sur Pueblo; and the Zuni Tribe of the Zuni Reservation, New Mexico have priority for disposition of the human remains described in the original notice.

Claims for Disposition

Written claims for disposition of the human remains in this notice must be sent to the appropriate official identified in this notice under **ADDRESSES**. If no claim for disposition is received by November 12, 2025, the human remains in this notice will become unclaimed human remains. Claims for disposition may be submitted by:

1. Any lineal descendant, Indian Tribe, or Native Hawaiian organization identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that they have priority for disposition.

Disposition of the human remains in this notice may occur on or after December 12, 2024. If competing claims for disposition are received, the Bureau of Land Management must determine the most appropriate claimant prior to disposition. Requests for joint disposition of the human remains are considered a single request and not competing requests. The Bureau of Land Management is responsible for sending a copy of this notice to the lineal descendants, Indian Tribes, and Native Hawaiian organizations identified in this notice and to any other consulting parties.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3002, and the implementing regulations, 43 CFR 10.7.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26085 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0038998; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: San Diego State University, San Diego, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), San Diego State University (SDSU) has completed an inventory of human remains and has determined that there is no lineal descendant and no Indian Tribe or Native Hawaiian organization with cultural affiliation.

DATES: Upon request, repatriation of the human remains in this notice may occur on or after December 12, 2024.

ADDRESSES: Jaime Lennox, San Diego State University, 5500 Campanile Drive, San Diego, CA 92182, telephone (619) 594–4575, email *jlennox@sdsu.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the SDSU, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, three individuals have been identified. No associated funerary objects are present. Collections BIOANTH–003 (B94), BIOANTH–004 (#9094), and BIOANTH–005 (#9093) each contain human remains representing one individual, were acquired at an unknown time, received from unknown individuals, and were removed under unknown circumstances from unknown locations. Two of the individuals (BIOANTH–004 and BIOANTH–005) are coated in a clear shellac or resin of unknown substance, applied at an unknown time by an unknown individual.

Consultation

Invitations to consult were sent to the Agua Caliente Band of Cahuilla Indians of the Agua Caliente Indian Reservation, California; Augustine Band of Cahuilla Indians, California; Barbareno Band of Chumash Indians; Barbareno/Ventureno Band of Mission Indians; Big Pine Paiute Tribe of the Owens Valley; Bishop Paiute Tribe; Cabazon Band of Cahuilla Indians (*previously* listed as Cabazon Band of Mission Indians, California); Cahuilla Band of Indians; Calaveras Band of Mi-Wuk Indians; California Valley Miwok Tribe, California; California Valley Miwok Tribe (Sheep Rancheria of Me-Wuk Indians of CA); Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Captain Grande Band of Diegueno Mission Indians of California (Barona Group of the Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California); Chemehuevi Indian Tribe of the Chemehuevi Reservation, California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Chumash Council of Bakersfield; Coastal Band of the Chumash Nation; Cocopah Tribe of Arizona; Ewiiaapaayp Band of Kumeyaay Indians, California; Fernandeno Tatviam Band of Mission Indians; Fort Independence Indian Community of Paiute Indians of the Fort Independence Reservation, California; Fort Mojave Indian Tribe of Arizona, California & Nevada; Gabrieleno Band of Mission Indians—Kizh Nation;

Gabrieleno/Tongva San Gabriel Band of Mission Indians; Gabrielino/Tongva Nation; Gabrielino Tongva Indians of California Tribal Council; Gabrielino-Tongva Tribe; Iipay Nation of Santa Ysabel, California; Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Ione Band of Miwok Indians of California; Jamul Indian Village of California; Juaneno Band of Mission Indians; Juaneno Band of Mission Indians Acjachemen Nation—Belardes; Juaneno Band of Mission Indians Acjachemen Nation 84A; Kern Valley Indian Community; Kitanemuk & Yowlumne Tejon Indians; Kwaaymii Laguna Band of Mission Indians; La Jolla Band of Luiseno Indians, California; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Lone Pine Paiute-Shoshone Tribe; Los Coyotes Band of Cahuilla and Cupeno Indians, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; Morongo Band of Mission Indians, California; Nashville Enterprise Miwok-Maidu-Nishinam Tribe; Northfork Rancheria of Mono Indians of California; North Valley Yokuts Tribe (Northern Valley Yokut/Ohlone Tribe); Northern Chumash Tribal Council; Pala Band of Mission Indians; Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California; Pechanga Band of Indians (*previously* listed as Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California); Quechan Tribe of the Fort Yuma Indian Reservation, California & Arizona; Ramona Band of Cahuilla, California; Rincon Band of Luiseno Mission Indians of Rincon Reservation, California; San Fernando Band of Mission Indians; San Luis Obispo County Chumash Council; San Luis Rey Band of Mission Indians; San Manuel Band of Mission Indians; San Pasqual Band of Diegueno Mission Indians of California; Santa Rosa Band of Cahuilla Indians, California; Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California; Serrano Nation of Mission Indians; Soboba Band of Luiseno Indians, California; Southern Sierra Miwuk Nation; Sycuan Band of the Kumeyaay Nation; Timbisha Shoshone Tribe; Torres Martinez Desert Cahuilla Indians, California; Tule River Indian Tribe of the Tule River Reservation, California; Twenty-Nine Palms Band of Mission Indians of California; Washoe Tribe of Nevada & California (Carson Colony, Dresslerville Colony, Woodfords Community, Stewart Community, & Washoe Ranches); Wuksache Indian Tribe/Eshom Valley Band; Xolon-Salinan Tribe; and yak tityu tityu yak tihini—Northern Chumash Tribe.

The following Indian Tribes and Groups responded to the invitations to consult: Agua Caliente Indian Reservation, California; Barbareno/Ventureno Band of Mission Indians; Cahuilla Band of Indians; Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Captain Grande Band of Diegueno Mission Indians of California (Barona Group of the Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California); Chicken Ranch Rancheria of Me-Wuk Indians of California; Cocopah Tribe of Arizona; Ewiiaapaayp Band of Kumeyaay Indians, California; Fernandeno Tatviam Band of Mission Indians; Fort Independence Indian Community of Paiute Indians of the Fort Independence Reservation, California; Iipay Nation of Santa Ysabel, California; Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; Juaneno Band of Mission Indians Acjachemen Nation 84A; Kern Valley Indian Community; La Jolla Band of Luiseno Indians, California; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; Pala Band of Mission Indians; Pauma Band of Luiseno Mission Indians of the Pauma & Yuima Reservation, California; Pechanga Band of Indians (*previously* listed as Pechanga Band of Luiseno Mission Indians of the Pechanga Reservation, California); Rincon Band of Luiseno Mission Indians of Rincon Reservation, California; San Luis Rey Band of Mission Indians; San Manuel Band of Mission Indians; San Pasqual Band of Diegueno Mission Indians of California; Santa Ynez Band of Chumash Mission Indians of the Santa Ynez Reservation, California; Soboba Band of Luiseno Indians, California; Sycuan Band of the Kumeyaay Nation; and the Twenty-Nine Palms Band of Mission Indians of California. Additionally, the United Auburn Indian Community of the Auburn Rancheria of California independently reached out to SDSU.

Cultural Affiliation

The following types of information about the cultural affiliation of the human remains in this notice are available: anthropological, archaeological, biological, geographical, historical, other relevant information, expert opinion, and Native American traditional knowledge. The information, including the results of consultation, identified

1. No earlier group connected to the human remains.

2. Campo Band of Diegueno Mission Indians of the Campo Indian Reservation, California; Captain Grande Band of Diegueno Mission Indians of California (Barona Group of the Capitan Grande Band of Mission Indians of the Barona Reservation, California; Viejas (Baron Long) Group of Capitan Grande Band of Mission Indians of the Viejas Reservation, California); Ewiiaapaayp Band of Kumeyaay Indians, California; Iipay Nation of Santa Ysabel, California; Inaja Band of Diegueno Mission Indians of the Inaja and Cosmit Reservation, California; Jamul Indian Village of California; La Posta Band of Diegueno Mission Indians of the La Posta Indian Reservation, California; Manzanita Band of Diegueno Mission Indians of the Manzanita Reservation, California; Mesa Grande Band of Diegueno Mission Indians of the Mesa Grande Reservation, California; San Pasqual Band of Diegueno Mission Indians of California; and the Sycuan Band of the Kumeyaay Nation as an Indian Tribe or Native Hawaiian organization connected to the human remains.

3. No relationship of shared group identity between the earlier group and the Indian Tribe or Native Hawaiian organization that can be reasonably traced through time.

Determinations

SDSU has determined that:

- The human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- No known lineal descendant who can trace ancestry to the human remains in this notice has been identified.
- No Indian Tribe or Native Hawaiian organization with cultural affiliation to the human remains in this notice has been clearly or reasonably identified.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by any lineal

descendant, Indian Tribe, or Native Hawaiian organization who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Upon request, repatriation of the human remains described in this notice may occur on or after December 12, 2024. If competing requests for repatriation are received, SDSU must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. SDSU is responsible for sending a copy of this notice to any consulting lineal descendant, Indian Tribe, or Native Hawaiian organization.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26080 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0039003; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Yale Peabody Museum, Yale University, New Haven, CT

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Yale Peabody Museum, Yale University has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes in this notice.

DATES: Repatriation of the human remains in this notice may occur on or after December 12, 2024.

ADDRESSES: Professor David Skelly, Director, Yale Peabody Museum, P.O. Box 208118, New Haven, CT 06520–8118, telephone (203) 432–3752, email *david.skelly@yale.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Yale Peabody Museum, and additional information on the determinations in this notice, including the results of consultation, can be found in its inventory or related records. The National Park Service is not responsible for the determinations in this notice.

Abstract of Information Available

Human remains representing, at least, one individual have been identified. No associated funerary objects are present. Between 1948 and 1952, H. Gordon Rowe removed the remains from a shell mound in the area of Oak Point on Deer Isle in Hancock County, ME. H. Gordon Rowe's wife donated the remains to the Yale Peabody Museum in 1969.

Cultural Affiliation

Based on the information available and the results of consultation, cultural affiliation is clearly identified by the information available about the human remains described in this notice.

Determinations

The Yale Peabody Museum has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a connection between the human remains described in this notice and the Houlton Band of Maliseet Indians; Mi'kmaq Nation (*previously* listed as Aroostook Band of Micmacs); Passamaquoddy Tribe; and the Penobscot Nation.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the authorized representative identified in this notice under **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.
2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or an Indian Tribe or Native Hawaiian organization with cultural affiliation.

Repatriation of the human remains described in this notice to a requestor may occur on or after December 12, 2024. If competing requests for repatriation are received, the Yale Peabody Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The Yale Peabody Museum is responsible for sending a copy of this notice to the Indian Tribes and Native Hawaiian organizations identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.10.

Dated: October 29, 2024.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2024–26089 Filed 11–8–24; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–1123 (Third Review)]

Steel Wire Garment Hangers From China; Scheduling of an Expedited Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on steel wire garment hangers from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: October 4, 2024.

FOR FURTHER INFORMATION CONTACT: Juan Carlos Pena Flores ((202) 205–3169), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On October 4, 2024, the Commission determined that the domestic interested party group response to its notice of institution (89 FR 54519, July 1, 2024) of the subject five-year review was adequate and that the respondent interested party group response was inadequate. The

Commission did not find any other circumstances that would warrant conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).[2]

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the review has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for this review on December 23, 2024. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[3] and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before January 2, 2025 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by January 2, 2025. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*, elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: November 5, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–26117 Filed 11–8–24; 8:45 am]

BILLING CODE 7020–02–P

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

[2] Commissioner David S. Johanson voted to conduct a full review.

[3] The Commission has found the response submitted on behalf of M&B Metal Products Company, Inc. to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1368]

Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof; [Revised] Notice of Commission Determination To Review in Part a Final Initial Determination Finding a Violation of Section 337; Request for Written Submissions on the Issues Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission has determined to review in part a final initial determination (''ID'') issued by the presiding administrative law judge (''ALJ'') in the above-captioned investigation finding a violation of section 337. The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding under the schedule set forth below.

FOR FURTHER INFORMATION CONTACT: Richard P. Hadorn, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3179. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal, telephone (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on August 7, 2023, based on a complaint filed by JUUL Labs, Inc. of Washington, DC and VMR Products LLC of San Francisco, California (together, ''JLI''). 88 FR 52207 (Aug. 7, 2023). The complaint, as supplemented, alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on the importation into the United States, the sale for importation, and/or the sale within the United States after importation of certain vaporizer devices, cartridges used therewith, and components thereof by reason of infringement of certain claims of U.S. Patent Nos. RE49,114 (''the '114 patent''), 10,130,123 (''the '123 patent''), 10,709,173 (''the '173 patent''), 11,134,722 (''the '722 patent''), and 11,606,981 (''the '981 patent''). *Id.* The complaint further alleges that a domestic industry (''DI'') exists. *Id.* The notice of investigation names five respondents: (1) NJOY, LLC of Phoenix, Arizona; (2) NJOY Holdings, Inc. of Scottsdale, Arizona; (3) Altria Group, Inc. of Richmond, Virginia; (4) Altria Group Distribution Company of Richmond, Virginia; and (5) Altria Client Services LLC of Richmond, Virginia (collectively, ''NJOY''). *Id.* The Office of Unfair Import Investigations (''OUII'') is also named as a party. *Id.* The Commission also directed the ALJ to take evidence on and provide factual findings and a recommended determination concerning the public interest. *Id.*

On April 3, 2024, the Commission terminated the investigation as to the following asserted claims based on partial withdrawal of the complaint: (i) claims 1, 5–7, 29, 30, 36, 80, 89, and 93 of the '114 patent; (ii) claims 16, 18, 29, and 31 of the '123 patent; (iii) claims 3, 8, 14, and 17 of the '722 patent; and (iv) claims 6, 9–11, 17, and 18 of the '981

patent. Order No. 18 (Mar. 6, 2024), *unreviewed by* Comm'n Notice (Apr. 3, 2024).

On April 26, 2024, the Commission terminated the investigation as to the following asserted claims based on partial withdrawal of the complaint: (i) claims 43, 44, 76, 77, 81, and 86 (all remaining claims) of the '114 patent, thus terminating the '114 patent in its entirety; (ii) claim 14 of the '123 patent; (iii) claims 2, 3, 6, 7, 15, 16, 18–25, 28, and 30 of the '173 patent; (iv) claims 5, 7, 9–13, 16, and 18–21 of the '722 patent; and (v) claims 2, 5, and 13–16 of the '981 patent. Order No. 21 (Apr. 2, 2024), *unreviewed by* Comm'n Notice (Apr. 26, 2024).

On June 18, 2024, the Commission affirmed an initial determination granting summary determination that JLI has satisfied the economic prong of the DI requirement as to the remaining asserted patents, *i.e.,* the '123, '173, '722, and '981 patents. Order No. 22 (Apr. 3, 2024), *aff'd by* Comm'n Notice (June 20, 2024).

On August 23, 2024, the ALJ issued the final ID, which finds a violation of section 337 as to claims 27 and 32 of the '123 patent, claims 1 and 4 of the '173 patent, claims 1 and 15 of the '722 patent, and claims 1 and 8 of the '981 patent. The ID also includes the ALJ's recommended determination (''RD'') on remedy, the public interest, and bonding. The RD recommends that, should the Commission determine that a violation of section 337 has occurred, the Commission should: (i) issue a limited exclusion order against NJOY's infringing products; (ii) issue cease and desist orders against each of the NJOY respondents; and (iii) impose no bond (0 percent bond) for importations of infringing products during the period of Presidential review. The ALJ also found that the statutory public interest factors do not support denying or delaying the recommended relief set forth in the RD.

On September 6, 2024, NJOY filed a petition seeking review of certain findings in the ID, including (i) claim construction and infringement of the asserted claims of the '722 and '981 patents, (ii) claim construction, infringement, the technical and economic prongs of the DI requirement, and validity of the asserted claims of the '123 patent, and (iii) claim construction, infringement, and the technical prong of the DI requirement of the asserted claims of the '173 patent. That same day, JLI filed a contingent petition seeking review of certain of the ID's findings concerning (i) claim construction, infringement, and validity of the '722 and '981 patents, (ii) the technical prong of the DI requirement and validity of the '123 patent, and (iii) validity of the '173 patent. On September 16, 2024, JLI and NJOY each filed a response opposing the other's petition. That same day, OUII filed a response addressing both petitions.

On September 23, 2024, NJOY filed a motion for leave to file a reply in support of its petition for review, addressing certain positions taken by OUII in its response to NJOY's petition. On September 25 and 27, 2024, OUII and JLI, respectively, filed a response opposing NJOY's motion for leave.

On September 24, 2024, JLI and NJOY each filed a submission on the public interest pursuant to Commission Rule 210.50(a)(4) (19 CFR 210.50(a)(4)). The Commission did not receive any submissions on the public interest from members of the public or interested government agencies in response to the Commission's **Federal Register** notice. *See* 89 FR 70668–69 (Aug. 30, 2024).

Having reviewed the record of the investigation, including the final ID, the parties' submissions to the ALJ, the petitions and the responses thereto, and NJOY's motion for leave and the responses thereto, the Commission has determined to review the ID in part.

Specifically, the Commission has determined to review the ID's construction of the ''pressure sensor'' limitations (limitations 27[d] and 27[e]) recited in claim 27 of the '123 patent. The Commission has also determined to review the ID's findings that the NJOY ACE accused product, the asserted [ ] and JAGWAR iterations of the JUUL DI system, and the asserted JUUL2 DI system literally practice limitations 27[d] and 27[e] of claim 27 of the '123 patent under the ID's construction of those limitations.

The Commission has further determined to review certain of the ID's findings regarding claim construction and satisfaction of the technical prong of the DI requirement with respect to the '173 patent. In particular, the Commission has determined to review the ID's construction of the claim terms ''mouthpiece'' and ''disposed within'' recited in the asserted claims 1 and 4 of the '173 patent. The Commission has further determined to review the ID's finding that the JUUL2 DI system practices claims 1 and 4 of the '173 patent.

In view of the parties' submissions and the issues raised with regard to satisfaction of the technical prong of the DI requirement, the Commission has further determined to reconsider its previous finding that JLI has satisfied the economic prong of the DI requirement with respect to the '123 patent and the '173 patent based on investments related to both the JUUL DI system and the JUUL2 DI system. 19 CFR 210.47, .48.

The Commission has determined not to review the remaining findings in the ID, including the ID's findings of a violation of section 337 as to the '722 and '981 patents. The Commission has further determined to deny NJOY's motion for leave to file a reply in support of its petition for review.

In connection with its review, the Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

(1) Please explain whether the final ID correctly finds that ''JLI does not rely on the [ ] iteration as a domestic industry product.'' ID at 123 (citing Case Management Conf. Tr. at 8:16–24 (April 26, 2024) (EDIS Doc. ID 820002)). To the extent it is argued that the final ID errs in this finding and JLI asserted the [ ] iteration of the JUUL system to satisfy the technical prong of the domestic industry requirement with respect to the '123 patent, please identify where in the record JLI timely preserved this contention so as to avoid a finding of waiver.

(2) Did JLI explicitly or implicitly waive its right to rely on the [ ] iteration of the JUUL system to satisfy the DI requirement with respect to the '123 patent?

(3) Can OUII, as a party to the investigation, assert that the [ ] iteration of the JUUL system satisfies the DI requirement with respect to the '123 patent where the complainant did not allege that this product satisfies that requirement? *See John Mezzalingua Assocs., Inc.* v. *ITC,* 660 F.3d 1322, 1331 (Fed. Cir. 2011); *but see Certain Liquid Transfer Devices with an Integral Vial Adapter,* Inv. No. 337–TA–1362, Comm'n Op. at 16–19 (July 26, 2024) (recognizing that OUII should have been allowed to raise an invalidity argument that was waived by respondents).

(4) Do the asserted JAGWAR iteration of the JUUL DI system and the asserted JUUL2 DI system practice (literally and/or under the doctrine of equivalents) limitations 27[d] and 27[e] of claim 27 of the '123 patent under a construction of those limitations requiring at least one ''pressure sensor'' that has both ''a first side . . . exposed to a sealed air flow path'' and ''a second side . . . exposed to a device air path open to ambient pressure.''

(5) Assuming that only the JAGWAR iteration of the JUUL DI system and the JUUL2 DI system can be relied upon to satisfy the technical prong of the DI requirement, is there any need to further consider the allocation of investments related to the economic prong findings as to the '123 patent in Order 22? In responding to this question, please address the ALJ's finding in Order 26 that JLI ''did not rely on its [ ] JUUL System for economic domestic industry for the '123 patent'' (Order 26 at 1) and the statement in NJOY's petition for review that it had not opposed the summary determination that JLI has satisfied the economic prong of the domestic industry

requirement ''based on the understanding that JUUL Jagwar and JUUL 2 were the only domestic industry products for the '123 Patent.'' NJOY Pet. at 29.

(6) Assuming that only the JAGWAR iteration of the JUUL DI system and the JUUL2 DI system can be relied upon to satisfy the technical prong of the DI requirement, does the record in this investigation support an allocation of JLI's investments to only one or both those DI products?

(7) Please confirm that the investments asserted by JLI as to the ''JUUL system'' regarding the '123 patent in Order 22 do not include investments relating to [ ]. If [ ] investments are included, what are the amounts specific only to JAGWAR and to JUUL2? Are these revised investments in JAGWAR and JUUL2 regarding the '123 patent significant under section 337(a)(3) (A) and (B)?

(8) Please comment on whether remand is necessary to determine whether the domestic industry requirement is satisfied as to the '123 patent.

The parties are invited to brief only the discrete issues requested above. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994).

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy, the public interest, and bonding.

In its initial written submission, JLI is also requested to identify the remedy sought and to submit proposed remedial orders for the Commission's consideration. JLI is further requested to state the dates that the asserted patents expire, to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. In its written submission, OUII is also requested to submit proposed remedial orders for the Commission's consideration.

The initial written submissions and proposed remedial orders from the parties must be filed no later than the close of business on November 7, 2024. Reply submissions from the parties must be filed no later than the close of business on November 14, 2024. Initial written submissions from interested government agencies, and any other interested parties must be filed no later than the close of business on November 20, 2024. Reply submissions from the interested government agencies, and any other interested parties must be filed no later than the close of business on November 27, 2024. Opening submissions are limited to 60 pages. Reply submissions are limited to 40 pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1368) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. Government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on October 24, 2024.

The authority for the Commission's determination is contained in section

337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 6, 2024.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2024–26161 Filed 11–8–24; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1123–0NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection; Title—COP Community Policing Advancement Performance Report

AGENCY: Office of Community Oriented Policing Services, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office of Community Oriented Policing Services, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until January 13, 2025.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Dave Neely, Department of Justice Office of Community Oriented Policing Services, 145 N St. NW, Washington, DC 20530, *-1584 -avid.neely2@usdoj.gov* (202) 514–8553.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: Under the Gambling Devices Act of 1962 (15 U.S.C. 1171–1178) mandates that the Department of Justice register all entities that participate in the interstate commerce of gambling devices. Registration involves the collection of certain information from the respondent, as specified in the Act.

Overview of This Information Collection

1. *Type of Information Collection:* New collection.

2. *The Title of the Form/Collection:* COPS Community Policing Advancement Performance Report.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* None. U.S. Department of Justice Office of Community Oriented Policing Services.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public Primary: Law enforcement agencies and other public and private entities that respond to a bi-annual performance report.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 430 respondents will complete the form on a bi-annual basis taking an estimated 20 minutes per report twice a year.

6. *An estimate of the total annual burden (in hours) associated with the collection:* There are an estimated 287 total annual burden hours associated with this collection.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency (biannual)	Total annual responses	Time per response (mins)	Total annual burden (hours)
Form	430	2	430	20	287
Unduplicated Totals	430	2	430	20	287

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: November 6, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–26133 Filed 11–8–24; 8:45 am]

BILLING CODE 4410–AT–P

DEPARTMENT OF JUSTICE

[OMB Number 1123–0010]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension of a Previously Approved Collection; Request for Registration Under the Gambling Devices Act of 1962

AGENCY: Criminal Division, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Criminal Division, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until January 13, 2025.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time,

suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Dawn Cauraugh, Office of Enforcement Operations, 1301 New York Avenue NW, Washington, DC 20530, (202) 353–3993, *dawn.cauraugh.usdoj.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;
—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: Under the Gambling Devices Act of 1962 (15 U.S.C. 1171–1178) mandates that the Department of Justice register all entities that participate in the interstate commerce of gambling devices. Registration involves the collection of certain information from the respondent, as specified in the Act.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *The Title of the Form/Collection:* Request for Registration Under the Gambling Act of 1962 (15 U.S.C. 1171–1178).

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* OMB No. 1123–0010 (7/31/2017); Office of Enforcement Operations.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public Primary: Business or other for-profit. Other: Not-for-profit institutions, individuals or household, and State, Local, or Tribe Government. The form can be used by any entity required to register under the Gambling Devices Act of 1962 (15 U.S.C. 1171–1178).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 7,800 respondents will complete each form within approximately 5 minutes.

6. *An estimate of the total annual burden (in hours) associated with the collection:* There are an estimated 650 total annual burden hours associated with this collection.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response (min)	Total annual burden (hours)
Form	7,800	1/annually	7,800	5	650
Unduplicated Totals	7,800	1/annually	7,800	5	650

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: November 6, 2024.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2024–26131 Filed 11–8–24; 8:45 am]

BILLING CODE 4410–14–P

DEPARTMENT OF JUSTICE

Parole Commission

Sunshine Act Meeting

DATE AND TIME: Thursday, November 14, at 1:00 p.m.

PLACE: U.S. Parole Commission, 90 K Street NE, 3rd Floor, Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Approval of June 12, 2024, Meeting Minutes.

2. Verbal Updates since the June Meeting from the Acting Chairman, Commissioner, Acting Chief of Staff/Case Operations Administrator, Case Services Administrator, Acting Executive Officer, and General Counsel.

CONTACT PERSON FOR MORE INFORMATION: Jacquelyn Graham, Staff Assistant to the Chairman, U.S. Parole Commission, 90 K Street NE, 3rd Floor, Washington, DC 20530, (202) 346–7010.

Dated: November 6, 2024.

Patricia K. Cushwa,

Chairman (Acting), U.S. Parole Commission.

[FR Doc. 2024–26320 Filed 11–7–24; 4:15 pm]

BILLING CODE 4410–31–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

[OMB Control No. 1219–0131]

Proposed Extension of Information Collection; Training Plans, New Miner Training, Newly-Hired Experienced Miner Training

AGENCY: Mine Safety and Health Administration, Labor.

ACTION: Request for public comments.

SUMMARY: The Department of Labor (DOL), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed collections of information, in accordance with the Paperwork Reduction Act of 1995. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and

the impact of collection requirements on respondents can be properly assessed. The Mine Safety and Health Administration (MSHA) is soliciting comments on the information collection entitled Training Plans, New Miner Training, Newly-hired Experienced Miner Training.

DATES: All comments must be received on or before January 13, 2025.

ADDRESSES: Comments concerning the information collection requirements of this notice may be sent by any of the methods listed below. Please note that late comments received after the deadline will not be considered.

- *Federal E-Rulemaking Portal: https://www.regulations.gov.* Follow the on-line instructions for submitting comments for docket number MSHA–2024–0035.
- *Mail/Hand Delivery:* DOL–MSHA, Office of Standards, Regulations, and Variances, 201 12th Street South, 4th Floor West, Arlington, VA 22202–5452. Before visiting MSHA in person, call 202–693–9455 to make an appointment.
- MSHA will post all comments as well as any attachments, except for information submitted and marked as confidential, in the docket at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: S. Aromie Noe, Director, Office of Standards, Regulations, and Variances, MSHA, at *MSHA.information.collections@dol.gov* (email); (202) 693–9440 (voice); or (202) 693–9441 (facsimile). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION:

I. Background

A. Legal Authority

Section 103(h) of the Federal Mine Safety and Health Act of 1977 as amended (Mine Act), 30 U.S.C. 813(h), authorizes the Mine Safety and Health Administration (MSHA) to collect information necessary to carry out its duty in protecting the safety and health of miners. Further, section 101(a) of the Mine Act, 30 U.S.C. 811(a), authorizes the Secretary of Labor (Secretary) to develop, promulgate, and revise, as may be appropriate, improved mandatory health or safety standards for the protection of life and prevention of injuries in coal, metal and nonmetal mines.

Section 2 of the Mine Act, 30 U.S.C. 801, recognizes that education and training is an important element of federal efforts to make the nation's mines safe. These provisions are intended to ensure that miners will be effectively trained in matters affecting their health and safety, with the ultimate goal of reducing the occurrence of injury and illness in the nation's mines.

B. Information Collection

In order to fulfill the statutory mandates to promote miners' health and safety, MSHA requires the collection of information under the information collection request entitled Training Plans, New Miner Training, Newly-Hired Experienced Miner Training. The information collection is intended to ensure that mine operators possess appropriate training plans and maintain records of the mandatory requirements for training and retraining miners and other persons at shell dredging, sand, gravel, surface stone, surface clay, colloidal phosphate, or surface limestone mines.

1. Training Plans

Mine operators are required to develop and implement a written training plan for approval by MSHA, that contains effective programs for: training new miners and newly hired experienced miners, training miners for new tasks, annual refresher training, and site-specific hazard awareness training. Miners are better protected when receiving timely and complete training described in the operators' written training plan.

Under 30 CFR 46.2(l), operators can be either a production-operator or an independent contractor whose employees perform services at a mine. A production-operator is defined as any owner, lessee, or other person who operates, controls, or supervises a mine (30 CFR 46.2(m)), and an independent contractor is any entity that contracts to perform services at a mine(30 CFR 46.2(e)).

Under 30 CFR 46.2(g), a miner is defined as any person, including any operator or supervisor, who works at a mine and is engaged in mining operations. This definition includes independent contractors and employees of independent contractors who are engaged in mining operations; and any construction worker who is exposed to hazards of mining operations. The definition of ''miner'' does not include scientific workers; delivery workers; customers (including commercial over-the-road truck drivers); vendors; or visitors. This definition also does not include maintenance or service workers who do not work at a mine site for frequent or extended periods. Following are information collection requirements at each step of the development of a training plan.

1–1. Develop Training Plans

Under 30 CFR 46.3(a), the operator must develop and implement a written plan, approved by MSHA, that contains effective programs for training new miners and newly hired experienced miners, training miners for new tasks, annual refresher training, and site-specific hazard awareness training.

The approval process is described in 30 CFR 46.3(b) through (i). Under 30 CFR 46.3(b), a training plan is considered approved by MSHA if it contains, at a minimum, the following information:

(1) The name of the production-operator or independent contractor, mine name(s), and MSHA mine identification number(s) or independent contractor identification number(s);

(2) The name and position of the person designated by the operator who is responsible for the health and safety training at the mine;

(3) A general description of the teaching methods and the course materials that are to be used in the training program, including the subject areas to be covered and the approximate time or range of time to be spent on each subject area;

(4) A list of the persons and/or organizations who will provide the training, and the subject areas in which each person and/or organization is competent to instruct; and

(5) The evaluation procedures used to determine the effectiveness of training.

1–2. Submit Proposed Training Plans to MSHA and Notify Miners or Miners' Representatives

Under 30 CFR 46.3(c), a plan that does not include the minimum information specified in 30 CFR 46.3 must be submitted to and approved by the Regional Manager, Educational Field Services Division, or designee, for the region in which the mine is located. The operator also may voluntarily submit a plan for Regional Manager approval. The operator must notify miners or their representatives when they submit a plan for Regional Manager approval. Within two weeks of receipt or posting of the plan, miners and their representatives may also request review and approval of the plan by the Regional Manager and must notify the operator of such request.

1–3. Provide Proposed Training Plans to Miners or Miners' Representatives

Under 30 CFR 46.3(d), the operator must provide the miners' representative, if any, with a copy of the plan at least 2 weeks before the plan is implemented or, if they request MSHA approval of the plan, at least two weeks before they

submit the plan to the Regional Manager for approval. At mines where no miners' representative has been designated, the operator must post a copy of the plan at the mine or provide a copy to each miner at least 2 weeks before they implement the plan or submit it to the Regional Manager for approval.

1–4. Miners or Miners' Representatives Submit Written Comments on Training Plans

Under 30 CFR 46.3(e), within 2 weeks following the receipt or posting of the training plan provided to the miners or their representatives under 30 CFR 46.3(d), miners or their representatives may submit written comments on the plan to the operator, or to the Regional Manager, as appropriate.

1–5. Provide Approved Training Plans to Miners and Miners' Representatives

Under 30 CFR 46.3(g), the operator must provide the miners' representative, if any, with a copy of the approved plan within one week after approval. At mines where no miners' representative has been designated, the operator must post a copy of the plan at the mine or provide a copy to each miner within one week after approval.

1–6. Submit Appeals for MSHA Decision

Under 30 CFR 46.3(h), if the operator, miners, or miners' representatives wish to appeal a decision of the Regional Manager, the operator must send the appeal, in writing, to the Director for Educational Policy and Development within 30 calendar days after notification of the Regional Manager's decision. The Director will issue a final decision of the Agency within 30 calendar days after receipt of the appeal.

1–7. Make Training Plans Available for Inspection and Examination

Under 30 CFR 46.3(i), the operator must make available at the mine a copy of the current training plan for inspection by MSHA and for examination by miners and their representatives. If the training plan is not maintained at the mine, the operator must have the capability to provide the plan within one business day upon request by MSHA, miners, or their representatives.

2. Training Records

Mine operators are required to conduct the following mandatory training: training new miners, training newly hired experienced miners, training miners for new tasks, annual refresher training, and site-specific hazard awareness training. The operators are required to make a record of and certify each type of training records. The discussion below is organized by the type of training records.

2–1. New Miner Training

Section 30 CFR 46.5 sets forth the provisions for the mandatory requirements for new miners training. Under 30 CFR 46.2(i), new miner means a person who is beginning employment as a miner with a mine operator and who is not an experienced miner.

Under 30 CFR 46.5(a), the operator must provide each new miner with no less than 24 hours of training as prescribed by:

(1) 30 CFR 46.5(b): Training before a new miner begins work at the mine, such as an introduction to the work environment and instruction on the recognition and avoidance of electrical hazards and other hazards present at the mine;

(2) 30 CFR 46.5(c): Training no later than 60 calendar days after a new miner begins work at the mine, such as an instruction and demonstration on the use, care, and maintenance of self-rescue and respiratory devices, if used at the mine and a review of first aid methods; and

(3) 30 CFR 46.5(d): Training no later than 90 calendar days after a new miner begins work at the mine on any other subjects that promote occupational health and safety for miners at the mine.

Miners who have not received the full 24 hours of new miner training must work where an experienced miner can observe that the new miner is performing his or her work in a safe and healthful manner.

Under 30 CFR 46.9(c)(1), the operator must make a record for new miner training, no later than:

(1) when the miner begins work at the mine as required under 30 CF 46.5(b);

(2) 60 calendar days after the miner begins work at the mine as required under 30 CFR 46.5(c); and

(3) 90 calendar days after the miner begins work at the mine as required under 30 CFR 46.5(d), if applicable.

Under 30 CFR 46.9(d)(1), the operator must ensure that all records of training are certified by the person designated in the MSHA-approved training plan and a copy provided to the miner upon completion of the 24 hours of new miner training.

2–2. Newly Hired Experienced Miner Training

Section 30 CFR 46.6 sets forth the provisions for the mandatory requirements for newly hired experienced miners training. Under 30 CFR 46.2(j), newly hired experienced miner means an experienced miner who is beginning employment with a mine operator. Experienced miners are a person who has completed 24 hours of new miner training and who has at least 12 cumulative months of surface mining or equivalent experience. Experienced miners who move from one mine to another, such as drillers and blasters, but who remain employed by the same operator are not considered newly hired experienced miners.

Under 30 CFR 46.6(a), the operator must provide each newly hired experienced miner with trainings as prescribed by paragraphs (b) and (c) that includes:

(1) 30 CFR 46.6(b): Training before a newly hired experienced miner begins work at the mine, such as an introduction to the work environment and instruction on the recognition and avoidance of electrical hazards and other hazards present at the mine; and

(2) 30 CFR 46.6(c): Training no later than 60 calendar days after a newly hired experienced miner begins work at the mine, such as an instruction and demonstration on the use, care, and maintenance of self-rescue and respiratory devices, if used at the mine.

Under 30 CFR 46.9(c)(2), the operator must make a record for newly hired experienced miner training, no later than:

(1) when the miner begins work at the mine as required under 30 CFR 46.6(b); and

(2) 60 calendar days after the miner begins work at the mine under 30 CFR 46.6(c).

Under 30 CFR 46.9(d)(2), the operator must ensure that all records of training are certified by the person designated in the MSHA-approved training plan and a copy provided to the miner upon completion of newly hired experienced miner training.

2–3. New Task Training

Section 30 CFR 46.7 sets forth the provisions for the mandatory requirements for new task training.

New Task Training—Reassigned Tasks

Under 30 CFR 46.7(a), the operator must provide to any miner that is reassigned to a new task in which he or she has no previous work experience with training in the health and safety aspects of the task to be assigned, including the safe work procedures of such task, information about the physical and health hazards of chemicals in the miner's work area, the protective measures a miner can take against these hazards, and the contents of the mine's HazCom program. This

training must be provided before the miner performs the new task.

New Task Training—Changes in Assigned Tasks

Under 30 CFR 46.7(b), if a change occurs in a miner's assigned task that affect the health and safety risks encountered by the miner, the operator must provide the miner with new task training that addresses the change. Under 30 CFR 46.9(c)(3), the operator must make a record upon completion of new task training. Under 30 CFR 46.9(d)(3), the operator must ensure that all records of training are certified by the person designated in the MSHA-approved training plan and a copy provided to the miner at least once every 12 months for new task training, or upon request by the miner, if applicable.

2–4. Annual Refresher Training

Section 30 CFR 46.8 sets forth the provisions for the mandatory requirements for new miners training. Under 30 CFR 46.8(a), the operator must provide each miner with no less than 8 hours of annual refresher training:

(1) No later than 12 months after miner begins working at the mine; and

(2) Thereafter no later than 12 months after the previous annual fresher training.

Under 30 CFR 46.8(b), the refresher training must include instruction on any changes at the mine that could adversely affect the miner's health and safety. Under 30 CFR 46.8(c), refresher training must also address other health and safety subjects that are relevant to mining operations at the mine. Recommended subjects include applicable health and safety requirements; information about the physical and health hazards of chemicals in the miner's work area; and water hazards, pits, and spoil banks. Under 30 CFR 46.9(c)(4), the operator must make a record after each session of annual refresher training. Under 30 CFR 46.9(d)(4), the operator must ensure that all records of training are certified by the person designated in the MSHA-approved training plan and a copy provided to the miner upon completion of the 8 hours of annual refresher training.

2–5. Site-Specific Hazard Awareness Training

Section 30 CFR 46.11 sets forth the provisions for the mandatory requirements for site-specific hazard awareness training.

Under 30 CFR 46.11(a), the operator must provide site-specific hazard awareness training before any person specified in 30 CFR 46.11(b) and (c) is exposed to mine hazards.

Under 30 CFR 46.11(b), the operator must provide site-specific hazard awareness training, as appropriate, to any person who is not a miner but is presented at a mine site, including:

(1) Office or staff personnel;

(2) Scientific workers;

(3) Delivery workers;

(4) Customers, including commercial over-the-road truck drivers;

(5) Construction workers or employees of independent contractors who are not miners;

(6) Maintenance or service workers who do not work at the mine site for frequent or extended periods; and

(7) Vendors or visitors.

Under 30 CFR 46.11(c), the operator must provide miners, such as drillers or blasters, who move from one mine to another mine while remaining employed by the same mine operator with site-specific hazard awareness training for each mine.

Under 30 CFR 46.11(d), site-specific hazard awareness training is information or instructions on the hazards a person could be exposed to while at the mine, as well as applicable emergency procedures. The training must address site-specific health and safety risks, such as unique geologic or environmental conditions, recognition and avoidance of hazards such as electrical and powered-haulage hazards, traffic patterns and control, and restricted areas; and warning and evacuation signals, evacuation and emergency procedures, or other special safety procedures.

Under 30 CFR 46.11(e), the operator may provide site-specific hazard awareness training through the use of written hazard warnings, oral instruction, signs and posted warnings, walkaround training, or other appropriate means that alert persons to site-specific hazards at the mine.

Under 30 CFR 46.11(f), site-specific hazard awareness training is not required for any person who is accompanied at all times by an experienced miner who is familiar with hazards specific to the mine site.

Under 30 CFR 46.9(c)(5), the operator must make a record upon completion by miners of site-specific hazard awareness training.

Under 30 CFR 46.9(d)(5), the operator must ensure that all records of training are certified by the person designated in the MSHA-approved training plan and a copy provided to the miner upon completion by miners of site-specific hazard awareness training.

2–6. Independent Contractor Training

Under 30 CFR 46.12(a), the production-operator has primary responsibility for ensuring that site-specific hazard awareness training is given to employees of independent contractors who are required to receive such training under 30 CFR 46.11. Each production-operator must provide information to each independent contractor who employs a person at the mine on site-specific mine hazards and the obligation of the contractor to comply with the regulations, including the requirements of 30 CFR part 46.

Under 30 CFR 46.12(b), independent contractors who employ a miner at the mine has primary responsibility for complying with 30 CFR 46.3 through 46.10, including providing new miner training, newly hired experienced miner training, new task training, and annual refresher training. The independent contractor must inform the production-operator of any hazards of which the contractor is aware that may be created by the performance of the contractor's work at the mine.

2–7. Training Records

Under 30 CFR 46.9, the operator must make a record of and certify each type of training detailed below to document that each miner has received their required training. Under 30 CFR 46.9(a), the operator must make a record of and certify on MSHA Form 5000–23 that each miner has received the training required in 30 CFR 46. The operator can, but is not required to, record the miner's training on MSHA Form 5000–23, Certificate of Training. MSHA Form 5000–23 is the mandatory approved form for Part 48 training associated with information collection request under OMB Control Number 1219–0009.

Alternatively, the operator can record and certify on a form that contains the following information listed in 30 CFR 46.9(b), including:

(1) The printed full name of the person trained;

(2) The type of training, the duration of the training, the date the training was received, the name of the competent person who provided the training;

(3) The name of the mine or independent contractor, MSHA mine identification number or independent contractor identification number, and location of training (if an institution, the name and address of the institution).);

(4) The statement, ''False certification is punishable under section 110(a) and (f) of the Federal Mine Safety and Health Act,'' printed in bold letters and in a conspicuous manner; and

(5) A statement signed by the person designated in the MSHA-approved

training plan for the mine as responsible for health and safety training, that states ''I certify that the above training has been completed.''

Under 30 CFR 46.9(f), when a miner leaves the operator's employment, the operator must provide each miner with a copy of his or her training records and certificates upon request.

Under 30 CFR 46.9(g), the operator must make available at the mine a copy of each miner's training records and certificates for inspection by MSHA and for examination by miners and their representatives. If training certificates are not maintained at the mine, the operator must be able to provide the certificates upon request to MSHA, miners, or their representatives.

Under 30 CFR 46.9(h), the operator must maintain copies of training certificates and training records for each currently employed miner during his or her employment, except for records and certificates of annual refresher training which must be maintained for only two years. The operator must maintain copies of training certificates and training records for at least 60 calendar days after a miner terminates employment.

Under 30 CFR 46.9(i), the operator is not required to make records of site-specific hazard awareness training to persons who are not miners. However, the operator, must be able to provide evidence to MSHA, upon request, that the training was provided, such as the training materials that are used; copies of written information distributed to persons upon their arrival at the mine, or visitor log books that indicate that training has been provided.

The information collection request under a currently approved OMB Control Number 1219–0009, Certificate of Training, covers the mandatory requirements for submitting and obtaining approval of programs for training and retraining miners working in underground mines (30 CFR part 48 Subpart A). The request also covers similar requirements for miners working at surface mines and surface areas of underground mines (30 CFR part 48 Subpart B). That information collection request under does not apply to training and retraining of miners at shell dredging, sand, gravel, surface stone, surface clay, colloidal phosphate, and surface limestone mines. The provisions of 30 CFR part 46 set forth the mandatory requirements for training and retraining miners and other persons for these miners.

II. Desired Focus of Comments

MSHA is soliciting comments concerning the proposed information collection related to Training Plans, New Miner Training, Newly-Hired Experienced Miner Training. MSHA is particularly interested in comments that:

- Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information has practical utility;
- Evaluate the accuracy of MSHA's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;
- Suggest methods to enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

The information collection request will be available on *https://www.regulations.gov.* MSHA cautions the commenter against providing any information in the submission that should not be publicly disclosed. Full comments, including personal information provided, will be made available on *https://www.regulations.gov* and *https://www.reginfo.gov.*

The public may also examine publicly available documents at DOL–MSHA, Office of Standards, Regulations and Variances, 201 12th Street South, 4th Floor West, Arlington, VA 22202–5452. Sign in at the receptionist's desk on the 4th Floor via the West elevator. Before visiting MSHA in person, call 202–693–9455 to make an appointment.

Questions about the information collection requirements may be directed to the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

III. Current Actions

This information collection request concerns provisions for Training Plans, New Miner Training, Newly-Hired Experienced Miner Training. MSHA has updated the data with respect to the number of respondents, responses, time burden, and burden costs supporting this information collection request from the previous information collection request.

Type of Review: Extension, without change, of a currently approved collection.

Agency: Mine Safety and Health Administration.

OMB Number: 1219–0131.

Affected Public: Business or other for-profit.

Number of Annual Respondents: 10,872.

Frequency: On occasion.

Number of Annual Responses: 2,275,623.

Annual Time Burden: 157,458 hours.

Annual Other Burden Costs: $351,967.

MSHA Form: Electronic Training Plan Advisor.

Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval of the proposed information collection request; they will become a matter of public record and be available at *https://www.reginfo.gov.*

Song-ae Aromie Noe,

Certifying Officer, Mine Safety and Health Administration.

[FR Doc. 2024–26113 Filed 11–8–24; 8:45 am]

BILLING CODE 4510–43–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–397; NRC–2024–0160]

Energy Northwest; Columbia Generating Station; Environmental Assessment and Finding of No Significant Impact

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Renewed Facility Operating License No. NPF–21, issued on May 22, 2012, held by Energy Northwest for the operation of Columbia Generating Station (Columbia) located in Benton County, Washington, on land leased from the U.S. Department of Energy (DOE). The proposed amendment would revise the Columbia Emergency Plan by changing the emergency response organization (ERO) staffing plan. The NRC staff evaluated the potential environmental effects of the proposed action (license amendment request) and is issuing an environmental assessment (EA) and finding of no significant impact (FONSI).

DATES: The EA and FONSI referenced in this document are available on November 12, 2024.

ADDRESSES: Please refer to Docket ID NRC–2024–0160 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available

information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0160. 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.
- *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.* For the convenience of the reader, information for obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mahesh L. Chawla, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–8371; email: *Mahesh.Chawla@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

By letter dated January 30, 2024, as supplemented by letters dated March 20, September 10, and September 24, 2024, Energy Northwest submitted a request to amend Renewed Facility Operating License No. NPF–21, issued to Energy Northwest, for the operation of Columbia Generating Station (Columbia), which is located in Benton County, Washington, on land leased from the DOE. If approved, the proposed amendment would revise the emergency plan to be consistent with the guidance of the Federal Emergency Management Agency (FEMA) Radiological Emergency Preparedness (REP) document in NUREG–0654/FEMA–REP–1, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants,'' Revision 2, December 2019. The proposed changes would revise the Columbia Emergency Plan by changing the ERO staffing plan to align staff functions and major task delineations, specifically, the on-shift and augmenting positions assigned within certain functional areas and remove references to non-minimum augmented ERO positions from the Columbia Emergency Plan while retaining appropriate positions in the applicable implementing procedures.

Each licensee for a nuclear power plant is required to establish an emergency plan to be implemented in the event of an accident in accordance with part 50, ''Domestic Licensing of Production and Utilization Facilities,'' section 50.47, ''Emergency plans,'' and appendix E, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' of title 10 of the *Code of Federal Regulations* (10 CFR). The emergency plan covers preparation for evacuation, sheltering, and other actions to protect people living near the nuclear power plant in the event of an accident. An effective emergency preparedness program decreases the likelihood of an initiating event at a nuclear facility proceeding to a severe accident. Emergency preparedness cannot affect the probability of the initiating event, but a high level of emergency preparedness increases the probability of accident mitigation if the initiating event proceeds beyond the need for initial operator actions.

The regulations in 10 CFR 50.54(q)(2) require licensees for nuclear power plants to follow and maintain the effectiveness of an emergency plan that meets the standards in 10 CFR 50.47(b) and the requirements in 10 CFR part 50, appendix E. Sections 50.54(q)(3) and (4) of 10 CFR specify the process by which a licensee may make changes to its emergency plan. In accordance with 10 CFR 50.54(q)(4), Energy Northwest submitted the January 30, 2024, license amendment request, pursuant to 10 CFR 50.90, to obtain NRC approval of the proposed changes to the Columbia Emergency Plan prior to implementation.

In accordance with 10 CFR 51.21, ''Criteria for and identification of licensing and regulatory actions requiring environmental assessments,'' the NRC prepared the following environmental assessment (EA) that analyzes the environmental impacts of the proposed licensing action. Based on the results of this EA, and in accordance with 10 CFR 51.31(a), the NRC has determined not to prepare an environmental impact statement for the proposed licensing action and is issuing a finding of no significant impact (FONSI).

In addition to this EA, the NRC is conducting a safety evaluation of Energy Northwest's proposed changes to the Columbia Emergency Plan, which will be documented separately. The safety evaluation of the proposed changes to the emergency plan will determine whether Columbia would continue to meet the requirements in 10 CFR 50.47(b) and the requirements in 10 CFR part 50, appendix E with the requested amendment.

II. Environmental Assessment

Description of the Proposed Action

The proposed action would revise the ERO staffing plan identified in the Columbia Emergency Plan, including the on-shift and augmenting ERO staffing requirements. The proposed revisions would remove reference to non-minimum augmenting ERO positions from the Columbia Emergency Plan while retaining appropriate positions in implementing procedures. The proposed action would also align the ERO staffing plan with the functions and major task delineations related to on-shift and augmenting ERO positions assigned within certain functional areas.

The NRC staff notes that Energy Northwest's request referred to on-shift and minimum augmenting ERO positions. Although NUREG–0654/FEMA–REP–1 does not refer to minimum augmenting ERO positions, the NRC staff understands phrases like minimum augmenting ERO positions to refer to those positions described in NUREG–0654/FEMA–REP–1. Similarly, the NRC staff understands phrases like non-minimum augmented ERO positions to refer to positions described by the Columbia Emergency Plan beyond those described in NUREG–0654/FEMA–REP–1. For clarity, this environmental assessment will refer to augmenting ERO positions instead of minimum augmenting ERO positions when discussing the positions described in NUREG–0654/FEMA–REP–1 but will refer to non-minimum augmenting ERO positions when discussing positions beyond those described in NUREG–0654/FEMA–REP–1.

The proposed action is in accordance with Energy Northwest's request for a license amendment, to revise the Columbia Emergency Plan dated January 30, 2024, notice of which the NRC published in the **Federal Register** (89 FR 49238).

Need for the Proposed Action

If granted, the proposed action would align the Columbia Emergency Plan

with the NRC's guidance for EROs in NUREG–0654/FEMA–REP–1, Revision 2. The application states that Energy Northwest shared the proposed Columbia Emergency Plan changes with offsite response organizations for the State of Washington, Benton County, and Franklin County, and these organizations had no concerns.

Environmental Impacts of the Proposed Action

The proposed action consists of changes related to staffing positions, position descriptions, titles, duties, duty locations, and response times specified in the Columbia Emergency Plan. The on-shift and augmenting ERO staffing requirements listed in the emergency plan would be revised. The proposed revisions include eliminating ERO positions; adding ERO positions; changing position descriptions, titles, duties, and duty locations; changing response times, and relocating certain position descriptions to other parts of the emergency plan or to implementing procedures.

The proposed changes would have no direct impacts on land use or water resources, including terrestrial and aquatic biota, as the proposed action involves no new construction, ground disturbing activities, or modification of nuclear power plant operational systems. For the same reasons, there would also be no changes to the quality or quantity of non-radiological effluents and no changes to the nuclear plant's National Pollutant Discharge Elimination System permits. Overall staffing levels are not expected to increase; therefore, worker vehicle air emissions are not expected to increase. In addition, for the reasons stated previously in this notice, there would be no noticeable effect on socioeconomic conditions in the region, no environment justice impacts, and no impacts to historic properties and cultural resources from the proposed licensing action. Therefore, there would be no significant non-radiological environmental impacts associated with the proposed agency action.

In addition, the proposed licensing action would not have a significant effect on the probability or consequences of radiological accidents because the emergency plan must continue to meet the standards of 10 CFR 50.47(b) and the requirements in 10 CFR part 50, appendix E. For the same reasons there would be no change to the types or amounts of non-radioactive effluents, there would also be no change to the types or amounts of radioactive effluents released into the environment and, therefore, no change in occupational or public radiation exposure from the proposed changes. Therefore, there would be no significant radiological impacts associated with the proposed agency action.

The NRC staff therefore concludes that the proposed licensing action would not significantly affect plant safety and would not have a significant adverse effect on the probability of or consequences from an accident. Accordingly, the NRC staff concludes that the proposed agency action would have no significant environmental effect on the quality of the human environment.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the NRC staff considered denial of the license amendment request (*i.e.,* the ''no-action'' alternative). Denial of the license amendment request would result in no change in current environmental impacts at Columbia. As determined above, the proposed action would have no significant environmental effect on the quality of the human environment. Accordingly, the environmental impacts of the proposed action and the no action alternative would be similar.

Alternative Use of Resources

There are no unresolved conflicts concerning alternative uses of available environmental resources under the proposed action.

Agencies and Persons Consulted

No additional agencies or persons were consulted regarding the environmental impact of the proposed action. Because the proposed action is not a type of activity that has the potential to cause effects on historic properties, the NRC has no further obligations under section 106 of the National Historic Preservation Act. Similarly, the proposed action would not affect threatened or endangered species. Therefore, consultation under section 7 of the Endangered Species Act is not required. However, in accordance with 10 CFR 50.91(b), the licensee provided copies of its application to the State of Washington, and the NRC staff will consult with the State prior to issuance of the amendment.

III. Finding of No Significant Impact

Energy Northwest has requested a license amendment pursuant to 10 CFR 50.90, consistent with the requirements of 10 CFR 50.54(q), ''Emergency plans,'' to revise the Columbia Emergency Plan by removing references to non-minimum augmenting ERO positions from the Emergency Plan while retaining appropriate positions in implementing procedures. The amendment would also revise the Columbia Emergency Plan by changing ERO staffing requirements to align staff functions and major task delineations, specifically, the on-shift and augmenting positions assigned within certain functional areas.

The environmental effects of the proposed license request are described in the EA, presented in Section II of this notice, and incorporated by reference in this FONSI. In the EA, the NRC staff determined the proposed licensing action would not have a significant adverse effect on the probability of or consequences from an accident, and would not have any significant radiological or non-radiological environmental effects. Based on information presented in the EA, the NRC concludes that the proposed agency action would not have a significant impact on the quality of the human environment. Accordingly, there is no need to prepare an environmental impact statement for this proposed action.

As required by 10 CFR 51.32(a)(5), the most recent document describing the environmental effects of ongoing reactor operations and a description of environmental conditions at Columbia is the ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Regarding Columbia Generating Station, Final Report,'' NUREG–1437, Supplement 47, April 2012.

This FONSI and other related documents may be examined, and/or copied for a fee, at the NRC's PDR, located at One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. Publicly available records are accessible electronically from ADAMS Public Electronic Reading Room on the internet at the NRC's website: *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS should contact the NRC's PDR Reference staff by telephone at 1–800–397–4209 or 301 415 4737, or by email to *PDR.Resource@nrc.gov.*

IV. Availability of Documents

The documents identified in the following table are available to interested persons through ADAMS.

Document description	ADAMS accession No.
Energy Northwest, Columbia Generating Station, Docket No. 50–397, License Amendment Request to Revise Columbia Generating Station Emergency Plan, dated January 30, 2024.	ML24030A844.
Energy Northwest, Columbia Generating Station, Docket No. 50–397, Supplement to License Amendment Request to Revise Columbia Generating Station Emergency Plan, dated March 20, 2024.	ML24081A193.
Energy Northwest, Columbia Generating Station, Docket No. 50–397, Response to Request for Additional Information Regarding License Amendment Request to Revise Columbia Emergency Plan, dated September 10, 2024.	ML24254A366.
Energy Northwest, Columbia Generating Station, Docket No. 50–397, Supplement to Response to Request for Additional Information Regarding License Amendment Request to Revise Columbia Emergency Plan, dated September 24, 2024.	ML24269A254.
U.S. Nuclear Regulatory Commission and Federal Emergency Management Agency, ''Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness,'' NUREG–0654/FEMA–REP–1, Revision 2, dated December 2019.	ML19347D139.
U.S. Nuclear Regulatory Commission, letter to Nuclear Energy Institute, ''Alternative Guidance for Licensee Emergency Response Organizations,'' dated June 12, 2018.	ML18022A352.
U.S. Nuclear Regulatory Commission, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Regarding Columbia Generating Station,'' NUREG–1437, Supplement 47, Volume 1, dated April 2012.	ML12096A334.
U.S. Nuclear Regulatory Commission, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Regarding Columbia Generating Station,'' NUREG–1437, Supplement 47, Volume 2, dated April 2012.	ML12096A336 (Package).

Dated: November 5, 2024.

For the Nuclear Regulatory Commission.

Mahesh Chawla,

Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–26109 Filed 11–8–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–352; 50–353; NRC–2024–0194]

Constellation Energy Generation LLC; Limerick Generating Station, Units 1 and 2; Exemption

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to letter dated February 17, 2023, as supplemented by letters dated July 21, 2023, July 31, 2023, August 16, 2023, and May 28, 2024. Constellation Energy Generation LLC (Constellation, the licensee) has requested exemption from specific requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants. Constellation is the holder of the Renewed Facility Operating License Nos. NPF–39 and NPF–85, which authorize the operation of Limerick Generating Station, Units 1 and 2 (Limerick).

DATES: This document was published in the **Federal Register** on November 12, 2024.

ADDRESSES: Please refer to Docket ID NRC–2024–0194 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0194. 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.
- *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.

FOR FURTHER INFORMATION CONTACT: Michael Marshall, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–2871; email: *Michael.Marshall@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Constellation is the holder of the Renewed Facility Operating License Nos. NPF–39 and NPF–85, which authorize the operation of Limerick Generating Station, Units 1 and 2. The facilities consist of boiling water reactors (BWRs) located in Montgomery County, Pennsylvania and is located next to the Schuylkill River.

By letter dated February 17, 2023, as supplemented by letters dated July 21, 2023, July 31, 2023, August 16, 2023, and May 28, 2024, Constellation has requested exemption from specific requirements of section 50.62 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants.'' A publicly available version of each letter is in ADAMS under Accession Nos. ML23052A023, ML23202A219, ML23212B105, ML23228A094, and ML24149A211, respectively. Constellation specifically requests an exemption from the requirements of 10 CFR 50.62(c)(3) and the automatic activation requirements of 10 CFR 50.62(c)(4) and (c)(5) for a period of 30 days before the calendar year 2027 refueling outage for Unit 2 and for a period of 30 days before the calendar year 2026 refueling outage for Unit 1. In conjunction with this exemption request the licensee submitted an associated license amendment request (ADAMS Accession No. ML23052A023) to add operational constraints to the limiting conditions of operations in the technical specifications (TSs) for each Limerick unit to be in effect during each respective exemption period to ensure that there is no increase in the potential

consequences of an ATWS. In the license amendment request, the licensee also described additional ATWS mitigation strategies (*i.e.,* compensatory measures) they will implement in addition to the TS changes. Specifically, in Attachment 7 of the license amendment request, the licensee stated, ''With the additional compensatory measures being taken, the same level ATWS mitigation protection will be achieved during the 30-day RRCS demolition period when the automatic systems designed to meet compliance with 10 CFR 50.62 ATWS requirements are out of service.''

II. Request/Action

Pursuant to 10 CFR 50.62, the Commission's regulations establish specific ATWS mitigation requirements for nuclear power plants, with paragraphs (c)(3), (c)(4), and (c)(5) applicable to BWRs like Limerick Units 1 and 2. The systems that are required are to be operational are the alternate rod injection (ARI) system, the automatic activation of the standby liquid control system (SLCS), and equipment to trip the reactor coolant recirculation pumps automatically under conditions of an ATWS. Constellation requested an exemption from all requirements for ARI capability in 10 CFR 50.62(c)(3) and only from the automatic response capability in 10 CFR 50.62(c)(4) for SLCS and in 10 CFR 50.62(c)(5) recirculation pumps trip (RPT) for a period of 30-days prior to the calendar year 2027 refueling outage for Unit 2 and the calendar year 2026 refueling outage for Unit 1. During each 30-day period prior to the refueling outage, referred to by Constellation as the 30-day redundant reactivity control system (RRCS) demolition period, Constellation will begin upgrading the RRCS by demolishing the existing analog system and replacing it with a new digital system which will be completed during the refueling outage. To support RRCS demolition period, Constellation submitted a license amendment request to temporarily modify certain TS limiting conditions for operation to: (1) not require operability of certain automatic initiation features of ATWS equipment that are in the scope of work being performed, and (2) establish operating condition that ensure that there would be no increase in the consequences of an ATWS event should one occur during the 30-day RRCS demolition period. In addition, they also requested that certain surveillance requirements related to the ATWS features within the scope of work not be required during the RRCS demolition period. The limiting condition for operation changes temporarily limit the maximum reactor thermal power during the 30-day RRCS demolition period based on combination of operating parameters. Specifically, the maximum power at which the plant is limited based on the number of out of safety relief valves, the ability to manually initiate SLCS within five minutes, a minimum suppression pool water level, and the operability of the reactor water level 3 recirculation runback system. The operational constraints identified by Constellation for each identified maximum thermal power limit are listed in the following table.

EXEMPTION'S OPERATIONAL CONSTRAINTS FOR A PERIOD OF 30-DAYS

Maximum reactor thermal power	Maximum number of SRVs out of service	Manual initiation time for SLCS (minutes)	Minimum suppression pool water level (feet)	Additional system credited
90%	0	5	23	Level 3 Recirculation Runback.
87%	0	5	22	Level 3 Recirculation Runback.
84%	1	5	22	Level 3 Recirculation Runback.

In addition, as stated in their license amendment request, as evaluated by NRC staff in the safety evaluation (SE) to the license amendment request (LAR) to reduce the risk from a potential ATWS event during the 30-day period, the licensee will implement additional ATWS mitigation strategies to provide an equivalent level of ATWS protection to their normal automatic ATWS mitigation capability.

III. Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemption from the requirements of 10 CFR part 50 when: (1) the exemptions are authorized by law, (2) will not present an undue risk to public health or safety, (3) are consistent with the common defense and security; and (4) when special circumstances are present, as defined in 10 CFR 50.12(a)(2). This exemption would allow Constellation to temporarily disable the ARI, and the automatic activation of the SLCS and recirculation pumps at Limerick so that digital upgrades can be made leading up to the refueling outages of each unit.

A. The Exemption Is Authorized by Law

The Atomic Energy Act of 1954, as amended, does not require any specific systems to reduce the risk from ATWS events. These systems are required by NRC regulation. The intent of the regulations requires systems to mitigate the ATWS conditions, should they occur. The NRC staff has determined that granting the exemption will not result in a violation of the Atomic Energy Act of 1954, as amended, NRC regulations, or any other laws. Therefore, the requested exemption is authorized by law.

B. The Exemption Presents no Undue Risk to Public Health and Safety

The NRC requires that an exemption demonstrate that it does not present undue risk to public health and safety if it is granted. Constellation provided an analysis that with the proposed systems offline, the lower power limit, the manual activation of the SLCS and the recirculation runback pumps, that the disabling of the ATWS mitigation measures will not present undue risk to public health and safety. The disabling of automatic ATWS mitigation systems for 30-days potentially increases the severity of an ATWS event should it occur within the window. An ATWS that is not successfully mitigated could result in core damage due to excessive heat generation. ATWS events are unlikely events that are expected to occur once or more during an operating reactor's service life. The proposed changes to the reactor systems do not change the likelihood of an ATWS event occurring. The consequences of an ATWS can vary from a minor event that can be addressed with the available protection systems, to more severe that require more significant measures leading to a sudden shutting down of a nuclear reactor, if necessary to protect the core from damage.

The proposed ATWS mitigation strategies and TS limits presented by the licensee in the analysis in its LAR in

attachment 4 (propriety) and attachment 5 (non-proprietary) demonstrate an effective strategy to mitigate the potential severity increase caused by disabling some of the automatic functions of the reactor protection system so that there is no net increase in the consequences of an ATWS during the 30-day RRCS demolition period. The NRC staff verified in the SE to the LAR that the analysis demonstrates that the consequences of the ATWS are not increased with the associated operational constraints included in the temporary modifications to the limiting conditions for operation (LCOs) proposed in the associated LAR to this exemption during the 30-day RRCS demolition period. Based on a review of the licensee's analysis as documented in the SE to the associated LAR to this exemption, the NRC staff has determined that the requested temporary exemption, with the licensee's compliance with the TS limiting conditions of operation requested by the licensee in the LAR, presents no undue risk to public health and safety.

C. The Exemption Is Consistent With the Common Defense and Security

The requested exemption does not change safeguards and security programs at Limerick. Constellation stated those programs will remain in full effect during the 30-day RRCS demolition period exemption time periods in calendar year 2027 for Unit 2 and in calendar year 2026 for Unit 1. Therefore, the NRC staff finds that the action is consistent with the common defense and security.

D. Special Circumstances

Pursuant to 10 CFR 50.12(a)(2)(ii), special circumstances are present when application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.62 is that there are systems available to operators to sufficiently mitigate the consequences of an ATWS event, that are reliable, independent and diverse from the reactor trip system. This is made clear in 49 FR 26040 as it states ''The equipment required by this amendment (10 CFR 50.62(c)) is for the purpose of reducing the probability of unacceptable consequences following anticipated operational occurrences.'' The systems that are required by 10 CFR 50.62 at BWRs are an alternative rod insertion system, automatic SLCS, and automatic reactor coolant recirculation pump trip system.

In 49 FR 26041, the Commission provided that some operating nuclear power plants licensed to operate prior to August 22, 1969, may be granted a permanent exemption from these requirements if they can demonstrate that their risk from an ATWS is sufficiently low. The Commission provided guidance for the factors that it determined to be important to this such as, power level, unique design features that could prevent or mitigate the consequences of an ATWS, or the remaining plant lifetime. The Commission has granted these exemptions for plants licensed to operate prior to 1969 based on the finding that the risk from an ATWS is sufficiently low and therefore was not necessary to achieve the underlying purpose of the rule for Haddam Neck (55 FR 10124) and Yankee Nuclear Power Station (53 FR 20704). While Limerick Units 1 and 2 were licensed to operate after August 22, 1969, they are seeking a temporary, not a permanent exemption from these requirements. The NRC staff notes that this 30-day RRCS demolition period is temporary in nature, one time per unit, and that the resulting RRCS modifications to upgraded, digital systems will restore permanent, full compliance with 10 CFR 50.62(c)(3)–(5) afterwards. This temporary nature of the exemption aligns with the factor the Commission considered to be important to grant a permanent exemption of ''the remaining plant lifetime.'' In addition, the licensee has proposed in the associated LAR to impose operational controls including restrictions on the power level of the plant during the 30-day RRCS demolition period, which in part is used by the licensee in its analysis to demonstrate that there is no net increase in the severity of an ATWS. This aligns with the factor of ''power level'' identified by the Commission as an important factor in granting such an exemption from the ATWS rules because the power level of Limerick Units 1 and 2 will be limited by the plant's TS during their respective 30-day RRCS demolition period. Finally, while the licensee has not identified any unique design features at Limerick Units 1 and 2, it has proposed unique limiting conditions of operations such as reactor power less than or equal to 90% RTP, all 14 SRVs operable, and suppression pool water level greater than or equal to 23 feet. If suppression pool water level is less than 23 feet, but greater than 22 feet, reactor power must be reduced to less than 87%. If one SRV becomes out of service reactor power must be further reduced to less than or equal to 84% RTP. If two SRVs become inoperable or suppression pool water level drops below 22 feet then LCO 3.3.4.1 would apply, and the licensee would have one hour to restore at least one ATWS Recirculation Pump trip system to operable status within one hour or place the plant in Startup Mode within the next six hours as required by Limerick TS Action 3.3.4.1.e. The licensee has demonstrated in its analysis that by implementing these limiting conditions for operations, results in no net increase in the severity of an ATWS event. Finally, while the rule requires automatic systems, the licensee has demonstrated that the relevant human factors can sufficiently mitigate an ATWS event in the analysis, as documented by NRC staff in the SE to the associated LAR. The NRC staff finds that the relevant human factors are appropriate for a temporary exemption from the requirement for automatic systems because the licensee has demonstrated that the temporary limiting conditions for operation provide sufficient time margin in the event of an ATWS for manual actuation of these systems to provide the same level of ATWS mitigation as the automatic systems required by 10 CFR 50.62(c)(3)–(5), as evaluated by NRC staff in the SE to the LAR associated with this exemption. Therefore, the NRC staff finds that the risk of an ATWS is sufficiently low in support of this temporary exemption request, using the factors the Commission identified for certain nuclear power plants, not including Limerick Units 1 and 2, to be granted permanent exemptions from the ATWS requirements in 10 CFR 50.62(c).

Specific to the application of the rule to Limerick, NRC staff notes that the Limerick updated final safety analysis report (UFSAR) and Tech Spec Bases provides specific descriptions of each system. As described in the UFSAR Section 4.6.1.2.5.4 for Limerick, the purpose of the alternative rod insertion system as required by 10 CFR 50.62(c)(3) is to provide independent solenoid valves to bleed air from the scram valve pilot air header on low water level or high dome pressure in the reactor pressure vessel when detected by the RRCS to increase the reliability of control rod insertion. As described in the UFSAR Section 9.3.5 and TS 3/4.1.5 and associated TS basis for Limerick, the purpose of the automatic SLCS as required by 10 CFR 50.62(c)(4) is to provide a backup capability for bringing the reactor from full power to a cold, Xenon-free shutdown, assuming that the withdrawn control rods remain fixed in the rated power pattern. As described in

the UFSAR Section 7.1 and 7.6 and TS 3/4.3.4 and associated TS basis for Limerick, the purpose of the automatic reactor coolant recirculation pump trip system as required by 10 CFR 50.62(c)(5) is to provide a means of limiting the consequences of the unlikely occurrence of a failure to scram during an anticipated transient.

The NRC staff notes that for 10 CFR 50.62(c)(3), the specific application of the rule over these temporary 30-day exemption periods is not necessary to achieve the purpose as stated in Limerick's UFSAR section 4.6.1.2.5.4 here because the compensatory actions to manually start the SLCS will provide the required negative reactivity to mitigate the ATWS. For 10 CFR 50.62(c)(4)–(5), the NRC staff notes that the licensee has demonstrated that the reactor operator's manual actuation of these systems will be able to provide the same level of ATWS mitigation as the automatic systems during the 30-day RRCS demolition period with the associated limiting conditions for operation, as evaluated by NRC staff in Section 3.4 ''Walkthroughs'' in its SE to the LAR associated with this exemption. Therefore, the specific application for automatic actuation of the systems required by the rule over these temporary 30-day exemption periods is not necessary to achieve the purposes as stated in Limerick's UFSAR sections 9.3.5, and TS 3/4.1.5 for 10 CFR 50.62(c)(4) and as stated in Limerick's UFSAR Section 7.1, 7.6, and TS 3/4.3.4 for 10 CFR 50.62(c)(5).

Application of 10 CFR 50.62(c)(3)–(5) during 30-day RRCS demolition period is not necessary to achieve the underlying purpose of the rule as Constellation stated that since the provided analysis shows that when the operational constraints of the lower power limit, a higher number of operable safety relief valves, an additional non-credited automatic action (recirculation pump runback), and manual activation of the SLCS system within a 5-minute time frame, an ATWS condition can be successfully mitigated using existing procedures. The NRC staff's independent review of the analysis provided that the comparable level of ATWS mitigation protection to the required systems in 10 CFR 50.62(c)(3)–(5) can be achieved with these proposed operational constraints and that the mitigation measures provide sufficient time margin for an operator to respond to an ATWS event in place of the required automatic systems for the limited period of the 30-day RRCS demolition period. Therefore, the underlying purpose of 10 CFR 50.62(c)(3)–(5), including the specific underlying purposes of each system as described in the Limerick UFSAR and Tech Spec Bases, are achieved by the licensee's implementation of additional ATWS mitigation strategies identified in the LAR associated with this exemption and compliance with the TS limiting conditions of operations proposed in LAR while the licensee turns off the ACI, automatic SLCS, and automatic RTP during the 30-day RRCS demolition period. Accordingly, compliance with the specific requirements of 10 CFR 50.62 is not necessary during the proposed 30-day RRCS demolition period to achieve the underlying purpose of the rule. The NRC staff finds that special circumstances are present pursuant to 10 CFR 50.12(a)(2)(ii).

Constellation also proposed that 10 CFR 50.12(a)(2)(iv) and 10 CFR 50.12(a)(2)(vi) as additional special circumstances that are applicable to the exemption request. The NRC staff has considered their applicability but found that the circumstances discussed above in 10 CFR 50.12(a)(2)(ii) were adequate to address the necessity of special circumstances for the exemption request.

E. Environmental Considerations

The NRC's approval of the exemption to 10 CFR 50.62(c)(3), (c)(4), and (c)(5) belongs to a category of actions that the NRC, by rule or regulation, has declared to be a categorical exclusion, after first finding that the category of actions does not individually or cumulatively have a significant effect on the human environment. Specifically, the exemption is categorically excluded from further environmental analysis under 10 CFR 51.22(c)(9).

Under 10 CFR 51.22(c)(9), the issuance of an amendment to a license for a reactor under part 50 or part 52 that changes a requirement or issuance of an exemption from the requirement of any regulation of 10 CFR is a categorical exclusion provided that:

- The proposed action involves the exemption from a requirement for the use of a facility component located within the restricted area, as defined in 10 CFR part 20;
- The exemption involves no significant hazards consideration. The basis for the NRC staff's determination is discussed in the no significant hazards consideration published in the **Federal Register** on October 27, 2023 (88 FR 73883);
- There is no significant change in the types or significant increase in the amounts of any effluents that may be released offsite. There are no additional quantities nor changes in effluents proposed to be released based on the proposed action;
- There is no significant increase in individual or cumulative public or occupational radiation exposure. All manual actions are proposed to be conducted from the main control room and no local actions are required based on information provided by Constellation in its letter dated August 16, 2023 (ADAMS Accession No. ML23228A094). The main control room is shielded and staffed 24 hours a day under normal circumstances;

Therefore, NRC staff has determined that these exemptions are categorically excluded from environmental review pursuant to 10 CFR 51.22(c)(9), and therefore no environmental assessment or environmental impact statement needs to be prepared in connection with the proposed exemption request.

IV. Conclusions

Accordingly, the NRC has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to public health and safety, and is consistent with the common defense and security. Special circumstances are also present at Limerick to justify the exemption. Therefore, the NRC hereby grants Constellation exemptions from all requirements for ARI capability under section 10 CFR 50.62(c)(3) and only from the automatic response capability of 10 CFR 50.62(c)(4) for SLCS and 10 CFR 50.62(c)(5) for RPT for a period of 30-days prior to the 2027 refueling outage for Unit 2 and the 2026 refueling outage for Unit 1 (also referred to by Constellation as the 30-day RRCS demolition period) while operating each respective Unit in accordance with the TS limiting conditions for operation and the additional ATWS mitigation strategies requested in the associated LAR to this exemption request dated February 17, 2023, as supplemented by letters dated July 21, 2023, July 31, 2023, August 16, 2023, and May 28, 2024. The exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances are present. Therefore, the Commission hereby grants Constellation a one-time exemption from 10 CFR part 50, section 50.62(c)(3) and only the automatic response capability of sections 50.62(c)(4) and 50.62(c)(5) during the 30-day RRCS demolition period to support the installation of the digital upgrade at Limerick.

Dated: November 5, 2024.

For the Nuclear Regulatory Commission.

Bo Pham,

Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2024–26075 Filed 11–8–24; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 72–26; NRC–2024–0185]

Pacific Gas and Electric Company; Diablo Canyon Independent Spent Fuel Storage Installation; Environmental Assessment and Finding of No Significant Impact

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering the renewal of Special Nuclear Materials (SNM) License No. SNM–2511 for the Diablo Canyon (DC) Independent Spent Fuel Storage Installation (ISFSI) located in San Luis Obispo County, California. If approved, under the renewed license SNM–2511, Pacific Gas and Electric Company (PG&E) will be able to continue to operate the DC ISFSI for an additional 40 years. The NRC staff has prepared an environmental assessment (EA) for this proposed license renewal in accordance with its regulations. Based on the EA, the NRC has concluded that a finding of no significant impact (FONSI) is appropriate. Therefore, in accordance with NRC regulations, preparation of an environmental impact statement (EIS) is not warranted for the proposed action. The NRC staff also is conducting a safety evaluation of the proposed license renewal.

DATES: The EA and FONSI referenced in this document are available on November 12, 2024.

ADDRESSES: Please refer to Docket ID NRC–2024–0185 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2024–0185. Address questions about Docket IDs 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.
- *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 in this document (if it is available in ADAMS) is provided in the ''Availability of Documents'' section.
- *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Isaac Johnston, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–5649, email: *Isaac.Johnston@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering a request from PG&E to renew license SNM–2511 for the DC specifically-licensed ISFSI located in San Luis Obispo County, California. PG&E is requesting to renew license SNM–2511 for the DC ISFSI for an additional 40-year period. The current license expiration date was March 22, 2024, and PG&E submitted the license renewal application in accordance with paragraphs 72.42(b) and (c) of title 10 of the *Code of Federal Regulations* (10 CFR). Accordingly, the license is in timely renewal. If approved, PG&E would be able to continue to possess and store spent nuclear fuel at the DC ISFSI in accordance with the requirements in 10 CFR part 72, ''Licensing Requirements for the Independent Storage of Spent Nuclear Fuel, High-Level Radioactive Waste, and Reactor-Related Greater than Class C Waste'' for an additional 40 years.

The NRC staff has prepared an EA as part of its review of this license renewal request in accordance with the requirements of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' Based on the EA, the NRC staff has determined that an EIS is not required for this proposed action and a FONSI is appropriate. The NRC staff is also conducting a safety evaluation of the proposed license renewal request pursuant to 10 CFR part 72 and the results will be documented in a separate Safety Evaluation Report (SER).

II. Summary of Environmental Assessment

Description of the Proposed Action

The proposed action is the review and approval, if appropriate, of PG&E's request to renew the SNM–2511 license for the DC specifically-licensed ISFSI for a 40-year period. The ISFSI consists of storage pads, a cask transfer facility, an onsite cask transporter, and the Holtec International HI–STORM™ 100 dry cask storage system. License SNM–2511 allows PG&E to use four different multipurpose canisters (MPC), which are part of HI–STORM™ 100 System, to store the spent nuclear fuel from the Diablo Canyon Power Plant (DCPP). Currently, only the MPC–32 is in use at the DC ISFSI.

Purpose and Need for the Proposed Action

The purpose and need for the proposed action is to provide an option for continued temporary dry storage of spent nuclear fuel generated by operations of two nuclear power generating units (Units 1 and 2) at the DCPP. This dry storage option would be needed until an interim or a permanent facility (or facilities) is available for offsite disposition of the spent nuclear fuel.

The DC ISFSI was constructed to store spent nuclear fuel associated with DCPP Units 1 and 2 through the current operating licenses, which expire in November 2024 and August 2025, respectively. License SNM–2511 currently allows PG&E to store up to 4,400 spent nuclear fuel assemblies in up to 140 HI–STORM™ 100SA overpacks at the DC ISFSI. This is sufficient space for all spent nuclear fuel that would be generated by Units 1 and 2 through their current license terms. However, this approved amount of storage does not include any fuel that would be generated by Units 1 and 2 beyond their current license terms. The DCPP is currently in timely renewal and would operate past the current license term dates while the NRC considers PG&E's DCPP license renewal request. Regardless of the NRC's ultimate decision on the DCPP license renewal request, the storage capacity of the DC ISFSI would not change unless PG&E

applied for a license amendment to increase the capacity of the DC ISFSI, and the NRC approved the request.

Environmental Impacts of the Proposed Action and Agencies and Persons Consulted

The NRC staff has assessed the potential environmental impacts of the proposed action. The results of the NRC's environmental review can be found in the EA. The NRC staff performed its environmental review in accordance with the requirements in 10 CFR part 51. In conducting the environmental review, the NRC considered information in the license renewal application; communications and consultation with the California State Historic Preservation Office (CA SHPO); the Santa Ynez Chumash Indians; Tule River Tribe; Yak Tityu Tityu Yak Tiłhini Northern Chumash Indians; the Northern Chumash Tribal Council; the Coastal Band of Chumash Indians; the San Luis Obispo County Chumash Indians; the Salian Tribe of Montgomery, San Luis Obispo; and the Sacramento Field Office of the U.S. Fish and Wildlife Service (FWS).

Approval of PG&E's proposed license renewal request would allow PG&E to continue to utilize the HI–STORM™ 100SA overpack to store spent fuel from the PG&E DCPP in the DC ISFSI for an additional 40 years.

In its license renewal request, PG&E is proposing no changes in how it handles or stores spent fuel at the DC ISFSI. Approval of the proposed action would not result in any new construction or expansion of the existing DC ISFSI footprint beyond that previously approved. The DC ISFSI is a largely passive facility that produces no liquid or gaseous effluents. No significant radiological or non-radiological impacts are expected from continued normal operations. Occupational dose estimates associated with the proposed action and continued operation and maintenance of the DC ISFSI are expected to be at as low as is reasonably achievable (ALARA) levels and within the limits of 10 CFR 20.1201 and 10 CFR 72.104(a).

Specifically, PG&E's estimated annual dose to the nearest potential member of the public from DC ISFSI activities is 179 micro-Sieverts per year (μSv/yr) (17.9 millirems per year [mrem/yr]), which is below the 0.25 mSv/yr (25 mrem/yr) limit specified in 10 CFR 72.104(a) and the 1 mSv/yr (100 mrem/yr) limit in 10 CFR 20.1301(a)(1). Furthermore, PG&E maintains a radiation protection program for the DC ISFSI in accordance with 10 CFR part 20, ''Standards for Protection against Radiation,'' to ensure that radiation doses are ALARA. Accordingly, no significant radiological or non-radiological impacts are expected to result from approval of the license renewal request, and the proposed action would not significantly contribute to cumulative impacts at the DC site. Additionally, there would be no disproportionately high and adverse impacts on minority and low-income populations.

Furthermore, the NRC staff determined that this license renewal request would have no effect on historic properties present consistent with 36 CFR 800.4(d)(1). As discussed in Section 3.8.1 of the EA, there are no known historic or cultural properties within the DC ISFSI direct area of potential effects (APE). There are several historic properties within the indirect APE. PG&E has no plans for construction activities within the DC ISFSI that would result in land disturbances that have not been evaluated. The DC ISFSI does not generate any liquid or gaseous effluents and the cask is a passive system designed to limit exposure to radiation. Transportation of the casks from the DCPP to the DC ISFSI would not affect any historic and cultural resources.

The NRC staff reached out to and informed the CA SHPO via letter dated November 15, 2023, the Santa Ynez Chumash Indians, Tule River Tribe, Yak Tityu Tityu Yak Tiłhini Northern Chumash Indians, the Northern Chumash Tribal Council, the Coastal Band of Chumash Indians, the San Luis Obispo County Chumash Indians, and the Salian Tribe of Montgomery, San Luis Obispo Native American Tribes via letters dated November 27 and 28, 2023, of the license renewal request (the undertaking) and sought input from them. Subsequently, on June 14, 2024, the NRC staff informed the CA SHPO of the results of identification and evaluation for consultation pursuant to section 106 of the National Historic Preservation Act (NHPA), consistent with 36 CFR 800.4(d)(1)(i). Additionally, the NRC staff provided copies of this determination letter to all consulting parties. To date, the NRC has received no response from the CA SHPO or any consulting parties. Further, on September 13, 2024, the NRC staff published the evaluation and results of effects to historic properties in the NRC website for public review and comment. The public comment period closed on October 15, 2024. The NRC staff received no comments from the public.

The NRC staff determined the proposed action ''may affect but is not likely to adversely affect'' the California red-legged frog and California condor. The NRC staff evaluated the potential for the license renewal to result in the injury or mortality of California red-legged frogs from vehicle collision and determined that PG&E's adherence to conservation measures, including limiting vehicle speeds and stopping work when a frog is observed, would reduce the likelihood of injury or mortality of California red-legged frogs during the proposed license renewal term such that, based on the NRC staff's best judgement, injury or mortality is extremely unlikely to occur. Accordingly, this represents a discountable effect. The NRC staff evaluated the potential for the California condor to be affected by consuming unfit material left out during DC ISFSI operations, vehicle collisions, and noise. The NRC staff determined these impacts to also be extremely unlikely to occur and discountable. The proposed action would have ''no effect'' on all other Federally listed species. No critical habitat occurs in the action area. The NRC staff is consulting with the FWS in accordance with Section 7 of the Endangered Species Act to address the DC ISFSI and DCPP license renewal applications concurrently. That consultation is ongoing and may result in additional requirements to ensure the protection of the California red legged frog, California condor, or other species the FWS determines may be affected by the continued operation of the DC ISFSI.

Additionally, on September 5, 2024, the NRC staff provided a copy of the draft EA to the California Department of Public Health for its review and comment. In a letter dated October 8, 2024, the State responded that they had no comments on the draft EA.

Environmental Impacts of the Alternatives to the Proposed Action

The NRC staff also assessed the potential environmental impacts of alternatives to the proposed action, including renewal of the license for a 20-year term, shipment of spent fuel to an offsite facility, and the no-action alternative.

The environmental impacts of a 20-year license renewal term would not be significantly different than environmental impacts for the proposed action because site operations and maintenance activities would be the same.

Shipment of the spent nuclear fuel to a commercial reprocessing facility, Federal repository, or interim storage facility is not a reasonable alternative, because these facilities currently do not exist in the United States.

The no-action alternative would consist of the NRC's denial of PG&E's

request to renew DC ISFSI license SNM–2511. The license, however, would continue to be in effect with respect to possession of licensed material per 10 CFR 72.54(c) until the NRC notifies the licensee in writing that the license is terminated. PG&E would continue to maintain the stored spent nuclear fuel at the ISFSI in a safe and secure condition. Although the license would continue in effect, PG&E would not be able to place additional casks on the ISFSI storage pad. If PG&E does not pursue other alternatives, reactor operations could cease once the spent nuclear fuel pool reaches its licensed capacity.

III. Finding of No Significant Impact

In accordance with the requirements in 10 CFR part 51, the NRC staff has concluded that the proposed action will not significantly affect the quality of the human environment. Therefore, the NRC staff has determined, pursuant to 10 CFR 51.31, that preparation of an EIS is not required for the proposed action and, and pursuant to 10 CFR 51.32, a FONSI is appropriate. Consistent with 10 CFR 51.32(a)(4), this FONSI incorporates the EA set forth in this notice by reference.

IV. Availability of Documents

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

Document description	ADAMS accession No.
PG&E's License Renewal Application (LRA) for the Diablo Canyon (DC) Independent Spent Fuel Storage Installation (ISFSI), dated March 9, 2022.	ML22068A189.
NRC's Request for Additional Information (RAI), Round 1, dated July 31, 2023	ML23159A236 (Package).
PG&E's Response to NRC's RAI, Round 1, dated September 21, 2023	ML23264A859.
NRC Letter to CA SHPO Notification and Request for Section 106 Consultation, dated November 15, 2023	ML23296A098.
NRC Tribal Letters for DC ISFSI LRA	ML24163A296 (Package).
NRC's RAI, Round 2, dated March 20, 2024	ML24065A123 (Package).
PG&E's Response to RAI, Round 2, dated April 30, 2024	ML24121A179.
NRC Letter to CA SHPO with results of identification and evaluation for NHPA Section 106, dated June 14, 2024	ML24129A176.
NRC email to California Department of Public Health (CDPH) "Diablo Canyon Independent Spent Fuel Storage Installation License Renewal Environmental Assessment," dated September 5, 2024.	ML24291A132.
California CDPH Response Email, "Email—Diablo Canyon Independent Spent Fuel Storage Installation License Renewal Environmental Assessment," dated October 8, 2024.	ML24285A190.
Diablo Canyon ISFSI License Renewal Environmental Assessment	ML24296A038.

Dated: November 5, 2024.

For the Nuclear Regulatory Commission.

Robert Sun,

Chief, Environmental Project Management Branch 2, Division of Rulemaking, Environment, and Financial Support, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2024–26107 Filed 11–8–24; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

Notice Initiating Docket(s) for Recent Postal Service Competitive Negotiated Service Agreement Filings

DATES: (Issued November 6, 2024)

	Docket No.
Competitive Product Prices: Global Reseller Expedited Package Contract 2 (MC2013–51). Negotiated Service Agreements.	CP2020–234
Competitive Product Prices: Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts. Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 630.	MC2025–278
Competitive Product Prices: Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 630 (MC2025–278). Negotiated Service Agreements.	K2025–276
Competitive Product Prices: Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts. Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 631.	MC2025–279
Competitive Product Prices: Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 631 (MC2025–279). Negotiated Service Agreements.	K2025–277
Competitive Product Prices: Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts. Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 632.	MC2025–280
Competitive Product Prices: Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 632 (MC2025–280). Negotiated Service Agreements.	K2025–278
Competitive Product Prices: Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts. Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 633.	MC2025–281
Competitive Product Prices: Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 633 (MC2025–281).	K2025–279

	Docket No.
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–282
Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 634.	
Competitive Product Prices:	K2025–280
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 634 (MC2025–282).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–283
Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 635.	
Competitive Product Prices:	K2025–281
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 635 (MC2025–283).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–284
Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 636.	
Competitive Product Prices:	K2025–282
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 636 (MC2025–284).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–285
Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail & USPS Ground Advantage Contract 432.	
Competitive Product Prices:	K2025–283
Priority Mail & USPS Ground Advantage Contract 432 (MC2025–285).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–286
Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 637.	
Competitive Product Prices:	K2025–284
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 637 (MC2025–286).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–287
Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 638.	
Competitive Product Prices:	K2025–285
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 638 (MC2025–287).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–288
Priority Mail Express International, Priority Mail International & First-Class Package International Service Contracts.	
Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 50.	
Competitive Product Prices:	K2025–286
Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 50 (MC2025–288).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–289
Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail & USPS Ground Advantage Contract 433.	
Competitive Product Prices:	K2025–287
Priority Mail & USPS Ground Advantage Contract 433 (MC2025–289).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–290
Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 639.	
Competitive Product Prices:	K2025–288
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 639 (MC2025–290).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–291
Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 640.	
Competitive Product Prices:	K2025–289
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 640 (MC2025–291).	
Negotiated Service Agreements.	
Competitive Product Prices:	MC2025–292
Priority Mail Express, Priority Mail & USPS Ground Advantage Contracts.	
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 641.	
Competitive Product Prices:	K2025–290
Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 641 (MC2025–292).	
Negotiated Service Agreements.	

I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

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]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such 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 and 39 CFR 3000.114 (Public Representative). Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. 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 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

II. Public Proceeding(s)

1. *Docket No(s).:* CP2020–234; *Filing Title:* Request of the United States Postal Service Concerning Modification Four to Global Reseller Expedited Package 2 Negotiated Service Agreement, Which Includes an Extension of that Agreement; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 CFR 3035.105, 39 CFR 3041.505, and 39 CFR 3041.515; *Public Representative:* Katalin Clendenin; *Comments Due:* November 14, 2024.

2. *Docket No(s).:* MC2025–278 and K2025–276; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 630 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* November 14, 2024.

3. *Docket No(s).:* MC2025–279 and K2025–277; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 631 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* November 14, 2024.

4. *Docket No(s).:* MC2025–280 and K2025–278; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 632 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jana Slovinska; *Comments Due:* November 14, 2024.

5. *Docket No(s).:* MC2025–281 and K2025–279; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 633 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* November 14, 2024.

6. *Docket No(s).:* MC2025–282 and K2025–280; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 634 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Gregory Stanton; *Comments Due:* November 14, 2024.

7. *Docket No(s).:* MC2025–283 and K2025–281; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 635 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* November 14, 2024.

8. *Docket No(s).:* MC2025–284 and K2025–282; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 636 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jennaca Upperman; *Comments Due:* November 14, 2024.

9. *Docket No(s).:* MC2025–285 and K2025–283; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 432 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Kenneth Moeller; *Comments Due:* November 14, 2024.

10. *Docket No(s).:* MC2025–286 and K2025–284; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 637 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Jana Slovinska; *Comments Due:* November 14, 2024.

11. *Docket No(s).:* MC2025–287 and K2025–285; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 638 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:*

[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).

Elsie Lee-Robbins; *Comments Due:* November 14, 2024.

12. *Docket No(s).:* MC2025–288 and K2025–286; *Filing Title:* USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 50 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Katalin Clendenin; *Comments Due:* November 14, 2024.

13. *Docket No(s).:* MC2025–289 and K2025–287; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 433 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Christopher Mohr; *Comments Due:* November 14, 2024.

14. *Docket No(s).:* MC2025–290 and K2025–288; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 639 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* November 14, 2024.

15. *Docket No(s).:* MC2025–291 and K2025–289; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 640 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Almaroof Agoro; *Comments Due:* November 14, 2024.

16. *Docket No(s).:* MC2025–292 and K2025–290; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 641 to the Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* November 5, 2024; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Elsie Lee-Robbins; *Comments Due:* November 14, 2024.

III. Summary Proceeding(s)

None. *See* Section II for public proceedings.

This Notice will be published in the **Federal Register**.

Media Inquiries: Gail Adams, *gail.adams@prc.gov.*

Erica A. Barker,

Secretary.

[FR Doc. 2024–26132 Filed 11–8–24; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, November 14, 2024.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information, please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

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

Dated: November 7, 2024.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–26215 Filed 11–7–24; 11:15 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101516; File No. SR–NYSE–2024–68]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Describe an Enhancement to How NYSE Would Make Certain Information It Receives From Its Listed Companies Publicly Available

November 5, 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 October 28, 2024, New York Stock Exchange LLC (''NYSE'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to describe how it intends to make certain information the Exchange receives from its listed companies publicly available. 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,

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

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

Pursuant to the Exchange's role as a listing venue, NYSE receives certain information from listed companies. This information may include action items such as stock splits, new listings, spin-offs, suspensions and delistings, name or trading symbol changes, and information about mergers and acquisitions, among other data. NYSE currently publishes this information on its website and makes it publicly available to investors and market participants.[4] NYSE also receives from listed companies certain information related to dividends which NYSE also currently publishes on its website and makes publicly available to investors and market participants.[5] Both data sets are currently published on the NYSE's website prior to, or at approximately the same time as, that information is sent to NYSE market data systems, which ultimately sends the information to the NYSE's market data subscribers throughout the trading day.[6]

The purpose of this proposed rule change is to describe an enhancement to how NYSE would publicly disseminate information received by the Exchange in its role as a listing venue. More specifically, in addition to the two places the NYSE currently publishes the information described above, NYSE proposes to contemporaneously publish a file that contains information received by the Exchange in its role as a listing venue and any new information it may receive in the future in its role as a listing venue in another format on a separate portion of its website.[7] The proposed new file would be available to all market participants and would serve as the sole source of this information for NYSE market data systems. The proposed change would ensure that NYSE market data systems would only be able to access information NYSE receives in its role as a listing venue through publicly-available sources at the same time as, or later than, other market participants. The information described above will be made available on the Exchange's public website for free to any party, for any purpose (including redistribution).

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 basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[8] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

NYSE believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, and is designed to promote just and equitable principles of trade and to protect investors and the public interest. The information provided by NYSE on its public website is disseminated by NYSE in its capacity as a provider of financial data for the benefit of investors and market participants, not in its capacity as an exchange. With this proposal, NYSE market data systems would not have unique access to any information, including information provided to the Exchange in its role as a listing venue and any new information the Exchange may receive in the future in its role as a listing venue, and therefore NYSE would not have any competitive advantage relative to any market participant with respect to the gathering and dissemination of such information. The information described above will be made available on the Exchange's public website for free to any party, for any purpose (including redistribution). Consequently, the publication of information the Exchange receives from listed companies in its role as a listing venue, together with the information published by listed companies that is generally available in the public domain, including on the Commission's website and other sources, would enable any market participant to contemporaneously assemble its own set of market data products containing the same information.

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 purpose of the Act. NYSE believes the proposal will benefit investors and the marketplace because information the Exchange receives from listed companies in its role as a listing venue that NYSE provides to its subscribers, would be exclusively sourced from publicly available files. Because the information would be made publicly available on its website, and the NYSE market data systems would be a consumer of these publicly available files, NYSE would have no material advantage in the gathering and processing of the information relative to any other market participant that chooses to gather and process the same information.

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 proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[9] and Rule 19b–4(f)(6) thereunder.[10]

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.

[4] *See https://www.nyse.com/corporate-actions.*

[5] *See https://www.nyse.com/ex-date-dividends.*

[6] Market data subscribers receive corporate action and dividend information in several reports made available by New York Stock Exchange, LLC. *See https://www.nyse.com/market-data/corporate-actions/corporate-actions-for-nyse-group-listings.*

[7] The proposed file would be posted on the NYSE website at *www.ftp.nyse.com.*

[8] 15 U.S.C. 78f(b)(5).

[9] 15 U.S.C. 78s(b)(3)(A).

[10] 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.

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–NYSE–2024–68 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NYSE–2024–68. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSE–2024–68 and should be submitted on or before December 3, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–26098 Filed 11–8–24; 8:45 am]

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[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101518; File No. SR–CboeBZX–2024–108]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule Related to Physical Port Fees

November 5, 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 October 28, 2024, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/BZX/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule relating to physical connectivity fees.[3]

By way of background, a physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,500 per physical port for a 1 gigabit (''Gb'') circuit and $7,500 per physical port for a 10 Gb circuit. The Exchange proposes to increase the monthly fee for 10 Gb physical ports from $7,500 to $8,500 per port. The Exchange notes the proposed fee change better enables it to continue to maintain and improve its market technology and services and also notes that the proposed fee amount, even as amended, continues to be in line with, or even lower than, amounts assessed by other exchanges for similar connections.[4] The Exchange also notes

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed fee changes on July 3, 2023 (SR–CboeBZX–2023–046). On September 1, 2023, the Exchange withdrew that filing and submitted SR–CboeBZX–2023–067. On September 29, 2023, the Securities and Exchange Commission issued a Suspension of and Order Instituting Proceedings to Determine whether to Approve or Disapprove a Proposed Rule Change to Amend its Fees Schedule Related to Physical Port Fees (the ''OIP'') in anticipation of a possible U.S. government shutdown. On October 2, 2023, the Exchange filed the proposed fee change (SR–CboeBZX–2023–080). On October 13, 2023, the Exchange withdrew that filing and on business date October 16, 2023 submitted SR–CboeBZX–2023–084. On December 12, 2023, the Exchange withdrew that filing and submitted SR–CboeBZX–2023–103. On February 9, 2024, the Exchange withdrew that filing and submitted SR–CboeBZX–2024–016. On April 9, 2024, the Exchange withdrew that filing and submitted SR–CboeBZX–2024–027. On June 7, 2024, the Exchange withdrew that filing and submitted SR–CboeBZX–2024–051. On August 29, 2024, the Exchange withdrew that filing and submitted SR–CboeBZX–2024–079. On October 25, 2024, the Exchange withdrew that filing and submitted SR–CboeBZX–2024–106. On October 28, 2024, the Exchange withdrew that filing and submitted this filing.

[4] *See e.g.*, The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN

Continued

that a single 10 Gb physical port can be used to access the Systems of the following affiliate exchanges: the Cboe BYX Exchange, Inc., Cboe EDGX Exchange, Inc. (options and equities platforms), Cboe EDGA Exchange, Inc., and Cboe C2 Exchange, Inc., (''Affiliate Exchanges'').[5] Notably, only one monthly fee currently (and will continue) to apply per 10 Gb physical port regardless of how many affiliated exchanges are accessed through that one port.[6]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)[10] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities. This belief is based on various factors as described below.

First, the Exchange believes its proposal is reasonable as it reflects a moderate increase in physical connectivity fees for 10 Gb physical ports and its offering, even as amended, continues to be more affordable as compared to analogous physical connectivity offerings at competitor exchanges.[11]

The Exchange also believes the current fee does not properly reflect the quality of the service and product, as fees for 10 Gb physical ports have been static in nominal terms since 2018, and therefore falling in real terms due to inflation. As a general matter, the Producer Price Index (''PPI'') is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (CPI), that measure price change from the purchaser's perspective.[12] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[13] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI (''Data PPI''), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics (BLS) as part of an ongoing effort to expand Producer Price Index coverage of the services sector of the U.S. economy and is identified as NAICS—518210 in the North American Industry Classification System.[14] According to the BLS ''[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.''[15]

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the 10 Gb physical port fee because the Exchange uses its ''own computer systems'' and ''proprietary software,'' *i.e.,* its own data center and proprietary matching engine software, respectively, to collect, organize, store, report and receive orders on the Exchange's proprietary trading platform. In other words, the Exchange is in the business of data processing and related services.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 2.16% increase for any one calendar year period since Data PPI was introduced into the PPI in January 2002. For example, the average calendar year change from January 2002 to December 2023 was .62%, with a cumulative increase of 15.67% over this 21-year period. The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar-year increases of more than 6.5%, and a cumulative increase of over 73% over the same period.[16]

Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

[5] The Affiliate Exchanges are also submitting contemporaneous identical rule filings.

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[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *Id.*

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[12] *See https://www.bls.gov/ppi/overview.htm.*

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[15] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-services-industry-naics-518210.htm.*

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As noted above, the current 10 Gb physical port fee remained unchanged for six years, particularly since June 2018.[17] Since its last increase over 6 years ago however, there has been notable inflation, including under the industry-specific PPI, which as described above is a tailored measure of inflation.[18] Particularly, the Data PPI had a starting value of 107 in June 2018 (the month the Exchange started assessing the current fee) and an ending value of 116.22 in August 2024, representing an 8.6% increase.[19] This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 8.6% during this period.

The Exchange also believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2018. The impact of this inflationary effect is also independent of any change in the Exchange's costs in providing its goods and services. The Exchange therefore believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. Additionally, the Exchange historically does not increase fees every year notwithstanding inflation. Other exchanges have also filed for increases in certain fees, based in part on comparisons to inflation.[20] Accordingly, based on the above-described percentage change, and in conjunction with the rationale further described above and below, the Exchange believes the proposed fee increase is reasonable.

Next, the Exchange believes significant investments into, and enhanced performance of, the Exchange, in the years following the last 10 Gb physical port fee increase support the reasonableness of the proposed fee increase. These investments enhanced the quality of its services, as measured by, among other things, increased throughput and faster processing speeds. Customers have therefore greatly benefitted from these investments, while the Exchange's ability to recoup its investments has been hampered.

For example, the Exchange and its affiliated exchanges recently launched a multi-year initiative to improve Cboe Exchange Platform performance and capacity requirements to increase competitiveness, support growth and advance a consistent world class platform. The goal of the project, among other things, is to provide faster and more consistent order handling and matching performance for options, while ensuring quicker processing time and supporting increasing volumes and capacity needs. For example, the Exchange recently performed switch hardware upgrades. Particularly, the Exchange replaced existing customer access switches with newer models, which the Exchange believes resulted in increased determinism. The recent switch upgrades also increased the Exchange's capacity to accommodate more physical ports by nearly 50%. Network bandwidth was also increased nearly two-fold as a result of the upgrades, which among other things, can lead to reduce message queuing. The Exchange also believes these newer models result in less natural variance in the processing of messages. The Exchange notes that it incurred costs associated with purchasing and upgrading to these newer models, of which the Exchange has not otherwise passed through or offset.

As of April 1, 2024, market participants also having the option of connecting to a new data center (*i.e.,* Secaucus NY6 Data Center (''NY6'')), in addition to the current data centers at NY4 and NY5. The Exchange made NY6 available in response to customer requests in connection with their need for additional space and capacity. In order to make this space available, the Exchange expended significant resources to prepare this space, and will also incur ongoing costs with respect to maintaining this offering, including costs related to power, space, fiber, cabinets, panels, labor and maintenance of racks. The Exchange also incurred a large cost with respect to ensuring NY6 would be latency equalized, as it is for NY4 and NY5.

The Exchange also has made various other improvements since the current physical port rates were adopted in 2018. For example, the Exchange has updated its customer portal to provide more transparency with respect to firms' respective connectivity subscriptions, enabling them to better monitor, evaluate and adjust their connections based on their evolving business needs. The Exchange also performs proactive audits on a weekly basis to ensure that all customer cross connects continue to fall within allowable tolerances for Latency Equalized connections. Accordingly, the Exchange expended, and will continue to expend, resources to innovate and modernize technology so that it may benefit its Members and continue to compete among other equities markets. The ability to continue to innovate with technology and offer new products to market participants allows the Exchange to remain competitive in the equities space which currently has 16 equities markets and potential new entrants. If the Exchange were not able to assess incrementally higher fees for its connectivity, it would effectively impact how the Exchange manages its technology and hamper the Exchange's ability to continue to invest in and fund access services in a manner that allows it to meet existing and anticipated access demands of market participants. Disapproval of fee changes such as the proposal herein, could also have the adverse effect of discouraging an exchange from improving its operations and implementing innovative technology to the benefit of market participants if it believes the Commission would later prevent that exchange from recouping costs and monetizing its operational enhancements, thus adversely impacting competition as well as the interests of market participants and investors.

Finally, the proposed fee is also the same as is concurrently being proposed for its Affiliate Exchanges. Further, Members are able to utilize a single port to connect to all of its Affiliate Exchanges and will only be charged one single fee (*i.e.,* a market participant will only be assessed the proposed $8,500 even if it uses that physical port to connect to the Exchange and another (or even all 6) of its Affiliate Exchanges. Particularly, the Exchange believes the proposed monthly per port fee is reasonable, equitable and not unfairly discriminatory since as the Exchange has determined to not charge multiple fees for the same port. Indeed, the Exchange notes that several ports are in fact purchased and utilized across one or more of the Exchange's affiliated Exchanges (and charged only once).

The Exchange also believes that the proposed fee change is not unfairly discriminatory because it would be assessed uniformly across all market participants that purchase the physical ports. The Exchange believes increasing the fee for 10 Gb physical ports and charging a higher fee as compared to the 1 Gb physical port is equitable as the 1 Gb physical port is 1/10th the size of the

[17] *See* Securities and Exchange Release No. 83442 (June 14, 2018), 83 FR 28675 (June 20, 2018) (SR–CboeBZX–2018–037).

[18] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[19] *Id.*

[20] *See, e.g.,* Securities Exchange Act Release Nos. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79) and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16).

10 Gb physical port and therefore does not offer access to many of the products and services offered by the Exchange (*e.g.,* ability to receive certain market data products). Thus, the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb physical ports utilize the most bandwidth and therefore consume the most resources from the network. The Exchange also anticipates that firms that utilize 10 Gb ports will benefit the most from the Exchange's investment in offering NY6 as the Exchange anticipates there will be much higher quantities of 10 Gb physical ports connecting from NY6 as compared to 1 Gb ports. Indeed, the Exchange notes that 10 Gb physical ports account for approximately 90% of physical ports across the NY4, NY5, and NY6 data centers, and to date, 80% of new port connections in NY6 are 10 Gb ports. As such, the Exchange believes the proposed fee change for 10 Gb physical ports is reasonably and appropriately allocated.

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 fee change will not impact intramarket competition because it will apply to all similarly situated Members equally (*i.e.,* all market participants that choose to purchase the 10 Gb physical port). Additionally, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can continue to buy the less expensive 1 Gb physical port (which cost is not changing) or may choose to obtain access via a third-party re-seller. While pricing may be increased for the larger capacity physical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most.

The proposed fee change also does not impose a burden on competition or on other Self-Regulatory Organizations that is not necessary or appropriate. As described above, the Exchange evaluated its proposed fee change using objective and stable metric with limited volatility. Utilizing Data Processing PPI over a specified period of time is a reasonable means of recouping a portion of the Exchange's investment in maintaining and enhancing the connectivity service identified above. The Exchange believes utilizing Data Processing PPI, a tailored measure of inflation, to increase certain connectivity fees to recoup the Exchange's investment in maintaining and enhancing its services and products would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received from Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [21] and paragraph (f) of Rule 19b–4 [22] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2024–108 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2024–108. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2024–108 and should be submitted on or before December 3, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–26097 Filed 11–8–24; 8:45 am]

BILLING CODE 8011–01–P

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101514; File No. SR–CboeEDGA–2024–043]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend its Fees Schedule Related to Physical Port Fees

November 5, 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 October 25, 2024, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule relating to physical connectivity fees.[3]

By way of background, a physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,500 per physical port for a 1 gigabit (''Gb'') circuit and $7,500 per physical port for a 10 Gb circuit. The Exchange proposes to increase the monthly fee for 10 Gb physical ports from $7,500 to $8,500 per port. The Exchange notes the proposed fee change better enables it to continue to maintain and improve its market technology and services and also notes that the proposed fee amount, even as amended, continues to be in line with, or even lower than, amounts assessed by other exchanges for similar connections.[4] The Exchange also notes that a single 10 Gb physical port can be used to access the Systems of the following affiliate exchanges: the Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc. (options and equities platforms), Cboe EDGX Exchange, Inc. (options and equities platforms), and Cboe C2 Exchange, Inc., (''Affiliate Exchanges'').[5] Notably, only one monthly fee currently (and will continue) to apply per 10 Gb physical port regardless of how many affiliated exchanges are accessed through that one port.[6]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)[10] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities. This belief is based on various factors as described below.

First, the Exchange believes its proposal is reasonable as it reflects a moderate increase in physical connectivity fees for 10 Gb physical ports and its offering, even as amended, continues to be more affordable as compared to analogous physical

[3] The Exchange initially filed the proposed fee changes on July 3, 2023 (SR–CboeEDGA–2023–011). On September 1, 2023, the Exchange withdrew that filing and submitted SR–CboeEDGA–2023–015. On September 29, 2023, the Securities and Exchange Commission issued a Suspension of and Order Instituting Proceedings to Determine whether to Approve or Disapprove a Proposed Rule Change to Amend its Fees Schedule Related to Physical Port Fees (the ''OIP'') in anticipation of a possible U.S. government shutdown. On September 29, 2023, the Exchange filed the proposed fee change (SR–CboeEDGA–2023–016). On October 13, 2023, the Exchange withdrew that filing and submitted SR–CboeEDGA–2023–017. On December 12 2023, the Exchange withdrew that filing and submitted SR–CboeEDGA–2023–022. On February 9, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGA–2024–006. On April 9, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGA–2024–013. On June 7, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGA–2024–022. On August 29, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGA–2024–036. On October 25, 2024, the Exchange withdrew that filing and submitted this filing.

[4] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

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connectivity offerings at competitor exchanges.[11]

The Exchange also believes the current fee does not properly reflect the quality of the service and product, as fees for 10 Gb physical ports have been static in nominal terms since 2018, and therefore falling in real terms due to inflation. As a general matter, the Producer Price Index (''PPI'') is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (CPI), that measure price change from the purchaser's perspective.[12] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[13] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

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[15] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-services-industry-naics-518210.htm.*

[16] *See https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changes-from-1913-to-2008/.*

[17] *See* Securities and Exchange Release No. 83449 (June 15, 2018), 83 FR 28890 (June 21, 2018) (SR–CboeEDGA–2018–010).

[18] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[19] *Id.*

[20] *See, e.g.,* Securities Exchange Act Release Nos. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79) and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16).

For example, the Exchange and its affiliated exchanges recently launched a multi-year initiative to improve Cboe Exchange Platform performance and capacity requirements to increase competitiveness, support growth and advance a consistent world class platform. The goal of the project, among other things, is to provide faster and more consistent order handling and matching performance for options, while ensuring quicker processing time and supporting increasing volumes and capacity needs. For example, the Exchange recently performed switch hardware upgrades. Particularly, the Exchange replaced existing customer access switches with newer models, which the Exchange believes resulted in increased determinism. The recent switch upgrades also increased the Exchange's capacity to accommodate more physical ports by nearly 50%. Network bandwidth was also increased nearly two-fold as a result of the upgrades, which among other things, can lead to reduce message queuing. The Exchange also believes these newer models result in less natural variance in the processing of messages. The Exchange notes that it incurred costs associated with purchasing and upgrading to these newer models, of which the Exchange has not otherwise passed through or offset.

As of April 1, 2024, market participants also having the option of connecting to a new data center (*i.e.,* Secaucus NY6 Data Center (''NY6'')), in addition to the current data centers at NY4 and NY5. The Exchange made NY6 available in response to customer requests in connection with their need for additional space and capacity. In order to make this space available, the Exchange expended significant resources to prepare this space, and will also incur ongoing costs with respect to maintaining this offering, including costs related to power, space, fiber, cabinets, panels, labor and maintenance of racks. The Exchange also incurred a large cost with respect to ensuring NY6 would be latency equalized, as it is for NY4 and NY5.

The Exchange also has made various other improvements since the current physical port rates were adopted in 2018. For example, the Exchange has updated its customer portal to provide more transparency with respect to firms' respective connectivity subscriptions, enabling them to better monitor, evaluate and adjust their connections based on their evolving business needs. The Exchange also performs proactive audits on a weekly basis to ensure that all customer cross connects continue to fall within allowable tolerances for Latency Equalized connections. Accordingly, the Exchange expended, and will continue to expend, resources to innovate and modernize technology so that it may benefit its Members and continue to compete among other equities markets. The ability to continue to innovate with technology and offer new products to market participants allows the Exchange to remain competitive in the equities space which currently has 16 equities markets and potential new entrants. If the Exchange were not able to assess incrementally higher fees for its connectivity, it would effectively impact how the Exchange manages its technology and hamper the Exchange's ability to continue to invest in and fund access services in a manner that allows it to meet existing and anticipated access demands of market participants. Disapproval of fee changes such as the proposal herein, could also have the adverse effect of discouraging an exchange from improving its operations and implementing innovative technology to the benefit of market participants if it believes the Commission would later prevent that exchange from recouping costs and monetizing its operational enhancements, thus adversely impacting competition as well as the interests of market participants and investors.

Finally, the proposed fee is also the same as is concurrently being proposed for its Affiliate Exchanges. Further, Members are able to utilize a single port to connect to all of its Affiliate Exchanges and will only be charged one single fee (*i.e.,* a market participant will only be assessed the proposed $8,500 even if it uses that physical port to connect to the Exchange and another (or even all 6) of its Affiliate Exchanges. Particularly, the Exchange believes the proposed monthly per port fee is reasonable, equitable and not unfairly discriminatory since as the Exchange has determined to not charge multiple fees for the same port. Indeed, the Exchange notes that several ports are in fact purchased and utilized across one or more of the Exchange's affiliated Exchanges (and charged only once).

The Exchange also believes that the proposed fee change is not unfairly discriminatory because it would be assessed uniformly across all market participants that purchase the physical ports. The Exchange believes increasing the fee for 10 Gb physical ports and charging a higher fee as compared to the 1 Gb physical port is equitable as the 1 Gb physical port is 1/10th the size of the 10 Gb physical port and therefore does not offer access to many of the products and services offered by the Exchange (*e.g.,* ability to receive certain market data products). Thus, the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb physical ports utilize the most bandwidth and therefore consume the most resources from the network. The Exchange also anticipates that firms that utilize 10 Gb ports will benefit the most from the Exchange's investment in offering NY6 as the Exchange anticipates there will be much higher quantities of 10 Gb physical ports connecting from NY6 as compared to 1 Gb ports. Indeed, the Exchange notes that 10 Gb physical ports account for approximately 90% of physical ports across the NY4, NY5, and NY6 data centers, and to date, 80% of new port connections in NY6 are 10 Gb ports. As such, the Exchange believes the proposed fee change for 10 Gb physical ports is reasonably and appropriately allocated.

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 fee change will not impact intramarket competition because it will apply to all similarly situated Members equally (*i.e.,* all market participants that choose to purchase the 10 Gb physical port). Additionally, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can continue to buy the less expensive 1 Gb physical port (which cost is not changing) or may choose to obtain access via a third-party re-seller. While pricing may be increased for the larger capacity physical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most.

The proposed fee change also does not impose a burden on competition or on other Self-Regulatory Organizations

that is not necessary or appropriate. As described above, the Exchange evaluated its proposed fee change using objective and stable metric with limited volatility. Utilizing Data Processing PPI over a specified period of time is a reasonable means of recouping a portion of the Exchange's investment in maintaining and enhancing the connectivity service identified above. The Exchange believes utilizing Data Processing PPI, a tailored measure of inflation, to increase certain connectivity fees to recoup the Exchange's investment in maintaining and enhancing its services and products would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [21] and paragraph (f) of Rule 19b–4 [22] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGA–2024–043 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeEDGA–2024–043. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGA–2024–043 and should be submitted on or before December 3, 2024

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–26096 Filed 11–8–24; 8:45 am]

BILLING CODE 8011–01–P

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101517; File No. SR–NYSE–2024–23]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on Proceedings To Determine Whether To Approve or Disapprove a Proposed Rule Change To Amend Section 703.12(II) of the NYSE Listed Company Manual To Expand the Circumstances Under Which Rights May Be Listed on the NYSE

November 5, 2024.

On April 29, 2024, the New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend Section 703.12(II) of the NYSE Listed Company Manual to expand the circumstances under which rights may be listed on the NYSE by allowing issuers to (i) issue rights to more than existing shareholders for a class of securities that is listed or to be listed on the Exchange, and (ii) list and trade rights on the Exchange prior to listing the security into which such rights will be exercisable. The proposed rule change was published for comment in the **Federal Register** on May 15, 2024.[3] On June 26, 2024, pursuant to Section 19(b)(2) of the Act,[4] the Commission designated a longer period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change.[5] On August 19, 2024, the Commission instituted proceedings pursuant to Section 19(b)(2)(B) of the Act [6] to determine whether to approve or disapprove the proposed rule change.[7] The Commission has received no comment letters on the proposed rule change.

Section 19(b)(2) of the Act [8] provides that, after initiating proceedings, the Commission shall issue an order approving or disapproving the proposed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 100102 (May 10, 2024), 89 FR 42543 (''Notice'').

[4] 15 U.S.C. 78s(b)(2).

[5] *See* Securities Exchange Act Release No. 100437, 89 FR 54894 (July 2, 2024).

[6] 15 U.S.C. 78s(b)(2)(B).

[7] *See* Securities Exchange Act Release No. 100720 (August 13, 2024), 89 FR 67120 (August 19, 2024).

[8] 15 U.S.C. 78s(b)(2).

rule change not later than 180 days after the date of publication of the notice of filing of the proposed rule change. The Commission may extend the period for issuing an order approving or disapproving the proposed rule change, however, by not more than 60 days if the Commission determines that a longer period is appropriate and publishes the reasons for such determination. The proposed rule change was published for notice and comment in the **Federal Register** on May 15, 2024.[9] The 180th day after publication of the Notice is November 11, 2024. The Commission is extending the time period for approving or disapproving the proposed rule change for an additional 60 days.

The Commission finds it appropriate to designate a longer period within which to issue an order approving or disapproving the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to Section 19(b)(2) of the Act,[10] designates January 10, 2025 as the date by which the Commission shall either approve or disapprove the proposed rule change (File No. SR–NYSE–2024–23).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–26093 Filed 11–8–24; 8:45 am]

BILLING CODE 8011–01–P

[9] *See* Notice, *supra* note 3.

[10] 15 U.S.C. 78s(b)(2).

[11] 17 CFR 200.30–3(a)(57).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101519; File No. SR–CboeBYX–2024–039]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule Related to Physical Port Fees

November 5, 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 October 25, 2024, Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/BYX/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule relating to physical connectivity fees.[3]

By way of background, a physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,500 per physical port for a 1 gigabit (''Gb'') circuit and $7,500 per physical port for a 10 Gb circuit. The Exchange proposes to increase the monthly fee for 10 Gb physical ports from $7,500 to $8,500 per port. The Exchange notes the proposed fee change better enables it to continue to maintain and improve its market technology and services and also notes that the proposed fee amount, even as amended, continues to be in line with, or even lower than, amounts assessed by other exchanges for similar connections.[4] The Exchange also notes that a single 10 Gb physical port can be used to access the Systems of the following affiliate exchanges: the Cboe BZX Exchange, Inc. (options and equities), Cboe EDGX Exchange, Inc. (options and equities platforms), Cboe EDGA Exchange, Inc., and Cboe C2 Exchange, Inc., (''Affiliate Exchanges'').[5] Notably, only one monthly fee currently (and will continue) to apply per 10 Gb physical port regardless of how many affiliated exchanges are accessed through that one port.[6]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section

[3] The Exchange initially filed the proposed fee changes on July 3, 2023 (SR–CboeBYX–2023–010). On September 1, 2023, the Exchange withdrew that filing and submitted SR–CboeBYX–2023–013. On September 29, 2023, the Securities and Exchange Commission issued a Suspension of and Order Instituting Proceedings to Determine whether to Approve or Disapprove a Proposed Rule Change to Amend its Fees Schedule Related to Physical Port Fees (the ''OIP'') in anticipation of a possible U.S. government shutdown. On September 29, 2023, the Exchange filed the proposed fee change (SR–CboeBYX–2023–014). On October 13, 2023, the Exchange withdrew that filing and submitted SR–CboeBYX–2023–015. On December 12, 2023, Exchange filed the proposed fee change (SR–CboeBYX–2023–018). On December 12, 2023, the Exchange withdrew that filing and submitted SR–CboeBYX–2023–019. On February 9, 2024, the Exchange withdrew that filing and submitted SR–CboeBYX–2024–006. On April 9, 2024, the Exchange withdrew that filing and submitted SR–CboeBYX–2024–012. On June 7, 2024, the Exchange withdrew that filing and submitted SR–CboeBYX–2024–021. On August 29, 2024, the Exchange withdrew that filing and submitted SR–CboeBYX–2024–032. On October 25, 2024, the Exchange withdrew that filing and submitted this filing.

[4] *See e.g.*, The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

[5] The Affiliate Exchanges are also submitting contemporaneous identical rule filings.

[6] The Exchange notes that conversely, other exchange groups charge separate port fees for access to separate, but affiliated, exchanges. *See e.g.,* Securities and Exchange Release No. 99822 (March 21, 2024), 89 FR 21337 (March 27, 2024) (SR–MIAX–2024–016).

[7] 15 U.S.C. 78f(b).

6(b)(5) [8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [9] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4) [10] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities. This belief is based on various factors as described below.

First, the Exchange believes its proposal is reasonable as it reflects a moderate increase in physical connectivity fees for 10 Gb physical ports and its offering, even as amended, continues to be more affordable as compared to analogous physical connectivity offerings at competitor exchanges.[11]

The Exchange also believes the current fee does not properly reflect the quality of the service and product, as fees for 10 Gb physical ports have been static in nominal terms since 2018, and therefore falling in real terms due to inflation. As a general matter, the Producer Price Index (''PPI'') is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (CPI), that measure price change from the purchaser's perspective.[12] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[13] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI (''Data PPI''), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics (BLS) as part of an ongoing effort to expand Producer Price Index coverage of the services sector of the U.S. economy and is identified as NAICS—518210 in the North American Industry Classification System.[14] According to the BLS ''[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.'' [15]

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the 10 Gb physical port fee because the Exchange uses its ''own computer systems'' and ''proprietary software,'' *i.e.,* its own data center and proprietary matching engine software, respectively, to collect, organize, store, report and receive orders on the Exchange's proprietary trading platform. In other words, the Exchange is in the business of data processing and related services.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 2.16% increase for any one calendar year period since Data PPI was introduced into the PPI in January 2002. For example, the average calendar year change from January 2002 to December 2023 was .62%, with a cumulative increase of 15.67% over this 21-year period. The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar-year increases of more than 6.5%, and a cumulative increase of over 73% over the same period.[16]

As noted above, the current 10 Gb physical port fee remained unchanged for six years, particularly since June 2018.[17] Since its last increase over 6 years ago however, there has been notable inflation, including under the industry-specific PPI, which as described above is a tailored measure of inflation.[18] Particularly, the Data PPI had a starting value of 107 in June 2018 (the month the Exchange started assessing the current fee) and an ending value of 116.22 in August 2024, representing an 8.6% increase.[19] This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 8.6% during this period.

The Exchange also believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2018. The

[8] 15 U.S.C. 78f(b)(5).

[9] *Id.*

[10] 15 U.S.C. 78f(b)(4).

[11] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gbps Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gbps physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gbps LX LCN Circuits (which are analogous to the Exchange's 10 Gbps physical port) are assessed $22,000 per month, per port.

[12] *See https://www.bls.gov/ppi/overview.htm.*

[13] *Id.*

[14] NAICS appears in table 5 of the PPI Detailed Report and is available at *https://data.bls.gov/timeseries/PCU518210518210.*

[15] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-services-industry-naics-518210.htm.*

[16] *See https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changes-from-1913-to-2008/.*

[17] *See* Securities and Exchange Release No. 83441 (June 14, 2018), 83 FR 28684 (June 20, 2018) (SR–CboeBYX–2018–006).

[18] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[19] *Id.*

impact of this inflationary effect is also independent of any change in the Exchange's costs in providing its goods and services. The Exchange therefore believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. Additionally, the Exchange historically does not increase fees every year notwithstanding inflation. Other exchanges have also filed for increases in certain fees, based in part on comparisons to inflation.[20] Accordingly, based on the above-described percentage change, and in conjunction with the rationale further described above and below, the Exchange believes the proposed fee increase is reasonable.

Next, the Exchange believes significant investments into, and enhanced performance of, the Exchange, in the years following the last 10 Gb physical port fee increase support the reasonableness of the proposed fee increase. These investments enhanced the quality of its services, as measured by, among other things, increased throughput and faster processing speeds. Customers have therefore greatly benefitted from these investments, while the Exchange's ability to recoup its investments has been hampered.

For example, the Exchange and its affiliated exchanges recently launched a multi-year initiative to improve Cboe Exchange Platform performance and capacity requirements to increase competitiveness, support growth and advance a consistent world class platform. The goal of the project, among other things, is to provide faster and more consistent order handling and matching performance for options, while ensuring quicker processing time and supporting increasing volumes and capacity needs. For example, the Exchange recently performed switch hardware upgrades. Particularly, the Exchange replaced existing customer access switches with newer models, which the Exchange believes resulted in increased determinism. The recent switch upgrades also increased the Exchange's capacity to accommodate more physical ports by nearly 50%. Network bandwidth was also increased nearly two-fold as a result of the upgrades, which among other things, can lead to reduce message queuing. The Exchange also believes these newer models result in less natural variance in the processing of messages. The Exchange notes that it incurred costs associated with purchasing and upgrading to these newer models, of which the Exchange has not otherwise passed through or offset.

As of April 1, 2024, market participants also having the option of connecting to a new data center (*i.e.,* Secaucus NY6 Data Center (''NY6'')), in addition to the current data centers at NY4 and NY5. The Exchange made NY6 available in response to customer requests in connection with their need for additional space and capacity. In order to make this space available, the Exchange expended significant resources to prepare this space, and will also incur ongoing costs with respect to maintaining this offering, including costs related to power, space, fiber, cabinets, panels, labor and maintenance of racks. The Exchange also incurred a large cost with respect to ensuring NY6 would be latency equalized, as it is for NY4 and NY5.

The Exchange also has made various other improvements since the current physical port rates were adopted in 2018. For example, the Exchange has updated its customer portal to provide more transparency with respect to firms' respective connectivity subscriptions, enabling them to better monitor, evaluate and adjust their connections based on their evolving business needs. The Exchange also performs proactive audits on a weekly basis to ensure that all customer cross connects continue to fall within allowable tolerances for Latency Equalized connections. Accordingly, the Exchange expended, and will continue to expend, resources to innovate and modernize technology so that it may benefit its Members and continue to compete among other equities markets. The ability to continue to innovate with technology and offer new products to market participants allows the Exchange to remain competitive in the equities space which currently has 16 equities markets and potential new entrants. If the Exchange were not able to assess incrementally higher fees for its connectivity, it would effectively impact how the Exchange manages its technology and hamper the Exchange's ability to continue to invest in and fund access services in a manner that allows it to meet existing and anticipated access demands of market participants. Disapproval of fee changes such as the proposal herein, could also have the adverse effect of discouraging an exchange from improving its operations and implementing innovative technology to the benefit of market participants if it believes the Commission would later prevent that exchange from recouping costs and monetizing its operational enhancements, thus adversely impacting competition as well as the interests of market participants and investors.

Finally, the proposed fee is also the same as is concurrently being proposed for its Affiliate Exchanges. Further, Members are able to utilize a single port to connect to all of its Affiliate Exchanges and will only be charged one single fee (*i.e.,* a market participant will only be assessed the proposed $8,500 even if it uses that physical port to connect to the Exchange and another (or even all 6) of its Affiliate Exchanges. Particularly, the Exchange believes the proposed monthly per port fee is reasonable, equitable and not unfairly discriminatory since as the Exchange has determined to not charge multiple fees for the same port. Indeed, the Exchange notes that several ports are in fact purchased and utilized across one or more of the Exchange's affiliated Exchanges (and charged only once).

The Exchange also believes that the proposed fee change is not unfairly discriminatory because it would be assessed uniformly across all market participants that purchase the physical ports. The Exchange believes increasing the fee for 10 Gb physical ports and charging a higher fee as compared to the 1 Gb physical port is equitable as the 1 Gb physical port is 1/10th the size of the 10 Gb physical port and therefore does not offer access to many of the products and services offered by the Exchange (*e.g.,* ability to receive certain market data products). Thus, the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb physical ports utilize the most bandwidth and therefore consume the most resources from the network. The Exchange also anticipates that firms that utilize 10 Gb ports will benefit the most from the Exchange's investment in offering NY6 as the Exchange anticipates there will be much higher quantities of 10 Gb physical ports connecting from NY6 as compared to 1 Gb ports. Indeed, the Exchange notes that 10 Gb physical ports account for approximately 90% of physical ports across the NY4, NY5, and NY6 data centers, and to date, 80% of new port connections in NY6 are 10 Gb ports. As such, the Exchange believes the proposed fee change for 10 Gb physical ports is reasonably and appropriately allocated.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose

[20] *See, e.g.,* Securities Exchange Act Release Nos. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79) and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16).

any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed fee change will not impact intramarket competition because it will apply to all similarly situated Members equally (*i.e.,* all market participants that choose to purchase the 10 Gb physical port). Additionally, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can continue to buy the less expensive 1 Gb physical port (which cost is not changing) or may choose to obtain access via a third-party re-seller. While pricing may be increased for the larger capacity physical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most.

The proposed fee change also does not impose a burden on competition or on other Self-Regulatory Organizations that is not necessary or appropriate. As described above, the Exchange evaluated its proposed fee change using objective and stable metric with limited volatility. Utilizing Data Processing PPI over a specified period of time is a reasonable means of recouping a portion of the Exchange's investment in maintaining and enhancing the connectivity service identified above. The Exchange believes utilizing Data Processing PPI, a tailored measure of inflation, to increase certain connectivity fees to recoup the Exchange's investment in maintaining and enhancing its services and products would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [21] and paragraph (f) of Rule 19b–4 [22] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBYX–2024–039 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBYX–2024–039. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBYX–2024–039 and should be submitted on or before December 3, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–26095 Filed 11–8–24; 8:45 am]

BILLING CODE 8011–01–P

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f).

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–101515; File No. SR–CboeEDGX–2024–071]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fees Schedule Related to Physical Port Fees

November 5, 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 October 25, 2024, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX Equities'') proposes to amend its Fees Schedule. The text of the proposed rule change is provided in Exhibit 5.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule relating to physical connectivity fees.[3]

By way of background, a physical port is utilized by a Member or non-Member to connect to the Exchange at the data centers where the Exchange's servers are located. The Exchange currently assesses the following physical connectivity fees for Members and non-Members on a monthly basis: $2,500 per physical port for a 1 gigabit (''Gb'') circuit and $7,500 per physical port for a 10 Gb circuit. The Exchange proposes to increase the monthly fee for 10 Gb physical ports from $7,500 to $8,500 per port. The Exchange notes the proposed fee change better enables it to continue to maintain and improve its market technology and services and also notes that the proposed fee amount, even as amended, continues to be in line with, or even lower than, amounts assessed by other exchanges for similar connections.[4] The Exchange also notes that a single 10 Gb physical port can be used to access the Systems of the following affiliate exchanges: the Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc. (options and equities platforms), Cboe EDGA Exchange, Inc., and Cboe C2 Exchange, Inc., (''Affiliate Exchanges'').[5] Notably, only one monthly fee currently (and will continue) to apply per 10 Gb physical port regardless of how many affiliated exchanges are accessed through that one port.[6]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[7] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[8] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[9] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. The Exchange also believes the proposed rule change is consistent with Section 6(b)(4)[10] of the Act, which requires that Exchange rules provide for the equitable allocation of reasonable dues, fees, and other charges among its Members and other persons using its facilities. This belief is based on various factors as described below.

First, the Exchange believes its proposal is reasonable as it reflects a moderate increase in physical connectivity fees for 10 Gb physical ports and its offering, even as amended, continues to be more affordable as compared to analogous physical connectivity offerings at competitor exchanges.[11]

The Exchange also believes the current fee does not properly reflect the quality of the service and product, as fees for 10 Gb physical ports have been static in nominal terms since 2018, and therefore falling in real terms due to inflation. As a general matter, the Producer Price Index (''PPI'') is a family of indexes that measures the average change over time in selling prices received by domestic producers of goods and services. PPI measures price change from the perspective of the seller. This contrasts with other metrics, such as the Consumer Price Index (CPI), that measure price change from the purchaser's perspective.[12] About 10,000 PPIs for individual products and groups of products are tracked and released each month.[13] PPIs are available for the output of nearly all industries in the goods-producing sectors of the U.S. economy—mining, manufacturing, agriculture, fishing, and forestry—as well as natural gas, electricity, and construction, among others. The PPI program covers approximately 69 percent of the service sector's output, as

[3] The Exchange initially filed the proposed fee changes on July 3, 2023 (SR–CboeEDGX–2023–044). On September 1, 2023, the Exchange withdrew that filing and submitted SR–CboeEDGX–2023–057. On September 29, 2023, the Securities and Exchange Commission issued a Suspension of and Order Instituting Proceedings to Determine whether to Approve or Disapprove a Proposed Rule Change to Amend its Fees Schedule Related to Physical Port Fees (the ''OIP'') in anticipation of a possible U.S. government shutdown. On September 29, 2023, the Exchange filed the proposed fee change (SR–CboeEDGX–2023–62). On October 13, 2023, the Exchange withdrew that filing and on business date October 16, 2023 submitted SR-CboeEDGX–2023–065. On December 12, the Exchange withdrew that filing and submitted SR–CboeEDGX–2023–079. On December 20, the Exchange withdrew that filing and submitted SR–CboeEDGX–2023–081. On February 12, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGX–2024–013. On April 9, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGX–2024–020. On June 7, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGX–2024–035. On August 29, 2024, the Exchange withdrew that filing and submitted SR–CboeEDGX–2024–056. On October 25, 2024, the Exchange withdrew that filing and submitted this filing.

[4] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gb Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gb physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gb LX LCN Circuits (which are analogous to the Exchange's 10 Gb physical port) are assessed $22,000 per month, per port.

[5] The Affiliate Exchanges are also submitting contemporaneous identical rule filings.

[6] The Exchange notes that conversely, other exchange groups charge separate port fees for access to separate, but affiliated, exchanges. *See e.g.,* Securities and Exchange Release No. 99822 (March 21, 2024), 89 FR 21337 (March 27, 2024) (SR–MIAX–2024–016).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(5).

[9] *Id.*

[10] 15 U.S.C. 78f(b)(4).

[11] *See e.g.,* The Nasdaq Stock Market LLC (''Nasdaq''), General 8, Connectivity to the Exchange. Nasdaq and its affiliated exchanges charge a monthly fee of $15,000 for each 10Gbps Ultra fiber connection to the respective exchange, which is analogous to the Exchange's 10Gbps physical port. *See also* New York Stock Exchange LLC, NYSE American LLC, NYSE Arca, Inc., NYSE Chicago Inc., NYSE National, Inc. Connectivity Fee Schedule, which provides that 10 Gbps LX LCN Circuits (which are analogous to the Exchange's 10 Gbps physical port) are assessed $22,000 per month, per port.

[12] *See https://www.bls.gov/ppi/overview.htm.*

[13] *Id.*

measured by revenue reported in the 2017 Economic Census.

For purposes of this proposal, the relevant industry-specific PPI is the Data Processing and Related Services PPI (''Data PPI''), which is an industry net-output PPI that measures the average change in selling prices received by companies that provide data processing services.

The Data PPI was introduced in January 2002 by the Bureau of Labor Statistics (BLS) as part of an ongoing effort to expand Producer Price Index coverage of the services sector of the U.S. economy and is identified as NAICS—518210 in the North American Industry Classification System.[14] According to the BLS ''[t]he primary output of NAICS 518210 is the provision of electronic data processing services. In the broadest sense, computer services companies help their customers efficiently use technology. The processing services market consists of vendors who use their own computer systems—often utilizing proprietary software—to process customers' transactions and data. Companies that offer processing services collect, organize, and store a customer's transactions and other data for record-keeping purposes. Price movements for the NAICS 518210 index are based on changes in the revenue received by companies that provide data processing services. Each month, companies provide net transaction prices for a specified service. The transaction is an actual contract selected by probability, where the price-determining characteristics are held constant while the service is repriced. The prices used in index calculation are the actual prices billed for the selected service contract.'' [15]

The Exchange believes the Data PPI is an appropriate measure to be considered in the context of the proposed rule change to modify the 10 Gb physical port fee because the Exchange uses its ''own computer systems'' and ''proprietary software,'' *i.e.,* its own data center and proprietary matching engine software, respectively, to collect, organize, store, report and receive orders on the Exchange's proprietary trading platform. In other words, the Exchange is in the business of data processing and related services.

The Exchange further believes the Data PPI is an appropriate measure for purposes of the proposed rule change on the basis that it is a stable metric with limited volatility, unlike other consumer-side inflation metrics. In fact, the Data PPI has not experienced a greater than 2.16% increase for any one calendar year period since Data PPI was introduced into the PPI in January 2002. For example, the average calendar year change from January 2002 to December 2023 was .62%, with a cumulative increase of 15.67% over this 21-year period. The Exchange believes the Data PPI is considerably less volatile than other inflation metrics such as CPI, which has had individual calendar-year increases of more than 6.5%, and a cumulative increase of over 73% over the same period.[16]

As noted above, the current 10 Gb physical port fee remained unchanged for six years, particularly since June 2018.[17] Since its last increase over 6 years ago however, there has been notable inflation, including under the industry-specific PPI, which as described above is a tailored measure of inflation.[18] Particularly, the Data PPI had a starting value of 107 in June 2018 (the month the Exchange started assessing the current fee) and an ending value of 116.22 in August 2024, representing an 8.6% increase.[19] This indicates that companies who are also in the data storage and processing business have generally increased prices for a specified service covered under NAICS 518210 by an average of 8.6% during this period.

The Exchange also believes that it is reasonable to increase its fees to compensate for inflation because, over time, inflation has degraded the value of each dollar that the Exchange collects in fees, such that the real revenue collected today is considerably less than that same revenue collected in 2018. The impact of this inflationary effect is also independent of any change in the Exchange's costs in providing its goods and services. The Exchange therefore believes that it is reasonable for it to offset, in part, this erosion in the value of the revenues it collects. Additionally, the Exchange historically does not increase fees every year notwithstanding inflation. Other exchanges have also filed for increases in certain fees, based in part on comparisons to inflation.[20] Accordingly, based on the above-described percentage change, and in conjunction with the rationale further described above and below, the Exchange believes the proposed fee increase is reasonable.

Next, the Exchange believes significant investments into, and enhanced performance of, the Exchange, in the years following the last 10 Gb physical port fee increase support the reasonableness of the proposed fee increase. These investments enhanced the quality of its services, as measured by, among other things, increased throughput and faster processing speeds. Customers have therefore greatly benefitted from these investments, while the Exchange's ability to recoup its investments has been hampered.

For example, the Exchange and its affiliated exchanges recently launched a multi-year initiative to improve Cboe Exchange Platform performance and capacity requirements to increase competitiveness, support growth and advance a consistent world class platform. The goal of the project, among other things, is to provide faster and more consistent order handling and matching performance for options, while ensuring quicker processing time and supporting increasing volumes and capacity needs. For example, the Exchange recently performed switch hardware upgrades. Particularly, the Exchange replaced existing customer access switches with newer models, which the Exchange believes resulted in increased determinism. The recent switch upgrades also increased the Exchange's capacity to accommodate more physical ports by nearly 50%. Network bandwidth was also increased nearly two-fold as a result of the upgrades, which among other things, can lead to reduce message queuing. The Exchange also believes these newer models result in less natural variance in the processing of messages. The Exchange notes that it incurred costs associated with purchasing and upgrading to these newer models, of which the Exchange has not otherwise passed through or offset.

As of April 1, 2024, market participants also having the option of connecting to a new data center (*i.e.,* Secaucus NY6 Data Center (''NY6'')), in addition to the current data centers at NY4 and NY5. The Exchange made NY6 available in response to customer requests in connection with their need for additional space and capacity. In

[14] NAICS appears in table 5 of the PPI Detailed Report and is available at *https://data.bls.gov/timeseries/PCU518210518210.*

[15] *See https://www.bls.gov/ppi/factsheets/producer-price-index-for-the-data-processing-and-related-services-industry-naics-518210.htm.*

[16] *See https://www.usinflationcalculator.com/inflation/consumer-price-index-and-annual-percent-changes-from-1913-to-2008/.*

[17] *See* Securities and Exchange Release No. 83450 (June 15, 2018), 83 FR 28884 (June 21, 2018) (SR–CboeEDGX–2018–016).

[18] *See https://fred.stlouisfed.org/series/PCU51825182#0.*

[19] *Id.*

[20] *See, e.g.,* Securities Exchange Act Release Nos. 34–100994 (September 10, 2024), 89 FR 75612 (September 16, 2024) (SR–NYSEARCA–2024–79) and 34–100398 (June 21, 2024), 89 FR 53676 (June 27, 2024) (SR–BOX–2024–16).

order to make this space available, the Exchange expended significant resources to prepare this space, and will also incur ongoing costs with respect to maintaining this offering, including costs related to power, space, fiber, cabinets, panels, labor and maintenance of racks. The Exchange also incurred a large cost with respect to ensuring NY6 would be latency equalized, as it is for NY4 and NY5.

The Exchange also has made various other improvements since the current physical port rates were adopted in 2018. For example, the Exchange has updated its customer portal to provide more transparency with respect to firms' respective connectivity subscriptions, enabling them to better monitor, evaluate and adjust their connections based on their evolving business needs. The Exchange also performs proactive audits on a weekly basis to ensure that all customer cross connects continue to fall within allowable tolerances for Latency Equalized connections. Accordingly, the Exchange expended, and will continue to expend, resources to innovate and modernize technology so that it may benefit its Members and continue to compete among other equities markets. The ability to continue to innovate with technology and offer new products to market participants allows the Exchange to remain competitive in the equities space which currently has 16 equities markets and potential new entrants. If the Exchange were not able to assess incrementally higher fees for its connectivity, it would effectively impact how the Exchange manages its technology and hamper the Exchange's ability to continue to invest in and fund access services in a manner that allows it to meet existing and anticipated access demands of market participants. Disapproval of fee changes such as the proposal herein, could also have the adverse effect of discouraging an exchange from improving its operations and implementing innovative technology to the benefit of market participants if it believes the Commission would later prevent that exchange from recouping costs and monetizing its operational enhancements, thus adversely impacting competition as well as the interests of market participants and investors.

Finally, the proposed fee is also the same as is concurrently being proposed for its Affiliate Exchanges. Further, Members are able to utilize a single port to connect to all of its Affiliate Exchanges and will only be charged one single fee (*i.e.,* a market participant will only be assessed the proposed $8,500 even if it uses that physical port to connect to the Exchange and another (or even all 6) of its Affiliate Exchanges. Particularly, the Exchange believes the proposed monthly per port fee is reasonable, equitable and not unfairly discriminatory since as the Exchange has determined to not charge multiple fees for the same port. Indeed, the Exchange notes that several ports are in fact purchased and utilized across one or more of the Exchange's affiliated Exchanges (and charged only once).

The Exchange also believes that the proposed fee change is not unfairly discriminatory because it would be assessed uniformly across all market participants that purchase the physical ports. The Exchange believes increasing the fee for 10 Gb physical ports and charging a higher fee as compared to the 1 Gb physical port is equitable as the 1 Gb physical port is 1/10th the size of the 10 Gb physical port and therefore does not offer access to many of the products and services offered by the Exchange (*e.g.,* ability to receive certain market data products). Thus, the value of the 1 Gb alternative is lower than the value of the 10 Gb alternative, when measured based on the type of Exchange access it offers. Moreover, market participants that purchase 10 Gb physical ports utilize the most bandwidth and therefore consume the most resources from the network. The Exchange also anticipates that firms that utilize 10 Gb ports will benefit the most from the Exchange's investment in offering NY6 as the Exchange anticipates there will be much higher quantities of 10 Gb physical ports connecting from NY6 as compared to 1 Gb ports. Indeed, the Exchange notes that 10 Gb physical ports account for approximately 90% of physical ports across the NY4, NY5, and NY6 data centers, and to date, 80% of new port connections in NY6 are 10 Gb ports. As such, the Exchange believes the proposed fee change for 10 Gb physical ports is reasonably and appropriately allocated.

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 fee change will not impact intramarket competition because it will apply to all similarly situated Members equally (*i.e.,* all market participants that choose to purchase the 10 Gb physical port). Additionally, the Exchange does not believe its proposed pricing will impose a barrier to entry to smaller participants and notes that its proposed connectivity pricing is associated with relative usage of the various market participants. For example, market participants with modest capacity needs can continue to buy the less expensive 1 Gb physical port (which cost is not changing) or may choose to obtain access via a third-party re-seller. While pricing may be increased for the larger capacity physical ports, such options provide far more capacity and are purchased by those that consume more resources from the network. Accordingly, the proposed connectivity fees do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation reflects the network resources consumed by the various size of market participants—lowest bandwidth consuming members pay the least, and highest bandwidth consuming members pays the most.

The proposed fee change also does not impose a burden on competition or on other Self-Regulatory Organizations that is not necessary or appropriate. As described above, the Exchange evaluated its proposed fee change using objective and stable metric with limited volatility. Utilizing Data Processing PPI over a specified period of time is a reasonable means of recouping a portion of the Exchange's investment in maintaining and enhancing the connectivity service identified above. The Exchange believes utilizing Data Processing PPI, a tailored measure of inflation, to increase certain connectivity fees to recoup the Exchange's investment in maintaining and enhancing its services and products would not impose a burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [21] and paragraph (f) of Rule 19b–4 [22] 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

[21] 15 U.S.C. 78s(b)(3)(A).

[22] 17 CFR 240.19b–4(f).

the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGX–2024–071 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR-CboeEDGX–2024–071. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGX–2024–071 and should be submitted on or before December 3, 2024.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Vanessa A. Countryman,

Secretary.

[FR Doc. 2024–26094 Filed 11–8–24; 8:45 am]

BILLING CODE 8011–01–P

[23] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20852 and #20853; CHEYENNE RIVER SIOUX TRIBE Disaster Number SD–20009]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Cheyenne River Sioux Tribe

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the Cheyenne River Sioux Tribe (FEMA–4842–DR), dated November 1, 2024.

Incident: Severe Storm, Straight-line Winds, and Flooding.

DATES: Issued on November 1, 2024.

Incident Period: July 13, 2024 through July 14, 2024.

Physical Loan Application Deadline Date: December 31, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: August 1, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on November 1, 2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Area: Cheyenne River Sioux Tribe.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 20852B and for economic injury is 208530.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–26108 Filed 11–8–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20831 and #20832; VIRGIN ISLANDS Disaster Number VI–20000]

Presidential Declaration of a Major Disaster for Public Assistance Only for the U.S. Virgin Islands

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the U.S. Virgin Islands (FEMA–4841–DR), dated October 25, 2024.

Incident: Tropical Storm Ernesto.

DATES: Issued on October 25, 2024.

Incident Period: August 13, 2024 through Aught 16, 2024.

Physical Loan Application Deadline Date: December 24, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: July 25, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Vanessa Morgan, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the President's major disaster declaration on October 25, 2024, Private Non-Profit organizations that provide essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or other locally announced locations. Please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955 for further assistance.

The following areas have been determined to be adversely affected by the disaster:

Primary Areas: Saint Croix, Saint John, Saint Thomas, and Water Island.

The Interest Rates are:

	Percent
For Physical Damage:	
Non-Profit Organizations with Credit Available Elsewhere ...	3.250
Non-Profit Organizations without Credit Available Elsewhere	3.250
For Economic Injury:	
Non-Profit Organizations without Credit Available Elsewhere	3.250

The number assigned to this disaster for physical damage is 208318 and for economic injury is 208320.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–26182 Filed 11–8–24; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #20778 and #20779; FLORIDA Disaster Number FL–20016]

Presidential Declaration Amendment of a Major Disaster for Public Assistance Only for the State of Florida

AGENCY: U.S. Small Business Administration.

ACTION: Amendment 3.

SUMMARY: This is an amendment of the Presidential declaration of a major disaster for Public Assistance Only for the State of Florida (FEMA–4834–DR), dated October 16, 2024.

Incident: Hurricane Milton.

DATES: Issued on November 4, 2024.

Incident Period: October 5, 2024 through November 2, 2024.

Physical Loan Application Deadline Date: December 16, 2024.

Economic Injury (EIDL) Loan Application Deadline Date: July 16, 2025.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Alan Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: The notice of the President's major disaster declaration for Private Non-Profit organizations in the State of Florida, dated October 16, 2024, is hereby amended to include the following areas as adversely affected by the disaster.

Primary Counties: Palm Beach.

All other information in the original declaration remains unchanged.

(Catalog of Federal Domestic Assistance Number 59008)

Alejandro Contreras,

Acting Deputy Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2024–26152 Filed 11–8–24; 8:45 am]

BILLING CODE 8026–09–P

STATE JUSTICE INSTITUTE

State Justice Institute Board of Directors Meeting, Notice

AGENCY: State Justice Institute (SJI).

ACTION: Notice of meeting.

SUMMARY: The purpose of this meeting is to consider grant applications for the 1st quarter of FY 2025, and other business.

DATES: The SJI Board of Directors will be meeting on Monday, December 9, 2024 at 1 p.m. ET.

ADDRESSES: Supreme Court of Virginia, 100 North 9th Street, Richmond, VA.

FOR FURTHER INFORMATION CONTACT: Jonathan Mattiello, Executive Director, State Justice Institute, 12700 Fair Lakes Circle, Suite 340, Fairfax, VA 22033, 703–660–4979, *contact@sji.gov.*

(Authority: 42 U.S.C. 10702(f))

Jonathan D. Mattiello,

Executive Director.

[FR Doc. 2024–26173 Filed 11–8–24; 8:45 am]

BILLING CODE 6820–SC–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2024–0072]

Agency Information Collection Activities: Notice of Request for an Extension of Currently Approved Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice of request for extension of currently approved information collection.

SUMMARY: The FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for extension of an existing information collection that is summarized below under **SUPPLEMENTARY INFORMATION**. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by January 13, 2025.

ADDRESSES: You may submit comments identified by DOT Docket ID Number 0072 by any of the following methods:

Website: For access to the docket to read background documents or comments received go to the Federal eRulemaking Portal: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Fax: 1–202–493–2251.

Mail: Docket Management Facility, U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001.

Hand Delivery or Courier: U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Janelle Hinton, (202) 941–6744, Office of Civil Rights, Federal Highway Administration, Federal Highway Administration, Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Federal-Aid Highway Construction Equal Employment Opportunity.

OMB Control: 2125–0019.

Background: Title 23, United States Code section 140(a), requires the FHWA to ensure equal opportunity regarding contractors' employment practices on

Federal-aid highway projects. To carry out this requirement, the contractors must submit employment workforce data to the State Transportation Agencies (STAs) on all work being performed on Federal-aid contracts during all or any part of the last payroll period preceding the end of July. This report provides the employment workforce data on these contracts and includes the number of minorities, women, and non-minorities in specific highway construction job categories. This information is reported on Form PR–1391, Federal-Aid Highway Construction Contractors Summary of Employment Data. The statute also requires the STAs to submit a report to the FHWA summarizing the data entered on the PR–1391 forms. This summary data is provided on Form PR–1392, Federal-Aid Highway Construction Contractors Summary of Employment Data. The STAs and FHWA use this data to identify patterns and trends of employment in the highway construction industry, and to determine the adequacy and impact of the STA's and FHWA's contract compliance and on-the-job (OJT) training programs. The STAs use this information to monitor the contractors-employment and training of minorities and women in the traditional highway construction crafts. Additionally, the data is used by FHWA to provide summarization, trend analyses to Congress, DOT, and FHWA officials as well as others who request information relating to the Federal-aid highway construction EEO program. The information is also used in making decisions regarding resource allocation; program emphasis; marketing and promotion activities; training; and compliance efforts.

Respondents: 11,077 annual respondents for form PR–1391, and 53 STAs and Territory annual respondents for Form PR–1392 that, total of 11,130.

Frequency: Annually.

Estimated Average Burden per Response: FHWA estimates it takes 30 minutes for Federal-aid contractors to complete and submit Form PR–1391 and 8 hours for STAs to complete and submit Form PR–1392.

Estimated Total Annual Burden Hours: Form PR–1391—5,539 hours per year; Form PR–1392—416 hours per year, total of 5,955 hours annually.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. chapter 35, as amended; and 49 CFR 1.48.

Issued on: November 6, 2024.

Jazmyne Lewis,

Information Collection Officer.

[FR Doc. 2024–26129 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

Great Lakes St. Lawrence Seaway Development Corporation

Great Lakes St. Lawrence Seaway Development Corporation Advisory Board; Notice of Meeting

AGENCY: Great Lakes St. Lawrence Seaway Development Corporation, DOT.

ACTION: Notice of public meeting.

SUMMARY: This notice announces the public meeting of the Great Lakes St. Lawrence Seaway Development Corporation Advisory Board.

DATES: The public meeting will be held on:

- Wednesday, December 4, 2024, from 2 p.m.–4 p.m. EST
  - Requests to attend the meeting must be received by November 27, 2024.
  - Requests for accommodations to a disability must be received by November 27, 2024.
  - If you wish to speak during the meeting, you must submit a written copy of your remarks to GLS by November 27, 2024.
  - Requests to submit written materials to be reviewed during the meeting must be received no later than November 27, 2024.

ADDRESSES: The meeting will be held in-person at the following location: St. Lawrence Seaway Management Corporation,151 Rue de l'Écluse, Saint-Lambert, QC J4R 2V6, Canada. A virtual option will be made available for individuals wishing to attend remotely. Details on how to participate will be forwarded to those who RSVP.

FOR FURTHER INFORMATION CONTACT: Kevin O'Malley, Strategic Advisor for Financial and Resource Management, Great Lakes St. Lawrence Seaway Development Corporation, 1200 New Jersey Avenue SE, Suite W62–300, Washington, DC 20590; (202) 366–0091.

SUPPLEMENTARY INFORMATION: Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463; 5 U.S.C. App. 2), notice is hereby given of meetings of the GLS Advisory Board. The agenda for each meeting is the same and will be as follows:

1. Opening Remarks
2. Consideration of Minutes of Past Meeting
3. Quarterly Report
4. Old and New Business
5. Closing Discussion
6. Adjournment

Public Participation

Attendance at the meeting is open to the interested public. With the approval of the Administrator, members of the public may present oral statements at the meeting. Persons wishing further information should contact the person listed under the heading, **FOR FURTHER INFORMATION CONTACT**. There will be three (3) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for each commenter may be limited. Individuals wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name, address, and organizational affiliation of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the GLS will conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks for inclusion in the meeting records and for circulation to GLS Advisory Board members. All prepared remarks submitted will be accepted and considered as part of the meeting's record. Any member of the public may submit a written statement after the meeting deadline, and it will be presented to the committee.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Any member of the public may present a written statement to the Advisory Board at any time.

Dated: November 6, 2024.

Carrie Lavigne,

Chief Counsel.

[FR Doc. 2024–26115 Filed 11–8–24; 8:45 am]

BILLING CODE 4910–61–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: This action was issued on November 6, 2024. See **SUPPLEMENTARY INFORMATION** for relevant dates.

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, 202–622–2420; Assistant Director for Licensing, 202–622–2480; or Assistant Director for Sanctions Compliance, 202–622–2490 or *https://ofac.treasury.gov/contact-ofac.*

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website: *https://ofac.treasury.gov.*

Notice of OFAC Action

On November 6, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individual

1. PERISIC, Vladimir, Bosnia and Herzegovina; DOB 14 Nov 1976; nationality Bosnia and Herzegovina; Gender Male; Passport B0786296 (Bosnia and Herzegovina) (individual) [BALKANS–EO14033] (Linked To: DODIK, Igor).

Designated pursuant to section 1(a)(vii) of E.O. 14033 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Igor Dodik, a person whose property and interests in property are blocked pursuant to E.O. 14033.

Entity

1. ELPRING D.O.O. LAKTASI, XVI Krajiske Motorizovane Brigade 63, Laktasi 78250, Bosnia and Herzegovina; Organization Established Date 17 Jul 2024; Tax ID No. 4405278340001 (Bosnia and Herzegovina); Business Registration Number 57–01–0312–24 (Bosnia and Herzegovina) [BALKANS–EO14033] (Linked To: DODIK, Igor).

Designated pursuant to section 1(a)(vii) of E.O. 14033 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Igor Dodik, a person whose property and interests in property are blocked pursuant to E.O. 14033.

Lisa M. Palluconi,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2024–26137 Filed 11–8–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Action

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: This action was issued on October 1, 2024. See **SUPPLEMENTARY INFORMATION** section for relevant date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Action

On October 1, 2024, OFAC determined that the property and interests in property subject to U.S. jurisdiction of the following person are blocked under the relevant sanctions authorities listed below.

Entity

Entity:

1. HILLTOP YOUTH (Hebrew: נוער הגבעות) (a.k.a. NO'AR HAGVA'OT), West Bank; Target Type Criminal Organization [WEST-BANK-EO14115].

Designated pursuant to section 1(a)(i)(B)(1) of Executive Order 14115 of February 1, 2024, "Imposing Certain Sanctions on Persons Undermining Peace, Security, and Stability in the West Bank," 89 FR 7605 (Feb. 5, 2024) (E.O. 14115) for being a foreign person that is responsible for or complicit in, or has directly or indirectly engaged or attempted to engage in planning, ordering, otherwise directing, or participating in an act of violence or threat of violence targeting civilians, affecting the West Bank.

Dated: October 1, 2024.

Lisa M. Palluconi,

Acting Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2024–26118 Filed 11–8–24; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Former Prisoners of War, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. ch. 10., that the Advisory Committee on Former Prisoners of War (Committee) will conduct a virtual meeting on December 4, 2024. Public participation will commence as follows:

Date	Time	Location	Open session
December 4, 2024	11 a.m.–5 p.m. eastern standard time (EST)	Microsoft TEAMS Link and Call-in Information Below.	Yes.

The meeting session is open to the public.

The purpose of the Committee is to advise the Secretary of VA on the administration of benefits under title 38 U.S.C., for Veterans who are former prisoners of war (FPOW) and the needs of these Veterans, in the areas of compensation, health care, and rehabilitation.

The Committee will assemble in open session for discussion and briefings from VA Central Office and Veterans Benefits Administration officials who will provide updates on issues impacting FPOW Veterans and their families.

Time will be allocated at this session to receive oral presentation from the public. The comment period will be at 3:45 p.m.–4:15 p.m. EST, and the public will be afforded three to five minutes to express their comments. Any member of the public may submit a 1–2-page commentary for the Committee's review.

Any member of the public wishing to virtually attend or seeking additional information should contact, Julian Wright, Designated Federal Officer, VA, Advisory Committee on FPOW at *Julian.Wright2@va.gov* no later than November 29, 2024. Any member of the public who wishes to participate in the virtual meeting may use the following Microsoft Teams Meeting Link:

Join On Your Computer or Mobile App: https://teams.microsoft.com/l/meetup-join/19%3ameeting_NDA3YzRkNmItZWY0Ni00NmQwLWFhNGItODlmNTUwZmQyOTk3%40thread.v2/0?context=%7b%22Tid%22%3a%22e95f1b23-abaf-45ee-821d-b7ab251ab3bf%22%2c%22Oid%22%3a%22b857b6c6-44d8-46b4-8041-6e7d50b9890a%22%7d.

You can dial 872–701–0185 and enter the access code below.

Access code: 158 370 812#.

Dated: November 6, 2024.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2024–26136 Filed 11–8–24; 8:45 am]

BILLING CODE 8320–01–P

FEDERAL REGISTER

Vol. 89 Tuesday,

No. 218 November 12, 2024

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413, 494, et al.

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 413, 494, and 512

[CMS–1805–F]

RIN 0938–AV27

Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, Conditions for Coverage for End-Stage Renal Disease Facilities, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: This final rule updates and revises the End-Stage Renal Disease (ESRD) Prospective Payment System for calendar year 2025. This rule also updates the payment rate for renal dialysis services furnished by an ESRD facility to individuals with acute kidney injury. In addition, this rule updates requirements for the Conditions for Coverage for ESRD Facilities, ESRD Quality Incentive Program, and ESRD Treatment Choices Model.

DATES: These regulations are effective on January 1, 2025.

FOR FURTHER INFORMATION CONTACT:

ESRDPayment@cms.hhs.gov or Nicolas Brock at (410) 786–5148 for issues related to the ESRD Prospective Payment System (PPS) and coverage and payment for renal dialysis services furnished to individuals with acute kidney injury (AKI).

ESRDApplications@cms.hhs.gov, for issues related to applications for the Transitional Drug Add-on Payment Adjustment (TDAPA) or Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES).

ESRDQIP@cms.hhs.gov, for issues related to the ESRD Quality Incentive Program (QIP).

ETC–CMMI@cms.hhs.gov, for issues related to the ESRD Treatment Choices (ETC) Model.

SUPPLEMENTARY INFORMATION:

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/*.

Current Procedural Terminology (CPT) Copyright Notice: Throughout this final rule, we use CPT® codes and descriptions to refer to a variety of services. We note that CPT® codes and descriptions are copyright 2020 American Medical Association (AMA). All Rights Reserved. CPT® is a registered trademark of the AMA. Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

Table of Contents

To assist readers in referencing sections contained in this preamble, we are providing a Table of Contents.

I. Executive Summary
- A. Purpose
- B. Summary of the Major Provisions
- C. Summary of Cost and Benefits

II. Calendar Year (CY) 2025 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)
- A. Background
- B. Provisions of the Proposed Rule, Public Comments, and Responses to the Comments on the CY 2025 ESRD PPS
- C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Applications and Technical Changes for CY 2025
- D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2025
- E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2025

III. Final CY 2025 Payment for Renal Dialysis Services Furnished to Individuals With AKI
- A. Background
- B. Public Comments and Responses on the Proposal To Allow Medicare Payment for Home Dialysis for Beneficiaries With AKI
- C. Annual Payment Rate Update for CY 2025
- D. AKI and the ESRD Facility Conditions for Coverage

IV. Updates to the End-Stage Renal Disease Quality Incentive Program (ESRD QIP)
- A. Background
- B. Updates to Requirements Beginning With the PY 2027 ESRD QIP
- C. Requests for Information (RFIs) on Topics Relevant to ESRD QIP

V. End-Stage Renal Disease Treatment Choices (ETC) Model
- A. Background
- B. Provisions of the Proposed Rule
- C. Request for Information

VI. Collection of Information Requirements

VII. Regulatory Impact Analysis
- A. Statement of Need
- B. Overall Impact Analysis
- C. Detailed Economic Analysis
- D. Accounting Statement
- E. Regulatory Flexibility Act (RFA)
- F. Unfunded Mandates Reform Act (UMRA)
- G. Federalism
- H. Congressional Review Act

VIII. Files Available to the Public via the Internet

I. Executive Summary

A. Purpose

This rule finalizes changes related to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS), payment for renal dialysis services furnished to individuals with acute kidney injury (AKI), the Conditions for Coverage for ESRD facilities, the ESRD Quality Incentive Program (QIP), and the ESRD Treatment Choices (ETC) Model. Additionally, this rule finalizes and discusses policies that reflect our commitment to achieving equity in health care for our beneficiaries by supporting our ability to assess whether, and to what extent, our programs and policies perpetuate or exacerbate systemic barriers to opportunities and benefits for underserved communities. For example, we are finalizing the proposal to allow Medicare payment for home dialysis for beneficiaries with acute kidney injury, which would assist this vulnerable population with transportation and scheduling issues and allow them to have flexibility in their dialysis treatment modality. Additionally, we discuss the incorporation of oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, which will expand access to these drugs to the 21 percent of the ESRD PPS population who do not have Part D coverage. Our internal data show that a significant portion of ESRD beneficiaries who lack Part D coverage are African American/Black patients with ESRD. Our policy objectives include a commitment to advancing health equity, which stands as the first pillar of the Centers for Medicare & Medicaid Services (CMS) Strategic Plan,[1] and reflect the goals of the Administration, as stated in the President's Executive Order 13985.[2] We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and

[1] Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

[2] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

health outcomes.'' [3] In the calendar year (CY) 2023 ESRD PPS final rule, we noted that, when compared with all Medicare fee-for-service (FFS) beneficiaries, Medicare FFS beneficiaries receiving dialysis are disproportionately young, male, African American/Black, have disabilities and low income as measured by eligibility for both Medicare and Medicaid (dual eligible status), and reside in an urban setting (87 FR 67183). In this final rule, we continue to address health equity for beneficiaries with ESRD who are members of underserved communities, including but not limited to those living in rural communities, those who have disabilities, racial and ethnic minorities, and American Indians and Alaska Natives. The term 'underserved communities' refers to populations sharing a particular characteristic, including geographic communities, that have been systematically denied a full opportunity to participate in aspects of economic, social, and civic life.[4]

1. End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services furnished by ESRD facilities as required by section 1881(b)(14) of the Social Security Act (the Act), as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Patient Protection and Affordable Care Act (the Affordable Care Act) (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary of the Department of Health and Human Services (the Secretary) shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This rule finalizes updates to the ESRD PPS for CY 2025.

2. Coverage and Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury (AKI)

On June 29, 2015, the President signed the Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27). Section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a new subsection (r) that provides for payment for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate beginning January 1, 2017. This final rule updates the AKI payment rate for CY 2025. Additionally, this rule extends payment for home dialysis and the payment adjustment for home and self-dialysis training to renal dialysis services provided to beneficiaries with AKI.

3. End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

The End-Stage Renal Disease Quality Incentive Program (ESRD QIP) is authorized by section 1881(h) of the Act. The Program establishes incentives for facilities to achieve high quality performance on measures with the goal of improving outcomes for ESRD beneficiaries. This rule finalizes our proposals to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy measure topic and to remove National Healthcare Safety Network (NHSN) Dialysis Event reporting measure beginning with Payment Year (PY) 2027. This rule also discusses feedback received in response to our requests for public comment on two topics relevant to the ESRD QIP.

4. End-Stage Renal Disease Treatment Choices (ETC) Model

The ETC Model is a mandatory Medicare payment model tested under section 1115A of the Act. The ETC Model is operated by the Center for Medicare and Medicaid Innovation (Innovation Center). The ETC Model tests the use of payment adjustments to encourage greater utilization of home dialysis and kidney transplants, to preserve or enhance the quality of care furnished to Medicare beneficiaries while reducing Medicare expenditures. The ETC Model was finalized as part of a final rule published in the **Federal Register** on September 29, 2020, titled ''Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures'' (85 FR 61114), referred to herein as the ''Specialty Care Models final rule.'' Subsequently, the ETC Model has been updated three times in the annual ESRD PPS final rules for calendar year (CY) 2022 (86 FR 61874), CY 2023 (87 FR 67136), and CY 2024 (88 FR 76344).

This final rule makes certain changes to the methodology CMS uses to identify transplant failure for the purposes of defining an ESRD beneficiary and attributing an ESRD beneficiary to the ETC Model. We also solicited input from the public through a Request for Information (RFI) on topics pertaining to increasing equitable access to home dialysis and kidney transplantation. Feedback we receive from the public will be used to inform CMS' thinking regarding opportunities and barriers the Innovation Center may address in potential successor models to the ETC Model.

B. Summary of the Major Provisions

1. ESRD PPS

- *Update to the ESRD PPS base rate for CY 2025:* The final CY 2025 ESRD PPS base rate is $273.82, an increase from the CY 2024 ESRD PPS base rate of $271.02. This amount reflects the application of the wage index budget-neutrality adjustment factor (0.988600), and a productivity-adjusted market basket percentage increase of 2.2 percent as required by section 1881(b)(14)(F)(i)(I) of the Act, equaling $273.82 (($271.02 × 0.988600) × 1.022 = $273.82).
- *Modification to the wage index methodology:* We are finalizing a new ESRD-specific wage index that will be used to adjust ESRD PPS payment for geographic differences in area wages on an annual basis. Beginning for CY 2025, we will change our methodology to use mean hourly wage data from the Bureau of Labor Statistics (BLS) Occupational Employment and Wage Statistics (OEWS) program and full time equivalent (FTE) labor and treatment volume data from freestanding ESRD facility Medicare cost reports to produce an ESRD-specific wage index for use, instead of using the hospital wage index values for each geographic area, which are derived from hospital cost report data. Additionally, we are finalizing updates to the wage index to reflect the latest core-based statistical area (CBSA) delineations determined by the Office of Management and Budget (OMB) to better account for differing wage levels in areas in which ESRD facilities are located.
- *Annual update to the wage index:* For CY 2025, we are finalizing updates to the wage index using the new methodology based on the latest available data. This is consistent with

[3] Centers for Medicare & Medicaid Services (2022). Health Equity. Available at: *https://www.cms.gov/pillar/health-equity.*

[4] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

our past approach to updating the ESRD PPS wage index on an annual basis but uses the new wage index methodology based on data from BLS and freestanding ESRD facility Medicare cost reports.

• *Modifications to the outlier policy:* We are finalizing several proposed revisions to the outlier policy. For the outlier payment methodology, we are finalizing the use of a drug inflation factor based on actual spending on drugs and biological products rather than the growth in the price proxy for drugs used in the ESRD Bundled (ESRDB) market basket. We are also finalizing the use of the growth in the ESRDB market basket price proxies for laboratory tests and supplies to estimate CY 2025 outlier spending for these items. Additionally, we are finalizing our proposal to account for the post-TDAPA add-on payment adjustment amount for outlier-eligible drugs and biological products during the post-TDAPA period. Lastly, we are finalizing the expansion of the list of eligible ESRD outlier services to include drugs and biological products that were or would have been included in the composite rate prior to establishment of the ESRD PPS.

• *Annual update to the outlier policy:* We are updating the outlier policy based on the most current data and the final methodology changes previously discussed. Accordingly, we are updating the Medicare allowable payment (MAP) amounts for adult and pediatric patients for CY 2025 using the latest available CY 2023 claims data. We are updating the ESRD outlier services fixed dollar loss (FDL) amount for pediatric patients using the latest available CY 2023 claims data and updating the FDL amount for adult patients using the latest available claims data from CY 2021, CY 2022, and CY 2023. For pediatric beneficiaries, the final FDL amount will increase from $11.32 to $234.26, and the MAP amount will increase from $23.36 to $59.60, as compared to CY 2024 values. For adult beneficiaries, the final FDL amount will decrease from $71.76 to $45.41, and the MAP amount will decrease from $36.28 to $31.02. We note that the inclusion of composite rate drugs and biological products will cause a significant increase in the final FDL and MAP amounts for pediatric patients due to high-cost composite rate drugs furnished to pediatric beneficiaries; this is discussed in further detail in section II.B.3.e of this final rule. The 1.0 percent target for outlier payments was achieved in CY 2023, as outlier payments represented approximately 1.0 percent of total Medicare payments.

• *Update to the offset amount for the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) for CY 2025:* The final CY 2025 average per treatment offset amount for the TPNIES for capital-related assets that are home dialysis machines is $10.22. This final offset amount reflects the application of the final productivity-adjusted ESRDB market basket update of 2.2 percent ($10.00 × 1.022 = $10.22). There are no capital-related assets set to receive the TPNIES in CY 2025 for which this offset would apply.

• *Update to the Post-TDAPA Add-on Payment Adjustment amounts:* We calculate the post-TDAPA add-on payment adjustment in accordance with § 413.234(g). The final post-TDAPA add-on payment adjustment amount for Korsuva® is $0.4601 per treatment, which will be included in the calculation of the total post-TDAPA add-on payment adjustment for each quarter in CY 2025. The estimated post-TDAPA add-on payment adjustment amount for Jesduvroq is $0.0096 per treatment, which will be included in the calculation for only the fourth quarter of CY 2025. We are finalizing our proposal to publish the final post-TDAPA add-on payment adjustment amount for drugs and biological products that do not have a full year of utilization data at the time of rulemaking after the publication of the final rule through a Change Request (CR). For CY 2025, this will be the case for Jesduvroq.

• *Update to the Low-Volume Payment Adjustment (LVPA):* We are finalizing our proposal to modify the LVPA policy to create a two-tiered LVPA whereby ESRD facilities that furnished fewer than 3,000 treatments per cost reporting year will receive a 28.9 percent upward adjustment to the ESRD PPS base rate and ESRD facilities that furnished 3,000 to 3,999 treatments will receive an 18.3 percent adjustment. We are also finalizing that the tier determination would be based on the median treatment count over the past 3 cost reporting years.

• *Inclusion of oral-only drugs in the ESRD PPS bundled payment:* Under 42 CFR 413.174(f)(6), payment to an ESRD facility for oral-only renal dialysis service drugs and biological products is included in the ESRD PPS bundled payment effective January 1, 2025. In this final rule, we are providing information about how we will operationalize the inclusion of oral-only drugs into the ESRD PPS as well as budgetary estimates of the effects of this inclusion for public awareness. After reviewing public comments, we are finalizing a $36.41 increase to the monthly TDAPA amount for claims which utilize phosphate binders to account for operational costs related to ESRD facilities providing phosphate binders that were not addressed when the ESRD PPS base rate was developed for CY 2011.

2. Payment for Renal Dialysis Services Furnished to Individuals With AKI

• *Update to the payment rate for individuals with AKI:* We are finalizing an update the AKI payment rate for CY 2025. The final CY 2025 payment rate is $273.82, which reflects the final CY 2025 ESRD PPS base rate of $273.82 reduced by the home and self-dialysis training add-on payment budget-neutrality adjustment of $0.00 (as detailed in section III.C.3 of this final rule).

• *Payment for home dialysis for beneficiaries with AKI:* We are finalizing our proposal to allow Medicare payment for beneficiaries with AKI to dialyze at home. Payment for home dialysis treatments furnished to beneficiaries with AKI will be made at the same payment rate as in-center dialysis treatments. We are finalizing our proposal to permit ESRD facilities to bill Medicare for the home and self-dialysis training add-on payment adjustment for beneficiaries with AKI, and to implement this adjustment in a budget neutral manner with a $0.00 reduction to the AKI base rate. We are finalizing modifications to the ESRD facility conditions for coverage (CfCs) to implement this policy change.

3. ESRD QIP

Beginning with PY 2027, we are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure, on which facility performance is scored on a single measure based on one set of performance standards, with a Kt/V Dialysis Adequacy measure topic, which would be comprised of four individual Kt/V measures and scored based on a separate set of performance standards for each of those measures. We are also finalizing our proposal to remove the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027. We are discussing feedback received in response to our request for public comment on a potential health equity payment adjustment and our request for public comment on potential future updates to the data validation policy.

4. ETC Model

Beginning for CY 2025, we are finalizing the proposed modification to

the methodology used to attribute ESRD Beneficiaries to the ETC Model, specifically, to the definition of an ESRD Beneficiary at 42 CFR 512.310. Under the ETC Model, CMS attributes ESRD beneficiaries to the ETC Model that meet several criteria including having a kidney transplant failure less than 12 months after the transplant date. We are refining the methodology we use to identify ESRD Beneficiaries with a kidney transplant failure to reduce the likelihood that CMS is overestimating the true number of transplant failures for the purposes of the model. We provide more detail on the finalized modification and its rationale in section V.B of this final rule.

We also sought input from the public through a RFI on the future of the ETC Model, potential successor Models and other approaches CMS may consider to support beneficiary access to patient-centered modalities for treatment of ESRD.

C. Summary of Costs and Benefits

In section VII.C.5 of this final rule, we set forth a detailed analysis of the impacts that the final changes would have on affected entities and beneficiaries. The impacts include the following:

1. Impacts of the Final ESRD PPS

The impact table in section VII.C.5.a of this final rule displays the estimated change in Medicare payments to ESRD facilities in CY 2025 compared to estimated Medicare payments in CY 2024. The overall impact of the CY 2025 payment changes is projected to be a 2.7 percent increase in Medicare payments. Hospital-based ESRD facilities will have an estimated 4.5 percent increase in Medicare payments compared with freestanding ESRD facilities with an estimated 2.6 percent increase. We estimate that the aggregate ESRD PPS expenditures will increase by approximately $220 million in CY 2025 compared to CY 2024 as a result of the proposed payment policies in this rule. Because of the projected 2.7 percent overall payment increase, we estimate there will be an increase in beneficiary coinsurance payments of 2.7 percent in CY 2025, which translates to approximately $40 million.

Section 1881(b)(14)(D)(iv) of the Act provides that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Under this authority, CMS implemented § 413.234 to establish the TDAPA, a transitional drug add-on payment adjustment for certain new renal dialysis drugs and biological products and § 413.236 to establish the TPNIES, a transitional add-on payment adjustment for certain new and innovative equipment and supplies. The TDAPA and the TPNIES are not budget neutral.

As discussed in section II.D of this final rule, since no new items were approved for the TPNIES for CY 2024 (88 FR 76431) there are no continuing TPNIES payments for CY 2025. In addition, since we did not receive any applications for the TPNIES for CY 2025, there will be no new TPNIES payments for CY 2025. As discussed in section II.E of this final rule, the TDAPA payment periods for Jesduvroq and DefenCath®, will continue into CY 2025. As described in section VII.C.5.b of this final rule, we estimate that the combined total TDAPA payment amounts for Jesduvroq and DefenCath® in CY 2025 will be approximately $25,633,599, of which, $5,126,719 will be attributed to beneficiary coinsurance amounts.

2. Impacts of the Final Payment Rate for Renal Dialysis Services Furnished to Individuals With AKI

The impact table in section VII.C.5.c of this final rule displays the estimated change in Medicare payments to ESRD facilities for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for such services in CY 2024. The overall impact of the CY 2025 changes is projected to be a 2.3 percent increase in Medicare payments for individuals with AKI. Hospital-based ESRD facilities will have an estimated 3.4 percent increase in Medicare payments compared with freestanding ESRD facilities that will have an estimated 2.3 percent increase. The overall impact reflects the effects of the final Medicare payment rate update and the final CY 2025 ESRD PPS wage index, as well as the policy to extend payment for AKI dialysis at home, which is not expected to have any impact on payment rates. As discussed in section III.C.3, we are finalizing our proposal to extend the ESRD PPS home and self-dialysis training add-on payment adjustment to AKI patients; however, that adjustment is required to be implemented in a budget neutral manner for AKI payments, so it will not have any impact on the overall payment amounts for AKI renal dialysis services and therefore is not included in these estimates. We estimate that the aggregate Medicare payments made to ESRD facilities for renal dialysis services furnished to individuals with AKI, at the final CY 2025 ESRD PPS base rate, will increase by $1 million in CY 2025 compared to CY 2024.

3. Impacts of the PY 2027 ESRD QIP

We estimate that, as a result of previously finalized policies and changes to the ESRD QIP that we are finalizing in this final rule, the overall economic impact of the PY 2027 ESRD QIP will be approximately $154 million. The $154 million estimate for PY 2027 includes $136.1 million in costs associated with the collection of information requirements and approximately $17.9 million in payment reductions across all facilities.

4. Impacts of the Proposed Changes to the ETC Model

The final change to the definition of an ESRD Beneficiary for the purposes of attribution in the ETC Model is not expected to have a net effect on the model's projected economic impact.

II. Calendar Year (CY) 2025 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS)

A. Background

1. Statutory Background

On January 1, 2011, CMS implemented the ESRD PPS, a case-mix adjusted bundled PPS for renal dialysis services furnished by ESRD facilities, as required by section 1881(b)(14) of the Act, as added by section 153(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Patient Protection and Affordable Care Act (Affordable Care Act) (Pub. L. 111–148), established that beginning with CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

Section 632 of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) included several provisions that apply to the ESRD PPS. Section 632(a) of ATRA added section 1881(b)(14)(I) to the Act, which required the Secretary, by comparing per patient utilization data from 2007 with such data from 2012, to reduce the single payment for renal dialysis services furnished on or after January 1, 2014, to reflect the Secretary's estimate of the change in the utilization of ESRD-related drugs and biologicals [5] (excluding oral-only ESRD-

[5] As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term ''biological products'' instead of ''biologicals'' under the ESRD PPS to be consistent with FDA

Continued

related drugs). Consistent with this requirement, in the CY 2014 ESRD PPS final rule, we finalized $29.93 as the total drug utilization reduction and finalized a policy to implement the amount over a 3- to 4-year transition period (78 FR 72161 through 72170).

Section 632(b) of ATRA prohibited the Secretary from paying for oral-only ESRD-related drugs and biologicals under the ESRD PPS prior to January 1, 2016. Section 632(c) of ATRA required the Secretary, by no later than January 1, 2016, to analyze the case-mix payment adjustments under section 1881(b)(14)(D)(i) of the Act and make appropriate revisions to those adjustments.

On April 1, 2014, the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) was enacted. Section 217 of PAMA included several provisions that apply to the ESRD PPS. Specifically, sections 217(b)(1) and (2) of PAMA amended sections 1881(b)(14)(F) and (I) of the Act and replaced the drug utilization adjustment that was finalized in the CY 2014 ESRD PPS final rule (78 FR 72161 through 72170) with specific provisions that dictated the market basket update for CY 2015 (0.0 percent) and how the market basket percentage increase should be reduced in CY 2016 through CY 2018.

Section 217(a)(1) of PAMA amended section 632(b)(1) of ATRA to provide that the Secretary may not pay for oral-only ESRD-related drugs under the ESRD PPS prior to January 1, 2024. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. Section 217(c) of PAMA provided that as part of the CY 2016 ESRD PPS rulemaking, the Secretary shall establish a process for (1) determining when a product is no longer an oral-only drug; and (2) including new injectable and intravenous products into the ESRD PPS bundled payment.

Section 204 of the Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) amended section 632(b)(1) of ATRA, as amended by section 217(a)(1) of PAMA, to provide that payment for oral-only renal dialysis drugs and biological products cannot be made under the ESRD PPS bundled payment prior to January 1, 2025.

nomenclature. We use the term ''biological products'' in this final rule except where referencing specific language in the Act or regulations.

2. System for Payment of Renal Dialysis Services

Under the ESRD PPS, a single per-treatment payment is made to an ESRD facility for all the renal dialysis services defined in section 1881(b)(14)(B) of the Act and furnished to an individual for the treatment of ESRD in the ESRD facility or in a patient's home. We have codified our definition of renal dialysis services at § 413.171, which is in 42 CFR part 413, subpart H, along with other ESRD PPS payment policies.

The ESRD PPS base rate is adjusted for characteristics of both adult and pediatric patients and accounts for patient case-mix variability. The adult case-mix adjusters include five categories of age, body surface area, low body mass index, onset of dialysis, and four comorbidity categories (that is, pericarditis, gastrointestinal tract bleeding, hereditary hemolytic or sickle cell anemia, myelodysplastic syndrome). A different set of case-mix adjusters are applied for the pediatric population. Pediatric patient-level adjusters include two age categories (under age 13, or age 13 to 17) and two dialysis modalities (that is, peritoneal or hemodialysis) (§ 413.235(a) and (b)(1)).

The ESRD PPS provides for three facility-level adjustments. The first payment adjustment accounts for ESRD facilities furnishing a low volume of dialysis treatments (§ 413.232). The second payment adjustment reflects differences in area wage levels developed from core-based statistical areas (CBSAs) (§ 413.231). The third payment adjustment accounts for ESRD facilities furnishing renal dialysis services in a rural area (§ 413.233).

There are six additional payment adjustments under the ESRD PPS. The ESRD PPS provides adjustments, when applicable, for: (1) a training add-on for home and self-dialysis modalities (§ 413.235(c)); (2) an additional payment for high cost outliers due to unusual variations in the type or amount of medically necessary care (§ 413.237); (3) a TDAPA for certain new renal dialysis drugs and biological products (§ 413.234(c)); (4) a TPNIES for certain new and innovative renal dialysis equipment and supplies (§ 413.236(d)); (5) a transitional pediatric ESRD add-on payment adjustment (TPEAPA) of 30 percent of the per-treatment payment amount for renal dialysis services furnished to pediatric ESRD patients (§ 413.235(b)(2)); and (6) a post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products after the end of the TDAPA period (§ 413.234(g)).

3. Updates to the ESRD PPS

Policy changes to the ESRD PPS are proposed and finalized annually in the **Federal Register**. The CY 2011 ESRD PPS final rule appeared in the August 12, 2010, issue of the **Federal Register** (75 FR 49030 through 49214). That rule implemented the ESRD PPS beginning on January 1, 2011, in accordance with section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA, over a 4-year transition period. Since the implementation of the ESRD PPS, we have published annual rules to make routine updates, policy changes, and clarifications.

Most recently, we published a final rule, which appeared in the November 6, 2023, issue of the **Federal Register**, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model,'' referred to herein as the ''CY 2024 ESRD PPS final rule.'' In that rule, we updated the ESRD PPS base rate, wage index, and outlier policy for CY 2024. We also finalized a post-TDAPA add-on payment adjustment; a TPEAPA for pediatric ESRD patients for CYs 2024, 2025, and 2026; administrative changes to the LVPA eligibility requirements to allow additional flexibilities for ESRD facilities impacted by a disaster or other emergency; clarifications on TPNIES eligibility requirements; and, effective January 1, 2025, requirements for ESRD facilities to report time on machine for in-center hemodialysis treatments, and to report discarded amounts of renal dialysis drugs and biological products from single-dose containers or single-use packages. For further detailed information regarding these updates and policy changes, see 88 FR 76344.

B. Provisions of the Proposed Rule, Public Comments, and Response to the Comments on the CY 2025 ESRD PPS

The proposed rule, titled ''Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model'' (89 FR 55760–55843), referred to as the ''CY 2025 ESRD PPS proposed rule,'' appeared in the July 5, 2024 issue of the **Federal Register**, with a comment period that ended on August 26, 2024. In that proposed rule, we proposed to make a number of updates and policy

changes for CY 2025, including annual updates to the ESRD PPS base rate, a new ESRD PPS wage index methodology, changes to the list of eligible ESRD outlier services, several methodological changes to the outlier policy, changes to the LVPA structure, updates to the post-TDAPA add-on payment adjustment amounts, and updates to the offset amount for the TPNIES.

We received 212 public comments on our proposals, including comments from kidney and dialysis organizations, such as large and small dialysis organizations, for-profit and non-profit ESRD facilities, ESRD networks, and dialysis coalitions. We also received comments from patients; healthcare providers for adult and pediatric ESRD beneficiaries; home dialysis services and advocacy organizations; provider and legal advocacy organizations; administrators and insurance groups; a non-profit dialysis association; a professional association; alliances for kidney care and home dialysis stakeholders; drug and device manufacturers; health care systems; a health solutions company; and the Medicare Payment Advisory Commission (MedPAC). Of these 212 public comments, approximately 70 were unique and approximately 130 were either duplicative submissions or were solely a form letter. We received approximately 110 comments from unique submitters, which reflected a form letter expressing support for a piece of ESRD-related draft legislation which would delay the inclusion of oral-only drugs into the ESRD PPS. We note that we do not comment on draft legislation in this rule will not be directly responding to the support for this draft legislation in this rule, but we are interpreting these letters as expressing support for a delay to the inclusion of phosphate binders into the ESRD PPS bundled payment and have responded to comments which express this sentiment in section II.B.7 of this final rule. Additionally, we note that many of the form letters we received appear to be duplicative submissions based on many names and contact information repeating, so we wish to encourage organizers of these and future campaigns in the future to avoid such duplication as it creates additional operational considerations when reviewing comments.

We received numerous comments on policies for which we did not make any proposals, including mandatory charity care requirements in dialysis clinics, care for undocumented patients, staff assistance for home dialysis, addressing disparities in the kidney transplant process, elevating and integrating patient and caregiver perspectives through a needs navigation model, dialysis commercials for ESRD and AKI, the continuation of TPEAPA, removing the budget neutrality requirement for TPEAPA, both replacing and preventing the replacement of nephrology nurses with other health professionals for prolonged care, including physician assistants or physician associates within the minimum requirement for a dialysis facility's interdisciplinary team, addressing the need for emergency planning for dialysis services in the event of power outages or extreme weather conditions, removing the prospective payment system for home dialysis patients, increasing Medicare Advantage (MA) program payments to beneficiaries in certain geographic areas, restructuring the functional categories for renal dialysis drugs and biological products, aligning CMMI voluntary model benchmarks with the ESRD PPS and its respective add-on payment adjustments, recognizing the mandatory network fee in cost-reports for independent dialysis facilities, removing or mitigating outdated barriers to the use of digital health technology solutions in the ESRD PPS, changing how ESRD patients pay copays, eliminating copays for home dialysis, adding codes for dialysis training onto the telehealth list, and the general need for statutory and regulatory refinements to the ESRD PPS bundled payment. While we are not providing detailed responses to these comments in this final rule because they are out of scope of the proposed rule, we thank the commenters for their input and will potentially consider the recommendations for future rulemaking.

We received several comments related to the requirement at § 413.198(b)(5)(i) to report ''time on machine'' data effective January 1, 2025. These comments generally requested that CMS amend or eliminate the requirement. Some commenters reiterated their concern that this requirement would be burdensome and potentially hazardous. Commenters also requested that CMS identify a consensus definition for time on machine, define time on machine based on ''clock time,'' exclude home dialysis claims from reporting requirements, and designate a claims-based code for an inability to report time on machine data. We did not include any proposals in the CY 2025 ESRD PPS proposed rule to modify the time on machine reporting requirement, and therefore we are not addressing these comments in this rule. We refer commenters to the CY 2024 ESRD PPS final rule (88 FR 76344 through 76507), and the additional guidance CMS posted on November 22, 2023.[6] However, we will consider these comments for potential future refinements to the requirement for reporting of ''time on machine'' data.

We received several comments not related to policies we proposed regarding the TDAPA, TPNIES, TPNIES for capital-related assets that are home dialysis machines, the post-TDAPA add-on payment adjustment, or other potential areas where commenters thought similar policies could be beneficial. Several commenters expressed concern that the ESRD PPS does not sufficiently incentivize innovation in dialysis care or reimburse for innovative technologies. Commenters' suggestions included extending the TDAPA and TPNIES payment periods from 2 years to 3 years, extending the duration of the post-TDAPA add-on payment adjustment to make it permanent, refining base rate-setting exercises based on TDAPA utilization and price data, and adjusting the base rate at the end of the TPNIES payment period. Commenters also suggested revisions to existing TPNIES policies such as expanding the TPNIES for capital related assets beyond home dialysis machines to include in-center dialysis machines or other equipment and supplies that are capital related assets. Commenters suggested that CMS further clarify the TPNIES substantial clinical improvement criteria, clarify whether software can be eligible for the TPNIES, and urged CMS to incentivize more manufacturers to apply for TPNIES. Several commenters suggested that CMS create a pathway for new clinical laboratory tests related to the treatment of ESRD either through an expansion of TPNIES or adoption of a parallel Transitional Laboratory Add-on Payment Adjustment, which the commenters called TLAPA. Commenters suggested changes to the ESRD facility cost reports and billing procedures that would allow for line-item reporting of TDAPA, post-TDAPA, and TPNIES related costs. We received several comments stating that the MA and ESRD PPS regulatory processes should be coordinated to ensure that beneficiaries with ESRD that are enrolled in MA can access items approved for the TDAPA and the TPNIES under the ESRD PPS. Finally, we received several comments on Medicare coverage for certain Humanitarian Use Devices.

[6] *https://www.cms.gov/files/document/mm13445-esrd-acute-kidney-injury-dialysis-cy-2024-updates.pdf.*

We are not providing detailed responses to these comments in this final rule because they are not related to the policy proposals of the CY 2025 ESRD PPS proposed rule. We thank the commenters for their input and will potentially consider the recommendations for future rulemaking.

Lastly, a commenter suggested that CMS had not allowed for a 60-day comment period for the proposed rule because the beginning of the comment period was calculated from the date the proposed rule was made available for public inspection on the **Federal Register** website rather than the date that it appeared in a print issue of the **Federal Register**. The commenter stated that the public comment deadline should have been September 4, 2024. We disagree with the commenter's assertion that we did not allow for the appropriate comment period for this rule. Section 1871(b) of the Act requires that we provide for notice of the proposed regulation in the **Federal Register** and a period of not less than 60 days for public comment thereon. The proposed rule was available for public inspection on *federalregister.gov* (the website for the Office of Federal Register) on June 27, 2024. We believe that beginning the comment period for the proposed rule on the date it became available for public inspection at the Office of the Federal Register fully complied with the statute and provided the required notice to the public and a meaningful opportunity for interested parties to provide input on the provisions of the proposed rule.

1. CY 2025 ESRD Bundled (ESRDB) Market Basket Percentage Increase; Productivity Adjustment; and Labor-Related Share

a. Background

In accordance with section 1881(b)(14)(F)(i) of the Act, as added by section 153(b) of MIPPA and amended by section 3401(h) of the Affordable Care Act, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase and reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The application of the productivity adjustment may result in the increase factor being less than 0.0 for a year and may result in payment rates for a year being less than the payment rates for the preceding year. Section 1881(b)(14)(F)(i) of the Act also provides that the market basket increase factor should reflect the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

As required under section 1881(b)(14)(F)(i) of the Act, CMS developed an all-inclusive ESRDB input price index using CY 2008 as the base year (75 FR 49151 through 49162). We subsequently revised and rebased the ESRDB input price index to a base year of CY 2012 in the CY 2015 ESRD PPS final rule (79 FR 66129 through 66136). In the CY 2019 ESRD PPS final rule (83 FR 56951 through 56964), we finalized a rebased ESRDB input price index to reflect a CY 2016 base year. In the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized a revised and rebased ESRDB input price index to reflect a CY 2020 base year.

Although ''market basket'' technically describes the mix of goods and services used for ESRD treatment, this term is also commonly used to denote the input price index (that is, cost categories, their respective weights, and price proxies combined) derived from a market basket. Accordingly, the term ''ESRDB market basket,'' as used in this document, refers to the ESRDB input price index.

The ESRDB market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time are not measured.

b. CY 2025 ESRD Market Basket Update

We proposed to use the 2020-based ESRDB market basket as finalized in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154) to compute the CY 2025 ESRDB market basket percentage increase based on the best available data. Consistent with historical practice, we proposed to estimate the ESRDB market basket percentage increase based on IHS Global Inc.'s (IGI) forecast using the most recently available data at the time of rulemaking. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. As discussed in section II.B.1.b.(3) of this final rule, we are calculating the final market basket update for CY 2025 based on the final market basket percentage increase and the final productivity adjustment, following our longstanding methodology.

(1) CY 2025 Market Basket Percentage Increase

Based on IGI's first quarter 2024 forecast of the 2020-based ESRDB market basket, the proposed CY 2025 market basket percentage increase was 2.3 percent. We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket percentage increase), we would use such data, if appropriate, to determine the CY 2025 market basket percentage increase in the final rule. Accordingly, based on IGI's third quarter 2024 forecast of the 2020-based ESRDB market basket, the final CY 2025 ESRDB market basket percentage increase is 2.7 percent.

(2) Productivity Adjustment

Under section 1881(b)(14)(F)(i) of the Act, as amended by section 3401(h) of the Affordable Care Act, for CY 2012 and each subsequent year, the ESRDB market basket percentage increase shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year (FY), year, cost reporting period, or other annual period) (the ''productivity adjustment'').

The Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the United States economy. As we noted in the CY 2023 ESRD PPS final rule (87 FR 67155), the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act previously was published by BLS as private nonfarm business MFP. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term ''multifactor productivity'' with ''total factor productivity'' (TFP). BLS noted that this is a change in terminology only and would not affect the data or methodology.[7] 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 *https://www.bls.gov/productivity/* for the BLS

[7] Total Factor Productivity in Major Industries—2020. Available at: *https://www.bls.gov/news.release/prod5.nr0.htm.*

historical published TFP data. A complete description of IGI's TFP projection methodology is available on CMS's 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 CY 2022 ESRD PPS final rule (86 FR 61879), we noted that effective for CY 2022 and future years, we would be changing the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment. We stated this was not a change in policy, as we would continue to use the same methodology for deriving the adjustment and rely on the same underlying data.

Based on IGI's first quarter 2024 forecast, the proposed productivity adjustment for CY 2025 (the 10-year moving average of TFP for the period ending CY 2025) was 0.5 percentage point. Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 productivity adjustment in the final rule. Accordingly, based on IGI's third quarter 2024 forecast, the CY 2025 final productivity adjustment remains unchanged at 0.5 percentage point.

(3) CY 2025 Market Basket Update

In accordance with section 1881(b)(14)(F)(i) of the Act, we proposed to base the CY 2025 market basket percentage increase on IGI's first quarter 2024 forecast of the 2020-based ESRDB market basket. We proposed to then reduce the market basket percentage increase by the estimated productivity adjustment for CY 2025 based on IGI's first quarter 2024 forecast. Therefore, the proposed CY 2025 ESRDB market basket update was equal to 1.8 percent (2.3 percent market basket percentage increase reduced by a 0.5 percentage point productivity adjustment). Furthermore, as noted previously, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of this final rule (for example, a more recent estimate of the market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 market basket percentage increase and productivity adjustment in the final rule. Accordingly, the final CY 2025 ESRDB market basket update is calculated using the final CY 2025 ESRDB market basket percentage increase, based on IGI's third quarter 2024 forecast of the 2020-based ESRDB market basket, and the final productivity adjustment, based on IGI's third quarter 2024 forecast. Therefore, the final CY 2025 ESRDB market basket update is equal to 2.2 percent (2.7 percent market basket percentage increase reduced by a 0.5 percentage point productivity adjustment).

(4) Labor-Related Share

We define the labor-related share as those expenses that are labor-intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of operating costs that are related to, influenced by, or vary with the local labor market. For the CY 2025 ESRD PPS payment update, we proposed, and are finalizing, to continue using a labor-related share of 55.2 percent, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154).

(5) Public Comments on the ESRDB Market Basket Increase Factor, Productivity Adjustment, Annual Update and Labor-Related Share

We invited public comment on our proposals related to the ESRDB market basket update and labor-related share. Approximately 25 unique commenters including large dialysis organizations (LDOs); small dialysis organizations (SDOs), patient advocacy organizations; nonprofit dialysis associations; two coalitions of dialysis organizations; professional organizations; and MedPAC commented on the proposed update. The following is a summary of the public comments received on these proposals and our responses.

Comment: Commenters generally supported increasing the ESRD PPS base rate and the utilization of the most recent data available (for example, a more recent estimate of the market basket or productivity adjustment) to determine the final CY 2025 ESRD PPS update. MedPAC recommended that the ESRD PPS base rate increase for CY 2025 should be updated by the amount determined under current law, and commented that analysis reported in the March 2024 Report to the Congress: Medicare Payment Policy concluded that this increase is warranted based on its analysis of payment adequacy (which includes an assessment of beneficiary access, supply and capacity of facilities, facilities' access to capital, quality, and financial indicators for the sector). Most other commenters, however, expressed concerns regarding the proposed productivity-adjusted ESRDB market basket update, the proposed ESRD PPS base rate and payment adequacy under the ESRD PPS.

Response: We appreciate commenters' support for an increase to the ESRD PPS base rate and MedPAC's support of the proposed update amount. We acknowledge that many commenters expressed numerous concerns related to the proposed payment rates and payment adequacy within the ESRD PPS. We agree with MedPAC that increasing the payment rate according to the established ESRD PPS methodology is the most appropriate course of action. We have summarized and addressed commenters' specific concerns regarding the payment rate and payment adequacy below.

Comment: Numerous commenters expressed concerns regarding payment rates within the ESRD PPS and the CY 2025 ESRDB market basket update. The general opinion of commenters was that the current ESRD PPS payment rate was not adequate. Many of these comments specifically indicated a belief that the proposed CY 2025 ESRDB market basket update was not a sufficient increase given inflation, specifically pointing to rising costs including labor costs. Many of these concerns were presented in concert with a request for a ''forecast error adjustment,'' which we discuss later in this section of the preamble. Some commenters included comparisons between the ESRD PPS payment rates or ESRDB market basket increases, and other figures not directly related to the furnishing of renal dialysis services such as other Medicare payment systems, overall healthcare costs and overall inflation. Most of these comments requested that CMS take some action to alleviate the perceived concern regarding payment rates. Commenters often cited certain costs which have contributed to the rising costs faced by ESRD facilities including costs related to labor and wages, costs related to training nurses and technicians, supply costs often resulting from limited competition for supplies or limited purchasing power for supplies, supply costs associated with receiving goods in geographically isolated areas, and costs of home dialysis supplies and equipment. Some commenters detailed the potential implications of inadequate ESRD PPS payments including worsened health outcomes, health equity concerns, access to care issues often resulting from ESRD facility closures or reduction of shifts, and inability for ESRD facilities to recruit and retain high quality staff. Several comments quoted MedPAC's estimated 2024 Medicare margins for ESRD facilities which were 0.0 percent as

published in the March 2024 Report to Congress.[8]

Response: We thank commenters for their insight into the payment adequacy of the ESRD PPS and the costs faced by ESRD facilities. We recognize that the input prices that ESRD facilities face have increased in recent years at a rate higher than the ESRDB market basket forecasts have predicted. We address commenters' related requests for a ''forecast error adjustment'' later in this section of the preamble. Payment rates under the ESRD PPS are established based on a methodology dictated by statute, which means the CY 2025 ESRD PPS base rate reflects the CY 2011 ESRD PPS base rate updated by each year's ESRDB market basket update. The ESRD PPS base rate has also been routinely adjusted by certain budget-neutrality factors, for example, budget neutrality adjustment factors related to the annual update to the wage index or related to various payment adjustments like the case mix adjustments or the LVPA. However, we note that the construction of these budget-neutrality factors is calculated to offset the effect of certain other updates and adjustments on total spending under the ESRD PPS and thereby maintain the level of overall payments, so we do not believe that the budget-neutrality factors have had a negative impact on the total payments under the ESRD PPS. Since CY 2011, the only time the ESRD PPS base rate was increased other than as part of a routine update or adjustment was in the CY 2021 ESRD PPS final rule, when we first incorporated calcimimetics into the bundled payment and increased the base rate by $9.93 (85 FR 71410). In summary, the ESRD PPS base rate is based on a longstanding, data driven method provided for by statute. We did not propose, and are not finalizing, any changes to the ESRD PPS payment update methodology.

We agree with commenters that payment adequacy is important as it has a wide variety of impacts both on ESRD facilities and ESRD patients, many of which have been described by commenters. We intend to continue monitoring the performance of the ESRD PPS, and any changes to the ESRD PPS payment rate or ESRDB market basket would be made through notice and comment rulemaking.

We recognize that MedPAC has found that the Medicare FFS margins for ESRD facilities are projected to be 0.0 percent for 2024. We wish to add that MedPAC found that Medicare marginal profit for ESRD facilities was approximately 18 percent for 2022.[9] We understand that the Medicare FFS margin is lower than many interested parties may believe would be appropriate; however, we believe that payments are sufficiently high relative to marginal costs to support the profitable operation of ESRD facilities generally. While we believe MedPAC margin estimates are generally a reasonable metric, we note that the ESRD PPS payment rate is based on the change in prices of a fixed bundle of goods and services, not based on continuously re-aligning payment with costs directly.

Comment: Several commenters discussed the current difficulties of recruiting and retaining healthcare workers. Commenters often characterized this as a healthcare labor shortage and stated that the accompanying increase in wage inflation was a major source of increased costs for ESRD facilities. Many commenters indicated a belief that the proposed CY 2025 ESRDB market basket update or the proposed CY 2025 ESRD PPS base rate were insufficient given this increase in labor costs. One analysis cited by commenters found that labor costs for ESRD facilities rose by 23.7 percent between 2017 and 2023 whereas the ESRD PPS base rate rose by only 14.7 percent during that same period.

Response: We appreciate the commenters' evaluation of labor costs for ESRD facilities. We acknowledge that many ESRD facilities are having increased difficulty in hiring due to overall trends present in the healthcare industry. We note that the ESRDB market basket includes several price proxies for the various cost categories of the ESRDB market basket, including labor. We agree with commenters that labor costs are a significant driver of overall rising costs for ESRD facilities; however, they are not the only costs faced by ESRD facilities and, therefore, are not the only component of the ESRDB market basket. As labor is a substantial driver of the overall input price increase, generally the other input prices faced by ESRD facilities are increasing less than labor prices, so the overall ESRDB market basket increase for a given year is less than the amount by which labor prices have increased. Our analysis of the ESRDB market basket increases from 2017 to 2023 has found that the ESRDB market basket forecasted compensation prices increased by a cumulative 20.9 percent over this time period. The actual ESRDB market basket compensation price growth (based on historical data) over this time period is 23.7 percent. This suggests the ESRDB market basket price proxies are projecting the increased price of labor faced by ESRD facilities with reasonable accuracy, and we believe that the data presented by the commenters supports this belief.

Comment: Several commenters, representing numerous industry interests, stated they believe that the ESRDB market basket is systemically flawed, because the market basket fails to accurately capture the changes over time in the prices in the goods and services included in renal dialysis services. The commenters believed the flaws are due to problems with the weights and price proxies used to assess the changes in costs year-over-year.

The commenters cited analysis from a contractor that suggests possible flaws in the market basket cost weights and price proxies. First, the commenters noted that the cost weights for capital costs are significantly higher in the ESRDB market basket compared to other CMS market baskets. They suggested that while 31 percent of the overall capital costs are determined to be labor-related, the price proxy for capital costs does not use a labor-related price proxy. The commenters suggested that the price proxy for capital costs should be a blended proxy that also includes a price proxy for labor. Another area of concern was that the weight for the ''All Other Goods and Services'' cost category is much larger than in other CMS market baskets—a weight of 11.1 percent is assigned to this category in the ESRDB market basket—and that similar categories under the inpatient prospective payment system (IPPS) and skilled nursing facility (SNF) PPS have weights of 1.2 percent and 0.3 percent, respectively. The commenters stated that further refining the category's definition under the ESRD PPS could reduce the weight and result in a more accurate update factor reflective of ESRD-specific costs.

Response: We appreciate the commenters' suggestions for areas that could benefit from technical improvements in the design and methodology for the ESRDB market basket cost weights and price proxies. We did not propose to rebase or revise the ESRDB market basket in the CY 2025 ESRD PPS proposed rule and further note that we finalized the 2020-based ESRDB market basket in the CY 2023 ESRD PPS final rule (87 FR 67141). At the time of the CY 2023 rulemaking cycle, the 2020 Medicare cost report data was the most recent, fully complete

[8] *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-2.pdf.*

[9] *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-2.pdf.*

cost data available and reflected cost data as submitted by freestanding ESRD facilities.

The share of capital costs referenced by the commenter are related to the allocation of a portion of the capital cost weight to the labor-related share since fixed capital costs (for example, construction or improvements to a building) would include costs associated with labor to perform the construction in the initial price, and that price is financed over time or incorporated with the lease contract. This methodology of allocating a portion of the market basket capital cost weight to the labor-related share is consistent across the other CMS PPSs such as those for SNFs, inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities (IPFs), and long-term care hospitals. For the CY 2023 ESRD PPS final rule (87 FR 67141 through 67154), we finalized the continued use of the Producer Price Index (PPI) Industry for Lessors of Nonresidential Buildings (BLS series code #PCU531120531120), to measure the price growth of the Capital-Related Building and Fixtures cost category. This PPI reflects the prices of leases for nonresidential buildings (including professional and office buildings). The North American Industrial Classification System (NAICS) definition for this industry comprises establishments primarily engaged in acting as lessors of buildings (except mini-warehouses and self-storage units) that are not used as residences or dwellings. Included in this industry are: (1) owner-lessors of nonresidential buildings; (2) establishments renting real estate and then acting as lessors in subleasing it to others; and (3) establishments providing full service office space, whether on a lease or service contract basis. The establishments in this industry may manage the property themselves or have another establishment manage it for them. We continue to believe that this is an appropriate price proxy, as it reflects the lease or replacement value of nonresidential buildings that would be influenced by both labor prices, such as those associated with construction costs, as well as other nonlabor factors, such as building supplies and interest rates.

In response to the concerns related to the ESRDB market basket cost weight for All Other Goods and Services, as stated in the CY 2023 ESRD PPS final rule (87 FR 67145), the All Other Goods and Services cost weight was derived by disaggregating the Administrative and General cost weight (calculated using the freestanding ESRD Medicare Cost Report data) using the 2012 Service Annual Survey data, which was the most recent year of detailed expense data (inflated to 2020 levels) published by the Census Bureau for NAICS Code 621492: Kidney Dialysis Centers. Though the resulting weight for this category may differ from the weight calculated for other indices, it appropriately reflects the cost distributions associated with providing ESRD services, as prescribed by law.

We note that changing the composition of the ESRDB market basket or changing the price proxies used for the ESRDB market basket would likely not have had a significant impact on the past forecast errors of the ESRDB market basket, since those forecast errors were calculated by comparing the forecasted ESRDB market basket update available at the time of rulemaking to the ''actual'' ESRDB market basket update based on that same index. Any change to the weights or price proxies in the ESRDB market basket would not by itself mitigate a forecast error. The forecast error would only be different or mitigated if the forecasts of alternative price proxies were more accurate than those for the current price proxies used in the ESRDB market basket.

CMS is open to hearing from the commenters and discussing any data or analysis the industry may provide regarding ways to ensure the Medicare payments are appropriate and that the market basket price proxies and weights are accurate. We welcome any publicly available and representative input cost data that reflects total and category-specific costs for the ESRD industry the commenters could provide. We will consider the commenters' suggestions when we propose to rebase and revise the ESRDB market basket in the future and note that any such proposal would occur through notice and comment rulemaking. We rebase and revise the CMS market baskets approximately every 4 to 5 years so that the cost weights reflect recent changes in the mix of goods and services that ESRD facilities purchase to furnish renal dialysis services between base periods. We last rebased in the CY 2023 ESRD PPS final rule (87 FR 67141 through 67153).

Comment: Several commenters expressed concern that the ESRDB market basket updates are disproportionately lower than for all other Medicare providers reimbursed under a PPS. The commenters stated they understand that different cost structures influence this outcome; however, they noted it is important to note these discrepancies given that all these healthcare sectors draw from the same labor pools, and lower ESRD PPS updates erode ESRD facilities' ability to attract caregivers in the current labor market. One commenter noted that the price proxy for buildings utilized by IPPS and SNF is the ''BEA—Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care—vintage weighted 27 years'' which the commenter stated is growing at a faster rate than the price proxy ''PPI Industry for Lessors of Nonresidential Buildings'' which is used by the ESRD PPS.

Response: The 2020-based ESRDB market basket percentage increase is equal to the weighted price change of the individual price proxies based on their respective cost weights. The cost weights are primarily derived using data from the freestanding ESRD facility Medicare cost reports and reflect relative shares of input costs needed to provide renal dialysis services to ESRD beneficiaries. Similarly, the other CMS PPS market baskets, such as the 2022-based SNF market basket and 2018-based IPPS market basket, reflect the relative share of input costs needed to provide skilled nursing and hospital care to Medicare beneficiaries based on the data reported on the respective provider cost reports.

While we understand that commenters may compare the annual updates in the ESRDB market basket to other Medicare payment system market baskets, the ESRDB market basket is developed in accordance with section 1881(b)(14)(F)(i) of the Act requiring that the index reflect the composition of costs associated with providing renal dialysis services. These costs (and the subsequent cost distributions) are reported by ESRD facilities on the Medicare cost reports and may differ (appropriately) from the relative distribution of costs of other medical care providers, such as inpatient hospitals or skilled nursing facilities. Additionally, the price proxies used in the ESRDB market basket are intended to reflect the price pressures faced by ESRD facilities. While some price proxies may be similar to those used across other CMS market baskets, in most cases they are appropriately different because they reflect the price pressures faced by ESRD facilities. For example, the rate of increase in the ESRDB market basket compensation category reflects the weighted average of the price increase for occupations employed by ESRD facilities.

At the time of the CY 2025 ESRD PPS proposed rule, based on the IGI's first quarter 2024 forecast with historical data through the fourth quarter of 2023,

the 2020-based ESRDB market basket increase was forecasted to be 2.3 percent for CY 2025, reflecting forecasted compensation price growth of 3.6 percent. In the CY 2025 ESRD PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final CY 2025 ESRDB market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy and expected price inflation for CY 2025. Based on IGI's third quarter 2024 forecast with historical data through the second quarter of 2024, we are projecting a CY 2025 ESRDB market basket increase of 2.7 percent (reflecting forecasted compensation price growth of 3.8 percent). Therefore, for CY 2025 a final ESRDB productivity-adjusted market basket update of 2.2 percent (2.7 percent less 0.5 percentage point for the productivity adjustment) will be applicable, compared to the 1.8 percent productivity-adjusted market basket update that was proposed.

Comment: Several commenters raised concerns about the labor-related share of the ESRD PPS. These commenters suggested that adjusting the labor-related share could better recognize changes in labor costs and result in a higher overall market basket update for the ESRD PPS. Some commenters noted that the ESRD PPS labor-related share for CY 2025 is 55.2 percent while the labor-related share for SNF PPS is 70.1 percent and 67.6 or 62 percent for IPPS.

Response: The purpose of the labor-related share is to reflect the proportion of the national ESRD PPS base payment rate that is adjusted by the wage index. CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of wages and wage-related costs in the geographic area in which the ESRD facility is located. The purpose of the labor-related share is to allocate ESRD payment between a labor-related portion and non-labor-related portion for purposes of geographic adjustment and the labor-related share does not directly impact the market basket update.

We define the labor-related share as those expenses that are labor intensive and vary with, or are influenced by, the local labor market. The labor-related share of a market basket is determined by identifying the national average proportion of costs that are related to, influenced by, or vary with the local labor market. In the CY 2023 ESRD PPS final rule (87 FR 67153 through 67154), we detailed the use of the 2020-based ESRDB market basket cost weights to determine the labor-related share for ESRD facilities. Specifically, effective for CY 2023, a labor-related share of 55.2 percent was determined based on the sum of Wages and Salaries, Benefits, Housekeeping, Operations & Maintenance, 87 percent of the weight for Professional Fees, and 46 percent of the weight for Capital-related Building and Fixtures expenses, which, with the exception of the Professional Fees (0.7 percent) cost weight, were derived from the ESRD Medicare cost reports (CMS Form 265–11, OMB NO. 0938–0236).

While the conceptual definition of the labor-related share used for the ESRD PPS is similar to that used for SNF PPS and IPPS, the cost structures for the various providers differ substantially. Thus, we believe the ESRD labor-related share of 55.2 percent is appropriate, and we are finalizing our proposal to continue to use this labor-related share for CY 2025 ESRD PPS payments.

We note that the labor-related share, as previously discussed, is used to determine the portion of the ESRD PPS base rate which is related to labor for the purposes of applying the ESRD PPS wage index. We believe some of the commenters who requested a higher labor-related share may have believed that increasing the labor-related share would change the proportion of the ESRDB market basket to which price proxies related to labor are applied. As discussed in the CY 2023 ESRD PPS final rule, the ESRDB market basket cost weights are derived from cost report data and, therefore, are the most appropriate measures of the proportion of the ESRDB to which we apply each pricy proxy. It would not be appropriate to apply one of the labor price proxies to other non-labor cost weights in the ESRDB market basket.

Comment: One commenter stated that while they understand CMS does not have authority to waive the application of the productivity adjustment, they were concerned that applying a one-size-fits-all approach in an effort to incentivize efficiencies fails to recognize the unique challenges facing ESRD facilities.

Response: Section 1881(b)(14)(F)(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 CY 2025 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending CY 2025. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, we are required pursuant to section 1881(b)(14)(F)(i) of the Act to apply the specific productivity adjustment described here and do not believe it can be removed from the calculation of the market basket update. As such, we are not finalizing any changes to the use of the productivity adjustment in the CY 2025 ESRDB market basket update.

As stated in the CY 2025 ESRD PPS proposed rule (89 FR 55765), 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 sections 1881(b)(14)(F)(i)(II) and 1886(b)(3)(B)(xi)(II) of the Act, the latter of which 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 CY 2025 proposed productivity adjustment of 0.5 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 final productivity adjustment for CY 2025 is also 0.5 percentage point for this final rule and is slightly higher than the productivity adjustment for CY 2024 (0.3 percent). This higher productivity adjustment is primarily a result of incorporating BLS revised historical data through 2022, the preliminary historical growth rate in TFP for 2023, and an updated forecast for TFP growth for 2024 reflecting higher expected growth in economic output.

Comment: Commenters reported that the IGI forecast continues to significantly underestimate the increasing costs ESRD facilities incur when providing services to Medicare

beneficiaries and that the market basket increases provided by CMS have not kept up with the rising costs of doing business, particularly labor costs. Commenters stated that while they recognize that updates to the ESRDB market basket are set prospectively, and some degree of forecast error is thus inevitable, they also believe that ESRD facilities should not be financially disadvantaged as a result of CMS market basket forecasting errors. Many commenters urged CMS to reconsider its decision not to adopt a forecast error policy. They stated that a forecast error adjustment for the ESRD PPS would be needed to ensure the funding that the Congress intended ESRD facilities to receive would be available to support patient care and help address health inequities.

The commenters stated that the CMS contractor that determines forecasted price growth for the bundled ESRD PPS market basket has failed to provide an accurate update for the last 4 years resulting in an approximately negative 7 percent forecast error since 2019. They further stated that they believe that the existing methodology will produce an inaccurate annual payment update for CY 2025. Furthermore, they stated that the forecast errors in the ESRD PPS are disproportionately worse than the forecast errors in the other Medicare payment systems and continue to urge CMS to address what they describe as the past underfunding of the payment system.

A few commenters stated that the failure to correct the known forecast errors over the last several years is contrary to the statutory requirement at section 1881(b)(14)(F)(i) of the Act to update the ESRD PPS payment rate based on the change in prices of the ESRDB. The commenters stated that the CMS response in the CY 2024 ESRD PPS final rule was that its market basket update forecast ''misses'' for CY 2021 and CY 2022 were largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID–19 Public Health Emergency (PHE) and that an analysis of the forecast error of the ESRDB market basket over a longer period shows the forecast error has been both positive and negative. The commenters highlighted our past statement that the difference between the projected and actual market basket increases can be both positive and negative. The commenters claimed that this is not the reality of the current situation, and that it would be unlikely that the forecast errors would ''miss'' to the same extent in the future. The commenters also noted that it appears that the under-forecast of the ESRDB market basket updates have continued into 2023, and they stated that preliminary evidence shows even into 2024.

The commenters requested that CMS reconsider its decision not to adopt a forecast error adjustment for the ESRD PPS to account for the underestimates from CMS' forecasted market basket updates in prior calendar years, and to eliminate the risk of further substantial forecast errors going forward by adopting a forecast error adjustment policy for future years modeled after the forecast error adjustment policy in the SNF PPS. Some commenters supported CMS finalizing a forecast error adjustment in this final rule effective for CY 2025, whereas other commenters supported CMS proposing a forecast error adjustment effective for CY 2026. The commenters further stated that addressing these forecast errors is essential to fulfill CMS's statutory obligation to ensure that the ESRD PPS market basket update reflects actual changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services.

Several commenters noted that when CMS first introduced the forecast error adjustment for SNFs, the agency explicitly determined that this type of adjustment would not be providing a source of new industry funding. Instead, the commenters noted that CMS stated that we were correcting an under-forecast of pricing levels that resulted in lower payments than we would otherwise have made if actual, instead of forecast, data were used. One commenter further stated that on the contrary in the CY 2024 ESRD PPS final rule, CMS justified not implementing stakeholder calls for a forecast error adjustment for the ESRD PPS by explaining that the cumulative under-forecast of the SNF market basket increases was not due to a PHE, which was the case for the ESRD PPS's under-forecast in recent years. However, the same commenter noted that CMS finalized a forecast error adjustment for the SNF payment system due to the rapid increase in the price of labor and because CMS concluded that a forecast error adjustment was appropriate for payment accuracy for SNFs. The commenter further rationalized that while the forces driving the under-forecast of the ESRDB market basket today may differ from those impacting the SNF market basket in 2003, the outcomes for providers are presenting in the same manner. Commenters stated that they believe implementation of a retroactive cumulative forecast error adjustment and continued forecast error adjustment in the future is within CMS's existing statutory authority under section 1881(b)(14)(F)(i) of the Act. Commenters referenced perceived similarities between this statutory language for the ESRD PPS and the statutory language for the SNF PPS annual update at section 1395rr(b)(F)(i)(I) of the Act, which CMS utilized when finalizing the SNF PPS forecast error adjustment.

Based on what the commenters characterized as the same statutory obligation and an even larger and longer record of forecast errors, the commenters requested CMS adopt the same retrospective forecast error adjustment and future forecast error adjustment process for the ESRD PPS. They provided further context for this request by referencing the justification of the forecast error adjustment policy in the SNF PPS as precedent.

Some commenters urged CMS to implement a one-time retrospective adjustment to the ESRD PPS base rate in the amount of the current cumulative forecast error calculated from the beginning of the ESRD PPS, while others requested such an adjustment for the period of 2019 or 2020 through 2023. Additionally, most commenters also supported the implementation of a forecast error correction policy for future years that would be triggered when the absolute (positive or negative) error is equal to or exceeds a 0.5 percentage point threshold. One commenter also requested that CMS acknowledge that the current forecast methodology has failed to produce accurate updates for 4 years and work with IGI to minimize forecast misses in the future. One commenter requested more transparency regarding the methodology for developing the price forecasts that are used in the CMS market baskets.

Response: The ESRDB market basket updates are set prospectively, which means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. For instance, the CY 2025 market basket update in this final rule reflects historical data through the second quarter of CY 2024 and forecasted data through the fourth quarter of CY 2025. While there is no precedent to adjust for market basket forecast error in the ESRD PPS payment update, a forecast error can be calculated by comparing the actual market basket increase for a given year to the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative, as has occurred

since the implementation of the ESRD PPS in CY 2011. Over most of this history the forecast errors were small in magnitude, with the largest error (in absolute terms) prior to 2021 being an over-forecast (the actual market basket increase was less than the forecasted market basket increase) of 0.8 percentage point in 2017. More recently the ESRDB market basket has been under-forecast, as noted by the commenters, with larger errors occurring for 2021 through 2023. The cumulative forecast error since ESRD PPS inception (CY 2012 to CY 2023) is an under-forecast of 4.3 percent.[10] These recent forecast errors were largely a function of uncertainty in the overall economy and the health sector specifically due to the nature of the COVID–19 PHE and the unforeseen inflationary environment.

We thank the commenters for their continued feedback on the ESRDB market basket. In the CY 2024 ESRD PPS proposed rule we explained why we did not believe a forecast error adjustment was appropriate at that time. We did not propose a forecast error adjustment in the CY 2025 ESRD PPS proposed rule for these same reasons and are not finalizing a forecast error adjustment at this time. Specifically, predictability in Medicare payments is important to enable ESRD facilities to budget and plan their operations, and forecast error calculations are unpredictable (88 FR 76356 through 76358). Historically, the positive differences between the actual and forecasted market basket increase have offset negative differences over time. Although we acknowledge that this has not been the case in recent years, we note that it may take a longer period of time for forecast errors to balance out. For example, in CY 2016 the cumulative forecast error for the ESRDB market basket since CY 2012 was 0.4 percent, and in each year from CY 2012 to CY 2016, the cumulative forecast error was positive, ranging from 0.2 percent to 0.5 percent. Then, beginning in CY 2017, the cumulative forecast error was negative, which continued through CY 2020, ranging from −0.4 percent to −0.6 percent. These examples illustrate that over time positive and negative differences between the actual and forecasted market basket increase have tended to balance out. Therefore, in accordance with our longstanding ESRD PPS payment update methodology, we are finalizing to update the CY 2025 ESRD PPS base rate without the application of a forecast error adjustment to the ESRDB market basket.

Given the concerns raised by the commenters, we intend to continue to monitor the pattern of the ESRDB market basket forecast errors to observe if the historical experience (where errors have balanced out) continues. Any changes to the ESRD PPS payment update methodology, including any forecast error adjustment policy, would be proposed through notice and comment rulemaking. We acknowledge the commenter's request for more transparency regarding the ESRDB market basket forecast methodology and have shared details in prior and this year's rules on these methods; however, we are limited in the amount of information we can provide regarding the forecast methodology, which is proprietary to IGI.

Comment: Some commenters expressed concern about whether CMS was adhering to Social Security Act and the Administrative Procedure Act requirements in declining to adopt a forecast error adjustment. One commenter stated that, given the past forecast errors, they did not believe our methodology fulfilled the requirement to update the payment system based on the change in prices of the ESRDB market basket. This commenter further stated a belief that because CMS had determined that a forecast error adjustment was appropriate for the SNF PPS in 2004, we would be in violation of the ESRD PPS's similarly worded statute unless we were to implement a forecast error adjustment for the ESRD PPS, due to the similarities between the circumstances of SNF PPS in 2004 and the ESRD PPS presently.

Response: We strongly disagree with the commenter's assertion that CMS's position regarding an ESRD PPS forecast error payment adjustment conflicts with any of the statutory requirements for the ESRD PPS. As we have discussed previously, we believe that the ESRDB market basket forecast reflects the change in prices of an appropriate mix of goods and services included in renal dialysis services, as required by statute. We note that the circumstances of the ESRD PPS in the present are not identical to the circumstances of the SNF PPS when we finalized a forecast error adjustment. The cumulative under-forecast of the SNF market basket increases in 2004 was based on a rapid increase in the price of labor, not due to a PHE that rapidly increased the price of most of the goods and services in the ESRDB market basket. Additionally, the increase in the price of labor uniquely impacted the SNF PPS at that time as the SNF PPS had only existed for a few years and had numerous under-forecasts in that short timeframe. This is unlike the current ESRD PPS environment, where the ESRD PPS had a decade of reasonably accurate forecasts, followed by a PHE resulting in multiple Medicare payment systems facing similar forecast errors. We continue to believe these differences in circumstances are relevant in evaluating the forecast errors in the ESRD PPS in recent years and their implications for the future performance of the payment system. We note that when CMS finalized a forecast error adjustment for the SNF payment system, we concluded that a forecast error adjustment was appropriate for payment accuracy for SNFs; not that it was required under the statute (68 FR 46057). For these reasons, we disagree with the commenter's stated belief that a forecast error adjustment would be required to fulfill the ESRD PPS statutory requirements, and, at this time, for the reasons discussed previously, we do not believe that a forecast error payment adjustment would be appropriate for the ESRD PPS. We also disagree with the commenter's assertion that by not implementing a forecast error adjustment we are in violation of the Administrative Procedure Act; as discussed previously, our established ESRDB market basket methodology has been set and revised through notice and comment rulemaking (75 FR 49151 through 49162, 79 FR 66129 through 66136, 83 FR 56951 through 56964, 87 FR 67141 through 67154). For the CY 2025 ESRD PPS proposed rule we provided a 60-day comment period, and we have considered and responded to all relevant comments in this final rule explaining our reasoning for the policies we are finalizing.

Comment: One coalition of dialysis organizations disagreed with CMS's evaluation that a forecast error adjustment would make ESRD PPS payments less predictable. The commenter stated that under the current payment system providers are uncertain whether the ESRDB market basket forecast would be accurate for a given year.

Response: We appreciate this commenter's perspective on predictability within the ESRD PPS as we work to improve the payment system. Our current view on predictability is that it is important for ESRD facilities to be able to plan for future years with the most complete information possible, which we believe would likely not be the case if the ESRD PPS base rate would be lowered in a given year due to an over-forecast in the prior year. We will take this input into consideration for future rulemaking.

[10] This figure does not include a forecast error for CY 2015, as section 1881(b)(14)(F)(i)(III) of the Act required a 0.0 percent update for that year.

Final Rule Action: We did not propose and are not finalizing any changes to the ESRDB market basket methodology for CY 2025. Thus, the final ESRDB market basket update for CY 2025 is 2.2 percent, representing a ESRDB market basket percentage increase of 2.7 percent reduced by a 0.5 percentage point productivity adjustment.

2. CY 2025 ESRD PPS Wage Indices

a. Background

Section 1881(b)(14)(D)(iv)(II) of the Act provides that the ESRD PPS may include a geographic wage index payment adjustment, such as the index referred to in section 1881(b)(12)(D) of the Act, as the Secretary determines to be appropriate. In the CY 2011 ESRD PPS final rule (75 FR 49200), we finalized an adjustment for wages at § 413.231. Specifically, we established a policy to adjust the labor-related portion of the ESRD PPS base rate to account for geographic differences in the area wage levels using an appropriate wage index, which reflects the relative level of hospital wages and wage-related costs in the geographic area in which the ESRD facility is located. Under current policy, we use the Office of Management and Budget's (OMB's) CBSA-based geographic area designations to define urban and rural areas and their corresponding wage index values (75 FR 49117). OMB publishes bulletins regarding CBSA changes, including changes to CBSA numbers and titles. The bulletins are available online at *https://www.whitehouse.gov/omb/information-for-agencies/bulletins/*.

We have also adopted methodologies for calculating wage index values for ESRD facilities that are located in urban and rural areas where there are no hospital data. For a full discussion, see the CY 2011 and CY 2012 ESRD PPS final rules at 75 FR 49116 through 49117 and 76 FR 70239 through 70241, respectively. For urban areas with no hospital data, we have computed the average wage index value of all hospitals in urban areas within the State to serve as a reasonable proxy for the wage index of that urban CBSA. For rural areas with no hospital data, we have computed the wage index using the average hospital wage index values from all contiguous CBSAs to represent a reasonable proxy for that rural area. We applied the statewide urban average based on the average of all urban areas within the State to Hinesville Fort Stewart, Georgia (78 FR 72173), and we applied the wage index for Guam to American Samoa and the Northern Mariana Islands (78 FR 72172).

Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Currently, all areas with wage index values that fall below the floor are located in Puerto Rico and the US Virgin Islands. However, the wage index floor value is applicable for any area that may fall below the floor. A further description of the history of the wage index floor under the ESRD PPS can be found in the CY 2019 ESRD PPS final rule (83 FR 56964 through 56967) and the CY 2023 ESRD PPS final rule (87 FR 67161).

An ESRD facility's wage index is applied to the labor-related share of the ESRD PPS base rate. In the CY 2023 ESRD PPS final rule (87 FR 67153), we finalized the use of a labor-related share of 55.2 percent. In the CY 2021 ESRD PPS final rule (85 FR 71436), we updated the OMB delineations as described in the September 14, 2018, OMB Bulletin No. 18–04, beginning with the CY 2021 ESRD PPS wage index. In that same rule, we finalized the application of a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. We finalized that the transition would be phased in over 2 years, such that the reduction in an ESRD facility's wage index would be capped at 5 percent in CY 2021, and no cap would be applied to the reduction in the wage index for the second year, CY 2022. In the CY 2023 ESRD PPS final rule (87 FR 67161), we finalized a permanent policy under § 413.231(c) to apply a 5 percent cap on any decrease in an ESRD facility's wage index from the ESRD facility's wage index from the prior CY. For CY 2025, as discussed in section II.B.1.b.(4) of this final rule, the final labor-related share to which the wage index would be applied is 55.2 percent.

In the CY 2011 ESRD PPS final rule (75 FR 49116) and the CY 2011 final rule on Payment Policies Under the Physician Fee Schedule (PFS) and Other Revisions to Part B (75 FR 73486) we established an ESRD PPS wage index methodology to use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the hospital inpatient prospective payment system (IPPS). The ESRD PPS wage index values have historically been calculated without regard to geographic reclassifications authorized for acute care hospitals under sections 1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix.

b. Methodology Changes for the CY 2025 ESRD PPS Wage Index

CMS has received feedback on our longstanding ESRD PPS wage index methodology from interested parties through comments on routine wage index updates in the annual ESRD PPS proposed rules. Commenters often suggested specific improvements for the ESRD PPS wage index. In the CY 2024 ESRD PPS final rule (88 FR 76359 through 76361), we discussed the comments on the routine wage index proposals from the CY 2024 ESRD PPS proposed rule (88 FR 42436); commenters, including MedPAC, suggested that we establish an ESRD PPS wage index for all ESRD facilities using wage data that represents all employers and industry-specific occupational weights, rather than the hospital wage data currently used. MedPAC specifically suggested that CMS implement the recommendations discussed in its June 2023 Report to Congress,[11] which recommended moving away from the current IPPS wage index methodology in favor of a methodology based on all employer wage data for all Medicare PPSs with industry specific occupational weights. Additionally, MedPAC suggested that the new methodology reflect local area level differences in wages between and within metropolitan statistical areas and statewide rural areas and smooth wage index differences across adjacent local areas. MedPAC stated that, compared to the current IPPS wage index methodology, a methodology based on all employer wage data with industry-specific occupational weights would improve the accuracy and equity of payments for provider types other than inpatient acute care hospitals, such as ESRD facilities.

In past years some interested parties have contended that the methodology used to construct the current ESRD PPS wage index does not accurately reflect the ESRD facility labor market. These interested parties have noted that the ESRD PPS wage index has been based on the IPPS wage index, which uses hospital data, which commenters have stated may not be applicable for ESRD facilities. More specifically, commenters have suggested that the types of labor used in ESRD facilities differ significantly from the types of labor used by hospitals, which may result in the use of relative wage values across the United States that do not accurately match the actual relative wages paid by ESRD facilities. For example, if ESRD

[11] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf.*

facilities have a different proportion of registered nurses (RNs), technicians and administrative staff compared to hospitals, and if wages for each of those labor categories vary differentially across the country, it is possible that relative wages for ESRD facilities, given their occupational mix, would vary differently from relative wages for hospitals across CBSAs. Because of this, some commenters have specifically requested that CMS develop an ESRD PPS wage index based only on data from ESRD facilities. Additionally, some commenters have criticized the time lag associated with using the IPPS wage index, which is generally based on data from four FYs prior to the rulemaking year (see, for example, 88 FR 58961).

(1) December 2019 Technical Expert Panel (TEP)

In response to feedback from interested parties on the ESRD PPS wage index, CMS's data contractor hosted a Technical Expert Panel (TEP) in December of 2019.[12] During this TEP, the contractor presented a potential alternative approach to the wage index, which utilized BLS data to address the concerns of commenters, to initiate a discussion on the ramifications of a potential new ESRD PPS wage index that would combine two sources of existing data to more closely reflect the occupational mix in ESRD facilities. The methodology presented at this TEP utilized publicly available wage data for selected occupations from the BLS OEWS survey and occupational and fulltime equivalency (FTE) data from freestanding ESRD facility cost reports (Form CMS 265–11, OMB No. 0938–0236). Specifically, this approach used the freestanding ESRD facility cost reports to determine the national average occupational mix and relative weights for ESRD facilities. Next, the contractor applied the estimated county-level wages based on BLS OEWS[13] to obtain occupation-specific wages in each county. The BLS OEWS data is updated annually using sample data collected in six semiannual survey panels over the prior 3-year period, which allows for the inclusion of more recent data than the hospital cost report data that is utilized by the IPPS wage index. Therefore, as noted during the TEP, this new methodology would allow CMS to adjust wage index values to reflect relative changes in wage conditions in a timelier fashion compared to the current ESRD PPS wage index methodology. Additionally, as noted during the TEP, by utilizing FTE data reported on the freestanding ESRD facility cost reports, this methodology is likely more reflective of the occupational mix employed by ESRD facilities than the hospital wage index.

Panelists at this TEP generally indicated their preference for the presented alternative wage index methodology, because it utilized more recent wage data from the BLS OEWS program. Panelists also favored how the alternative methodology was more targeted to ESRD facilities by utilizing FTE data from ESRD facility cost reports in determining the occupational mix. Some panelists voiced concerns about using publicly available BLS geographic area data, as the data do not disaggregate wages by health care sector, and therefore wages from acute care hospitals are not differentiated from outpatient care centers and other non-hospital health care settings. Some panelists noted that this would result in a wage index based on the publicly available BLS OEWS data having some of the same limitations for which the use of the IPPS wage index has been criticized—mainly that it includes wage data from hospitals.

(2) Proposed New Methodology for Using BLS Data To Calculate the ESRD PPS Wage Index

Based on feedback we received in response to past ESRD PPS proposed rules and from the December 2019 TEP, we developed a new ESRD PPS wage index methodology that we believe better reflects the ESRD facility labor market, which we proposed in the CY 2025 ESRD PPS proposed rule (89 FR 55766 through 55782). Similar to the methodology presented in the December 2019 TEP, this new methodology utilizes two data sources: one for occupational mix and one for geographic wages. First, we determine a national ESRD facility occupational mix (NEFOM) based on cost report data from freestanding ESRD facilities. Second, we extract and use data from the publicly available BLS OEWS survey on the average wages in each CBSA for each labor category present in the NEFOM. We note that because the publicly available BLS data are available at the Metropolitan Statistical Area (MSA), non-MSA and New England City and Town Area (NECTA) levels, and the wage index is designated at the CBSA level (which uses MSAs and other area designations that differ from non-MSAs and NECTAs), we use the area definition dataset[14] that accompanies the BLS data to assign wages at the county level, and map counties to CBSAs using a crosswalk. This crosswalk is included in Addendum B, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*.

(a) Description of Data Sources Utilized in the Proposed Methodology

In the CY 2025 ESRD PPS proposed rule we discussed the data sources which we utilized for the proposed new ESRD PPS wage index methodology. We described the data sources in detail alongside explanations of the ways in which we proposed to use the data, potential benefits and weaknesses compared to the IPPS wage index data, and the lag associated with the data.

(i) Data From the BLS OEWS Metropolitan and Nonmetropolitan Area Occupational Employment and Wage Estimates

The BLS OEWS program publishes annual estimates of employment and wages by occupation. Each set of OEWS estimates is based on data from six semiannual survey panels collected over a 3-year period. For example, the May 2022 OEWS wage estimates, published in April 2023, are based on six semiannual survey panels from November 2019 to May 2022. We proposed to use publicly available mean hourly wage data at the MSA level,[15] which is available online at *https://www.bls.gov/oes/*. OEWS wage data collected in earlier survey panels are ''aged'' or updated to the reference date of the estimates based on adjustment factors derived from the OEWS survey data using a regression model. The BLS OEWS mean hourly wage data that was presented in the CY 2025 ESRD PPS proposed rule and was utilized for the proposed new wage index methodology described in detail later in this section of this final rule reflect these wage aging adjustments. Table 1 shows the

[12] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-may-2020.pdf*.

[13] The OEWS program produces estimates of employment and wages by occupation based on a survey of business establishments. OEWS data are released annually with a May reference date. Each set of OEWS estimates is based on data from six semiannual survey panels collected over a 3-year period. For example, the May 2022 OEWS wage estimates are based on six semiannual survey panels from November 2019 through May 2022. We note that we use a crosswalk between counties and MSAs, non-MSAs and NECTAs to get county level wage estimates.

[14] For more information on MSAs and non-MSAs please see: *https://www.bls.gov/oes/current/msa_def.htm*. For more information on the most recent CBSA delineations (as discussed later in this section) please see: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*.

[15] We use the territory-level data for Guam and Virgin Islands, since the MSA and non-MSA level data is not available.

occupation codes based on the Standard Occupational Classification (SOC) and the corresponding occupational title for each SOC, alongside the common name that we use to refer to workers in specific occupations throughout this final rule. The ESRD PPS common names match the FTE categories captured on Worksheet S–1, lines 23 through 30 of the freestanding ESRD facility cost report form. The SOC System is a United States government system for classifying occupations. It is used by Federal Government agencies collecting occupational data, enabling comparison of occupations across data sets. When we considered the use of BLS data we had to determine which occupation code was appropriate for each occupation in the NEFOM. For many of these occupations, the corresponding BLS code was straightforward. For example, BLS code 29–1141 is for ''Registered Nurses'' which matches the category on the cost reports from which the NEFOM is derived exactly. For the occupations that were not necessarily specific to the healthcare field, for example administrative staff, we used BLS codes that were specific for healthcare, such as code 43–6013 for ''Medical Secretaries and Administrative Assistants.'' In the proposed rule, we explained that we believe that these are the most appropriate codes, as a more general code may not capture the specifics of the healthcare labor market.

TABLE 1: Crosswalk of BLS Occupation Codes to ESRD Facility Cost Reports Occupation Classifications

ESRD PPS Colloquial Name	BLS Occupation Title	Occupation Code
Registered Nurses (RN)	Registered Nurses	29-1141
Licensed Practical Nurses (LPN)	Licensed Practical and Licensed Vocational Nurses	29-2061
Nurse Aides	Nursing Assistants	31-1131
Technicians	Health Technologists and Technicians, All Other	29-2099
Social Workers	Healthcare Social Workers	21-1022
Dietitians	Dietitians and Nutritionists	29-1031
Administrative Staff	Medical Secretaries and Administrative Assistants	43-6013
Management	Medical and Health Services Managers	11-9111

The BLS OEWS data used for the analysis presented in the proposed rule included mean wages by occupation for all industries combined located in a MSA (or non-MSA area or NECTA), including the hospital industry. While interested parties have criticized the current ESRD PPS wage index methodology's sole reliance on hospital data, we stated that inpatient hospital data is appropriate to include in this analysis for several reasons. Principally, as explained later in this section, the wage data is being weighted based on an occupational mix that is specific to ESRD facilities, which makes this methodology more accurate to the wage environment of ESRD facilities regardless of the source of the wage data. Additionally, ESRD facility data is included in the BLS data, while ESRD facilities generally are not included in the hospital cost report data used in the IPPS wage index (with the exception of hospital-based ESRD facilities). Lastly, hospitals are a major contributor to labor markets, and it is reasonable to believe that ESRD facilities compete with hospitals (as well as other healthcare facilities) when it comes to hiring labor; as such, the inclusion of hospital data would provide additional insight into the labor markets of these areas.

In the proposed rule, we discussed that a limitation of the publicly available BLS OEWS data is that the survey only includes information on the wages that employers paid to their employees. Therefore, the OEWS does not include self-employed contract labor wages or benefits paid to employees, which are reflected in the IPPS wage index. Nevertheless, we believed, and we continue to believe, that this data source would be an improvement over the use of the IPPS wage index for the ESRD PPS, as its purpose is to identify geographic differences in wages. In the proposed rule, we noted that assuming wages spent on self-employed contract labor wages and employee benefits vary similarly to employee wages, we would not expect any significant difference arising from this limitation of the BLS data. We anticipated that most traveling nurses and technicians would be employed by a staffing agency, and therefore would be included in the OEWS estimates; however, as worksite location reporting is optional,[16] we note it is possible that some of the wages for these traveling nurses and technicians could be included in the MSA in which their employing agency is located, rather than the MSA in which they worked. However, we noted that we would not anticipate that this would have an appreciable impact on the OEWS estimates used for this methodology. Additionally, we noted that the OEWS would only include the wages paid by the contract agency to these contract workers, so the OEWS estimates would likely not include the full cost of the contract labor paid by the ESRD facilities to the contracting agency. We could not separately estimate the prevalence of self-employed contract labor at ESRD facilities from the rest of contract labor, which we believe would still provide some insight into the potential limitation of the exclusion of self-employed contract labor wages from the BLS OEWS. We noted that all contract labor costs represent approximately 5 percent of compensation costs in the 2020-based ESRDB market basket (87 FR 67143). As discussed in the CY 2025 ESRD PPS proposed rule, our analysis of freestanding ESRD facility cost report FTE data indicated that approximately 1.3 percent of RN hours and 1.1 percent

[16] *https://www.bls.gov/respondents/oes/instructions.htm#online.*

of technician hours were contract labor in 2022. Additionally, our data showed that the share of contract labor hours has been relatively stable over time but has increased slightly over the past few years.

In the proposed rule, we discussed that one potential concern about use of the BLS OEWS data is that in some cases, the BLS OEWS may not have usable data for a county for an occupation, which is used in the construction of the new ESRD PPS wage index according to the methodology presented later in this section. This occurs when BLS is unable to publish a wage estimate for a specific occupation and area because the estimate does not meet BLS quality or confidentiality standards.[17] For reference, among the 25,808 unique county-occupation combinations in the May 2022 BLS OEWS data used in the analysis in the proposed rule, the wage information missing rate was 5.2 percent. To impute the missing data for the methodology presented in the proposed rule, we performed a regression using the most similar (by mean hourly wage) occupation (of the occupations we proposed to include in the wage index methodology, presented in Table 1) for which there was no missing data. For dietitians we used RNs, for technicians we used LPNs and for nurses' aides we used administrative staff. The regression included controls for whether the county is rural, the census region in which the county is located, and the natural logarithm of the treatment count of the county. For the wage index presented in the CY 2025 ESRD PPS proposed rule, we only had to impute missing county-level data for dietitians, technicians, and nurses' aides; however, for future years, we noted that we may have to impute data for other occupations and will be sure to note any imputations through notice and comment rulemaking.

In the proposed rule, we presented an analysis on historical BLS OEWS data for the occupations presented in Table 1.[18] We found that mean hourly wages for these categories are increasing over time, consistent with what we would expect given the ESRD PPS market basket increases. Given this analysis, we stated that the BLS OEWS data are reasonably stable and appropriately reflect general wage inflation trends that ESRD facilities face.

(ii) Data From Freestanding ESRD Facility Cost Reports

Under § 413.198(b)(1), all ESRD facilities must submit the appropriate CMS-approved cost report in accordance with §§ 413.20 and 413.24, which provide rules on financial data and reports, and adequate cost data and cost finding, respectively. Generally, these cost reports have a time range of January 1 to December 31 of a given year, but they can represent any 12-month period. Included in these cost reports is information on the number of full-time equivalent (FTE) positions employed by the ESRD facility. FTEs are stratified by occupation type, such as RNs, LPNs, technicians, and administrative staff. For the purpose of these cost reports, an FTE represents a 40-hour work week averaged across the year. Specifically, the cost reports define FTEs as the sum of all hours for which employees were paid during the year divided by 2080 hours. The cost reports also state personnel involved in more than one activity must have their time prorated among those activities. For example, an RN who provided professional services and administrative services is counted in both the RN line and the administrative line according to the number of hours spent in each activity.

For the methodology presented in the proposed rule, we proposed to use FTEs to calculate the occupational mix for all freestanding ESRD facilities. For the purposes of this proposal, we used the term ''freestanding ESRD facilities'' to mean ESRD facilities that complete the independent renal dialysis facility cost report (Form CMS 265–11, OMB No. 0938–0050). We noted that these ESRD facilities are a subset of ''independent'' facilities as defined at § 413.174(b), as cost-reporting is only one of 5 criteria used in the determination of whether an ESRD facility is independent or hospital-based as listed at § 413.174(c). For the purposes of this proposal, we referred to ESRD facilities that complete the hospital cost report (Form CMS 2552–10, OMB No. 0938–0050) as ''ESRD facilities that are financially integrated with a hospital,'' per the criteria at § 413.174(c)(5). The occupational mix data presented in the proposed rule represented the average proportion of hours spent on the duties of that occupation at all freestanding ESRD facilities nationally for CY 2022. This national mix includes FTE data on both staff and contract labor from freestanding ESRD facility cost reports for each occupational category.

Table 2 presents the NEFOM calculated from the freestanding ESRD facility cost report data from cost reporting periods beginning on or after January 1, 2022, and before December 31, 2022 (2022 cost report data), with four decimal places of precision. For the purposes of comparison, Table 2 includes both the occupational mix we presented in the CY 2025 ESRD PPS proposed rule, as well as an updated version of this occupational mix with more complete CY 2022 cost report data. In the proposed rule, we noted that CY 2022 would be the most recent complete year of cost reporting data for both the proposed rule and for this CY 2025 ESRD PPS final rule, as the latest 2022 cost reports could have begun in December 2022 and ended in December 2023, although some 2022 cost reports were not yet available at the time of the analysis for the proposed rule. For the approximately 1.7 percent of freestanding ESRD facilities without 2022 cost report data available at the time of rulemaking for the proposed rule, 2021 cost report data was used. At the time of proposed rulemaking, we anticipated that we would have complete CY 2022 cost report data; however, this has proved not to be the case. For this final rule, some CY 2022 cost report data was still not available, so 2021 cost report data was used for 126 ESRD facilities. The occupational mix weights used in the proposed new wage index methodology are presented in terms of the number of FTEs per 1000 treatments, although we note that the specific denominator does not impact the calculation, as these are relative weights. Table 2 also includes percentages that represent the percent of FTEs for each occupation in the NEFOM. For example, RNs represent approximately 30 percent of the NEFOM, which means that across the nation, 30 percent of all hours worked by employees at freestanding ESRD facilities are worked by RNs. We note that we did not include FTEs that were reported as ''other'' occupations in the cost reports in this occupational mix, because we could not determine what occupation(s) this represented and, therefore, could not get appropriate wage estimates. ''Other'' occupations would have accounted for 3.8 percent of the NEFOM if included.

[17] *https://www.bls.gov/oes/oes_ques.htm.*

[18] We note that the BLS OEWS wage data is not intended to be used as a time-series analysis, but rather as cross-sectional estimate of wages in a geographic area (*https://www.bls.gov/oes/oes_ques.htm#other*). We reviewed and presented this data primarily to demonstrate the stability of the methodology by evaluating the robustness of the input data source.

TABLE 2: CY 2025 National ESRD Facility Occupational Mix (NEFOM)

Occupation	Freestanding Facilities 2022 Occupational Mix (FTEs/1000 treatments) as Presented in the Proposed Rule	Freestanding Facilities 2022 Occupational Mix Percentage as Presented in the Proposed Rule	Updated Freestanding Facilities 2022 Occupational Mix (FTEs/1000 treatments)	Updated Freestanding Facilities 2022 Occupational Mix Percentage
Registered Nurse	0.4208	29.9690%	0.4234	29.9628%
Licensed Practical Nurse	0.0566	4.0310%	0.0568	4.0224%
Nurse Aide	0.0339	2.4131%	0.0341	2.4130%
Technicians	0.5350	38.1040%	0.5381	38.0815%
Social Worker	0.0661	4.7078%	0.0666	4.7098%
Administrative staff	0.1505	10.7194%	0.1520	10.7565%
Dietitian	0.0635	4.5220%	0.0639	4.5237%
Management	0.0777	5.5337%	0.0781	5.5301%

We note that the NEFOM is calculated as a part of the proposed wage index methodology described in detail later in this section of this final rule, from freestanding ESRD facilities cost reports, and that the NEFOM is not an input in the wage index calculation. However, we presented the NEFOM in the proposed rule to inform the calculation process for any interested parties which wish to replicate the calculation.

For this methodology, we proposed to only utilize data from freestanding ESRD facilities, which comprise the vast majority of ESRD facilities. ESRD facilities that are financially integrated with a hospital represent approximately 4.5 percent of ESRD facilities. It was necessary to make this distinction, as ESRD facilities that are financially integrated with a hospital complete a different cost report form (Form CMS 2552–10, OMB No. 0938–0050), which does not include all the occupational categories included on the freestanding facility cost report (Form CMS 265–11, OMB No. 0938–0050). Specifically, ESRD facilities that are financially integrated with a hospital do not include administrative and management staff hours in their cost reports. FTE data for administrative and management staff are necessary for this analysis, so we proposed to exclude hospital-integrated cost reports. We stated that we believe that the occupational mix for freestanding ESRD facilities is likely similar to the mix for ESRD facilities that are financially integrated with a hospital (which, as noted earlier, make up a small proportion of all ESRD facilities), such that we would not expect significantly different results if we were able to include ESRD facilities that are financially integrated with a hospital in this analysis.

As discussed in the proposed rule, we conducted additional analyses to ensure that this occupational mix data would be appropriate for the construction of an ESRD facility wage index. First, we reviewed the occupational mix for ESRD facilities on a regional level to determine if the use of a single national occupational mix was appropriate. While we found some variation across regions, the variation was relatively small between regions, with the weight values for each occupation being within a few percentage points. The main exceptions to this were in the United States Territories, which had higher variation in occupational mix, likely due in large part to the relatively few ESRD facilities in those regions. Additionally, we found that lower volume ESRD facilities tended to have slightly different occupational mixes, requiring relatively more administrative and management staff FTEs, likely due to the lack of economies of scale for these occupations at lower treatment volume levels. Second, we conducted an analysis on the change in the national occupational mix over the past 5 years and found little variation over this time period. Both of these analyses indicate that the use of a single national occupational mix is appropriate for constructing an ESRD facility wage index as the occupational mix is reasonably similar to most region's occupational mixes and relatively stable over time.

Additionally, we proposed to use treatment volume data from freestanding ESRD facilities as reported on freestanding ESRD facility cost reports. This treatment volume data is used in the proposed wage index methodology as a weight on the county level wages when calculating the wages for a CBSA. The calculation is described in further detail in section II.B.2.b.(2)(b) of this final rule.

In the proposed rule, we emphasized the importance of accurate cost report data for this proposed policy as well as other current and potential policies under the ESRD PPS, such as facility-level or case-mix adjustment refinement. We strongly urged ESRD facilities to carefully review cost report data to ensure continued accuracy so that future refinements to the ESRD PPS are based on the best data possible.

(iii) IPPS Hospital Wage Index

As discussed in the proposed rule, the proposed new wage index methodology used the established ESRD PPS wage index methodology, which is based on the IPPS hospital wage index, for the purposes of standardizing the new wage index (step 6 in the methodology described in section II.B.2.b.(2)(b)). Consistent with our established ESRD PPS methodology, we use the most recent pre-floor, pre-reclassified hospital wage data collected annually under the IPPS. For the purposes of the proposed new wage index methodology, we referred to this older wage index methodology as the ''ESRD PPS legacy wage index.'' The ESRD PPS wage index values under the legacy methodology are calculated without regard to geographic reclassifications authorized for acute care hospitals under sections

1886(d)(8) and (d)(10) of the Act and utilize pre-floor hospital data that are unadjusted for occupational mix. For CY 2025, the updated wage data are generally for hospital cost reporting periods beginning on or after October 1, 2020, and before October 1, 2021 (FY 2021 cost report data). Under § 413.231(d), a wage index floor value of 0.6000 is applied under the ESRD PPS as a substitute wage index for areas with very low wage index values, as finalized in the CY 2023 ESRD PPS final rule (87 FR 67161). Consistent with our established policy of updating wage indices in the final rule, we stated in the CY 2025 ESRD PPS proposed rule that we intend to use the most recent IPPS wage index for the construction of the CY 2025 ESRD PPS legacy wage index for the final rule (89 FR 55771). We noted that the purpose of calculating the ESRD PPS legacy wage index is solely for standardizing the new ESRD PPS wage index, ensuring that the treatment weighted average of the new ESRD PPS wage index is the same as it would have been under the established methodology. This would ensure that the changes associated with the proposed new wage index methodology are contained to the wage index, whereas changes associated with shifts in utilization would be reflected in the wage index budget neutrality factor. For example, if the new methodology resulted in a significant increase in the number of high-wage index facilities, the standardization factor would decrease wage index values across the board to keep the treatment-weighted average of the legacy and new wage index methodologies the same; in contrast, if utilization trends resulted in a significant increase in the number of treatments furnished by ESRD facilities in high-wage index areas, the treatment weighted average of both the legacy and new wage index methodologies would increase, which would need to be accounted for by the wage index budget neutrality adjustment factor. This is described in more detail in step 6 of the proposed new wage index methodology described in section II.B.2.b.(2)(b) of this final rule.

(iv) Time Lag Associated With New Data Sources

One concern expressed by interested parties about the current ESRD PPS wage index methodology is that the IPPS wage index, used as its basis, uses data from approximately 4 fiscal years prior. Interested parties have opined that this delay makes the ESRD PPS wage index less responsive to certain changes in wages, such as inflation.[19] In the proposed rule, we noted that the purpose of the wage index is to reflect geographic difference in the area wage levels, and that national trends in wages, including wage inflation, are accounted for by the ESRDB market basket percentage increase. We noted that the IPPS wage index is generally responsive to geographic variation in wages, including variation stemming from local or regional inflation. However, as interested parties have raised concerns about the time lag associated with our use of the IPPS wage data, we discussed the difference between the time lag associated with our use of the IPPS wage index for the ESRD PPS and the proposed new ESRD PPS wage index methodology.

As previously discussed in this section, the new ESRD PPS wage index methodology that we proposed would use data from BLS OEWS and freestanding ESRD facility cost reports. BLS publishes OEWS data annually with a May reference date, with estimates typically released in late March or early April of the following year. Each set of OEWS estimates is based on six semi-annual survey samples spanning the prior 3 years. Wages collected in earlier survey panels are updated to the reference date of the estimates based on wage adjustment factors derived from the OEWS survey data using a regression model. The freestanding ESRD facility cost report data that can be analyzed at the time of rulemaking are generally from 2 CYs prior. Specifically, for the proposed wage index presented in Addendum A of the ESRD PPS proposed rule, the BLS OEWS data represent wages as of May 2022 (based on survey panels collected from November 2019 through May 2022), and the cost report data generally covered cost reporting periods beginning on or after January 1, 2022, and before December 31, 2022.[20] The publicly available BLS OEWS data is an average using data collected over a 3-year period due to the large sample involved in the survey. This pooled sampling improves stability and predictability of the OEWS estimates over time. In the CY 2025 ESRD PPS proposed rule (89 FR 55772), we noted that, should the proposed methodology be finalized, we would use the most recent update of BLS OEWS data for the ESRD PPS final rule. Under this new proposed methodology, BLS OEWS estimates for May 2023 would be utilized for the final CY 2025 ESRD PPS wage index.

Both the ESRD facility cost report data and the BLS OEWS data are more recent than the data used for the IPPS wage index. Additionally, the purpose of using the freestanding ESRD facility cost report data in this proposed methodology would be to establish a national occupational mix for ESRD facilities, which we are calling the NEFOM. In the proposed rule, we stated that we intend to present the NEFOM annually to reflect the latest complete year of cost report data at the time of rulemaking to inform the public of the relative weights assigned to each occupation. Given that freestanding facility cost reports are submitted on a rolling basis, the most recent data would generally be obtained from cost reports beginning in the CY three years prior to the CY for which we are setting rates (that is, for the CY 2025 proposed rule, the latest complete year of cost report data are from cost reports beginning in CY 2022). Based on our analysis of prior years' cost report data, we did not anticipate that the national occupational mix would change much from year-to-year. Additionally, we noted that the use of a single national occupational mix for all ESRD facilities would limit the impact of changes in employment patterns on the wage index, as all ESRD facilities would be similarly impacted by a change in the NEFOM. As the wage index is a relative value, the main way that a change in the NEFOM would impact an ESRD facility's wage index would be if the CBSA in which that ESRD facility is located has relatively high or low wages for an occupation that experiences growth or shrinkage in the NEFOM. Thus, the main driver in changes from year-to-year under the proposed new wage index methodology likely would be the BLS OEWS data, which, for the final rule, would be based on estimates with a reference date of the May prior to the rulemaking year.

We noted that, at the time of the analysis conducted for the proposed rule, the May 2023 BLS OEWS estimates were not yet available; however, they were available at the time of the analysis conducted for this final rule. As previously discussed, some ESRD

[19] In accordance with section 1886(d)(14)(E)(1) of the Act, the IPPS wage index is required to employ data based on ''a survey conducted by the Secretary (and updated as appropriate) of the wages and wage-related costs of subsection (d) hospitals in the United States.'' The IPPS is based on the most current audited hospital wage data from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 (OMB Control Number 0938–0050 with an expiration date of September 30, 2025) (see, for example, 88 FR 58961).

[20] In cases where 2022 freestanding cost report data were not available at the time of the proposed rule, 2021 data was used. This was the case for 131 ESRD facilities, approximately 1.7 percent of the ESRD facilities in this analysis. In calculating the wage indices for this final rule there were 126 ESRD facilities for which 2021 cost report data was used.

facilities' CY 2022 cost reports were not available for the proposed rule but are available now for the final rule; however, we still do not have complete CY 2022 data, so we must utilize some CY 2021 cost reports for this final rule. In the proposed rule, we stated that should the proposed new wage index methodology be finalized, we would update the wage index values based on the most recent BLS OEWS data available. We also proposed to use most recent cost report data available for cost reporting periods beginning in CY 2022 and update the NEFOM in Table 2 accordingly in the final rule (89 FR 55772). Using the most recent 2022 data available for the calculation of the new ESRD PPS wage index methodology in the final rule would be consistent with our established ESRD PPS wage index methodology of updating ESRD facility wage indices between the proposed and final rules.

In the proposed rule, we noted that our proposed new wage index methodology does use the IPPS wage index to create the ESRD PPS legacy wage index, which is used to standardize the results of the new ESRD PPS wage index methodology. We recognized the concerns we have heard regarding the data lag associated with our use of the IPPS wage index for the ESRD PPS. However, as the ESRD PPS legacy wage index would only be used to calculate a treatment-weighted average of the legacy wage index to standardize the wage index values derived under the proposed new methodology, the proposed new ESRD PPS wage index would continue to reflect the relative differences in area wages based on the more recent BLS OEWS data. Therefore, any effect of any data lag of the ESRD PPS legacy wage index on the proposed new ESRD PPS wage index would be minimal.

(v) Comparison Between Proposed New Wage Index Methodology Data Sources and Hospital Wage Index Data

The other main concern that interested parties have raised about our current ESRD PPS wage index methodology is that the IPPS wage index is based on hospital cost report data. As previously discussed, interested parties have stated that hospital cost report data is not necessarily the most appropriate source for estimating geographic differences in wages paid by ESRD facilities. These interested parties predominantly point to the different occupational mix employed by ESRD facilities as the main differentiator between inpatient hospitals and ESRD facilities; however, there may also be differences in wages paid for the same occupational labor category in the two settings. Differences in wages within the same occupation could arise from any number of factors, including differences in duties, hours, required experience, or desirability of the position.

In the proposed rule we presented Table 3 in the context of the proposed new wage index methodology. Table 3 compares the national average occupational mix and corresponding wages for occupations employed by freestanding ESRD facilities to that of hospitals from IPPS data. The source of average wages used here for ESRD facilities is the BLS OEWS mean hourly wage data, which is then weighted by ESRD PPS treatment count in the geographical area. Average IPPS wages are derived from the IPPS occupational survey (Form CMS–10079) as presented in the fiscal year (FY) 2024 IPPS Public Use File (PUF),[21] representing data from 2019. The mean hourly wage data from BLS is from the May 2022 OEWS estimates, which are based on six panels of survey data from November 2019 through May 2022.

TABLE 3: Comparison of Occupational Mix and Mean Hourly Wages for Selected Occupations between Freestanding ESRD Facilities and Acute Care Hospitals

Occupation (Column A)	**Freestanding Facilities Occupational Mix** (Column B)	**Mean Hourly Wage – BLS** (Column C)		**Occupation** (Column D)	**Acute Care Hospitals Occupational Mix** (Column E)	**Mean Hourly Wage – IPPS** (Column F)
Registered Nurse	30.0%	$42.97		Registered Nurse	28.2%	$44.42
Licensed Practical Nurse	4.0%	$27.30		Licensed Practical Nurse	2.6%	$26.85
Nurse Aide	2.4%	$17.34		Nurse Aide	7.8%	$18.53
Medical Aide	-	-		Medical Aide	1.5%	$19.51
Technicians	38.1%	$24.42		Other	60.0%	$34.92
Social Worker	4.7%	$30.61				
Administrative staff	10.7%	$19.42				
Dietitian	4.5%	$32.63				
Management	5.5%	$60.45				

In discussing this data in the proposed rule, we noted that the hospital wage data (column F) in Table 3 presents the wages paid by hospitals to employees, as derived from the IPPS occupational survey data, for the purposes of comparing to the BLS data. This data is used to adjust the hospital average hourly wage, calculated using hospital cost report data, based on the provider-specific occupational mix. This differs from the hospital cost report

[21] Files related to the FY 2024 IPPS final rule are available online at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2024-ipps-final-rule-home-page.*

data used for the IPPS wage index, as that does not break down all wages and related costs by occupation.

Compared to hospitals, ESRD facilities generally use slightly higher proportions of RNs and LPNs and significantly fewer nurse aides and medical aides (column B). Additionally, the freestanding ESRD facility cost reports include additional occupational categories to reflect the labor mix employed by ESRD facilities.

(b) Construction of the New ESRD PPS Wage Index

In the proposed rule, we presented these general steps, which we stated we would use when constructing a wage index based on the proposed new ESRD PPS wage index methodology; for a more detailed look at the specific computational steps we execute in the code to calculate the wage index according to the proposed methodology, including steps related to data collection and cleaning, we provided the supplementary document Addendum C of the proposed rule.

1. We calculate the treatment count-weighted mean hourly wage for each occupation for each CBSA by multiplying the mean hourly wage data from the BLS OEWS by the treatment count for each county within that CBSA and dividing by the total treatment count of all counties within the CBSA. We weight mean hourly wage by treatment count to ensure that the mean hourly wage for the CBSA is proportional with the actual wages paid by ESRD facilities in the CBSA. This avoids a situation where a particularly high or low wage county within a CBSA has no ESRD facilities but still has a large impact on the wage index for that CBSA. This reasoning extends to each instance in which we weight values by treatment counts. We use a crosswalk that relates counties to MSAs, non-MSAs and NECTAs.

2. We calculate the ESRD facility mean hourly wage in each CBSA by multiplying the treatment count-weighted mean hourly wage (from step 1) for each occupation for a given CBSA with the corresponding weight of the NEFOM for each occupation and then sum each category's amount to get the total.

3. We calculate the treatment count-weighted mean hourly wage for each occupation at the national level by multiplying the mean hourly wage for the occupation in each CBSA by the treatment count of that CBSA and dividing by the aggregated treatment count nationally.

4. We calculate the national ESRD facility mean hourly wage by multiplying the national mean hourly wage (from step 3) for each occupation by the corresponding weight of the NEFOM for each occupation and then sum each category's amount to get the total.

5. We divide the ESRD facility mean hourly wage for each CBSA by the national ESRD facility mean hourly wage to create a raw wage index level (that is, a wage index that has not been normalized as described in step 6).

6. We multiply the raw wage index level for each CBSA by a treatment weighted average of the CY 2025 ESRD PPS legacy wage index constructed using the established ESRD PPS methodology based on IPPS Medicare cost report data and divide the product by the treatment weighted average of raw wage indices, which equals 1 by construction.[22] This is to ensure that the treatment-weighted average of new BLS-based wage indices is the same as the weighted average of the current wage indices. By ensuring the weighted average of the new wage index is the same as the weighted average of the pre-floor pre-reclassification IPPS wage index we have normalized the new wage index such that it is more comparable to the former ESRD PPS wage index methodology. This prevents the possibility that the treatment-weighted average of the new wage index is significantly different than the treatment-weighted average of the established methodology. We include this step because our goal in establishing the proposed new wage index methodology is not to alter the significance of the wage index in determining each ESRD facility's payment, but rather to ensure that the wage index values better reflect relative labor costs that affect ESRD facilities specifically. We note that because we apply a wage index budget neutrality adjuster (discussed in section II.B.4.b), the new wage index methodology would not increase total payments to ESRD facilities even absent this step.

7. We apply the 0.6000 floor to the wage index by replacing any wage index values that fall below 0.6000 with a value of 0.6000, which is the wage index floor for the ESRD PPS as established in the CY 2023 ESRD PPS final rule (87 FR 67166).

After following these steps, we would obtain the wage index values for each CBSA (based on the new OMB delineations as discussed later in this section of the preamble) according to the proposed ESRD PPS wage index methodology described previously. In the proposed rule, we noted that the 5 percent cap in year-over-year decreases in wage index values would be applied for each ESRD facility after the new wage index is calculated based on the proposed methodology for the CBSA in which the ESRD facility is located and, therefore, is not reflected in the proposed wage index value for a CBSA in Addendum A of the proposed rule, available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices* under the page for CMS–1805–P. This was necessary as this cap protects ESRD facilities in the rare circumstances when changes in policy related to the wage index methodology or CBSA delineations cause an ESRD facility to be in a significantly lower wage index area in a given year when compared to the previous year (87 FR 67161). As discussed later in this section, for CY 2025 we proposed to adopt new OMB delineations of CBSAs relative to those used in the CY 2024 ESRD PPS wage index. As this 5 percent cap applies to an ESRD facility, and not to a CBSA, it would protect any ESRD facility that is delineated into a much lower wage-index CBSA for CY 2025.

(c) Methodological Alternatives Considered

While developing the proposed new wage index methodology, we considered several different alternatives regarding both data sources used for the new wage index methodology and construction of the wage index itself. We considered the feasibility of requesting the use of confidential BLS OEWS data. This was one suggestion from the December 2019 TEP. Confidential data would have some benefits over public data, primarily that it would provide greater disaggregation of wages by employer type, such as wages paid by ESRD facilities. Additionally, confidential BLS data could have a timeframe other than the 3-year pooled sample used in the public data, for example, using only the most recent year's data. However, we noted that the OEWS survey sample is designed to be statistically representative only when all 3 years of the sample are combined, so the use of an alternative or shorter timeframe may not be appropriate. We determined that the publicly available BLS data would be the most appropriate for our wage index, as it still provides precise estimates of wages and would allow for far better transparency. Additionally, we

[22] Treatment weighted averages of wage indices are calculated by multiplying the wage index value for each CBSA by the treatment count in the CBSA and dividing by the aggregate national treatment count.

stated that we believed that the inclusion of data from other employers (meaning employers that are not ESRD facilities) would improve the robustness of the methodology, as ESRD facilities compete for labor against these other employers.

When considering the use of BLS data we had to determine which occupation code was appropriate for each occupation in the NEFOM. As discussed previously, for many of these occupations, the corresponding BLS code was straightforward as many of the occupations present in the freestanding ESRD facility cost reports matched a single BLS code. However, for technicians employed by ESRD facilities we gave further consideration to two different BLS codes. As presented in Table 1, we proposed to use code 29–2099 for ''Health Technologists and Technicians, All Other'' for the construction of the methodology to account for the labor costs of technicians. This is the most appropriate category, as ''technicians'' in the freestanding ESRD facility cost reports generally refers to dialysis technicians, which do not fall into any of the other BLS codes for health technologists and technicians. Additionally, we noted that the SOC uses ''dialysis technician'' as an illustrative example for code 29–2099.[23] However, we had some concerns about using this category, as it does not specifically represent dialysis technicians, but rather all health technicians that do not fit in the other categories. Because the category is non-specific, also known as a ''residual'' category, we were concerned with the impact of the inclusion of other, non-dialysis technicians in this category. To avoid any issues arising from the use of a residual category, we considered using code 29–2010 for ''Clinical Laboratory Technologists and Technicians.'' Although this category does not fit dialysis technicians as well, it had the benefit of not being a residual category, and it had fewer counties with missing data. However, we determined that it was most appropriate to use the most similar category for dialysis technicians, being the category in which data for dialysis technicians would be included, which is code 29–2099 ''Health Technologists and Technicians, All Others.''

As an alternative to using a single national occupational mix for ESRD facilities we considered using regional or state-level occupational mixes. The considered alternative would use a similar methodology to the construction of the NEFOM, but with a different occupational mix for each census region or state and would apply the occupational mix in the same way in the construction of the wage index. That is, the BLS data for a CBSA would be weighted by the occupational mix for the region or state in which that CBSA is located. This alternative was considered, in part, because of a suggestion from a panelist at the December 2019 TEP who pointed out that different states have different laws regarding staffing requirements for ESRD facilities, which was not reflected in the methodology presented at the TEP. We conducted an analysis comparing a state-level occupational mix wage index to the national occupational mix wage index methodology presented previously. This analysis found some notable differences, including higher wage index values for ESRD facilities in the Pacific census region, but many regions experienced little change. We decided against the use of state-level or regional occupational mixes for three main reasons. The first is that the use of different occupational mixes for different ESRD facilities made the methodology significantly more complicated and difficult to understand. The second is that this methodology made it so that one ESRD facility could be in an area with higher wages for all occupations compared to another ESRD facility but receive a lower wage index value due to having an occupational mix which favored lower-paying occupations. In the proposed rule, we noted that this could be perceived as being inconsistent with the intent of the wage index to recognize differences in ESRD facility resource use for wages specific to the geographic area in which facilities are located (83 FR 56967). Lastly, we were concerned about the possibility that, should we use anything other than a national occupational mix, the state-level or regional occupational mix could be manipulated. This would be especially relevant for states or regions with few ESRD facilities and, therefore, individual ESRD facilities would have an outsized impact on the occupational mix for that state or region. Accordingly, we did not propose this alternative because we believed that the use of a single national occupational mix is the most appropriate for this new ESRD facility wage index methodology.

We considered proposing a ''phase-in'' policy for this wage index methodology change, which could be implemented in addition to the 5 percent cap on wage index decreases. One potential example of a phase-in policy could be a 50/50 blended methodology, where an ESRD facility would receive the average of their wage indices from the proposed new and legacy methodologies for the first year of implementation. However, we decided that such a phase-in policy was unnecessary in light of the 5 percent cap on year-to-year wage index decreases for ESRD facilities. We believed that an additional, or alternative, phase-in policy would further complicate this change. Additionally, a phase-in policy could hurt ESRD facilities that would receive a higher wage-index under the new methodology, which we do not believe would be appropriate, as we believe the new methodology based on BLS data is the best approximation of the labor costs those ESRD facilities face.

We considered setting the NEFOM through rulemaking separately from the routine wage index update. Under this alternative, we would periodically update the NEFOM, for example every 2 years, with potentially more years of freestanding ESRD facility cost report data. This would mean that the NEFOM would be a rounded input in the wage index methodology, rather than a figure precisely calculated as an intermediary step in the methodology. This would slightly simplify the calculation steps and would allow for complete transparency on the NEFOM. However, we have decided to instead derive the FTEs per 1,000 treatments for each occupation as the weights as a part of the wage index calculation as that would increase the precision of this calculation. Additionally, given the transparency of the FTE data derived from publicly available cost reports, we noted that we could still publish the NEFOM for the coming year in rulemaking alongside the updated wage index; however, we note that the NEFOM we publish would have a lower precision so replications using the published NEFOM as an input may be slightly off. Furthermore, compared to setting the NEFOM through rulemaking less frequently than annually, the proposed methodology to calculate the NEFOM as a part of the wage index methodology annually would be more responsive to national trends in occupational mix for ESRD facilities.

Finally, we considered whether it was most appropriate to use something other than the mean hourly wage for the BLS OEWS data for the construction of the wage index. We noted that there were always concerns when using the mean of a data set that the figure could be unduly influenced by outliers. One potential alternative would be to use the

[23] *https://www.bls.gov/soc/2018/major_groups.htm.*

median hourly wage data instead. The median hourly wage is available by occupation in publicly available BLS data, and the median is not as influenced by outliers as the mean. We also considered using the geometric mean, instead of arithmetic mean, as that is also less influenced by outliers; however, the geometric mean is not provided in publicly available BLS data. Ultimately, we determined that the mean hourly wage is the most appropriate for this new wage index methodology, as any outliers are relevant data points insofar as some ESRD facilities may pay wages significantly higher than the average.

c. Example Calculation Using the Proposed New Wage Index Methodology

Table 4 is an example of a calculation of the wage index for a hypothetical ESRD facility in a hypothetical CBSA under the proposed new methodology which was presented in the CY 2025 ESRD PPS proposed rule. This CBSA contains three counties, each with a different mean hourly wage and treatment count. Table 4 presents the mean hourly wage and treatment count used in the calculation.

TABLE 4: Hypothetical BLS Data for Example

	County 1	County 2	County 3
Treatment count	200 treatments	300 treatments	500 treatments
RN wage	$45	$40	$50
LPN wage	$30	$30	$35
Nurse aide wage	$15	$20	$10
Technicians wage	$30	$35	$25
Social worker wage	$30	$25	$35
Administration wage	$20	$25	$20
Dietitian wage	$35	$30	$30
Management wage	$60	$65	$50

Step 1. Calculate the treatment count-weighted mean hourly wage for each occupation for each CBSA by multiplying the mean hourly wage data from the BLS OEWS by the treatment count for each county within that CBSA and dividing by the total treatment count of all counties within the CBSA.

RN wage = [(200 * $45) + (300 * $40) + (500 * $50)]/1000 = $46.0

LPN wage = [(200 * $30) + (300 * $30) + (500 * $35)]/1000 = $32.5

Nurse aide wage = [(200 * $15) + (300 * $20) + (500 * $10)]/1000 = $14.0

Technicians wage = [(200 * $30) + (300 * $35) + (500 * $25)]/1000 = $29.0

Social worker wage = [(200 * $30) + (300 * $25) + (500 * $35)]/1000 = $31.0

Administration wage = [(200 * $20) + (300 * $25) + (500 * $20)]/1000 = $21.5

Dietitian wage = [(200 * $35) + (300 * $30) + (500 * $30)]/1000 = $31.0

Management wage = [(200 * $60) + (300 * $65) + (500 * $50)]/1000 = $56.5

Step 2. Calculate the ESRD facility mean hourly wage in the CBSA by multiplying the treatment count-weighted mean hourly wage (from step 1) for each occupation for the CBSA with the corresponding weight of the NEFOM for each occupation and sum each category's amount to get the total. The NEFOM for CY 2025 that we presented in the CY 2025 ESRD PPS proposed rule is presented again in Table 5. For the purposes of ensuring the calculation in this section is as easy to understand as possible we are using the percentage values from the NEFOM rounded to the nearest tenth of a percent. This makes the wage values calculated in this step and step 4 more intuitive as they would represent a weighted average of the wages in the CBSA. We note that in the actual calculation of the wage index, as described in Addendum C, we calculate the number of FTEs per 1000 treatments for each occupation and use those as the weights, so that the weights have a higher level of precision.

TABLE 5: CY 2025 National ESRD Facility Occupational Mix (NEFOM)

Occupation	**ESRD Freestanding Facilities FTE Percentage as Presented in the Proposed Rule (rounded)**
Registered Nurse	30.0%
Licensed Practical Nurse	4.0%
Nurse Aide	2.4%
Technicians	38.1%
Social Worker	4.7%
Administration	10.7%
Dietitian	4.5%
Management	5.5%

ESRD facility mean hourly wage for this CBSA = (0.300 * $46.0) + (0.040 * $32.5) + (0.024 * $14.0) + (0.381* $29.0) + (0.047 * $31.0) + (0.107 * $21.5) + (0.045 * $31.0) + (0.055 * $56.5) = $34.75

Step 3. Calculate the treatment count-weighted mean hourly wage for each occupation at the national level by multiplying the mean hourly wage for the occupation in each CBSA by the treatment count of that CBSA and dividing by the aggregated treatment count nationally.

To simplify this calculation, assume there are 3 CBSAs as presented in Table 6:

TABLE 6: Hypothetical Wage Data for 3 CBSAs in Example

	CBSA 1	CBSA 2	CBSA 3	Calculated National
Treatment count	1000 treatments	800 treatments	1550 treatments	3350 treatments
RN wage	$46	$42	$50	$46.90
LPN wage	$32.5	$28	$35	$32.58
Nurse aide wage	$14	$20	$21	$18.67
Technicians wage	$29	$35	$33	$32.28
Social worker wage	$31	$30	$35	$32.61
Administration wage	$21.5	$20	$18	$19.52
Dietitian wage	$31	$35	$30	$31.49
Management wage	$56.5	$60	$55	$56.64

Step 4. Calculate the national ESRD facility mean hourly wage by multiplying the national mean hourly wage (from step 3) for each occupation by the corresponding weight of the NEFOM for each occupation and sum each category's amount to get the total. Similarly to step 2, we are using the percentages from the NEFOM as weights for the purposes of this example calculation.

National average ESRD facility wage = (0.300 * $46.90) + (0.040 * $32.58) + (0.024 * $18.67) + (0.381 * $32.28) + (0.047 * $32.61) + (0.107 * $19.52) + (0.045 * $31.49) + (0.055 * $56.64) = $36.27

Step 5. Divide the ESRD facility mean hourly wage for each CBSA by the national ESRD facility mean hourly wage to create a raw wage index level.

Raw wage index value = $34.75/$36.27 = 0.95809

Step 6. Multiply the raw wage index for each CBSA by a treatment weighted average of the CY 2025 ESRD PPS legacy wage index constructed using the established ESRD PPS methodology based on IPPS data and divide the product by the treatment weighted average of raw wage indices (which equals 1 by construction). This is to ensure that the treatment-weighted average of new BLS-based wage indices is the same as the weighted average of the current wage indices (for the purpose of this hypothetical calculation we have used a value of 1.00679).

Pre-floor wage index value = 0.95809 * 1.00679/1 = 0.9646

Step 7. Apply the 0.6000 floor to the wage index by replacing any wage index values which fall below 0.6000 with 0.6000.

Final wage index value = 0.9646

d. Estimated Impacts of Change to Wage Index Methodology

In the proposed rule, included a discussion on the estimated impacts of the new wage index methodology (89 FR 55778 through 55780). We discussed that this methodological change would be associated with significant changes in wage index values, and therefore payment amounts, for ESRD facilities. Full impacts for the final CY 2025 ESRD PPS wage index, alongside the updated CBSA delineations and rural transition policy discussed in section II.B.2.f of this final rule, are presented in Table 19 in section VII.C.5.a of this final rule, including application of the 5 percent cap on year-to-year wage index decreases. In the proposed rule we presented a table which included the impacts of this change with and without the 5 percent cap on wage index decreases. This table demonstrated how the application of the 5 percent cap mitigates negative changes for CY 2025 associated with the new wage index methodology.

We noted that the 5 percent cap on wage index decreases would apply to ESRD facilities that are located in a CBSA (based on CY 2025 CBSA delineations) with a wage index value 5 percent lower than the CY 2024 wage index value for their CBSA (based on CY 2024 CBSA delineations). The table in the proposed rule was presented for the sole purpose of illustrating the potential long-term ramifications of the proposed new wage index methodology once sufficient time has passed such that the 5 percent cap on year-over-year decreases would no longer constrain the overall effect of this new methodology on wage index values.

In the proposed rule, we discussed our analysis comparing the hypothetical results of applying this new wage index methodology in past years to the actual ESRD PPS wage index methodology based on the IPPS wage index for those years. We found that the application of the new wage index methodology consistently yields mean and median wage index values slightly higher than the actual mean and median wage index values used for those years, implying that the wage index resulting from this new methodology is relatively stable. Additionally, we found that the payment impacts based on facility type did not change much when using data from claim years 2019 through 2022, with most facility types that are projected to receive a payment increase for CY 2025 associated with the new wage index methodology seeing a payment increase in past years. Similarly, most facility types that are projected to receive a payment decrease in CY 2025 associated with the proposed new wage index methodology were found to have received payment decreases in our hypothetical analysis of past years. Therefore, we determined that this new wage index methodology is relatively stable when analyzing the differences between the new proposed wage index and the ESRD PPS legacy wage index.

e. CY 2025 ESRD PPS Wage Index

For CY 2025, we are updating the wage indices to account for updated wage levels in areas in which ESRD facilities are located. We proposed to use the new wage index methodology described previously, in subpart b of this section, according to the most recent available data. We believe that the use of this new wage index methodology is appropriate and responds to the feedback we have received from interested parties regarding the limitations of the current wage index. Specifically, the use of BLS OEWS data would allow for this new wage index methodology to be more responsive to differences in ESRD facility wage levels across the country. Additionally, by using occupational mix data from the freestanding ESRD facility cost reports, this new wage index methodology would better reflect the actual wage costs incurred by ESRD facilities and be most appropriate to use for the ESRD PPS due to several reasons specific to ESRD facilities. First, freestanding ESRD facility cost reports contain detailed occupational FTE data, which allows CMS to create a wage index that is tailored to the wage costs faced by ESRD facilities based on their unique staffing needs. Dissimilarities between hospital occupation mix and ESRD facility occupational mix make the use of the IPPS data less appropriate for ESRD facilities. In addition, the ESRD PPS has a lower labor-related share than most other Medicare payment systems.[24] This new ESRD PPS wage index methodology addresses these specific circumstances.

In the proposed rule, we recognized that there were several methodological limitations to using a wage index based on publicly available BLS OEWS data. Specifically, the BLS OEWS data source lacks information on employee benefits and the full cost of contract labor and includes information from hospitals and other healthcare providers. However, we stated that we believed that the benefits of using this new wage index methodology would outweigh these limitations, as the use of BLS OEWS wage data weighted by an occupational mix derived from freestanding ESRD facility cost report data would allow for a wage index that is more representative of the geographic variation in wages faced by ESRD facilities.

For CY 2025, we also proposed to use OMB's most recent CBSA delineations as published in OMB Bulletin No. 23–01, which are based on the data from the 2020 decennial census, for the purposes of the CY 2025 ESRD PPS wage index and rural facility adjustment. This was consistent with our historical practice of updating the CBSA delineations periodically according to the most recent OMB delineations, most recently in the CY 2021 ESRD PPS final rule (85 FR 71430 through 71434). We discuss this policy in greater detail in section II.B.2.f of this final rule. For more information on the OMB delineations, we refer readers to the OMB Bulletin No. 23–01: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*.

To implement the proposed change in wage index methodology, we proposed to amend the regulations at 42 CFR 413.196(d)(2) and 413.231(a). Effective January 1, 2025, the amended § 413.196(d)(2) would state that CMS updates on an annual basis ''[t]he wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics and occupational mix data from the most recent complete calendar year of Medicare cost reports submitted in accordance with § 413.198(b).'' The amended § 413.231(a) would state that ''CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of wages relevant to the furnishing of renal dialysis services in the geographic area in which the ESRD facility is located.''

For CY 2025, we proposed to update the ESRD PPS wage index to use the most recent BLS OEWS wage data and the most recent CY 2022 freestanding ESRD facility cost report occupational mix and treatment volume data available. At the time the analysis was conducted for the proposed rule, the most recent BLS OEWS wage data available represented May 2022. We proposed that if more recent data become available after the development of this ESRD PPS rule and before the publication of the ESRD PPS final rule (for example, the April 2024 release of May 2023 OEWS data, which was published after the analysis performed for the proposed rule), we would use such data, if appropriate, to determine the CY 2025 ESRD PPS wage index in the ESRD PPS final rule.

(1) Alternative CY 2025 ESRD PPS Wage Index Using Established Methodology

In the proposed rule, we presented a version of the current ESRD PPS wage index constructed using our established methodology with the most recent available data, which we referred to as the ESRD PPS legacy wage index methodology. The purpose of presenting the legacy methodology with modifications was to illustrate an alternative to the new methodology described previously for consideration by interested parties to facilitate comments on the proposed rule. The inclusion of a CY 2025 version of the ESRD PPS legacy wage index methodology allowed for interested parties to compare wage index values under the current methodology and proposed new methodology. For the reasons previously discussed, we believed and continue to believe that the proposed new wage index methodology based on BLS OEWS data and ESRD Medicare cost report data is the most appropriate for ESRD facilities; however, we considered commenters' input on this proposal and the alternative wage index based on the established methodology (updated with the most recent data) when making a determination about the best approach in this final rule.

In the CY 2025 ESRD PPS proposed rule we presented the ESRD PPS legacy wage index, which is based on the most recent pre-floor, pre-reclassified hospital wage data collected annually under the IPPS, as an alternative wage index. Please see the proposed rule (89 FR 55781) for a detailed description of this alternative wage index, which followed our legacy methodology.

(2) Request for Comments on This Proposal

In the proposed rule, we explained our belief that our new ESRD PPS wage index methodology more accurately estimates the geographic variation in wages paid by ESRD facilities when compared to the current ESRD PPS wage index based on the IPPS wage index. We acknowledged that this new methodology would represent a significant change to the established ESRD PPS wage index methodology, both by changing the data sources and the calculations for the wage index. We requested comments on all aspects of the new methodology, including the use of BLS OEWS data for CBSA-level wage estimates, the use of mean hourly wage (rather than median hourly wage), the use of freestanding ESRD facility cost reports for deriving occupational mix weights based on FTEs for each occupation per 1000 treatments as presented in the NEFOM, the use of the ESRD PPS legacy wage index for standardization, and the computational steps used to calculate the wage index.

[24] For example, under section 1886(d)(3)(E) of the Act, the IPPS applies a labor-related share of 62 percent for each hospital unless this would result in lower payments to the hospital than would otherwise be made.

We welcomed any insights into potential methodological improvements, particularly related to some of the limitations of the new data sources discussed previously, including the absence of the cost of employee benefits and the full cost of contract labor in the BLS data, and the inability of this methodology to capture differences in ESRD facility occupational mix across different geographic areas. In the proposed rule we stated that we would consider modifying the methodological steps used to calculate the wage index in the final rule, depending on the comments we received. Additionally, we requested comments on the proposed use of the new wage index methodology compared to the established wage index methodology based on the IPPS wage index which was used to create the alternative ESRD PPS legacy wage index. We also requested comments on the distributional implications of this wage index proposal, with specific consideration to rural areas and remote or isolated areas such as the United States Territories in the Pacific. Lastly, we requested comments on our proposal to begin using our new wage index methodology beginning on January 1, 2025.

We invited public comment on our proposal for our new ESRD PPS wage index methodology and its use for CY 2025. Approximately 20 commenters including LDOs, SDOs, provider advocacy organizations, coalitions of dialysis organizations, a professional organization, several ESRD facilities, and MedPAC commented on the proposed new ESRD PPS wage index methodology. The following is a summary of the public comments received on these proposals and our responses.

Comment: Most commenters who expressed an opinion on the new ESRD PPS wage index methodology, including a coalition of kidney organizations, several LDOs and MedPAC, stated that the use of the IPPS wage index within the ESRD PPS was flawed. Some commenters specified reasons why the IPPS methodology was not appropriate for the ESRD PPS including data lag and the fact that it is based on hospital cost report data. The majority of these commenters indicated that they believed the new wage index methodology would be an improvement over the IPPS wage index for the ESRD PPS. Many commenters supported the wage index proposal and requested that CMS finalize the proposal for CY 2025.

Response: We thank commenters for their opinions on the proposed new wage index methodology as well as their opinions on the ESRD PPS's current use of the IPPS wage index. We agree that the ESRD PPS wage index proposed for CY 2025 has advantages over use of the IPPS wage index when applied to the ESRD PPS. We appreciate the support for the new ESRD PPS wage index methodology, which we are finalizing in this rule.

Comment: Many commenters expressed concerns over some of the impacts of the proposed new ESRD PPS wage index methodology. Among these comments, the most frequently mentioned impact was the wage index budget neutrality adjustment factor. Multiple commenters requested that we implement this new wage index methodology in a non-budget neutral manner. Several commenters noted that there was no statutory requirement for budget neutrality for the ESRD PPS wage index. Some commenters expressed concerns about payment adequacy within the ESRD PPS and stated a belief that the corresponding decrease to the ESRD PPS base rate would lead to inadequate payments. One commenter attributed the budget neutrality reduction to the occupational mix used in calculating the new wage index methodology.

Response: We appreciate the thoughtful comments on the impacts of the proposed new ESRD PPS wage index methodology. We acknowledge that the new wage index methodology, implemented budget neutrally, would decrease the ESRD PPS base rate for CY 2025 relative to use of the legacy wage index methodology for CY 2025. However, as discussed in the proposed rule, we note that this decrease to the CY 2025 ESRD PPS base rate is predominantly due to the application of the 5 percent cap on year-over-year wage index decreases under § 413.231(c), which raises the average ESRD PPS wage index. Although the ESRD PPS base rate would be decreased for CY 2025, as this cap becomes less impactful (that is, in future years, as fewer facilities would quality for the application of the 5 percent cap as a result of the change in wage index methodology), the ESRD PPS base rate would increase over time, eventually attaining the level at which it would have been otherwise. The occupational mix has minimal impact on the budget neutrality adjustment factor, as the NEFOM serves as weights for the wage index, which are applied equally to the individual CBSA wages and national wages in the wage index calculation and, therefore, are essentially cancel out concerns on their impact on the average wage index value.

Although there is no explicit statutory requirement to implement the ESRD PPS wage index in a budget neutral manner, our longstanding philosophy within the ESRD PPS is that when we adjust for relative resource use and the costs for which we are adjusting are already included in the ESRD PPS base rate, those adjustments should be implemented budget neutrally. Under section 1881(b)(14)(A) of the Act our payment system is based on total costs from ESRD facility cost reports from 2007 and is increased annually based on the ESRDB market basket reflecting the changes over time in the prices of an appropriate mix of goods and services included in renal dialysis services. Labor-related costs, including wages and benefits, were included in the cost reports used in the initial analysis (75 FR 49071 through 49083); therefore, we generally believe it is appropriate to implement any adjustment factors which are based on the allocation of those costs in a budget neutral manner.

We have received many comments regarding concerns about payment adequacy in response to our proposed rule, many of which were combined with calls to implement the new ESRD PPS wage index in a non-budget neutral manner. While we acknowledge commenters' concerns about payment adequacy and address them in section II.B.1.b and below in section II.B.4 of this final rule, we note that the purpose of the ESRD PPS wage index is to estimate geographic variation in wages. It would not be appropriate to make changes to the ESRD PPS wage index methodology to attempt to increase total payments to address the commenters' perceived inadequacies. We note that the construction of the wage index budget neutrality factor ensures that the change in the CY 2024 and CY 2025 wage indices does not result in an increase or decrease of estimated aggregate payments. Although for CY 2025 the wage index budget neutrality factor is lower than it has been in the past years, resulting in a larger decrease to the ESRD PPS base rate, this does not change the fact that aggregate payments are estimated to be unchanged implementing the wage index methodology for CY 2025. As noted previously, the main driver of the lower-than-typical budget neutrality factor is the application of the 5 percent cap in wage index decreases, which raises the average wage index value for CY 2025. Although each year's wage index budget neutrality factors are independent, they are derived using the prior year's wage index. The higher-than-typical average wage index value of CY 2025 results in

a smaller budget-neutrality factor. The smaller budget-neutrality factor results in a larger decrease to the ESRD PPS base rate. Consequently, this would likely lead to a higher budget-neutrality factor in future years where the average wage index value would be lower than in CY 2025, as ESRD facilities that received the 5 percent cap in CY 2025 would receive lower wage index values in CY 2026. This will likely result in an increase to the ESRD PPS base rate in CY 2026 related to the wage index budget neutrality factor.

Comment: MedPAC reiterated support for their wage index methodology, which was described in the June 2023 Report to Congress, as discussed earlier.[25] MedPAC noted that their recommended methodology would include two features which our proposed new wage index methodology lacked: a methodology to smooth wage index values across adjacent CBSAs and a methodology to allow for variation in wage index values within a single CBSA.

Response: We thank MedPAC for their recommendations. We did not propose a smoothing methodology across CBSAs because we do not believe it would serve the purpose of the ESRD PPS wage index, which is to estimate geographic differences in area wages. Furthermore, a smoothing methodology would increase the complexity of the methodology and likely involve parameter choices that could be seen as arbitrary. The fact that ESRD facilities which are near each other but located in different CBSAs would have different wage index values is unavoidable and persists within the ESRD PPS legacy wage index. Under the stated rationalization for a smoothing methodology, ESRD facilities in different CBSAs which are geographically near each other would compete for labor. We agree with this evaluation of local labor markets, but we note that should these ESRD facilities and other healthcare employers in the area be competing for labor, their wages would likely reflect that, which would in turn be reflected in the BLS OEWS data and used in the new wage index methodology. As for the recommendation to allow variation within a single CBSA, we acknowledge that such a fine level of detail would have certain advantages if the precision of the wage index could be maintained. However, we do not believe that there is any way to allow such variation without using data sources which would be lower quality, when applied to the ESRD PPS, than the BLS OEWS. In addition, MedPAC recommends the use of American Community Survey (ACS) data, which could allow for some information on average wages, but that information would not be specific to the types of labor used in ESRD facilities. We proposed this new wage index methodology to create a wage index that is specific to ESRD facilities, so the use of such nonspecific data, like the ACS data, would not align with our goals of creating an ESRD-specific PPS wage index. Additionally, similar to the smoothing methodology, utilizing ACS data to allow for further variation of wage index values would increase the complexity of an already complex methodology. We believe that our new ESRD PPS wage index methodology as proposed, without either of these methodological steps (that is, not incorporating either smoothing across CBSAs or variation within CBSAs), strikes a balance between simplicity and accuracy by estimating geographic wages at the CBSA level using the highest quality, publicly-available data, without arbitrary model parameters. We did not propose and, for the reasons stated previously, we are not finalizing in this rule either of the commenter's suggestions of smoothing across CBSAs or accounting for variation within CBSAs.

Comment: Several commenters expressed support for the use of the IPPS wage index for the ESRD PPS. Some commenters highlighted the lack of hospital-based ESRD facility data used in constructing the NEFOM and stated a belief that due to this lack of data the IPPS wage index would be more appropriate for hospital-based ESRD facilities. One commenter stated that this omission would unfairly penalize hospital-based ESRD facilities, particularly pediatric hospital-based ESRD facilities. One commenter requested we make changes to the methodology to utilize hospital-based ESRD facilities' cost report data in the occupational mix, as hospital-based ESRD facilities have hiring practices and occupational mixes more similar to hospitals. One commenter stated that the omission of hospital-based ESRD facility data would have distributional implications due to varying ranges of hospital-based ESRD facilities in different geographical areas.

Response: We appreciate commenters' insight into the extent to which the ESRD PPS legacy wage index based on IPPS data is appropriate for ESRD facilities. We note that we generally agree that the use of the IPPS wage index for the ESRD PPS has historically been reasonably appropriate for estimating geographic variation in wages for many of the reasons the commenters stated, however, this does not change our belief that the new ESRD PPS wage index is more appropriate for the ESRD PPS moving forward compared to the legacy methodology based on the IPPS wage index. Many of the objections these commenters raised to the new methodology revolved around the fact that the NEFOM was based solely on freestanding ESRD facility cost reports and, therefore, did not include data from hospital-based ESRD facilities. While we agree that including data from hospital-based ESRD facilities into the NEFOM would be an improvement, we could not incorporate data from hospital-based ESRD facility cost reports into the NEFOM in an appropriate way. As we explained in the proposed rule (89 FR 55770), hospital-based ESRD facilities lacked certain occupational categories which are present in freestanding ESRD facility cost reports, and therefore, in the NEFOM. The omission of these categories not only means that we do not have data on those occupations for hospital-based ESRD facilities, but it also makes it impossible to appropriately incorporate any data on occupations present in the hospital-based ESRD facility cost reports, since it would not be an appropriate comparison. We would have absolute numbers on the clinical staff of the hospital-based ESRD facility, which would be useful for other analyses, but without knowing the proportion of labor costs spent on the omitted hospital cost report categories, any attempt to incorporate the present data would rely on an assumption that the data reported for the categories not present in the cost report is comparable to that reported for those categories in freestanding ESRD facility cost reports. We did not believe that such an assumption was necessary as hospital-based ESRD facilities are a significant minority of the total population of ESRD facilities (about 5 percent), meaning their inclusion in the NEFOM would not have a substantial impact; furthermore, we believe freestanding ESRD facilities are a good proxy for the average national occupational mix for hospital-based ESRD facilities. Since the NEFOM only serves as weights for the mean wages for the occupations, we believe that the lack of hospital-based data would not unfairly disadvantage hospital-based ESRD facilities, or hospital-based pediatric ESRD facilities, since they would receive the same wage index as freestanding ESRD facilities in the same

[25] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_MedPAC_Report_To_Congress_SEC.pdf.*

area. Furthermore, any shift to the NEFOM associated with the hypothetical inclusion of hospital-based ESRD facility cost report data, should it be possible, would not have any specific impact on hospital-based ESRD facilities compared to other ESRD facilities, as the NEFOM would be applied in the wage index calculation for all ESRD facilities in the same way. Additionally, we note that our analysis shows that hospital-based ESRD facilities would, on average, receive increased payments under this proposed new methodology.

We disagree with the claim that the IPPS wage index would be more appropriate for hospital-based ESRD facilities. Although hospital-based ESRD facilities' cost report data could not be incorporated into the NEFOM, we still believe that the freestanding ESRD facility cost report data is a reasonable proxy for hospital-based ESRD facilities. Furthermore, the new wage index methodology uses mean wage data from the BLS OEWS for occupations related to the furnishing of renal dialysis services, which we believe makes the new wage index methodology more appropriate for hospital-based ESRD facilities when compared to the IPPS wage index. While it is true that hospital-based ESRD facility data would be included in the IPPS wage index there are many other departments (including but not limited to the adults and pediatric unit, intensive care unit and surgical intensive care unit) included in the hospital cost reports which we would anticipate would be less similar to hospital-based ESRD facilities than freestanding ESRD facilities are. As we do not have comprehensive occupational mix data from hospital-based ESRD facilities, we cannot directly evaluate the claim about hospital-based ESRD facilities having more similar occupational mixes to hospitals overall than freestanding ESRD facilities, but we would not anticipate that this would be the case because of the unique types of labor required in furnishing renal dialysis services compared to other hospital services. Lastly, we would not anticipate the omission of hospital-based ESRD facilities from the NEFOM as having any geographic distributional implications, because the NEFOM only serves as a set of weights in the new wage index methodology, so any change to the NEFOM that could potentially arise from including hospital-based cost reports (if that were operationally feasible) would change the weights in the same way for all ESRD facilities.

Comment: One commenter suggested allowing pediatric hospital-based ESRD facilities to continue using the IPPS-based legacy wage index.

Response: We do not believe it would be appropriate for hospital-based pediatric ESRD facilities to be allowed to receive a different wage index value, as we believe that this new wage index methodology is the most appropriate for all ESRD facilities, including pediatric and hospital-based ESRD facilities, for the reasons discussed previously. We do not believe that the IPPS wage index is more applicable for hospital-based pediatric ESRD facilities. We believe these ESRD facilities are likely more similar to freestanding ESRD facilities than other divisions of hospitals because the provision of renal dialysis services likely dictates the occupational mix more than the location of the ESRD facility. That is, pediatric hospital-based ESRD facilities utilize the occupations for which we have utilized BLS OEWS data, as those are the occupations relevant in furnishing renal dialysis services. Furthermore, as the ESRD PPS wage index is intended to reflect the wages in the geographic area in which an ESRD facility is located, it generally would not be appropriate for two ESRD facilities in the same geographic areas to have different methodologies determine their wage index values, as they would generally draw from the same geographic labor market.

Comment: Several commenters expressed concerns with the BLS OEWS data used in the construction of the new ESRD PPS wage index methodology. An LDO and a coalition of dialysis organizations expressed concerns with the BLS OEWS data centered around the lack of data on employee benefits and limitations on traveling contract labor data. These comments emphasized both the importance of benefits in attracting staff and the necessity of using contract labor, which would include labor contracted across CBSAs. Another coalition of dialysis organizations suggested that we study these costs to ensure they are accounted for in this policy. One commenter noted that the BLS OEWS data was not based solely on ESRD facility wage costs and that BLS geographic area estimates do not stratify data by healthcare sector. One commenter noted that evidence shows that wages and benefits vary across labor markets. One commenter expressed a preference for a wage index derived only from ESRD facility wage data from ESRD facility cost reports.

Response: We appreciate these detailed evaluations of the potential limitations of the data sources used in the proposed methodology. In the proposed rule we acknowledged that a lack of information on employee benefits was a limitation of using the BLS OEWS data source. However, we note that the omission of benefits would only have a significant impact on the resulting wage index if the geographic variation in benefit costs is different from the geographic variation in wages. We note that this condition is different from the consideration one commenter raised that wages and benefits both vary geographically. While we cannot say for certain whether the geographic variation in wages is exactly the same as the geographic variation in benefits, we believe that ESRD facility wages are likely a fair proxy for the way ESRD facility benefits vary geographically, particularly when compared to the IPPS wage index, which is based on many factors unrelated to the furnishing of renal dialysis services. Our analysis of cost report data indicates that the percentage of labor costs associated with benefits does not vary substantially by geographic region, with all census regions' shares being between 22 and 24 percent. This is what we would expect to see if wages and benefits vary similarly across geographic regions. We agree with the commenter that benefits are an important tool in recruiting and retaining staff, but we note that wages are also an important tool, so we believe that generally ESRD facilities which need to expend additional money to attract more staff would likely use both increased wages and increased non-wage benefits. We note that employee benefits represent 9.5 percent of the cost weights in the 2020-based ESRDB (87 FR 67146) and, on average, represent approximately 23 percent of all compensation costs.

We note that contract labor is directly included in this policy in two ways, both as a part of the NEFOM and in the BLS OEWS data, although we note that self-employed contract workers are not captured by the OEWS. However, we understand the concern that the commenters raised regarding traveling contract laborers that may be included in the data for a different CBSA from where the ESRD facility is located. We anticipate that many contract laborers would be included in the BLS OEWS survey data for the CBSA in which the ESRD facility where they work is located. We note that the BLS OEWS data allows for the reporting of a worker's site of work; however, we wish to clarify that worksite reporting does not change the CBSA for which an employee would be counted. That is, a contract worker employed by an agency that is physically located in one CBSA but works in a different CBSA would be included in the wage estimates for the

CBSA in which their employing agency is located. We wish to reiterate that, as the wage index is relative, this would only have a significant impact on the wage index methodology if the way in which traveling contract labor is utilized varies geographically from other wages. We intend to continue to monitor and evaluate the performance of the new wage index methodology, including the extent to which contract labor is utilized and would consider making changes to the methodology in future rulemaking, if warranted. We believe the BLS OEWS wage data would better approximate the labor costs of ESRD facilities even if the omitted traveling contract labor differed greatly compared to the included wages, because contract labor hours are generally a small portion of total hours for ESRD facilities. Our data suggest that contract labor hours accounted for 1.3 percent and 1.1 percent of RN and Technician hours in 2022, respectively.

We recognize that the BLS OEWS data used in this methodology is not based solely on ESRD facility wage data; however, we note that this is also true for the IPPS wage index. We have decided on several occupations related to furnishing renal dialysis services for which to utilize BLS OEWS data. We believe it is appropriate to include data from other healthcare employers, as it is likely that ESRD facilities compete with other employers for labor. It is technically correct to say that BLS OEWS does not stratify their geographic area data by healthcare sector; however, we do not believe this is a flaw in the methodology, as the occupations we have chosen to utilize are, generally, healthcare specific. Table 1 in this final rule describes the full occupation titles for all of the occupations included in this wage index methodology. Many of these are inherently healthcare specific, such as nurses or health technologists and technicians. However, for those categories that may not be healthcare specific, such as administrative staff, we are using BLS data from the category that is healthcare specific (that is, Medical Secretaries and Administrative Assistants (SOC code 43–6013)). We believe that these categories are the most appropriate for the types of labor employed by ESRD facilities. Insofar as these categories do not separate data by type of healthcare facility, we believe this is appropriate, as different healthcare employers likely compete with each other for labor. Similarly, we do not believe a wage index based only on ESRD facility cost report data would be appropriate, because ESRD facilities compete against other healthcare employers and, furthermore, in certain CBSAs the number of ESRD facilities could be very small, leading to the ESRD facilities present having a very large impact on the cost report data and, therefore, the wage data for that CBSA.

Comment: Some commenters expressed an opinion that the data sources used in the proposed methodology were appropriate despite some of the limitations we discussed in the proposed rule. Several commenters stated that the omission of hospital-based ESRD facility cost report data from the NEFOM was reasonable and did not jeopardize the methodology as a whole. Other commenters stated that the OEWS data provided a better estimation of geographic wages even if it did not include benefit data and certain contract labor wages. Some commenters supported the occupations we have chosen and stated they were appropriate for the ESRD PPS. Some commenters, including MedPAC, suggested that we continue to monitor the validity of data sources and the resulting wage indices.

Response: We thank commenters for their support and agree that the data sources used in the new wage index methodology are generally appropriate for such a methodology. We intend to continue to monitor both the data sources and the ESRD PPS wage index to ensure they remain appropriate for use in the ESRD PPS.

Comment: Several commenters, including MedPAC and a coalition of dialysis organizations noted that several adjustments used in the ESRD PPS, such as the case-mix adjustments, are derived from a model which might be influenced by a change in the ESRD PPS wage index. MedPAC and one LDO requested that we conduct analysis in future years to determine whether some of the adjustment factors should be changed.

Response: We appreciate the commenters' thoughts on the interconnected relationship between the ESRD PPS wage index and the other adjustments used within the ESRD PPS. We note that we have not routinely updated the case-mix or facility-level adjustment factors when we have made updates to the ESRD PPS wage index in the past. However, we acknowledge that the new wage index methodology would result in more significant facility-level changes than past routine updates to the ESRD PPS wage index. We did not propose any changes to the ESRD PPS case-mix adjustments or facility-level adjustments for CY 2025. One reason for this was because the proposed new wage index methodology would represent a substantial change to the ESRD PPS, and we believe it is appropriate to avoid making multiple significant methodological changes to the wage index and other adjustment factors concurrently as payments to ESRD facilities could change substantially in multiple different ways. We generally believe it is most appropriate to update all of the case-mix and facility-level adjustment factors concurrently because of the interconnected nature of the factors. By this we mean that the case-mix and facility-level adjustment factors are originally derived from a cost-regression from the CY 2011 ESRD PPS final rule, and updated in the CY 2016 ESRD PPS final rule, which includes all such adjustments. By including multiple variables in the regression as adjustment factors we can derive the appropriate adjustment factor for each of the facility-level and case-mix adjustment, as the regression isolates the marginal impact of that facility-level or case-mix characteristic on the cost variable. This does not mean that it is inappropriate to update only one of these adjustment factors, but when we do so we generally intend to be cautious as not to change the adjustment factor in a way that would lead to duplicative payment from other adjustment factors, which could theoretically happen if there were two independent variables which are highly correlated. This is part of the reason why we proposed to update the LVPA adjustment factors in a manner which was budget neutral within the LVPA, rather than reduce the ESRD PPS base rate. We are considering how to update the case-mix and facility-level adjustment factors in a way which would best align relative payments with resource use and cost. We did not propose to update the case-mix and facility-level adjustment factors in the CY 2025 ESRD PPS proposed rule because we did not believe we had the proper data to make the most appropriate updates to the case-mix and facility-level adjustment factors at that time. As we explained in the CY 2024 ESRD PPS final rule, additional data would serve to provide moredata to better inform CMS's pursuit of equitable payment policies in the future by helping us evaluate and monitor the accuracy of our patient-level adjustment factors (88 FR 76397). Specifically, we do not yet have the data from either the updated reporting requirement effective January 1, 2025, for time on machine or the updates to the cost reports to better capture data on the costs for pediatric patients. We believe it is most appropriate to wait until we have these additional data sources and update the

case-mix and facility-level adjustment factors at that time as these additional data sources may allow us to better allocate resource use. Although sometimes substantial changes are unavoidable, they can create challenges for ESRD facilities when planning for future payment years, so we believe it is most prudent to make such a substantial change when we have the most appropriate data. We are not finalizing any changes to the case-mix or facility-level adjustment factors related to the new ESRD PPS wage index methodology, but we intend to consider whether such changes would be appropriate in future years.

Comment: Some commenters expressed concerns with the use of a single national occupational mix for all ESRD facilities. Several interested parties expressed concerns with the application of a wage index based on a national occupational mix to the U.S. Territories in the Pacific, stating that they believed a regional occupational mix would be more appropriate. One commenter suggested CMS allow some ESRD facilities to continue to receive the legacy wage index based on the IPPS wage index.

Response: The NEFOM's purpose in the wage index methodology is to weight the BLS OEWS mean wage data so that the resulting wage index would be more representative of the actual wage costs faced by ESRD facilities. We believe that a single national occupational mix achieves this goal in the most straightforward way. The new wage index methodology is the most appropriate estimation of wages for ESRD facilities. Although some types of ESRD facilities, such as ESRD facilities located in U.S. Territories, may have some other costs that are higher due to their location, if these costs are not directly related to wages it would not be appropriate for them to be reflected in the wage index methodology. As discussed earlier, we do not believe it would be appropriate for different ESRD facilities in a given CBSA to receive different wage index values, so we are not finalizing any exceptions to the new wage index methodology that would allow certain ESRD facilities or facility types to receive the legacy wage index.

Comment: One commenter stated that it would not be appropriate to apply a different wage index value to hospital-based ESRD facilities compared to other units of the hospital as they would have the same hiring practices.

Response: We recognize that hospital-based ESRD facilities likely share some practices with the hospital in which they are located. However, we do not agree with this assertion. We believe it is reasonable for a hospital-based ESRD facility to receive a different wage index from other units in the hospital, as the labor employed by ESRD facilities is different from the labor employed by other parts of a hospital. We note that under the current payment systems, hospitals functionally receive different payment rates for labor for different units, as the payment rates are based on more than the wage index, including the labor-related share and the base payment rate. Furthermore, we do not believe it would be appropriate for hospital-based ESRD facilities to receive different payment rates from similar ESRD facilities in the same CBSA, as we would generally expect ESRD facilities in the same CBSA to face similar labor costs both in mean hourly wage and in the types of labor employed.

Comment: One commenter stated a concern that the NEFOM had a large portion of dialysis technicians which, according to the commenter, would hurt independent ESRD facilities.

Response: We believe the commenter is saying that independent ESRD facilities utilize dialysis technicians at a lower rate than LDOs, and therefore would likely utilize more nurse labor. Our analysis of occupational mix data does not indicate that this statement is true. Our analysis showed that independent ESRD facilities had a slightly lower ratio of nurses to technicians compared to LDOs. The largest difference we found between independent ESRD facilities and LDOs was that independent ESRD facilities had higher rates of administrative staff and management, likely due to economies of scale for these occupations leading to larger organizations requiring relatively fewer of these staff compared to direct patient care staff. We would note that our analysis did find that regional dialysis organizations utilized significantly fewer technicians compared to both LDOs and independent facilities, instead hiring significantly more nurse aides (which are more similar in wages to technicians than RNs). Separate from this analysis, we acknowledge the commenter's stated belief that some ESRD facilities would have an occupational mix that differs from the NEFOM, but we disagree with the statement that this would ''hurt'' those ESRD facilities. The purpose of the ESRD PPS wage index is to best estimate the geographic variation in wages and, to that point, this new wage index better estimates how wages faced by ESRD facilities vary across different geographic areas. In this methodology, the NEFOM serves to weight the BLS OEWS wage data in a way that is generally appropriate for ESRD facilities. While some ESRD facilities would certainly have occupational mixes that differ from the NEFOM, we do not believe it would be more appropriate to pay according to each ESRD facility's occupational mix. ESRD facilities make hiring decisions based on their local labor market and other relevant factors, which may result in occupational mixes that differ from the NEFOM. This is consistent with the philosophy behind a PPS where we provide payment to ESRD facilities, which they can allocate to costs in the most efficient and appropriate manner for them.

Comment: One commenter stated that CMS did not adequately demonstrate that the proposed new wage index methodology would more accurately reflect ESRD facilities' labor markets. This commenter believed that implementing the new wage index methodology would be detrimental for some ESRD facilities.

Response: We understand the commenter's apprehension regarding such a significant methodological change. We believe that we have adequately explained why the proposed new ESRD PPS wage index methodology better estimates the realities of the labor markets for ESRD facilities. With respect to the commenter's desire for CMS to ''demonstrate'' the accuracy of the wage index methodology, we note that by its nature the wage index reflects an estimate of the general economic conditions in a labor market, and there is no more objective measure of those conditions against which its accuracy could be measured. We conducted an analysis of the cost versus payment ratio under the proposed new ESRD PPS wage index methodology and the legacy wage index methodology which found that, on average, ESRD facilities had a cost versus payment ratio of 0.997 under the proposed new methodology (without the application of the 5 percent cap) and 0.991 under the legacy methodology. Using this metric, the proposed new wage index methodology better aligns payment with resource use compared to the legacy methodology.

Comment: Several commenters expressed support for the 5 percent cap on wage index decreases. Some of these commenters stated that they believed the 5 percent cap would help smooth the transition between the legacy and proposed new methodologies. One LDO stated that they did not believe any other sort of transition would be necessary given the 5 percent cap. MedPAC reiterated support for a symmetrical cap on wage index increases. Another LDO suggested that a

symmetric cap on wage index increases could ameliorate some of the impact of this new wage index methodology on the ESRD PPS base rate resulting from budget neutrality.

Response: We appreciate the continued support for the cap on year-over-year wage index decreases. We agree that this 5 percent cap would help mitigate the negative impacts of this policy on certain ESRD facilities in certain years, allowing for a transition period for these ESRD facilities to adjust their business planning. We did not propose any changes to the 5 percent cap policy for CY 2025 and are not finalizing any changes. When we finalized the 5 percent cap in the CY 2023 ESRD PPS final rule (87 FR 67161), we explained why we did not believe a symmetrical cap on increases would be appropriate. We still believe that capping increases in wage index values would be inappropriate, as the new wage index value is the most appropriate for these ESRD facilities. The purpose of the cap is to increase the predictability of ESRD PPS payment for ESRD facilities and mitigate instability and significant negative impacts to ESRD facilities resulting from significant changes to the wage index. In the CY 2023 ESRD PPS final rule we explained that the transition policies are not intended to curtail the positive impacts of certain wage index changes, so it would not be appropriate to also apply the 5 percent cap to wage index increases (87 FR 67159). Although, we appreciate the suggestion for ameliorating the other commenters' budget neutrality concerns, as discussed, we do not believe that a cap on increases to wage index values would be appropriate, and we are not finalizing a cap on increases to wage index values.

Comment: One commenter raised concerns that the ESRD PPS wage index methodology did not include overtime wages. Specifically, the commenter emphasized that some geographic areas have laws which dictate rates for overtime, for example time-and-a-half, which would lead to higher relative costs compared to ESRD facilities in areas which did not have such legislation.

Response: We acknowledge that the BLS OEWS mean hourly wage data is not intended to capture overtime by its definition of wages. However, we do not believe that this is an issue with the methodology. Our goal in designing the new ESRD PPS wage index methodology was to better estimate geographic variation in wages, which this new methodology does. We interpret the commenter's main concern to be that because some geographic areas have legislation which dictates certain overtime rates, overtime costs would likely vary differently from non-overtime wages. Although the commenter is accurate in noting that regulations regarding overtime differ across the country, since overtime rates are generally based on non-overtime hourly wages, we believe it's reasonable to assume that on average places with higher non-overtime wages would generally have higher overtime wages. While non-overtime wages paid by ESRD facilities may not be a perfect proxy for overtime wages paid by ESRD facilities, we believe that they are a fairly good proxy and that use of the BLS OEWS data is nonetheless superior to using the IPPS wage index. In other words, we believe that most variation between geographic areas is captured by the variation in base wages utilized by the proposed new wage index methodology.

We appreciate the commenter raising this concern, and we have considered how we could incorporate overtime labor costs into this methodology. There are some technical limitations to the inclusion of overtime labor costs into this methodology, as overtime is not included in the BLS OEWS data source, and the source of the increased cost resulting from overtime could derive from either different overtime payment rates or different overtime utilization amounts. We did not propose to include overtime in the mean wage data used in the proposed new wage index methodology, and we are not finalizing any such changes in this final rule. We will consider proposing changes to account for overtime wages, if appropriate and feasible, in future rulemaking years.

Comment: One commenter expressed concern that we did not present the uncapped wage index value for each ESRD facility.

Response: The uncapped wage index value for each ESRD facility was available in Addendum A to the CY 2025 ESRD PPS proposed rule, as the uncapped wage index value for an ESRD facility is simply the wage index value for the CBSA in which the ESRD facility is located. We did not include that value in Addendum B, as that could have caused confusion, since the wage index after the application of the 5 percent cap would apply for CY 2025.

Comment: One commenter expressed support for the 0.6000 wage index floor. Several commenters requested CMS perform further analysis on the wage index floor and expressed a belief that such analysis would support an increase in the wage index floor. Commenters specifically suggested that a wage index floor of 0.7000 would be appropriate. These commenters specifically highlighted Puerto Rico and enumerated certain labor costs which they stated contributed to the cost of care in Puerto Rico.

Response: We thank commenters for the continued support of the wage index floor. We did not propose to change the wage index floor for CY 2025 and are not finalizing any changes in this final rule. We will continue to monitor the appropriateness of the current wage index floor, as well as the extent to which ESRD facilities in U.S. Territories may face certain higher costs and will consider any further changes through notice-and-comment rulemaking in future years.

Comment: MedPAC reiterated concerns that a wage index floor is not appropriate, as it distorts area wage indices.

Response: We appreciate the continued evaluation of the impact of the wage index floor. We did not propose, and are not finalizing, any changes to the wage index floor. We will take these concerns into consideration when determining whether further changes to the wage index floor are needed in future rulemaking.

Comment: Several commenters, including one letter from several interested parties concerning the U.S. Pacific Territories, expressed concerns over the impact of the proposed wage index methodology on the U.S. Pacific Territories. This letter from the interested parties stated that they believed that this new wage index methodology was a ''one-size fit all'' approach that would have negative impacts on marginalized communities. This letter expressed some support for the alternative state-level occupational mix which we discussed in the proposed rule, which would result in higher payments to for ESRD facilities in the Pacific Census region and expressed criticism for our choice to propose the simpler methodology using a national occupation mix. One ESRD facility located in the Northern Marianas Island noted that ESRD facilities in these regions face higher costs due to the nature of the isolated regions requiring importation of goods, including medication. This commenter requested that we develop a new methodology that would better account for actual wages rather than state-level wages.

Response: We thank the commenters for their insight on the impact of the proposed wage index policy on ESRD facilities in the U.S. Pacific Territories. We note that the purpose of the wage

index is to reflect the geographic variation in wages faced by ESRD facilities. We believe that this new wage index methodology achieves this goal, especially when compared to the legacy methodology based on the IPPS wage index. We recognize that this new policy will lead to a decrease in payment to ESRD facilities in the U.S. Pacific Territories. However, we note that the BLS OEWS data indicates that this is appropriate, as the new ESRD PPS wage index methodology represents the most recently available BLS OEWS mean wage estimates for the U.S. Pacific Territories. We do not agree with the characterization of this policy as a ''one size fits all'' approach, as this methodology uses BLS OEWS data which is CBSA specific.

We considered as an alternative state-level or regional occupational mixes rather than the proposed NEFOM reflecting the national occupational mix. Our concern with the state-level occupational mix policy was that it was a significantly more complicated alternative to a policy that already represented a significant increase in complexity to the legacy methodology. In addition, the use of a state-level occupational mix for weighting the mean hourly wage data would allow it to be possible that an area could have lower average hourly wages for all occupations but receive a higher wage index when compared to another area. It is accurate that the state-level occupational mix alternative would lead to higher payments to ESRD facilities in the U.S. Pacific Territories compared to the proposed methodology, but we wish to clarify that payments to these ESRD facilities would decrease under either methodology, because the main driver of the decrease in wage index values is the OEWS mean hourly wage data. The difference between payments for ESRD facilities in the U.S. Pacific Territories using state-level occupational mix data and the proposed national occupational mix was less than one percent.

We acknowledge that for the U.S. Pacific Territories the CBSA-level OEWS data serves functionally as a territory-level wage measure due to each of these territories containing exactly one CBSA; however we believe that this is appropriate. We note that the current IPPS wage index is also determined at the CBSA level and, therefore, combines the wages for the entire territory for each of Guam, American Samoa and the Northern Marianas Islands. Lastly, we appreciate the insight into additional costs paid by ESRD facilities in the U.S. Pacific Territories. We note that many of the additional costs listed were non-labor costs, and that the wage index serves to estimate the geographic difference in wages. We acknowledge that there is some evidence that non-labor costs may be relatively higher in regions which require importation of most goods, including the U.S. Pacific Territories; however, it would not be appropriate to address these higher costs through the wage index. We intend to carefully evaluate both the labor and non-labor costs for the U.S. Pacific Territories and other outlying regions of the United States and will consider whether any additional policies are warranted in future rulemaking.

Comment: One association commented that they commissioned an analysis of the impacts of the proposed new wage index methodology, which found that independent and small ESRD facilities would be worse off within industry segments under the new wage index methodology.

Response: Our analysis does not concur exactly with the conclusion the commenter drew about the new wage index methodology. As we presented in Table 6 of the proposed rule, our analysis showed that small ESRD facilities would receive higher payments under the new wage index methodology. Our analysis does show that independent ESRD facilities would receive lower payments. However, since the new wage index methodology is derived from the best available wage data, we believe this is appropriate, as the underlying BLS OEWS mean wage data indicates that the areas in which these independent ESRD facilities are located have lower relative mean wages compared to the legacy wage index.

Comment: One commenter expressed concerns that hospital cost report data was excluded from the calculation of the wage index budget neutrality factor.

Response: We wish to clarify that hospital cost reports were not included in the analysis for the NEFOM because of differences in the labor categories between the hospital-based and freestanding ESRD facility cost reports. Hospital-based ESRD facilities were included in the claims data that were used for determining the budget neutrality adjustment factor for the CY 2025 ESRD PPS wage index. We agree with the commenter that it is important to include hospital-based ESRD facilities in any impacts analysis, including the analysis used to determine average payments under the final CY 2025 ESRD PPS wage index, which was used to determine the wage index budget-neutrality factor. Omitting these hospital-based ESRD facilities would reduce the accuracy of the analysis without any good reason.

Comment: A few commenters recommended CMS allow ESRD facilities to reclassify their CBSA for the wage index, similar to the IPPS, which allows hospitals to reclassify.

Response: We appreciate this suggestion, and we recognize that many ESRD facilities stated that they would be better suited for an adjacent CBSA. However, our belief is that allowing reclassifications would not be appropriate for the ESRD PPS, as we believe the most appropriate wage index for an ESRD facility is for the CBSA in which it is located. We believe our new wage index methodology better estimates the actual wages paid by ESRD facilities in a given CBSA by utilizing data from the BLS OEWS. We did not propose to allow reclassifications under the proposed new wage index methodology, similar to how we did not allow reclassifications under the legacy methodology, and we are not finalizing any such changes in this final rule. We discuss our reasoning for not allowing reclassifications for the wage index for the ESRD PPS in further detail in the CY 2024 ESRD PPS final rule (88 FR 76360 through 76361).

Comment: One commenter, while discussing the proposed wage index budget-neutrality adjustment factor, stated an expectation that we would adjust the base rate down in future years according to this policy.

Response: We want to clarify that we do not anticipate significant repeated downward adjustments to the ESRD PPS base rate as a result of this proposal. The lower-than-typical wage index budget-neutrality adjustment factor is primarily a result of the application of the 5 percent cap on year-over-year wage index decreases, which is particularly impactful in CY 2025 due to the significant proposed change to the wage index methodology. We note that although this 5 percent cap could apply for multiple years in a row as a result of the adoption of the new wage index methodology, each year it is applied, the affected ESRD facilities' wage index values would become closer to the wage index values for their CBSAs, until their wage index values would be equal their CBSA's wage index value. In future years we anticipate the 5 percent cap would cause fewer ESRD facilities to receive wage index values higher than that of their CBSA, so the wage index budget-neutrality factor for CY 2026 would be higher than the wage index budget-neutrality factor for CY 2025. We note that the wage index budget-neutrality adjustment factor is multiplicative, so a ''higher'' value would lead to either a smaller decrease in the ESRD PPS base rate, should the

value still remain below 1, or to an increase to the ESRD PPS base rate, should the value rise above 1.

Comment: One commenter generally supported the idea of the proposal but noted the complexity of the proposal and requested additional time to review the new wage index methodology and impacts. One LDO suggested further analysis and potentially another TEP to continue to refine and test the methodology.

Response: We believe the 60-day timeframe provided a sufficient opportunity for interested parties to review the proposed rule and provide comments. To help interested parties understand the complexities and impacts of this proposal we included 3 addenda to the proposed rule. Addendum B included facility level impacts for all of our proposed policies, including the proposed change in the wage index methodology, as well as a side-by-side comparison of wage index values under the proposed new wage index and the legacy wage index based on IPPS data. Addendum C included a detailed methodological breakdown for this proposed new wage index methodology. We believe that this provided the public with ample information to thoroughly review the policy in the time available. In the proposed rule, we explained that we believe it would be beneficial to implement this proposed new wage index methodology alongside the more-routine updates to the CBSA delineations according to OMB 23–01. Additionally, we believe that this new wage index methodology is more appropriate for ESRD facilities and, therefore, should be implemented as soon as feasible. Similarly, we believe that we have sufficient information to determine that this policy is an improvement to the use of the IPPS wage index for the ESRD PPS and that holding another TEP would be an unnecessary delay for this policy. We are not finalizing any delay to the implementation date for this new wage index methodology, but we intend to carefully monitor the new ESRD PPS wage index, maintain a dialogue with interested parties, and consider further modifications to the methodology in future rulemaking.

Final Rule Action: After considering the comments received on this proposal, we are finalizing the use of the new ESRD PPS wage index methodology for CY 2025 without modification. Consistent with prior years, we are updating the CY 2025 proposed ESRD PPS wage index with the most recent available data. Most notably, this includes the release of the May 2023 BLS OEWS data as well as updated CY 2022 cost report data. We note that, contrary to our expectation, some CY 2022 cost report data was still not available at the time of the analysis conducted for this final rule, so we are finalizing to use CY 2021 cost report data where necessary. We believe that omitting these ESRD facilities without CY 2022 cost report data would be inappropriate, and CY 2021 cost report data is the most reasonable proxy for this missing data. Additionally, we are finalizing the proposed updates to 42 CFR 413.196(d)(2) and 413.231(a) to codify the new ESRD PPS wage index methodology with one change. To avoid confusion in connection with the use of the phrase ''most recent complete year of Medicare cost reports,'' as some CY 2022 freestanding ESRD facility cost reports are not available, we are finalizing to instead revise 413.196(d)(2) to read ''most recent full year of Medicare cost reports.'' This change clarifies our original intention to use the most recent completed cost-reporting CY, which is CY 2022 because CY 2023 cost reports beginning in November of 2023 (and ending November of 2024) would not be finished at the time of this final rule's publishing. This avoids confusion insofar as the word ''complete'' could refer either to the year (as intended) or the dataset of cost reports (which is not complete, as some CY 2022 cost reports were still not available at the time of this final rulemaking).

The final CY 2025 ESRD PPS wage index is set forth in Addendum A to this final rule and is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*. Addendum A provides a crosswalk between the CY 2024 wage index and the proposed CY 2025 wage index. Addendum B to this final rule provides an ESRD facility level impact analysis. Addendum B is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*.

f. Implementation of New OMB Labor Market Delineations

(1) Background

As previously discussed in this final rule, the wage index used for the ESRD PPS was historically calculated using the most recent pre-floor, pre-reclassified hospital wage data collected annually under the IPPS and is assigned to an ESRD facility based on the labor market area in which the ESRD facility is geographically located. In the CY 2025 ESRD PPS proposed rule, we proposed a new wage index methodology that would similarly be based on the labor market in which an ESRD facility is located. ESRD facility labor market areas are delineated based on the CBSAs established by OMB. In accordance with our established methodology, we have historically adopted through rulemaking CBSA changes that are published in the latest OMB bulletin. 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.

In the CY 2015 ESRD PPS final rule (79 FR 66137 through 66142), we finalized changes to the ESRD PPS wage index based on the newest OMB delineations, as described in OMB Bulletin No. 13–01 [26] issued on February 28, 2013. We implemented these changes with a 2-year transition period (79 FR 66142). OMB Bulletin No. 13–01 established revised delineations for United States Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas based on the 2010 Census. OMB Bulletin No. 13–01 also provided guidance on the use of the delineations of these statistical areas using standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252).

On July 15, 2015, OMB issued OMB Bulletin No. 15–01,[27] which updated and superseded OMB Bulletin No. 13–01 issued on February 28, 2013. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the United States Census Bureau population estimates for July 1, 2012, and July 1, 2013.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01,[28] which updated and superseded OMB Bulletin No. 15–01 issued on July 15, 2015. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the United States Census Bureau population estimates for July 1, 2014, and July 1,

[26] *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2013/b13-01.pdf.*

[27] *https://www.bls.gov/bls/omb-bulletin-15-01-revised-delineations-of-metropolitan-statistical-areas.pdf.*

[28] *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2017/b-17-01.pdf.*

2015. In OMB Bulletin No. 17–01, OMB announced a new urban CBSA, Twin Falls, Idaho (CBSA 46300).

On April 10, 2018, OMB issued OMB Bulletin No. 18–03 [29] which updated and superseded OMB Bulletin No. 17–01 issued on August 15, 2017. On September 14, 2018, OMB issued OMB Bulletin No. 18–04,[30] which updated and superseded OMB Bulletin No. 18–03 issued on April 10, 2018. OMB Bulletin Numbers 18–03 and 18–04 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. These updates were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to the United States Census Bureau population estimates for July 1, 2015, and July 1, 2016. In the CY 2021 ESRD PPS final rule (85 FR 71430 through 71434), we finalized changes to the ESRD PPS wage index based on the most recent OMB delineations from OMB Bulletin No 18–04. This was the most recent time we have updated the labor market delineations used for the ESRD PPS and, therefore, reflects the labor market delineations we used for CY 2024 (88 FR 76360).

In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey, an ongoing survey conducted by the Census Bureau. In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. A copy of OMB Bulletin No. 23–01 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.* According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data).

In the CY 2025 ESRD PPS proposed rule, we explained that we believe it is important for the ESRD PPS to use, as soon as 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 OMB delineations would increase the integrity of the ESRD PPS wage index system by creating a more accurate representation of geographic variations in wage levels, especially given the proposed new wage index methodology discussed previously. We carefully analyzed the impacts of adopting the new OMB delineations and found no compelling reason to delay implementation. Therefore, we proposed to adopt the updates to the OMB delineations announced in OMB Bulletin No. 23–01 effective for CY 2025 under the ESRD PPS for use in determining both the wage index and the rural adjustment for ESRD facilities. We proposed that this would be implemented along with the new ESRD PPS wage index methodology, if finalized, or along with the alternative ESRD PPS legacy wage index based on IPPS data, should the proposed new wage index methodology not be finalized.

As previously discussed, we finalized a 5 percent cap on any decrease to a provider's wage index from its wage index in the prior year in the CY 2023 ESRD PPS final rule (87 FR 67161). We did not propose any additional transition policy for the CY 2025 wage index as we believe the 5 percent cap effectively mitigates the negative impact of large wage index decreases for an ESRD facility in a single year. In addition, we proposed to phase out the rural adjustment for ESRD facilities that are transitioning from rural to urban based on these CBSA revisions, as discussed in section II.B.2.f.(2) of this final rule. For a further discussion of changes to OMB's CBSA delineations, including a list of changes to specific CBSAs, see the FY 2025 IPPS proposed rule (89 FR 36139).

We invited public comment on our proposal to use the updated CBSA delineations. We received four comments regarding our proposal to use the updated CBSA delineations. The following is a summary of the public comments received on this proposal and our responses.

Comment: One commenter expressed specific support for our use of the updated CBSA delineations according to the most recent OMB delineations set forth in OMB Bulletin No. 23–01. Several other comments referenced our proposal to update the CBSA delineations; however, no other comment expressed a strong opinion on this policy. These comments that referenced the proposal generally included it alongside other proposals that appeared to be the focus of the comment, such as the new wage index methodology.

Response: We appreciate the commenters for reviewing the proposal to update CBSA delineations and appreciate the commenter for expressing support for the updated delineations.

Final Rule Action: After reviewing the comments received, we are finalizing our use of the most recent CBSA delineations from OMB Bulletin 23–01 for ESRD PPS wage index and rural adjustment for CY 2025 and beyond, consistent with prior updates to CBSA delineations.

(2) Proposal To Phase Out the Rural Facility Adjustment for Facilities Affected by Changes to CBSAs

In the CY 2016 ESRD PPS final rule (80 FR 69001), we established a policy to provide a 0.8 percent payment adjustment to the base rate for ESRD facilities located in a rural area. This adjustment was based on a regression analysis, which indicated that the per diem cost of providing renal dialysis services for rural facilities was 0.8 percent higher than that of urban facilities after accounting for the influence of the other variables included in the regression. This 0.8 percent adjustment has been part of the ESRD PPS each year since it was finalized beginning for CY 2016, and its inclusion in the ESRD PPS is codified at § 413.233.

As previously discussed in this final rule, we proposed a change to the ESRD PPS wage index methodology as well as changes to the CBSA delineations. In the CY 2023 ESRD PPS final rule, we finalized a policy to cap year-to-year decreases in the wage index for any ESRD facility at 5 percent (87 FR 67161). The primary purpose of this change was to mitigate the negative effect associated with an ESRD facility being reclassified into a lower wage index CBSA as a result of changes in OMB's most recent CBSA delineations. We anticipated that the proposed change to the CBSA delineations and the changes to the wage index methodology, if finalized, would lead to numerous ESRD facilities having a significant decrease in wage index value in CY 2025 compared to CY 2024.

As previously discussed, we are finalizing the adoption of OMB Bulletin No. 23–01, which will determine whether an ESRD facility is classified as urban or rural for purposes of the rural facility adjustment in the ESRD PPS.

[29] *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf.*

[30] *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf.*

Although the rural facility adjustment is not directly related to the wage index, the application of both is determined by the CBSA in which an ESRD facility is located and, therefore, is potentially subject to significant changes associated with the new CBSA delineations. It is reasonable to conclude that these proposed shifts in the CBSA delineations, in combination with the wage index methodological changes finalized in this final rule, could lead to a year-over-year decrease in payment greater than what a 5 percent decrease to the wage index would cause even if the decrease in the wage index value alone would be less than 5 percent. To mitigate the scope of changes that would impact ESRD facilities in any single year, we proposed to implement a 3-year phase out of the rural facility adjustment for ESRD facilities that are located in a CBSA that was categorized as rural in CY 2024 and is recategorized as urban in CY 2025, as a result of the updates to the CBSA delineations associated with the proposed adoption of OMB Bulletin No. 23–01.

We stated that overall, we believe implementing updated OMB delineations would result in the rural facility adjustment being applied where it is appropriate to adjust for higher costs incurred by ESRD facilities in rural locations. However, in the proposed rule we recognized that implementing these changes would have different effects among ESRD facilities and that the loss of the rural facility adjustment could lead to some hardship for ESRD facilities that had anticipated receiving the rural facility adjustment in CY 2025. Therefore, we stated it would be appropriate to consider whether a transition period should be used to implement these changes. For ESRD facilities located in a county that transitioned from rural to urban in OMB Bulletin 23–01, we considered whether it would be appropriate to phase out the rural facility adjustment for affected ESRD facilities. Adoption of the updated CBSAs in OMB Bulletin 23–01, which we are finalizing as proposed, will change the status of 44 ESRD facilities currently designated as ''rural'' to ''urban'' for CY 2025 and subsequent CYs. As such, these 44 newly urban ESRD facilities would no longer receive the 0.8 percent rural facility adjustment. Consistent with the rural transition policy proposed for IPFs and IRFs for FY 2025 (89 FR 23188, 89 FR 22267 through 22268) we proposed a 3-year, budget neutral phase-out of the rural facility adjustment for ESRD facilities located in the 54 rural counties that would become urban under the new OMB delineations, given the potentially significant payment impacts for these ESRD facilities. We believed that a phase-out of the rural facility adjustment transition period for these 44 ESRD facilities would be appropriate, because we expected these ESRD facilities would experience a steeper and more abrupt reduction in their payments compared to other ESRD facilities. We proposed to adopt these new CBSA delineations in a year in which we also proposed substantial methodological changes to our wage index. We noted that, while these proposed changes, would increase payment accuracy across the ESRD PPS, we also recognize that some ESRD facilities could lose the rural facility adjustment and receive a significantly lower wage index value in the same year. We stated that it would be appropriate for this transition policy to be budget-neutral compared to ending the rural adjustment for these facilities in CY 2025 because it is an extension of the rural facility adjustment, which was implemented budget-neutrally, and a result of the change in CBSA delineations, which was proposed to be implemented budget-neutrally alongside the wage index changes. The reasoning behind this proposal is similar to the reasoning behind the 5 percent cap on year-to-year decreases in wage index values, which was finalized in the CY 2023 ESRD PPS final rule (87 FR 67161), as it would ameliorate unexpected negative impacts to certain ESRD facilities. This rural phase-out in combination with the 5 percent cap policy would best reduce the negative effects on any single ESRD facility resulting from changes to the CBSA delineations. Therefore, we proposed to phase out the rural facility adjustment for these facilities to reduce the impact of the loss of the CY 2024 rural facility adjustment of 0.8 percent over CYs 2025, 2026, and 2027, consistent with the similar IPF and IRF proposals previously discussed. This policy would allow ESRD facilities that are classified as rural in CY 2024 and would be classified as urban in CY 2025 to receive two-thirds of the rural facility adjustment for CY 2025, or a 0.53 percent adjustment. For CY 2026, these ESRD facilities would receive one-third of the rural facility adjustment, or a 0.27 percent adjustment. For CY 2027, these ESRD facilities would not receive a rural facility adjustment. We believed, and continue to believe, that a 3-year budget-neutral phase-out of the rural facility adjustment for ESRD facilities that transition from rural to urban status under the new CBSA delineations would best accomplish the goals of mitigating the loss of the rural facility adjustment for existing CY 2024 rural ESRD facilities. The purpose of the gradual phase-out of the rural facility adjustment for these ESRD facilities is to mitigate payment reductions and promote stability and predictability in payments for existing rural ESRD facilities that may need time to adjust to the loss of their CY 2024 rural payment adjustment or that experience a reduction in payments solely because of this re-designation. This policy would be specifically for the 44 ESRD facilities that are rural in CY 2024 that become urban in CY 2025. We did not propose a transition policy for urban ESRD facilities that become rural in CY 2025 because these ESRD facilities will receive the full rural facility adjustment of 0.8 percent beginning January 1, 2025, so they would not experience the same adverse effects as an ESRD facility that unexpectedly loses the rural facility payment adjustment. We noted that we understand that compared to rural payment adjustments in other Medicare payment systems, the ESRD PPS rural facility adjustment is not large in magnitude (for example, the rural adjustments for IPFs and IRFs are 17 percent and 14.9 percent, respectively), but we stated that it is important for ESRD facilities to be able to reasonably predict what their payments from the ESRD PPS would be in the next year.

We invited public comment on our proposal for a rural transition policy. One interested party commented on this proposal. The following is a summary of the public comment received on this proposal and our response.

Comment: One commenter expressed support for the rural transition policy and stated that this policy would avoid disruption of patient care.

Response: We thank the commenter and agree that this policy would help to stabilize payments for ESRD facilities in CBSAs which are losing their rural status for CY 2025.

Final Rule Action: After reviewing the comments on this proposal, we are finalizing the rural transition phase-out policy as proposed. For ESRD facilities that were in CBSAs designated as rural for CY 2024, but that would be designated as urban for CY 2025, claims for renal dialysis services provided to all adult ESRD patients would receive 2/3rds of the rural adjustment, or a 0.53 percent adjustment factor, for CY 2025 and 1/3rd of the rural adjustment, or a 0.27 percent adjustment factor, for CY 2026. Similarly, this transition would be applied for the current rural facility adjustment factor of 0.978 used for the

MAP calculation to determine the outlier payment made under § 413.237 for any eligible adult ESRD patient. This 0.978 adjustment factor represents a 2.2 percent reduction to the predicted MAP amount, so we will apply 2/3rds of the adjustment factor for CY 2025 and 1/3rd of the adjustment factor for CY 2026. For CY 2025 the rural transition adjustment factor applied to the outlier MAP calculation will be 0.9853 and for CY 2026 the rural facility transition adjustment factor applied to the outlier MAP calculation will be 0.9927.

3. CY 2025 Update to the Outlier Policy

a. Background

Section 1881(b)(14)(D)(ii) of the Act requires that the ESRD PPS include a payment adjustment for high-cost outliers due to unusual variations in the type or amount of medically necessary care, including variability in the amount of erythropoiesis stimulating agents (ESAs) necessary for anemia management. Some examples of the patient conditions that may be reflective of higher facility costs when furnishing dialysis care are frailty and obesity. A patient's specific medical condition, such as secondary hyperparathyroidism, may result in higher per treatment costs. The ESRD PPS recognizes that some patients require high-cost care, and we have codified the outlier policy and our methodology for calculating outlier payments at § 413.237.

Section 413.237(a)(1) enumerates the following items and services that are eligible for outlier payments as ESRD outlier services: (i) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (ii) Renal dialysis laboratory tests that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iii) Renal dialysis medical/surgical supplies, including syringes, used to administer renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, separately billable under Medicare Part B; (iv) Renal dialysis drugs and biological products that were or would have been, prior to January 1, 2011, covered under Medicare Part D, including renal dialysis oral-only drugs effective January 1, 2025; and (v) Renal dialysis equipment and supplies, except for capital-related assets that are home dialysis machines (as defined in § 413.236(a)(2)), that receive the transitional add-on payment adjustment as specified in § 413.236 after the payment period has ended.[31]

In the CY 2011 ESRD PPS final rule (75 FR 49142), CMS stated that for purposes of determining whether an ESRD facility would be eligible for an outlier payment, it would be necessary for the ESRD facility to identify the actual ESRD outlier services furnished to the patient by line item (that is, date of service) on the monthly claim. Renal dialysis drugs, laboratory tests, and medical/surgical supplies that are recognized as ESRD outlier services were specified in Transmittal 2134, dated January 14, 2011.[32] We use administrative issuances and guidance to continually update the renal dialysis service items available for outlier payment via our quarterly update CMS Change Requests, when applicable. For example, we use these issuances to identify renal dialysis oral drugs that were or would have been covered under Part D prior to 2011 to provide unit prices for determining the imputed MAP amounts. In addition, we use these issuances to update the list of ESRD outlier services by adding or removing items and services that we determined, based our monitoring efforts, are either incorrectly included or missing from the list.

Under § 413.237, an ESRD facility is eligible for an outlier payment if its imputed (that is, calculated) MAP amount per treatment for ESRD outlier services exceeds a threshold. In past years, the MAP amount has reflected the average estimated expenditure per treatment for services that were or would have been considered separately billable services prior to January 1, 2011. The threshold is equal to the ESRD facility's predicted MAP per treatment plus the fixed dollar loss (FDL) amount. As described in the following paragraphs, the ESRD facility's predicted MAP amount is the national adjusted average ESRD outlier services MAP amount per treatment, further adjusted for case-mix and facility characteristics applicable to the claim. We use the term ''national adjusted average'' in this section of this final rule to more clearly distinguish the calculation of the average ESRD outlier services MAP amount per treatment from the calculation of the predicted MAP amount for a claim. The average ESRD outlier services MAP amount per treatment is based on utilization from all ESRD facilities, whereas the calculation of the predicted MAP amount for a claim is based on the individual ESRD facility and patient characteristics of the monthly claim. In accordance with § 413.237(c), ESRD facilities are paid 80 percent of the per treatment amount by which the imputed MAP amount for outlier services (that is, the actual incurred amount) exceeds this threshold. ESRD facilities are eligible to receive outlier payments for treating both adult and pediatric dialysis patients.

In the CY 2011 ESRD PPS final rule and codified in § 413.220(b)(4), using 2007 data, we established the outlier percentage—which is used to reduce the per treatment ESRD PPS base rate to account for the proportion of the estimated total Medicare payments under the ESRD PPS that are outlier payments—at 1.0 percent of total payments (75 FR 49142 through 49143). We also established the FDL amounts that are added to the predicted outlier services MAP amounts. The outlier services MAP amounts and FDL amounts are different for adult and pediatric patients due to differences in the utilization of separately billable services among adult and pediatric patients (75 FR 49140). As we explained in the CY 2011 ESRD PPS final rule (75 FR 49138 through 49139), the predicted outlier services MAP amounts for a patient are determined by multiplying the adjusted average outlier services MAP amount by the product of the patient-specific case-mix adjusters applicable using the outlier services payment multipliers developed from the regression analysis used to compute the payment adjustments.

Lastly, in the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177). We explained that for several years, outlier payments had consistently landed below the target of 1.0 percent of total ESRD PPS payments (87 FR 67169). Commenters raised concerns that the methodology we used to calculate the outlier payment adjustment since CY 2011 results in underpayment to ESRD facilities, as the base rate has been reduced by 1.0 percent since the establishment of the ESRD PPS to balance the outlier payment (85 FR 71409, 71438 through 71439; 84 FR 60705 through 60706; 83 FR 56969). In response to these

[31] Under § 413.237(a)(1)(vi), as of January 1, 2012, the laboratory tests that comprise the Automated Multi-Channel Chemistry panel are excluded from the definition of outlier services.

[32] Transmittal 2033 issued August 20, 2010, was rescinded and replaced by Transmittal 2094, dated November 17, 2010. Transmittal 2094 identified additional drugs and laboratory tests that may also be eligible for ESRD outlier payment. Transmittal 2094 was rescinded and replaced by Transmittal 2134, dated January 14, 2011, which included one technical correction. *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R2134CP.pdf.*

concerns, beginning with CY 2023, we began calculating the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. We stated in the CY 2023 ESRD PPS final rule that we would continue to calculate the adult and pediatric MAP amounts for CY 2023 and subsequent years following our established methodology. In that same CY 2023 ESRD PPS final rule, we provided a detailed discussion of the methodology we use to calculate the MAP amounts and FDL amounts (87 FR 67167 through 67169).

For CY 2025, we proposed several methodological and policy changes to the ESRD PPS outlier policy to address a number of concerns that interested parties have raised in recent years. We noted that although the 1.0 percent outlier target was achieved in CY 2023, it was not achieved in the majority of the years since the establishment of the ESRD PPS in 2011. We stated that we expect each of these proposed changes would support the ability of the ESRD PPS to continue targeting outlier payments at 1.0 percent in CY 2025 and subsequent years. We discuss each of these proposed changes in detail in the following sections.

b. Expansion of ESRD Outlier Services

(1) Background and Current Issues

In the CY 2011 ESRD PPS final rule we finalized a policy that only renal dialysis services that were or would have been separately billable prior to the inception of the ESRD PPS would be eligible for the outlier payment. In the CY 2011 ESRD PPS proposed rule we explained that we believed that any unusual variation in the cost of the renal dialysis services comprising the base rate under the ESRD PPS would likely to be due to variation in the items and services that were, at that time, separately billable under Part B or renal dialysis service drugs and biological products that were then covered under Part D (74 FR 49988). We received some comments at that time that requested CMS consider alternative ways to determine outlier eligibility, including expanding eligibility to all renal dialysis services. However, we noted that we did not have adequate data at that time to include all Composite Rate Services (that is, renal dialysis services included in the composite payment system established under section 1881(b)(7) of the Act and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act, as defined in regulation at § 413.171) in the outlier calculation (74 FR 49989, 75 FR 49135).

In the CY 2019 ESRD PPS proposed rule we issued a comment solicitation on the potential expansion of outlier payments to composite rate supplies, drugs, and biological products (83 FR 34332). In this RFI, we detailed that such a change could promote appropriate payment for composite rate drugs once the TDAPA period has ended. Commenters' responses to this comment solicitation were mixed (83 FR 56969 through 56970). One commenter expressed that such a change would promote and incentivize the development of innovative new therapies and devices to treat the highly vulnerable ESRD adult and pediatric patient populations. Some commenters responded specifically regarding the TDAPA that extending availability of outlier payments would be particularly important when no additional money is being added to the base rate for the drug, as is the case with most drugs and biological products receiving the TDAPA. However, some commenters, including MedPAC, did not agree that such an expansion of the outlier eligible services would improve care, generally indicating that expanding the list of ESRD outlier services would hamper the outlier payment's functionality. One commenter stated that the purpose of the outlier adjustment was to pay for unusually costly patients, not new drugs and biological products, which the commenter noted the outlier payment was unable to do adequately. MedPAC commented that an outlier policy should act as a stop-loss insurance for medically necessary care, and outlier payments are needed when the ESRD PPS' payment adjustments do not capture all of the factors affecting providers' costs of delivering care. To that end, MedPAC stated that to develop an effective outlier policy, CMS must first develop accurate patient-level and facility-level payment adjustments. MedPAC further cautioned that should CMS expand the list of eligible ESRD outlier services, we should be clear as to what would qualify for the outlier payment.

In subsequent years, we took steps to expand the outlier policy to include certain potentially costly renal dialysis services that would have been included in the composite rate prior to the ESRD PPS. In the CY 2020 ESRD PPS final rule we finalized that any new and innovative renal dialysis equipment or supply would be eligible for the outlier adjustment after the end of the TPNIES period, regardless of whether it would have been separately billable prior to 2011 (84 FR 60697). In that rule, we explained that we believed allowing these items to be outlier eligible after the end of the TPNIES period would allow for these new and innovative supplies to be competitive with the other equipment and supplies also accounted for in the ESRD PPS base rate by establishing a level playing field where products could gain market share by offering the best practicable combination of price and quality (84 FR 60693). In the CY 2021 ESRD PPS final rule, we finalized that capital-related assets that are home dialysis machines will not become ESRD outlier services at the end of the TPNIES payment period (85 FR 71399). We explained that as assets, capital-related home dialysis machines are distinct from operating expenses such as the disposable supplies and leased equipment with no conveyed ownership rights. Unlike assets, these latter items are generally accounted for on a per patient basis and therefore, when used in excess of the average, constitute outlier use, which makes them eligible for outlier payments (85 FR 71424).

The definition of ESRD outlier services is codified at § 413.237(1)(a). Currently, drugs and biological products that were or would have been paid under the composite rate are not considered ESRD outlier services, and costs for these drugs are not included in the calculation for outlier payments on ESRD PPS claims. Current regulations at § 413.171 define Composite Rate Services as: ''Items and services used in the provision of outpatient maintenance dialysis for the treatment of ESRD and included in the composite payment system established under section 1881(b)(7) and the basic case-mix adjusted composite payment system established under section 1881(b)(12) of the Act.'' Under our longstanding policy, drugs and biological products that are substitutes for composite rate drugs and biological products are considered to be included in the composite rate portion of the ESRD PPS. In the CY 2011 ESRD PPS final rule (75 FR 49048), we cited existing guidance in the Medicare Benefit Policy Manual, Pub. 100–02, chapter 11, section 30.4.1, which explicitly stated, ''drugs used in the dialysis procedure are covered under the facility's composite rate and may not be billed separately. Drugs that are used as a substitute for any of these items, or are used to accomplish the same effect, are also covered under the composite rate.'' This guidance remains in effect and was subsequently re-designated to section 20.3.F of the same chapter.

In the CY 2024 ESRD PPS final rule (88 FR 76391), we finalized a policy to

pay, beginning for CY 2024, a post-TDAPA add-on payment adjustment for any new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate that has previously been paid for using the TDAPA under § 413.234(c)(1). This post-TDAPA add-on payment adjustment generally will be applied for a period of 3 years following the end of the TDAPA period for those products. We finalized that the post-TDAPA add-on payment adjustment amount will be calculated based on the most recent available 12 months of claims data and the latest available full calendar quarter of average sales price (ASP) data (88 FR 76396). We explained that we divide the total expenditure of the new renal dialysis drug or biological product by the total number of ESRD PPS treatments furnished during the same 12-month period. In addition, we finalized that we adjust the post-TDAPA add-on payment adjustment amount paid on claims by the patient-level case-mix adjustment factors; accordingly, we apply a reduction factor to the post-TDAPA add-on payment adjustment amount to account for the application of the patient-level case-mix adjustment factors. We codified these policies by revising § 413.234(c)(1)(i) and adding regulations at § 413.234(b)(1)(iii), (c)(1)(ii), (c)(3), and (g) that describe the post-TDAPA add-on payment adjustment and the calculation we use to determine the post-TDAPA add-on payment adjustment amount. In addition, we amended § 413.230 by adding reference to the post-TDAPA add-on payment adjustment in the calculation of the ESRD PPS per treatment payment amount.

In the same CY 2024 ESRD PPS final rule, we summarized comments regarding the outlier policy as it pertains to the post-TDAPA add-on payment adjustment (88 FR 76396). One commenter pointed out that the CY 2024 ESRD PPS proposed rule did not indicate whether the ESRD PPS outlier adjustment would apply to products for which a post-TDAPA add-on payment adjustment is calculated. In response, CMS stated that under current policy, after the end of the TDAPA period, a drug or biological product is considered an eligible outlier service only if it meets the requirements of § 413.237(a)(1). We clarified that any renal dialysis drug or biological product included in the calculation of the post-TDAPA add-on payment adjustment would be considered an eligible ESRD outlier service only if it meets the requirements of § 413.237(a)(1). However, we further clarified that under current policy, Korsuva®, the only renal dialysis drug with a TDAPA period ending in CY 2024, would not be considered an eligible ESRD outlier service after the end of its TDAPA period, because it is a substitute for diphenhydramine hydrochloride, which was included in the composite rate prior to 2011, and therefore does not meet the requirements of § 413.237(a)(1) (that is, it would not have been, prior to January 1, 2011, separately billable under Medicare Part B).

Most recently, we have heard concerns from interested parties that excluding drugs and biological products that are substitutes for—or are used to achieve the same effect as—composite rate drugs and biological products from the definition of ESRD outlier services could limit the ability of the ESRD PPS outlier adjustment to appropriately recognize the drivers of cost for renal dialysis services. We considered these concerns, as well as the comments we received in response to prior rulemaking, to develop proposed changes to the definition of ESRD outlier services.

(2) Definition of ESRD Outlier Services

Effective for CY 2025, we proposed to change the definition of ESRD outlier services at § 413.237(a)(1) to include drugs and biological products that were or would have been included in the composite rate prior to the establishment of the ESRD PPS. We noted that this proposal would expand outlier eligibility to longstanding drugs and biological products that were historically included in the composite rate, as well as newer drugs and biological products that are currently included in the calculation of the post-TDAPA add-on payment adjustment. As discussed in section II.B.3.c of this final rule, we proposed and are finalizing technical changes to the calculation of outlier payments that will appropriately account for the post-TDAPA add-on payment adjustment for ESRD outlier services that are drugs and biological products.

In the CY 2025 ESRD PPS proposed rule, we stated that we considered the original intent behind the policy to limit outlier payments to drugs that were or would have been separately billable prior to 2011, which was that these drugs were likely the main drivers of the variation in the costs of treatment (74 FR 49988). We explained that we continue to believe an important aspect of the outlier adjustment should be its ability to target ESRD cases that are unusually costly. We noted that if the outlier adjustment methodology failed to recognize the main drivers of variation in the costs of ESRD treatment, then it could result in cases that are not unusually costly qualifying for the outlier adjustment, which would mean the impact of the outlier adjustment would be diluted. We also noted that many of the responses to the comment solicitation in the CY 2019 ESRD PPS proposed rule expressed concerns that expanding the scope of ESRD outlier services would potentially dilute the impact of the outlier adjustment. We explained that for CY 2025 we considered the potential impact of expanding the definition of ESRD outlier services to include additional drugs and biological products not currently included. We stated that we agree with the commenters who noted that the purpose of the outlier payment is not to pay for new drugs and biological products (83 FR 56969). We further stated that in the CY 2011 ESRD PPS final rule (75 FR 49134), CMS established the current outlier policy, including the 1.0 percent outlier target, because it struck an appropriate balance between our objective of paying an adequate amount for the costliest, most resource-intensive patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We noted that under our current policy, new renal dialysis drugs and biological products that are paid for using the TDAPA are not considered ESRD outlier services. As we explained in the CY 2016 ESRD PPS final rule (80 FR 69023), this is because during the TDAPA period we make a payment adjustment for the specific drug in addition to the base rate, whereas outlier services have been incorporated into the base rate. In contrast, we noted that the post-TDAPA add-on payment adjustment is paid on all claims, and drugs that are included in the post-TDAPA add-on payment adjustment amount are considered included in the ESRD PPS base rate. We explained that as a result, the amount paid under the post-TDAPA add-on payment adjustment does not correspond to the amount of a drug or biological product used on a claim, which would not be accounted for in any existing payment adjustment other than the outlier adjustment. For example, we stated that our analysis shows that patients using Korsuva® have costs of approximately $150 per treatment; however, because this drug is not recognized as an ESRD outlier service, these costs are not accounted for in determining the payment amount for the claim. Beginning April 1, 2024, the CY 2024 post-TDAPA add-on payment adjustment for Korsuva®

increases the payment amount per treatment by approximately $0.25, which is adjusted by the patient-level case-mix adjusters applicable to the claim. In aggregate, the post-TDAPA add-on payment adjustment accounts for 65 percent of the cost of furnishing Korsuva®; however, this payment is spread across all ESRD PPS treatments.

In the proposed rule, we explained that we did not propose to expand outlier eligibility to drugs and biological products that are paid for using the TDAPA during the TDAPA period, as the TDAPA amount is based on the full price (100 percent of ASP) for the amount of such drugs that is utilized and billed on the claim.

We further explained that we considered only expanding the definition of ESRD outlier services to include drugs and biological products that were previously paid for using the TDAPA. We noted the suggestion of past commenters that new renal dialysis drugs and biological products are likely to be drivers of cost, because these drugs are typically more expensive. We explained that we recognized the importance of supporting access to new renal dialysis drugs and biological products under the ESRD PPS through the establishment of the post-TDAPA add-on payment adjustment beginning in CY 2024 (88 FR 76391). We further noted that in the CY 2024 ESRD PPS final rule we agreed with commenters who expressed concerns that the ESRD PPS' current mechanisms may not fully account for the costs of these new drugs (88 FR 76388). We noted that several commenters stated that the outlier adjustment and the ESRDB market basket updates cannot adequately account for these costs, and several organizations noted that if additional renal dialysis drugs and biological products with significant costs were incorporated into the outlier payment calculation, the threshold to qualify for outlier payments would increase dramatically, thus adversely affecting access to products traditionally eligible for the outlier payment adjustment. We described comments which expressed that this increase in the outlier threshold may also raise health equity concerns because, as we noted in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67171), the outlier adjustment protects access for beneficiaries whose care is unusually costly. We recognized that if the outlier threshold were to increase significantly due to significant use of a new renal dialysis drug or biological product after the end of the TDAPA period, then ESRD facilities might be incentivized to avoid treating costlier beneficiaries.

We stated that we believe it would be appropriate for the definition of ESRD outlier services to include all drugs and biological products that previously were paid for using the TDAPA. We explained that the inclusion of these drugs and biological products would help ensure appropriate payment when a patient's treatment is exceptionally expensive due to an ESRD facility furnishing such drugs or biological products to the patient whose treatment requires them. In the CY 2011 ESRD PPS proposed rule, we explained that significant variations in formerly separately billable items and services could impair access to appropriate care, as an ESRD facility may have a disincentive to provide adequate treatment to those ESRD patients likely to have significantly higher than average costs (74 FR 49988). We stated in the CY 2025 ESRD PPS proposed rule that we believe ESRD facilities may face similar disincentives for furnishing drugs and biological products that previously received payment under the TDAPA. We further stated that we believe this change would also align with the statutory authority for the outlier adjustment under section 1881(b)(14)(D)(ii) of the Act by protecting patients' access to medically necessary care through a payment adjustment that more fully recognizes unusual variations in the type or amount of such care. Specifically, we explained that we believe this change would encourage ESRD facilities to take on ESRD patients who would potentially require expensive new drugs and biological products, promoting health equity for these patients who require costlier care. Additionally, we noted that the technical changes we proposed, and which we are finalizing in section II.B.3.c of this final rule, would limit the impact of such drugs and biological products on the outlier threshold calculation, thereby enabling the ESRD PPS outlier adjustment to continue to protect access for beneficiaries whose care is unusually costly.

We stated that in light of the past comments that we described in the proposed rule, we further considered whether expanding eligibility to all renal dialysis drugs and biological products that are Composite Rate Services, as defined at § 413.171, would be appropriate. We reiterated that the purpose of the outlier adjustment is to protect access for beneficiaries whose care is unusually costly. We stated that although we continue to expect that the main drivers of cost would be drugs and biological products that were previously separately billable under Part B or Part D, or were previously paid for using the TDAPA, we nevertheless recognize that some patients could require higher utilization of composite rate drugs and biological products, which may result in the overall cost of their renal dialysis care being unusually high. For example, as we noted in section II.B.3.e of the proposed rule, our analysis identified that certain composite rate drugs are significant drivers of cost for pediatric patients, and therefore the proposed inclusion of those drugs as ESRD outlier services would improve the ability of the ESRD PPS outlier adjustment to target payment for pediatric patients whose care is exceptionally costly. We stated that including composite rate drugs and biological products in the calculation of the outlier adjustment could appropriately support care for such ESRD patients, because payments under the outlier adjustment would better align with resource use.

We explained that we also considered the comments from MedPAC in response to the CY 2019 ESRD PPS proposed rule. Specifically, MedPAC stated that to develop an effective outlier policy, CMS must first develop accurate patient-level and facility-level payment adjustments. As we stated in the CY 2024 ESRD PPS final rule, interested parties have encouraged CMS to develop a patient cost model that is based on a single patient-level cost variable that accounts for all composite rate and formerly separately billable services (88 FR 76399). We noted that we finalized the collection of time on machine data, beginning for CY 2025, which we stated would allow for a higher proportion of composite rate costs to be allocated to patients with longer renal dialysis treatment times, and ultimately inform CMS refinements to existing patient-level adjusters, including age and comorbidities (88 FR 76400). We stated that we believe expanding the definition of ESRD outlier services could further support our understanding of the costs of Composite Rate Services, because it would encourage more comprehensive reporting of renal dialysis drugs and biological products that were formerly included in the composite rate for the purposes of calculating outlier payments. We further stated that this increased reporting would in turn support future revisions to patient-level adjustment factors that consider more complete information about costs at the patient level.

We stated that we do not agree that the proposed inclusion of composite rate drugs and biological products would dilute the impact of the outlier

adjustment, as some commenters in response to the CY 2019 ESRD PPS proposed rule suggested. Rather, we explained that our analysis indicates the inclusion of these drugs and biological products would appropriately recognize the situations when the provision of these services is unusually costly, which we estimate would increase the amount of outlier payment per outlier-eligible claim, thereby more effectively protecting access for beneficiaries whose care is exceptionally costly. We stated that if we made no changes to our outlier methodology or the definition of ESRD outlier services for CY 2025, the average outlier payment for outlier-eligible cases among pediatric patients would be $25.02, and the average outlier payment for adult patients would be $53.45. We noted that under the proposed changes to outlier eligibility, the average outlier payment for pediatric and adult patients would increase to $73.24 and $57.16, respectively. Furthermore, we explained that the inclusion of composite rate drugs and biological products would increase the pediatric MAP amount by a large amount, reflecting the utilization of certain high-cost composite rate drugs. We explained that although the proposed CY 2025 adult MAP amount was lower than the final CY 2024 adult MAP amount, the proposed adult MAP amount for CY 2025 was approximately $0.79 higher than it would have been absent the proposed policy changes in this rule, which we stated demonstrates that the inclusion of composite rate drugs and biological products would result in a higher MAP amount for adults.

In summary, we stated that the inclusion of composite rate drugs and biological products as ESRD outlier services would include more costs in the calculation of the ESRD PPS outlier adjustment for each case. We explained that as a result, fewer claims would qualify for outlier payments, but the amount of outlier payment per claim would be higher. Therefore, we stated that rather than diluting the impact of the outlier adjustment, these proposed changes would increase the impact of the outlier adjustment.

We proposed to amend the language at 42 CFR 413.237 by adding a new paragraph (a)(1)(vii), which would add to the list of renal dialysis services defined as ESRD outlier services the following: ''Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.''

We invited public comment on our proposal to include renal dialysis drugs and biological products that are composite rate services in the definition of ESRD outlier services. Approximately 13 commenters commented on this proposal. These commenters included LDOs, drug manufacturers, a nonprofit dialysis organization, a nonprofit kidney care alliance, a professional organization of nephrologists, a coalition of dialysis organizations, and MedPAC. The following is a summary of the public comments received on this proposal and our responses.

Comment: Several commenters expressed support for the proposed definition of ESRD outlier services. One LDO stated its belief that new drugs regardless of their status as a former composite rate service should be eligible for outlier payment. Similarly, a professional organization of nephrologists stated that if the proposed definition of ESRD outlier services is finalized, it would educate its members about this change and the importance of pediatric dialysis units appropriately billing for use of alteplase and other qualifying drugs to collect the outlier payment when appropriate. This commenter requested that CMS highlight any specific requirements for billing.

MedPAC likewise expressed support for expanding ESRD outlier services to include drugs and biological products that were or would have been included in the composite rate prior to the ESRD PPS. MedPAC reiterated its position that CMS should develop an outlier policy that addresses variation in the total cost of providing the entire ESRD PPS payment bundle, thereby avoiding the potential for misidentifying outliers (for example, a patient with very high costs for outlier-eligible services may have offsetting, lower costs for outlier-ineligible services). MedPAC further explained that considering the cost of the full ESRD PPS payment bundle would be more patient-centric and would align the ESRD PPS outlier policy with the policies that Medicare uses for other PPSs. One commenter expressed that CMS's continued reliance upon a distinction between ''composite rate'' and other products continues to confound the goals of moving the ESRD PPS toward a modern standard of care.

Response: We appreciate the comments in support of the proposed change to the definition of ESRD outlier services. We agree with commenters that the proposed definition would more broadly recognize ESRD PPS patients whose care is costlier. Regarding the commenter's statement that the distinction between renal dialysis drugs and biological products that were formerly separately billable and those that were or would have been historically paid under the composite rate does not best serve the goals of the ESRD PPS, we note that this distinction derives from the statutory definition of renal dialysis services in section 1881(b)(14)(B)(iii) of the Act. However, we recognize that providing payment under the ESRD PPS outlier adjustment for former composite rate and non-composite rate services would better serve CMS's goals, specifically CMS's longstanding efforts to develop a comprehensive patient cost model for the purposes of considering future refinements to the ESRD PPS adjustment factors.

In response to the request for specific billing guidance, we direct readers to the Medicare Claims Processing Manual (CPM), Chapter 8. ESRD facilities are instructed to report all renal dialysis drugs and biological products on the claim. Specific information about revenue codes and other billing requirements are found in section 50.2 of Chapter 8 of the CPM.

Comment: Several commenters, including LDOs, drug manufacturers, a nonprofit dialysis organization, a coalition of dialysis organizations, and a professional organization of nephrologists expressed that the proposed change to the definition of ESRD outlier services does not address what commenters stated is an underlying lack of payment adequacy for new drugs that are renal dialysis services. One LDO acknowledged that access to outlier funds is a small step in the right direction but stated that CMS policy for incorporating such drugs into the PPS is insufficient to adequately compensate dialysis providers. This commenter further stated that new drugs that represent a substantial clinical improvement should be incorporated into the bundled payment with new money regardless of their placement in a functional category. As an example of how the commenter believes the current policy is flawed, this commenter noted that lack of adequate payment has artificially depressed access to Korsuva® treatment and that nephrologists are reluctant to prescribe a therapy that does not have adequate long-term funding. Several commenters stated that approximately 16 percent of the ESRD patient population has severe pruritus for which Korsuva® is indicated. These commenters noted that if all of these patients were to receive Korsuva®, the total outlier payment for that one drug would be $350 million for CY 2025, more than three times the current outlier pool. Another commenter stated that changes still need to be made to fix the base rate and support innovation in

new drugs, biological products, and devices for pediatric kidney patients.

Several commenters stated that CMS should not finalize the proposed definition of ESRD outlier services but should instead advance funding mechanisms that would appropriately safeguard patient access to new drugs and biological products after the two-year TDAPA period expires.

Response: We appreciate the commenters' concerns regarding payment for new renal dialysis drugs and biological products under the ESRD PPS. As the commenters pointed out, and as we have previously stated, the purpose of the ESRD PPS outlier adjustment is not to pay for new drugs and biological products. Rather, the purpose of the ESRD PPS outlier adjustment is to protect access to care for beneficiaries whose care is exceptionally costly. In the proposed rule, we stated that including new renal dialysis drugs that previously received payment using the TDAPA would help ensure appropriate payment when a patient's treatment is exceptionally expensive due to an ESRD facility furnishing such drugs or biological products to the patient whose treatment requires them.

We disagree with commenters who stated that lack of adequate payment has artificially depressed access to Korsuva® treatment and that nephrologists are reluctant to prescribe a therapy that the commenters stated does not have adequate long-term funding. Nephrologists and ESRD patients make decisions about which drugs and biological products best serve the patients' needs, and these decisions depend on a number of factors including but not limited to considerations about the efficacy for the individual patient, side effects and interactions with other drugs and biological products the patient may be taking, and considerations related to affordability for the patient. As we explained in the CY 2019 ESRD PPS final rule, the purpose of providing the TDAPA for drugs that fall into an existing functional category is to help ESRD facilities to incorporate new drugs and make appropriate changes in their businesses to adopt such drugs; provide additional payment for such associated costs, as well as promote competition among drugs and biological products within the ESRD PPS functional categories (83 FR 56935). A new renal dialysis drug or biological product must demonstrate to patients and nephrologists that it presents value relative to existing treatment options, and the TDAPA further allows new products to become competitive by providing payment at 100 percent of ASP for the new drug or biological product. We expect that nephrologists and patients would consider all relevant factors and all available treatment options, and make the most appropriate decision for each patient. We do not believe we can infer that utilization of Korsuva® was depressed due to lack of adequate payment during the TDAPA period, because payment under the TDAPA for Korsuva® was based on 100 percent of ASP. Furthermore, in the CY 2024 ESRD PPS final rule, we finalized a policy to pay a post-TDAPA add-on payment adjustment for a period of 3 years following the payment of TDAPA. We stated that one goal of the post-TDAPA add-on payment adjustment is to support continued access to new renal dialysis drugs and biological products and to support ESRD facilities' long-term planning and budgeting for such drugs after the TDAPA period (88 FR 76393). Therefore, we believe that ESRD PPS policy provides appropriate and adequate payment in the short term during the 2-year TDAPA period, in the medium term during the 3 years of payment under the post-TDAPA add-on payment adjustment following the payment of TDAPA, and during the long term when such new renal dialysis drugs and biological products are paid for under the ESRD PPS base rate with no adjustment and are expected to compete with other drugs and biological products in the ESRD PPS.

We also cannot assume that utilization of Korsuva® should be higher than it was during the TDAPA period or that it would increase in response to the proposed outlier policy changes. We note that utilization of Korsuva® during the TDAPA period was significantly lower than the 16 percent figure cited by the commenters. We anticipate that the utilization of Korsuva® in CY 2025 would align with the levels of utilization observed during the TDAPA period, as these levels best reflect the actual prescribing patterns of nephrologists for that drug. Nevertheless, if utilization for Korsuva® were to increase significantly in CY 2025, then under our longstanding outlier methodology we would take such changes in utilization into consideration when establishing the FDL and MAP amounts prospectively in future years. As we have stated, we establish the outlier FDL and MAP amounts each year at a level that our analysis indicates would effectively protect access for the costliest beneficiaries while maintaining an appropriate ESRD PPS base rate for all other beneficiaries.

Lastly, we do not believe that the current definition of ESRD outlier services better supports payment for new renal dialysis drugs and biological products than the proposed definition, because it excludes new renal dialysis drugs and biological products that are substitutes for drugs and biological products that were included in the composite rate. That is, the current definition of ESRD outlier services excludes certain new renal dialysis drugs and biological products that may be significant drivers of cost, and therefore we do not believe it would be more appropriate to maintain the existing definition of ESRD outlier services. We believe our proposed definition of ESRD outlier services would be more appropriate, because it would recognize all renal dialysis drugs and biological products that are significant drivers of cost for ESRD patients. Therefore, as discussed later in this final rule, we are finalizing our proposed revision to the definition of ESRD outlier services. We refer readers to section II.B.4 of this CY 2025 ESRD PPS final rule for a discussion about payment for innovation and the ESRD PPS base rate.

Comment: MedPAC reiterated its prior concerns from the CY 2019 ESRD PPS proposed rule about how CMS estimates the ESRD PPS's case-mix adjustments, including patient-level adjustments, and the accuracy of the adjustments' coefficients. MedPAC stated that these coefficients are used to calculate the Medicare allowable payment amount, which when combined with the fixed dollar loss amount, determines which treatments will receive an outlier payment. Therefore, MedPAC stated that to ensure the ability of the outlier policy to account for beneficiaries with high costs, the agency must improve the accuracy of the ESRD PPS's patient- and facility-level payment adjustments.

Response: We agree with MedPAC's assessment of the importance of accurate ESRD PPS case-mix adjustments for the ESRD PPS outlier adjustment. As we noted in the proposed rule, we believe expanding the definition of ESRD outlier services could further support our understanding of the costs of Composite Rate Services, because it would encourage more comprehensive reporting of renal dialysis drugs and biological products that were formerly included in the composite rate for the purposes of calculating outlier payments. In addition, we anticipate that this increased reporting would support future revisions to patient-level adjustment factors that consider more

complete information about the cost of furnishing renal dialysis services to a patient.

Comment: One commenter stated that a smaller outlier percentage on the order of 0.5 percent would be preferable to maintaining the existing 1.0 percent outlier percentage. This commenter encouraged CMS to consider exercising its discretion to set a lower outlier percentage.

Response: While we agree that section 1881(b)(14)(D)(ii) of the Act provides the Secretary with discretion to set an appropriate outlier percentage under the ESRD PPS, we note that we continue to believe the 1.0 percent target is more appropriate than a lower outlier percentage. As discussed in the CY 2011 ESRD PPS final rule (75 FR 49134), we established the 1.0 percent outlier percentage because it struck an appropriate balance between our objective of paying an adequate amount for the costliest, most resource-intensive patients while providing an appropriate level of payment for those patients who do not qualify for outlier payments. We continue to believe the 1.0 percent target strikes the appropriate balance, and as we further noted in the CY 2023 ESRD PPS final rule (87 FR 67171), a reduced outlier percentage may not provide the appropriate level of payment for outlier cases and may not protect access for beneficiaries whose care is unusually costly. This is because if we were to decrease the target outlier percentage, we would need to significantly increase the FDL amounts, which would make it more difficult for ESRD facilities to receive outlier payment based on their claims. We did not propose to reduce the outlier percentage for CY 2025, and we are not finalizing any such reduction in this rule.

Comment: Several commenters expressed concern about the burden of reporting renal dialysis drugs and biological products that were or would have been paid under the composite rate before the establishment of the ESRD PPS, and about the reliability of such reported data. One commenter stated that these drugs would not make any difference in a facility getting an outlier payment because of the relatively inexpensive cost of such drugs compared to new high-cost drugs on the market now or in the future. Other commenters acknowledged that the reporting of information on composite rate drugs is not as comprehensive as other data elements but stated that this is because ESRD facilities have never been required to report information about composite rate drugs and biological products because such information does not serve any ESRD PPS-related purpose. Several commenters stated that the observed disparity in alteplase utilization described in the CY 2025 ESRD PPS proposed rule is a difference in reporting and not a meaningful clinical or operational difference. An LDO and a coalition of dialysis organizations expressed concerns about CMS's ability to calculate MAP and FDL amounts for CY 2025 given the lack of complete information about utilization of composite rate drugs and biological products.

Response: We appreciate the concerns that commenters raised about the completeness of data on the utilization of composite rate drugs and the perceived burden associated with reporting these drugs on ESRD PPS claims. We disagree with the commenters who stated that composite rate drugs and biological products would not make any difference in a facility receiving payment under the outlier adjustment. As we explained in the proposed rule, we found that certain composite rate drugs such as alteplase were significant drivers of cost for pediatric patients. Although we acknowledge that some composite rate drugs and biological products are relatively low-cost, our analysis has found that this is not generally true of all composite rate drugs. We believe it would be most appropriate to make payment under the outlier adjustment for any renal dialysis drugs and biological products that do cause a patient's ESRD treatment to be exceptionally costly.

We further disagree with the commenters who stated that the proposed definition of ESRD outlier services would expand reporting burden for ESRD facilities. Section 60.2 of Chapter 8 of the CPM states that effective January 1, 2011, section 153b of the MIPPA requires that all drugs and biologicals used in the treatment of ESRD are included in the ESRD PPS payment amount and must be billed by the ESRD facility. Although we acknowledge that many ESRD facilities have not historically included composite rate drugs and biological products on ESRD PPS claims, we remind readers that ESRD facilities have long been encouraged to report all renal dialysis drugs and biological products on ESRD PPS claims, including composite rate drugs. In the CY 2016 ESRD PPS final rule (80 FR 69033), we clarified that ESRD facilities should begin reporting on their monthly claims those composite rate drugs that are on the consolidated billing list. Therefore, the proposal to change the definition of ESRD outlier services would not change the requirements for ESRD facilities to report composite rate drugs on ESRD PPS claims. In fact, we observe in our analysis of ESRD PPS claims data that hospital-based ESRD facilities are already more consistently reporting composite rate items and services, which in part explains the outsized impact of composite rate drugs and biological products on the FDL and MAP amounts for pediatric patients, who more frequently receive renal dialysis services from hospital-based ESRD facilities. In addition to reporting differences, we believe the differential rates of alteplase utilization between pediatric patients and adult patients could be related to higher rates of catheter use among pediatric patients.

Lastly, we do not agree with the concerns that commenters articulated about CMS's ability to calculate MAP and FDL amounts for CY 2025 given the lack of complete information about utilization of composite rate drugs and biological products. Our longstanding methodology for prospectively setting the MAP and FDL amounts uses the best available year of ESRD PPS claims, which is generally the most recent available year, to simulate claims for the upcoming CY. Additionally, we use the three most recent years to calculate the FDL amount which would have achieved the 1 percent outlier target. In any given year, changes in utilization of ESRD outlier services from the historical claims data to the upcoming CY can result in over- or under-estimates of the outlier percentage. CMS relies on the information reported by ESRD facilities for accurate modeling of ESRD PPS outlier payments. To the extent that the proposed change to the definition of ESRD outlier services further encourages ESRD facilities to report when composite rate drugs and biological products are used, we believe this would result in future claims data that is more complete and better fit for not only estimating future outlier payments, but also for analyzing comprehensive patient-level cost information to potentially inform future revisions to ESRD PPS adjustment factors.

Comment: Several commenters, including LDOs, drug manufacturers, a nonprofit dialysis organization, and a coalition of dialysis organizations, expressed concern that the proposed change to the definition of ESRD outlier services could result in outlier payments that exceed the 1.0 percent outlier percentage. Some commenters stated that since the 1.0 percent outlier percentage was achieved in CY 2023, CMS should use caution before making

further changes to the outlier policy. One commenter suggested that CMS might be required to reduce the ESRD PPS base rate if the 1.0 percent outlier percentage is exceeded in future years.

Response: We are reiterating that our longstanding methodology establishes FDL and MAP amounts prospectively. That is, we establish the outlier FDL and MAP amounts each year at a level that our analysis indicates will effectively protect access for the costliest beneficiaries while maintaining an appropriate ESRD PPS base rate for all other beneficiaries. If our analysis indicates that the FDL and MAP amounts would result in outlier payments that are below 1.0 percent, we would reduce the FDL and MAP amounts accordingly in the subsequent year. Alternatively, if our analysis indicates that the FDL and MAP amounts would result in outlier payments that are above 1.0 percent, we would increase the FDL and MAP amounts accordingly in the subsequent year. In this methodology, we do not make modifications to the base rate in response to either exceeding or falling short of the 1.0 percent outlier percentage target.

Final Rule Action: After consideration of the comments, we are finalizing our proposal to amend the language at 42 CFR 413.237 by adding a new paragraph (a)(1)(vii), which adds the following to the list of renal dialysis services defined as ESRD outlier services: ''Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.'' The final CY 2025 FDL and MAP amounts are discussed in section II.B.3.e of this final rule.

c. Changes to Predicted MAP Calculation for Outlier Eligibility

As we discussed in the CY 2023 ESRD PPS final rule (87 FR 67169), a claim is eligible for outlier payment when its imputed MAP amount exceeds the sum of the predicted MAP amount and the fixed dollar loss threshold. The predicted MAP amount for a claim is based on the national average MAP amount, adjusted by the case-mix adjustment factors that apply for that claim's patient-level and facility-level characteristics. As a result, when a claim's adjustment factors increase the payment amount per treatment, the claim's predicted MAP is also increased. This is because we expect that more complex patients would require a higher amount of spending for outlier services. However, this higher expected cost is recognized through a higher per treatment payment amount. In other words, a more complex patient must have even higher costs than are already accounted for in the adjustment factors compared to a less complex patient to be considered unusually costly. By increasing the predicted MAP based on the case-mix adjustment factors, the ESRD PPS outlier policy ensures that only cases that are unusually costly are considered for outlier payment.

As previously discussed in this final rule, we finalized a post-TDAPA add-on payment adjustment in the CY 2024 ESRD PPS final rule. The post-TDAPA add-on payment adjustment for certain new renal dialysis drugs and biological products is generally applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). The amount of this post-TDAPA add-on payment adjustment that is applied to an ESRD PPS claim is adjusted by any applicable patient-level case-mix adjustments under § 413.235, and this adjusted amount is added to the payment amount for each ESRD PPS treatment billed. We explained in the CY 2024 ESRD PPS final rule that during this 3-year post-TDAPA add-on payment period, a drug or biological product would be eligible for the outlier add-on payment if it met all of the other criteria for the outlier payment (88 FR 76396). The only drug or biological product which was set to end its TDAPA period in CY 2024 (and therefore would receive the post-TDAPA add-on payment adjustment that year) was Korsuva®, which is a substitute for a composite rate drug and, therefore, not outlier eligible under existing § 413.237(a)(1) (88 FR 76396). Accordingly, we did not propose any changes to the ESRD PPS outlier methodology to account for the post-TDAPA add-on payment adjustment in the CY 2024 ESRD PPS proposed rule as that would not have affected payments for CY 2024.

As discussed in section II.B.3.b of this final rule, we are finalizing our proposal to expand outlier eligibility to include renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171. This means that new drugs and biological products that are included in the calculation of the post-TDAPA add-on payment adjustment amount will become outlier eligible after the end of the TDAPA period, regardless of whether they are substitutes for composite rate drugs or biological products.

Accordingly, in the CY 2025 ESRD PPS proposed rule, we also proposed changes to the ESRD PPS outlier methodology to account for any future drugs and biological products which are outlier eligible during the post-TDAPA period. We proposed to add the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for a patient. We stated that this is appropriate because the post-TDAPA add-on payment adjustment amount represents average utilization of a drug or biological product, and is added to the payment amount, adjusted by the case-mix adjusters for the patient. We stated that this proposal would prevent duplicate payment for these drugs and biological products by accounting for the portion of the cost for these drugs or biological products which is included in the ESRD PPS bundled payment. We noted that this change would not affect the calculation of the imputed MAP for a claim, because a claim's imputed MAP would include the actual utilization of the drug or biological product that is included in the calculation of the post-TDAPA add-on payment adjustment, if that drug or biological product is billed on the claim.

We explained that we considered modifying the average MAP amount to account for outlier eligible drugs and biological products that are already included in the calculation of the post-TDAPA add-on payment adjustment amount, rather than proposing to modify the predicted MAP amount for each claim. However, we noted two main limitations with taking such an approach. First, the average MAP is set annually for an entire year and does not change from quarter to quarter; in contrast, the post-TDAPA add-on payment adjustment amount can change from quarter to quarter depending on when a drug or biological product's TDAPA period ends, and depending on the number of drugs and biological products included in the calculation. Second, our longstanding methodology for calculating the predicted MAP for outlier payments applies the outlier services multipliers to the average MAP. However, when we calculate the post-TDAPA add-on payment adjustment amount for a claim, we apply the ESRD PPS case-mix adjusters, which are different from the outlier services multipliers. We stated that we believe it would be most appropriate to continue to apply the ESRD PPS case-mix adjusters to the post-TDAPA add-on payment adjustment amount for the purposes of outlier calculation, so that the estimate of a claim's expected spending would align with the calculation used for the post-TDAPA add-on payment adjustment. For these reasons, we stated that we believe that it is more appropriate and more operationally feasible to apply the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for claims during the

quarters in which the drug or biological product is receiving the post-TDAPA add-on payment adjustment, rather than publishing different average MAPs for different quarters of a single year.

For CY 2025, we explained that the impact of this technical modification would be a small increase to the pediatric and adult FDL amounts, due to the small post-TDAPA add-on payment adjustment amount calculated for each quarter of CY 2025, which is discussed in section II.B.6 of this final rule. We noted that without this proposed methodological change, the pediatric FDL amount would increase by $0.68. Likewise, we noted that the adult FDL amount would increase by $0.89. We stated that this proposed methodological change would avoid those increases, resulting in the proposed CY 2025 adult and pediatric MAP and FDL amounts shown in Table 7 of the proposed rule. We noted that although the effect would be small for CY 2025, the increase would be larger in potential future situations when utilization of a drug or biological product during the post-TDAPA period could be higher.

We invited public comment on our proposal to apply the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for claims during the quarters in which the drug or biological product is receiving the post-TDAPA add-on payment adjustment. Two commenters commented on this proposal. The following is a summary of the public comments received on these proposals and our responses.

Comment: MedPAC reiterated its concerns about how CMS estimates the ESRD PPS case-mix adjustments and recommended that CMS must improve the accuracy of the patient- and facility-level adjustments.

Response: We appreciate the recommendation, and as discussed earlier in this final rule, we believe that the proposed change to the definition of ESRD outlier services, combined with the collection of time on machine data beginning January 1, 2025, will contribute to CMS's ability to develop a patient cost model for the purposes of considering future refinements to the patient- and facility-level adjustments. We believe the application of the case-mix adjusted post-TDAPA add-on payment adjustment to the predicted MAP is the most technically appropriate methodology for calculating the predicted MAP in CY 2025 and future years. We would incorporate any relevant revisions to the patient-level case-mix adjustments into this calculation in future years, as appropriate.

Comment: One commenter stated that CMS should not include TDAPA or TPNIES values in outlier calculation for any future drugs or equipment and supplies that may be eligible for these adjustments as they are clearly not eligible for outlier services during the TDAPA or TPNIES period.

Response: We agree that under our longstanding policy, which CMS established in the CY 2016 ESRD PPS final rule (80 FR 69023), it would not be appropriate to include the payment amount for a new drug or biological product in the outlier calculation during the TDAPA period. Accordingly, we have excluded drugs that are receiving the TDAPA from the outlier calculation, and our calculations of the FDL and MAP amounts do not include TDAPA utilization as outlier-eligible utilization for drugs and biological products that will be paid under the TDAPA in the upcoming CY. However, we note that under § 413.220(b)(4), we established the outlier percentage is 1.0 percent of total payments (75 FR 49142 through 49143). By definition, total ESRD PPS expenditures for the non-outlier components include the base rate, TDAPA, TPNIES, post-TDAPA add-on payment adjustment, and other applicable adjustments. Additionally, since the TPNIES and TDAPA are components of the non-outlier portion of the total ESRD PPS spending, to remove them would shrink the base for which the total outlier target payment amount is calculated, and therefore increase the FDL and outlier threshold. In addition, as we finalized in the CY 2023 ESRD PPS final rule, we rely on historical TDAPA and TPNIES spending amounts to calculate the ''alternative'' retrospective FDL calculations for ESRD outlier services, which allows our projection of the FDL to appropriately account for increased utilization of ESRD outlier services in years when a new renal dialysis drug or biological product becomes an ESRD outlier service after the end if its TDAPA period (87 FR 67172 through 67175).

We are clarifying that we did not propose to include TDAPA or TPNIES values in the outlier calculation for CY 2025. Rather, the proposed incorporation of the post-TDAPA add-on payment adjustment to the predicted MAP would apply only for ESRD outlier services if the TDAPA period for such drugs or biological products has already ended, as they are excluded from the outlier calculation during the TDAPA period based on our longstanding policy, as discussed in the prior paragraph.

Final Rule Action: After consideration of the comments received, we are finalizing our proposal to apply the case-mix adjusted post-TDAPA add-on payment adjustment amount to the predicted MAP for claims during the quarters in which the drug or biological product is receiving the post-TDAPA add-on payment adjustment.

d. Technical Modifications to the Inflation Factors Used for the Outlier Calculations

(1) Background

In the CY 2011 ESRD PPS final rule we finalized our ESRD PPS outlier methodology, which included our methodology for updating data from past years to the CY for which CMS is establishing payment rates (75 FR 49134). In the CY 2023 ESRD PPS final rule, we finalized an update to the outlier methodology to better target 1.0 percent of total Medicare payments (87 FR 67170 through 67177) by prospectively calculating the adult FDL amounts based on the historical trend in FDL amounts that would have achieved the 1.0 percent outlier target in the 3 most recent available data years. In that final rule we also clarified our longstanding methodology for updating data from prior years for the purposes of the outlier calculations (87 FR 67167). For drugs and biological products, we use a blended 4-quarter moving average of the ESRDB market basket price proxies for pharmaceuticals to inflate drug prices to the CY for which CMS is establishing payment rates. For laboratory tests, we inflate prices to the CY for which CMS is establishing payment rates using a CPI forecast to estimate changes for years in which a new data reporting period will take place for the purpose of setting Clinical Laboratory Fee Schedule (CLFS) rates.[33] For supplies, we apply a 0 percent inflation factor, because these prices are based on predetermined fees or prices established by the Medicare contractor.

In the CY 2023 ESRD PPS final rule (87 FR 67173), we noted that MedPAC supported the proposed revisions to the FDL methodology, but also urged CMS to refine its approach for applying the pricing data that the agency uses to project future spending for outlier services, particularly for drugs. Specifically, MedPAC suggested CMS use a drug price inflation factor based on ASP values and noted that the ASP data that CMS uses to determine

[33] Since 2018, there has been no updated reporting for most clinical diagnostic laboratory tests; therefore, the forecast estimate used since CY 2018 for the ESRD PPS outlier methodology has been 0.

facilities' actual outlier payments might be a more accurate data source on drug prices than the ESRDB market basket pharmaceutical price proxies that are currently used.

For CY 2025, we stated that we have undertaken analysis of prices for ESRD outlier services and proposed several technical changes to the inflation factors, which are discussed in the following sections.

(2) Changes to the Inflation Factor for Outlier Eligible Drugs and Biological Products

As described earlier, we use a blended 4-quarter moving average of the ESRDB market basket price proxy for Pharmaceuticals to inflate drug prices to the upcoming CY for the purpose of estimating spending for outlier drugs and biological products in that CY. In the proposed rule, we explained that historically, this 4-quarter moving average is a positive factor, meaning that our longstanding methodology for modeling outlier spending amounts assumes that prices for ESRD outlier drugs and biological product will increase. For example, we noted that the projection of the CY 2025 price growth for ESRD outlier drugs and biological products, based on the ESRDB market basket price proxy for Pharmaceuticals for the CY 2025, was 1.9 percent, based on the IGI 1st quarter 2024 forecast with historical data through the 4th quarter of 2023.

We explained that to compare the actual changes in prices for ESRD outlier drugs and biological products against the assumed rate of change derived from the ESRDB market basket price proxies, we constructed an index of prices for ESRD outlier drugs and biological products. As we discussed in section II.B.3.b of the proposed rule, we proposed to expand the definition of ESRD outlier services to include renal dialysis drugs and biological products that were or would have been included in the composite rate prior to the establishment of the ESRD PPS. Accordingly, our constructed drug price index included these drugs and biological products as well as drugs and biological products that have historically been included in the definition of ESRD outlier services.

We stated that because the list of ESRD outlier drugs and biological products changes over time, we proposed to derive a chained Laspeyres price index of the drugs and biological products included in the definition of the ESRD outlier services. We explained that a chained Laspeyres price index does not require a fixed basket of drugs and biological products during the observation window. We explained that we constructed and then trended forward the year-over-year change in price index levels for this outlier drug index to calculate a projected inflation factor for ESRD outlier drugs and biological products for CY 2025, using the following steps:

Step 1: We obtained the annual list of ESRD outlier service drugs and biological products that appear in ESRD PPS claims during the CYs 2017 through 2023. These include both composite rate and formerly separately billable drugs and biological products.

Step 2: We obtained quarterly ASP for each drug and biological product during the same period 2017 through 2023, substituting annual ASP when quarterly information was not available.

Step 3: We obtained quarterly utilization data for each drug and biological product for the period 2017 through 2023.

Step 4: For each quarter, we established the base period as the prior quarter and held utilization fixed at the base period. We then constructed a Laspeyres price index based on all drugs and biological products that had price information in that quarter and the prior quarter.

Step 5: We chained together the quarterly indices starting from the 1st quarter 2017 through the 4th quarter 2023 to express price changes in the 4th quarter 2017 relative to the 1st quarter 2017. This step was repeated for all prior quarters, keeping the starting period fixed at the 1st quarter 2017.

Step 6: We calculated the percentage change between the current and prior 4th quarter chained price index for each year for CY 2021, 2022, and 2023, which we used as the annual drug price inflation factor for each year.

Step 7: Using the chained price indexes for the three most recent CYs (2021, 2022, and 2023), we used a linear regression to project forward these three historical inflation factors to determine the CY 2025 inflation factor.

Using this methodology, we calculated a projected inflation factor of -0.7 percent, meaning that prices for ESRD outlier drugs and biological products were projected to be 0.7 percent lower in CY 2025 relative to the prices of the ESRD outlier drugs and biological products in than in CY 2024. We noted that our analysis of year-over year changes in prices for ESRD outlier drugs and biological products shows a consistent, downward trend in prices, which stands in contrast to the positive inflation factors we have historically used to model outlier payments. As a result, we stated that our modeling of outlier spending in prior years has assumed that outlier prices will increase, when the ASP data shows that, overall, the prices have decreased.

Based on the results of our analysis, we stated that we believe applying an inflation factor based on the actual change in prices for ESRD outlier drugs and biological products would enable the ESRD PPS outlier adjustment to better target 1.0 percent of outlier payments in CY 2025, because such an inflation factor would better reflect the observed historical trend in spending and utilization for such drugs and biological products. We noted that although we have historically used the ESRDB market basket price proxy for Pharmaceuticals as the basis of our inflation assumptions for outlier modeling, and we believe that market basket price proxies would continue to be a reasonable and technically appropriate source for such assumptions, the market basket price proxies serve a distinctly different purpose than the inflation factors used in the outlier modeling. As we explained in the CY 2023 ESRD PPS final rule (87 FR 67147), we select the most appropriate wage and price proxies currently available to represent the rate of price change for each cost category in the ESRDB market basket. In contrast, we explained that the purpose of the inflation factors used in our outlier modeling is to represent the expected rate of change in price and utilization, so that we can prospectively set accurate FDL and MAP amounts that will result in outlier payments that equal 1.0 percent of total ESRD PPS payments. We stated that decreasing our estimates of future outlier spending, as we proposed to do, would result in lower FDL and MAP amounts, thereby increasing the number of claims that could be eligible for the outlier payment adjustment and the amount of outlier payments that would be paid on each claim. We stated that revising our assumptions about future spending for ESRD outlier drugs and biological products would improve the ability of the ESRD outlier adjustment to pay for the costliest ESRD PPS claims. Therefore, we proposed to use the projected inflation factor for ESRD outlier services that are drugs and biological products derived from the historical trend in prices and utilization for ESRD outlier drugs, as described in the previous paragraph.

(3) Changes to the Inflation Factors for Outlier Eligible Laboratory Tests and Supplies

In the proposed rule, we explained that CMS uses different methodologies for the inflation factors for laboratory

tests and supplies. We explained that we inflate laboratory test prices to the upcoming CY using a CPI forecast to estimate changes for years in which a new data reporting period will take place for the purpose of setting CLFS rates; however, the forecast estimate used since CY 2018 for the ESRD PPS outlier methodology has been 0, because there has been no updated reporting for most clinical diagnostic laboratory tests since the CY 2018 CLFS. We further explained that for supplies, we apply a 0 percent inflation factor, because these prices are based on predetermined fees or prices established by the Medicare contractor. In the CY 2011 ESRD PPS proposed rule, we explained that we chose to use these factors so that the MAP would be based on pricing mechanisms currently in place for these services (74 FR 49991).

In the CY 2025 ESRD PPS proposed rule, we noted that the ESRDB market basket uses price proxies for goods and services included in furnishing renal dialysis services to determine the ESRDB market basket update. For example, we stated that the market basket price proxy for laboratory services is the PPI Industry for Medical and Diagnostic Laboratories (BLS series code #PCU621511621511) representing the change in the price of laboratory services conducted by medical and diagnostic laboratories reported on the ESRD facility cost reports. Similarly, we stated that the market basket price proxy for supplies is the PPI Commodity for Surgical and Medical Instruments (BLS series code #WPU1562) representing the change in the price of medical supplies reported on the ESRD facility cost reports.

We stated that we considered whether these longstanding assumptions about price changes for laboratory tests and supplies would be appropriate for modeling changes in spending for outlier-eligible laboratory tests and supplies. Unlike with drugs and biological products, we explained that we do not have detailed historical pricing data for ESRD outlier laboratory tests and supplies to permit us to perform a similar analysis for these services as we did for drugs and biological products. However, we stated that we can compare the historical inflation factors we have used to the growth in the market basket price proxies for these categories of renal dialysis services. For supplies, we noted that we would typically assume a 0 percent update; however, we noted that the average 10-year historical growth in the PPI Commodity for Surgical and Medical Instruments is 0.9 percent. Likewise, we stated that in years when there is a CLFS data reporting period, we would typically use an inflation factor for laboratory tests based on a CPI projection, reduced by the productivity adjustment, through June of the year prior to the update year; however, we noted that the average 10-year historical annual growth for the PPI Industry for Medical and Diagnostic Laboratories was −0.4 percent.

Beginning for CY 2025, we proposed to use the ESRDB market basket price proxies for laboratory tests and supplies for the purpose of calculating the growth in estimated spending for these outlier services in the upcoming CY. We stated that these would replace the current inflation factors which are used for laboratory tests and supplies. Compared to the current inflation factors we use, we stated that we anticipate the market basket price proxies for laboratory tests and supplies would more appropriately reflect the change in prices of the laboratory tests and supply costs that are used by ESRD facilities. We stated that we believe using the market basket price proxies would better allow the ESRD PPS to estimate the changes in the prices of laboratory tests and supplies, which would improve the ability for CMS to target outlier payments at 1.0 percent of total ESRD PPS payments. We noted that decreasing our estimates of future outlier spending would result in lower FDL and MAP amounts, thereby increasing the number of claims that could be eligible for the outlier payment adjustment and the amount of outlier payment that would be paid on each claim. We further stated that revising our assumptions about future spending for ESRD outlier drugs and biological products would improve the ability of the ESRD PPS outlier adjustment to pay for the costliest ESRD PPS claims.

We invited public comments on our proposed changes to the inflation factors for outlier eligible drugs and biological products, laboratory tests, and supplies. Approximately 4 commenters including MedPAC, a non-profit kidney organization, a coalition of dialysis organizations, and one LDO commented on these proposed technical changes. The following is a summary of the public comments received on these proposals and our responses.

Comment: MedPAC expressed support for CMS's proposal to modify its method for calculating the increase in future spending for outlier drugs and biological products. MedPAC stated that this proposal is consistent with the Commission's comment letter on the CY 2024 proposed rule, in which the Commission urged CMS to use a drug price inflation factor based on ASP values to project future spending for outlier services. MedPAC further noted that the ASP data used by CMS to determine facilities' actual outlier payments might be a more accurate data source for drug prices than the ESRDB market basket pharmaceutical price proxies that are currently used.

Response: We appreciate the support for the proposed technical changes to the inflation factors.

Comment: Some commenters stated that since the 1.0 percent outlier percentage was achieved in CY 2023, CMS should not finalize the proposed changes to the inflation factors. In particular, commenters expressed concern that the proposed inflation factor for drugs and biological products is negative as compared to the ESRDB price proxy that CMS has historically used. Commenters suggested that CMS might be required to reduce the ESRD PPS base rate if the 1.0 percent outlier percentage is exceeded in future years.

Response: We appreciate the concerns of commenters about these proposed technical modifications. CMS's analysis of year-over-year price changes for ESRD outlier drugs and biological products reveals a consistent downward trend. However, should prices for outlier drugs and biological products begin to increase as reflected in the ASP prices, such changes would be reflected in future updates to the chained Laspeyres drug price index.

We are reiterating that our longstanding methodology establishes FDL and MAP amounts prospectively. That is, we establish the outlier FDL and MAP amounts each year at a level that our analysis indicates will effectively protect access for the costliest beneficiaries while maintaining an appropriate ESRD PPS base rate for all other beneficiaries. If our analysis indicates that the FDL and MAP amounts would result in outlier payments that are below 1.0 percent, we would reduce the FDL and MAP amounts accordingly in the subsequent year. Alternatively, if our analysis indicates that the FDL and MAP amounts would result in outlier payments that are above 1.0 percent, we would increase the FDL and MAP amounts accordingly in the subsequent year. In this methodology, we do not make modifications to the base rate in response to either exceeding or falling short of the 1.0 percent outlier percentage.

Final Rule Action: After consideration of the comments, we are finalizing our proposed changes to the inflation factors for outlier eligible drugs and biological products, laboratory tests, and supplies. For ESRD outlier drugs and biological

products, we will use the projected inflation factor for ESRD outlier services that are drugs and biological products derived from the historical trend in ASP prices and utilization for ESRD outlier drugs. For ESRD outlier laboratory tests and supplies, we will use the growth in the PPI Industry for Medical and Diagnostic Laboratories and the PPI Commodity for Surgical and Medical Instruments, respectively. In section II.B.3.e of this final rule, we present the final CY 2025 MAP and FDL amounts calculated using these inflation factors.

e. CY 2025 Update to the Outlier Services MAP Amounts and FDL Amounts

For CY 2025, we proposed to update the MAP amounts for adult and pediatric patients using the latest available CY 2023 claims data. We proposed to update the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2023 claims data, and to update the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2021, CY 2022, and CY 2023, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174). We stated that the latest available CY 2023 claims data showed outlier payments represented approximately 1.0 percent of total Medicare payments. We did not receive any comments on this proposal, and we are finalizing the CY 2025 FDL and MAP amounts based on the latest available data.

We are updating the ESRD outlier services FDL amount for pediatric patients using the latest available CY 2023 claims data and updating the ESRD outlier services FDL amount for adult patients using the latest available claims data from CY 2021, CY 2022, and CY 2023, in accordance with the methodology finalized in the CY 2023 ESRD PPS final rule (87 FR 67170 through 67174). The latest available CY 2023 claims data shows that outlier payments represented approximately 1.0 percent of total Medicare payments.

The impact of this final update is shown in Table 7, which compares the outlier services MAP amounts and FDL amounts used for the outlier policy in CY 2024 with the updated estimates for this final rule for CY 2025. The estimates for the final CY 2025 MAP amounts, which are included in column II of Table 7, are inflation adjusted to reflect projected 2025 prices for ESRD outlier services, in accordance with the final changes to the inflation factors discussed in section II.B.3.d of this final rule.

TABLE 7: Outlier Policy: Impact of Updated Data for the Outlier Policy

	Column I Final outlier policy for CY 2024 (based on 2022 data, price inflated to 2024)*		Column II Final outlier policy for CY 2025 (based on 2023 data, price inflated to 2025)**	
	Age < 18	Age >= 18	Age < 18	Age >= 18
Average outlier services MAP amount per treatment	$22.30	$37.92	$58.30	$32.40
Adjustments				
Standardization for outlier services	1.0691	0.9763	1.0432	0.9768
MIPPA reduction	0.98	0.98	0.98	0.98
Adjusted average outlier services MAP amount	$23.36	$36.28	$59.60	$31.02
Fixed-dollar loss amount that is added to the predicted MAP to determine the outlier threshold	$11.32	$71.76	$234.26	$45.41
Patient-month-facilities qualifying for outlier payment	20.86%	4.87%	6.09%	7.05%

*Column I was obtained from column II of Table 1 from the CY 2024 ESRD PPS final rule (88 FR 76363).
**The FDL amount for adults incorporates retrospective adult FDL amounts calculated using data from CYs 2021, 2022, and 2023.

As demonstrated in Table 7, the estimated FDL per treatment that determines the CY 2025 outlier threshold amount for adults (column II; $45.41) is lower than that used for the CY 2024 outlier policy (column I; $71.76). The lower threshold is accompanied by a decrease in the adjusted average MAP for outlier services from $36.28 to $31.02. For pediatric patients, there is an increase in the FDL amount from $11.32 to $234.26. There is a corresponding increase in the adjusted average MAP for outlier services among pediatric patients, from $23.36 to $59.60. We note that this substantial increase in the outlier threshold for pediatric patients reflects the inclusion of certain composite rate drugs for outlier consideration, notably Healthcare Common Procedure Coding System (HCPCS) code J2997 (Injection, alteplase recombinant, 1 mg). As a result, we estimate that a smaller proportion of pediatric patients will receive outlier payments, but the

average outlier payment amounts will be significantly higher.

We estimate that the percentage of patient months qualifying for outlier payments in CY 2025 will be 7.05 percent for adult patients and 6.09 percent for pediatric patients, based on the 2023 claims data and methodology changes in sections II.B.3.c and II.B.3.d of this final rule.

f. Outlier Percentage

In the CY 2011 ESRD PPS final rule (75 FR 49081) and under § 413.220(b)(4), we reduced the per treatment base rate by 1.0 percent to account for the proportion of the estimated total payments under the ESRD PPS that are outlier payments as described in § 413.237. In the 2023 ESRD PPS final rule, we finalized a change to the outlier methodology to better achieve this 1.0 percent target (87 FR 67170 through 67174). Based on the CY 2023 claims, outlier payments represented approximately 1.0 percent of total payments, which has been our policy goal since the establishment of the ESRD PPS outlier adjustment. We believe the methodological changes to the outlier calculation and the change to the definition of ESRD outlier services, which we are finalizing for CY 2025, will continue to effectively set the outlier MAP and FDL amounts for CY 2025 and future years, enabling the ESRD PPS to continue targeting outlier payments at 1.0 percent of total payments. We also note that the recalibration of the FDL amounts will result in no change in payments to ESRD facilities for beneficiaries with renal dialysis items and services that are not eligible for outlier payments.

4. Final Impacts to the CY 2025 ESRD PPS Base Rate

a. ESRD PPS Base Rate

In the CY 2011 ESRD PPS final rule (75 FR 49071 through 49083), CMS established the methodology for calculating the ESRD PPS per-treatment base rate, that is, the ESRD PPS base rate, and calculating the per-treatment payment amount, which are codified at §§ 413.220 and 413.230. The CY 2011 ESRD PPS final rule also provides a detailed discussion of the methodology used to calculate the ESRD PPS base rate and the computation of factors used to adjust the ESRD PPS base rate for projected outlier payments and budget neutrality in accordance with sections 1881(b)(14)(D)(ii) and 1881(b)(14)(A)(ii) of the Act, respectively. Specifically, the ESRD PPS base rate was developed from CY 2007 claims (that is, the lowest per patient utilization year as required by section 1881(b)(14)(A)(ii) of the Act), updated to CY 2011, and represented the average per treatment MAP for composite rate and separately billable services. In accordance with section 1881(b)(14)(D) of the Act and our regulation at § 413.230, the per-treatment payment amount is the sum of the ESRD PPS base rate, adjusted for the patient specific case-mix adjustments, applicable facility adjustments, geographic differences in area wage levels using an area wage index, and any applicable outlier payment, training adjustment add-on, the TDAPA, the TPNIES, the post-TDAPA add-on payment adjustment, and the TPEAPA for CYs 2024, 2025 and 2026.

b. Annual Payment Rate Update for CY 2025

We are finalizing an ESRD PPS base rate for CY 2025 of $273.82. This will be a 1.0 percent increase from the CY 2024 ESRD PPS base rate of $271.02. This final update reflects several factors, described in more detail as follows:

Wage Index Budget-Neutrality Adjustment Factor: We compute a wage index budget-neutrality adjustment factor that is applied to the ESRD PPS base rate. For CY 2025, we did not propose any changes to the methodology used to calculate this factor, which is described in detail in the CY 2014 ESRD PPS final rule (78 FR 72174). We computed the CY 2025 wage index budget-neutrality adjustment factor using treatment counts from the 2023 claims and facility-specific CY 2024 payment rates to estimate the total dollar amount that each ESRD facility would have received in CY 2024. The total of these payments became the target amount of expenditures for all ESRD facilities for CY 2025. Next, we computed the estimated dollar amount that would have been paid for the same ESRD facilities using the proposed CY 2025 ESRD PPS wage index and proposed labor related share for CY 2025. As discussed in section II.B.2 of this final rule, the ESRD PPS wage index for CY 2025 includes the new wage index methodology based on BLS data, and the use of the most recent OMB delineations based on 2020-census data.[34] The total of these payments becomes the new CY 2025 amount of wage adjusted expenditures for all ESRD facilities. The wage index -budget-neutrality factor is calculated as the target amount divided by the new CY 2025 amount. When we multiplied the wage index budget-neutrality factor by the applicable CY 2025 estimated payments, aggregate Medicare payments to ESRD facilities would remain budget neutral when compared to the target amount of expenditures. That is, the wage index budget-neutrality adjustment factor ensures that the wage index updates and revisions do not increase or decrease aggregate Medicare payments. The final CY 2025 wage index budget-neutrality adjustment factor is 0.988600. This final CY 2025 wage index budget-neutrality adjustment factor reflects the impact of all final wage index policy changes, including the CY 2025 ESRD PPS wage index using the new ESRD PPS wage index methodology based on BLS data, the 5 percent cap on year-to-year decreases in wage index values, the updated CBSA delineations, the 3 year rural phase-out for ESRD facilities in currently-rural CBSAs that will become urban under the new delineations, and the labor-related share (which we did not propose to change from CY 2024). We note that the application of the 5 percent cap on wage index decreases has a sizable impact on the budget-neutrality factor this year due to the new wage index methodology. That is, because a substantial number of ESRD facilities would have experienced a greater than 5 percent decrease in their wage index value as a result of the new wage index methodology, the budget-neutrality adjustment factor needed to offset the effect of limiting those decreases to 5 percent is larger than we expect it would be in a typical year. We note that the final CY 2025 wage index budget-neutrality factor does not include any impacts associated with the TPEAPA, as was the case with last year's combined wage index-TPEAPA budget-neutrality factor. This is consistent with how we have historically applied budget neutrality for case-mix adjusters, including pediatric case-mix adjusters. We do not routinely apply a budget-neutrality factor to account for changes in overall payment associated with changes in patient case-mix in years in which we do not propose any changes to the case-mix adjustment amount. Although the TPEAPA was established under the authority in section 1881(b)(14)(D)(iv) of the Act, which does not require budget neutrality, we stated in the CY 2024 ESRD PPS final rule that we were implementing the TPEAPA in a budget neutral manner because it was similar to the pediatric case-mix adjusters, and it accounts for costs which would have been included in the cost reports used in the analysis conducted when we created the ESRD PPS bundled payment in the CY 2011 ESRD PPS final rule (88

[34] *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.*

FR 76378). Because the adjustment to maintain budget neutrality associated with the TPEAPA was accounted for in the CY 2024 combined wage index and TPEAPA budget neutrality factor, it would not be appropriate to apply a budget-neutrality factor for the TPEAPA for CY 2025.

Market Basket Update: Section 1881(b)(14)(F)(i)(I) of the Act provides that, beginning in 2012, the ESRD PPS payment amounts are required to be annually increased by an ESRD market basket percentage increase. As discussed in section II.B.1.b.(1) of this final rule, the latest CY 2025 projection of the ESRDB market basket percentage increase is 2.7 percent. In CY 2025, this amount must be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, as required by section 1881(b)(14)(F)(i)(II) of the Act. As previously discussed in section II.B.1.b.(2) of this final rule, the latest CY 2025 projection of the productivity adjustment is 0.5 percentage point, thus yielding a final CY 2025 productivity-adjusted ESRDB market basket update of 2.2 percent for CY 2025. Therefore, the final CY 2025 ESRD PPS base rate is $273.82 (($271.02 × 0.988600) × 1.022 = $273.82). In the CY 2025 ESRD PPS proposed rule (89 FR 55766), the productivity-adjusted ESRDB market basket update was 1.8 percent (reflecting a 2.3 percent market basket percentage increase reduced by a 0.5 percentage point productivity adjustment). We proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2025 ESRDB market basket update in the final rule.

We invited public comment on our proposed CY 2025 ESRD PPS base rate. Approximately 25 unique commenters including LDOs; SDOs, patient advocacy organizations; nonprofit dialysis associations; two coalitions of dialysis organizations; professional organizations; and MedPAC commented on the proposed payment rate. Many of these comments primarily focused on the proposed CY 2025 productivity-adjusted ESRDB market basket update, which we discuss and respond to in section II.B.1.b.(5) of this final rule. The following is a summary of the other public comments received on the proposed CY 2025 ESRD PPS base rate and our responses.

Comment: All commenters supported increasing the ESRD PPS base rate. Most commenters indicated a belief that the proposed CY 2025 ESRD PPS payment rates were too low. Commenters generally stated that the cause of these lower-than-appropriate payment rates was a combination of the proposed CY 2025 ESRDB market basket percentage increase and prior ESRDB market basket percentage increases being lower-than-appropriate. Only MedPAC stated a belief that the proposed CY 2025 ESRD PPS payment rate was appropriate.

Response: We appreciate the support for increasing payments under the ESRD PPS. We agree with MedPAC that payment rates under the ESRD PPS are generally appropriate. We concur with the commenters' general consensus that perceived inadequacies in the proposed CY 2025 ESRD PPS base rate are related to the perceived inadequacies of the ESRDB market basket. We have primarily addressed commenters' concerns related to the ESRDB market basket update in section II.B.1.b.(5) of this final rule. We wish to reiterate that the ESRD PPS base rate is calculated annually using the ESRDB market basket update and applying any applicable budget-neutrality factors, so the ESRD PPS base rate for a given year is constructed using several factors which are each derived from the best available data, as described in section II.B.1 and in section II.B.4. While we understand the concerns of commenters regarding the payment rates, we strongly believe that any change to this methodology should be data driven. We will take commenters' concerns into consideration for future rulemaking years to determine if any changes to the ESRD PPS base rate calculation or ESRDB market basket methodology are appropriate. Any changes to the ESRD market basket methodology or ESRD PPS base rate calculation would be made through notice and comment rulemaking.

Comment: Several commenters stated a belief that increasing the ESRD PPS base rate by 0.8 percent was not sufficient.

Response: We note that the proposed ESRDB productivity-adjusted market basket increase for CY 2025 was 1.8 percent (reflecting a proposed ESRDB market basket increase of 2.3 percent reduced by the statutorily-mandated proposed productivity adjustment estimated to be 0.5 percentage point). The proposed 0.8 percent increase to the ESRD PPS base rate was lower than the market basket increase as it also reflected the application of the proposed wage index budget-neutrality adjustment factor of 0.990228. Since the wage index budget neutrality factor is calculated to ensure that the changes between the CY 2024 and CY 2025 wage indices do not result in an increase or decrease of estimated aggregate payments, the application to the ESRD PPS base rate does not result in a decrease to total ESRD PPS payments.

Comment: One commenter noted that the proposed CY 2025 ESRD PPS base rate of $273.20 is only $43.57 more than the CY 2011 ESRD PPS base rate of $229.63. This commenter stated a belief that this has contributed to the ongoing net closures of ESRD facilities in recent years.

Response: We acknowledge that the ESRD PPS base rate has not increased as much as costs have for ESRD facilities; however, we note that the ESRD PPS base rate is not meant to be interpreted as an average or typical payment rate for renal dialysis services furnished to ESRD patients, because the ESRD PPS base rate is adjusted by several factors including the wage index and several case-mix and facility-level adjusters. Generally, these adjusters are implemented in a budget-neutral manner, which usually decreases the ESRD PPS base rate to account for the usually positive adjustment factor. For example, when we updated the case-mix adjustment factors in the CY 2016 ESRD PPS final rule, we applied a refinement budget-neutrality adjustment factor of 0.960319, which decreased the ESRD PPS base rate by approximately nine and a half dollars without reducing total estimated payments for CY 2016 (80 FR 69013). Thus, we do not believe it is appropriate to judge the payment adequacy of the ESRD PPS based on the base rate alone without accounting for the other adjustment factors, which heavily influence the actual payment amount received by ESRD facilities. The actual payment rate is generally higher than the unadjusted ESRD PPS base rate. The ESRD PPS base rate incorporates offsetting adjustments to maintain budget neutrality which, as discussed, have generally reduced the ESRD PPS base rate, so it should not be evaluated in isolation. As these adjustment factors have generally increased since the inception of the ESRD PPS in CY 2011, we believe that this increase in the ESRD PPS base rate from CY 2011 to CY 2025 is appropriate.

Comment: Many commenters who opined that the current payments under the ESRD PPS were too low included potential implications of a lower-than-appropriate payment rate. These implications included concerns related to quality of care, ability for ESRD facilities to remain open, ability for ESRD facilities to remain staffed, reduction of the hours of operation at ESRD facilities, and access concerns.

One commenter highlighted potential health equity concerns related to what they characterized as lower-than-appropriate payments. This commenter stated that dialysis patients are disproportionately African American/Black, live in medically underserved areas and are low income, so lower-than-appropriate payments would risk perpetuating health disparities.

Response: We appreciate the commenter's concerns regarding the wide range of potential implications of the proposed payment rate update. We note that we are statutorily required to increase the ESRD PPS base rate by a ESRDB market basket increase factor that reflects the forecasted change in prices of an appropriate mix of goods and services included in renal dialysis services. The final CY 2025 market basket update is 2.2 percent according to the latest available projection of the ESRDB market basket and productivity adjustment, which we note is 0.4 percentage point higher than the proposed ESRDB market basket update. We recognize that many commenters are concerned about payment adequacy, and we agree that it is important to ensure payments to ESRD facilities are adequate. We note that MedPAC's 2024 Report to Congress [35] projected a 2024 aggregate FFS Medicare margin for ESRD facilities of 0.0 percent. While we understand why interested parties may perceive these margins as being too low, we note that they indicate that in general ESRD facilities are being paid a reasonable amount given their costs.

We appreciate the thoughtful comments on the health equity implications of the ESRD PPS payment rate. We agree with the commenters that appropriate payments for renal dialysis services are important due to the potential vulnerability of many ESRD beneficiaries and the health disparities they may experience. We did not propose any changes to the ESRD PPS payment update methodology to further account for health equity, and we are statutorily required to update ESRD PPS payments based on the change in prices as measured by the ESRDB market basket. We intend to continue to consider a wide range of potential options for how we can address health equity concerns, for example, through refined case-mix and facility-level adjustment factors, in future rulemaking.

Comment: We received some comments which specifically discussed ESRD facilities in Puerto Rico and the appropriateness of the current ESRD PPS base rate there. One comment stated that relative rates between MA and FFS Medicare were larger than in the mainland United States. This commenter also mentioned several cost factors that were unique to Puerto Rico, including energy issues, laboratory costs, costs related to the importations of goods to areas outside the mainland United States, local legislation on administrative staff at ESRD facilities, and high property insurance rates.

Response: We appreciate the insight into the specific costs related to operating ESRD facilities in Puerto Rico. We believe that the ESRDB market basket appropriately accounts for all of the costs which the commenters described; however, we acknowledge that there could be geographic variation in these costs which would not be captured by the ESRDB market basket update. We understand that MA payment is critical for many ESRD facilities; however, MA payment rates are not the subject of this ESRD PPS rulemaking, and we are not substantively responding to any comments regarding MA payment rates in this final rule. We may consider how we could address the unique costs associated with the geographic isolation of U.S. Territories in the ESRD PPS in future policymaking.

Comment: Several commenters stated that the ESRD PPS does not adequately support innovation. These commenters generally expressed that payments under the ESRD PPS are not enough to incentivize new products, drugs, biological products, or other efficiencies to be developed for treatment of ESRD. Many of these comments were combined with more specific concerns regarding outlier payments for renal dialysis drugs that received the TDAPA after the end of the TDAPA period and the post-TDAPA add-on payment adjustment amounts, which we address in sections II.B.3 and II.B.6 respectively.

Response: Under section 1881(b)(14)(A)(ii) of the Act, the ESRD PPS is based on a fixed bundle of goods and services using data from 2007, 2008 or 2009, whichever had the lower per-patient utilization. Therefore, in the CY 2011 ESRD PPS final rule, we derived the ESRD PPS base rate from 2007 cost report data (75 FR 49152) which has been, and continues to be, annually updated based on the ESRDB market basket, reflecting the changes over time in the prices of an appropriate mix of the goods and services involved in furnishing renal dialysis services. Per this statutory scheme, the ESRD PPS is not designed to provide additional payment for new and innovative good or services through the ESRD PPS base rate. To promote innovation and achieve other objectives, we have finalized several policies using the statutory authority at section 1881(b)(14)(D)(iv) of the Act to provide temporarily increased payment to ESRD facilities that use certain new and innovative renal dialysis services. These include the TDAPA for certain new renal dialysis drugs and biological products (80 FR 69023), the TPNIES for certain new and innovative renal dialysis equipment and supplies (84 FR 60684), the TPNIES for certain capital related assets that are home dialysis machines when used in the home for a single patient (85 FR 71416) and, most recently, the post-TDAPA add-on payment adjustment for certain new drugs and biological products after the TDAPA period ends (88 FR 76388 through 76397). All of these add-on payment adjustments serve to provide increased payment compared to the ESRD PPS base rate, which we believe appropriately recognizes innovation through increased payment. As the statute specifically requires that the ESRD PPS be based on a fixed bundle of goods and services, we do not believe it would be appropriate to directly increase the ESRD PPS base rate for new goods and services which are broadly similar to goods and services within the ESRDB market basket, such as drugs and biological products in existing ESRD PPS functional categories.

Final Rule Action: We are not finalizing any changes to our methodology for calculating the ESRD PPS base rate. The final CY 2025 ESRD PPS base rate is $273.82, as described previously in this final rule.

5. Update to the Average per Treatment Offset Amount for Home Dialysis Machines

In the CY 2021 ESRD PPS final rule (85 FR 71427), we expanded eligibility for the TPNIES under § 413.236 to include certain capital-related assets that are home dialysis machines when used in the home for a single patient. To establish the TPNIES basis of payment for these items, we finalized the additional steps that the Medicare Administrative Contractors (MACs) must follow to calculate a pre-adjusted per treatment amount, using the prices they establish under § 413.236(e) for a capital-related asset that is a home dialysis machine, as well as the methodology that CMS uses to calculate the average per treatment offset amount for home dialysis machines that is used in the MACs' calculation, to account for the cost of the home dialysis machine that is already in the ESRD PPS base

[35] *https://www.medpac.gov/wp-content/uploads/2024/03/Mar24_MedPAC_Report_To_Congress_SEC-2.pdf.*

rate. For purposes of this final rule, we refer to this as the ''TPNIES offset amount.''

The methodology for calculating the TPNIES offset amount is set forth in § 413.236(f)(3). Section 413.236(f)(3)(v) states that effective January 1, 2022, CMS annually updates the amount determined in § 413.236(f)(3)(iv) by the ESRD bundled market basket percentage increase factor minus the productivity adjustment factor. The TPNIES for capital-related assets that are home dialysis machines is based on 65 percent of the MAC-determined pre-adjusted per treatment amount, reduced by the TPNIES offset amount, and is paid for 2 CYs.

There are currently no capital-related assets that are home dialysis machines set to receive TPNIES for CY 2025, as the TPNIES payment period for the Tablo® System ended on December 31, 2023, and there are no TPNIES applications for CY 2025. However, as required by § 413.236(f)(3)(v), we proposed to update the TPNIES offset amount annually according to the methodology described previously.

We are finalizing a CY 2025 TPNIES offset amount for capital-related assets that are home dialysis machines of $10.22, based on the final CY 2025 ESRDB productivity-adjusted market basket update of 2.2 percent (final 2.7 percent market basket percentage increase reduced by the final 0.5 percentage point productivity adjustment). Applying the final update factor of 1.022 to the CY 2024 offset amount resulted in the CY 2025 offset amount of $10.22 ($10.00 × 1.022 = $10.22). This is slightly higher than the proposed CY 2025 TPNIES offset amount for capital related assets that are home dialysis machines of $10.18. We did not receive any comments on our proposal to update the TPNIES offset for capital-related assets for CY 2025.

6. Post-TDAPA Add-On Payment Adjustment Updates

a. Updates to the Post-TDAPA Add-On Payment Adjustment Amounts for CY 2025

In the CY 2024 ESRD PPS final rule we finalized an add-on payment adjustment for certain new renal dialysis drugs and biological products, which would be applied for 3 years after the end of the TDAPA period (88 FR 76388 through 76397). This adjustment, known as the post-TDAPA add-on payment adjustment, is adjusted by the patient-level case-mix adjuster and is applied to every ESRD PPS claim. In that final rule we also clarified that for each year of the post-TDAPA period we would update the post-TDAPA add-on payment adjustment amounts based on utilization and ASP of the drug or biological product. For CY 2024 there is one drug, Korsuva® (difelikefalin), included in the calculation of the post-TDAPA add-on payment adjustment. In the CY 2024 ESRD PPS final rule (88 FR 76397), we finalized that the post-TDAPA add-on payment adjustment amount for Korsuva® would be $0.2493 and would begin on April 1, 2024.

For CY 2025, we will have two drugs included in the calculation of the post-TDAPA add-on payment adjustment. The post-TDAPA add-on payment adjustment period for one of these drugs, Korsuva®, began on April 1, 2024, so, conditional upon the continued receipt of the latest full calendar quarter of ASP data as described in § 413.234(c)(3), Korsuva® will be included in the calculation for the post-TDAPA add-on payment adjustment for the entirety of CY 2025. The other drug, Jesduvroq (daprodustat), began its 2-year TDAPA period on October 1, 2023, so its post-TDAPA add-on payment adjustment period will begin on October 1, 2025, conditional upon the continued receipt of the latest full calendar quarter of ASP data.

In the CY 2025 ESRD PPS proposed rule we presented the proposed post-TDAPA add-on payment adjustment amounts for Korsuva® and Jesduvroq based on the most recently available utilization data at the time. Consistent with the methodology finalized in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389), we proposed to update these calculations with the most recent available data in the final rule.

Based on the most recent utilization data, and following the calculation explained in the CY 2024 ESRD PPS final rule (88 FR 76388 through 76389) and § 413.234(g), the final post-TDAPA add-on payment adjustment amount for Korsuva® is $0.4601 for all 4 quarters of CY 2025, an increase from the proposed post-TDAPA add-on payment adjustment amount of $0.4047. Under that same methodology, the current estimate of the post-TDAPA add-on payment adjustment amount for Jesduvroq is $0.0096 for only the last quarter of CY 2025, an increase from the proposed post-TDAPA add-on payment adjustment amount of $0.0019. We note that utilization data available for Jesduvroq available at the time the analysis was conducted for this final rule includes only data from October 2023 through June 2024. Table 8 shows the final post-TDAPA add-on payment adjustment amounts for each quarter of CY 2025.

TABLE 8: Final Post-TDAPA Add-on Payment Adjustment Amounts for CY 2025 by Quarter

Quarter	Final Add-on amount for Korsuva®	Add-on amount for Jesduvroq (Estimate)	Total post-TDAPA add-on payment adjustment amount
Q1 (January – March)	$0.4601	0	$0.4601
Q2 (April – June)	$0.4601	0	$0.4601
Q3 (July – September)	$0.4601	0	$0.4601
Q4 (October – December)	$0.4601	$0.0096	$0.4697

We invited public comment on our proposed CY 2025 post-TDAPA add-on payment adjustment amounts. Approximately 8 commenters including coalitions of dialysis organizations and several drug manufacturers commented on the proposed post-TDAPA add-on payment adjustment amounts. The following is a summary of the public comments received on these proposals and our responses.

Comment: We received several comments that reiterated concerns about the post-TDAPA add-on payment adjustment calculation that we addressed in the CY 2024 ESRD PPS final rule, in which we finalized the post-TDAPA add-on payment adjustment (88 FR 76388 through 76397). Commenters requested CMS calculate the post-TDAPA add-on payment adjustment amount based only on TDAPA claims that included the drug or biological product and then only apply the post-TDAPA add-on payment adjustment to claims with that drug or biological product. Commenters generally stated that this methodology would better support innovation and expressed access concerns for expensive drugs and biological products with low utilization after the TDAPA period. Some commenters included figures that they believed would be more appropriate amounts for the post-TDAPA add-on payment adjustment amount for Korsuva®, generally calculated using the suggested methodological changes.

Response: We did not propose a new methodology for the calculation of the post-TDAPA add-on payment adjustment for the same reasons we did not finalize the requested methodology in the CY 2024 ESRD PPS final rule (88 FR 76395). Specifically, calculating the post-TDAPA add-on payment adjustment amount by dividing the total payment for the drug or biological product across only those patients who utilize it would directly incentivize utilization of a particular drug or biological product, which can result in overutilization. We note that in future rulemaking we may propose changes to the case-mix adjustment factors, which could result in higher payments for treatments provided to some patients who utilize drugs or biological products that previously received the TDAPA, should the analysis show that treating these patients is more costly.

Final Rule Action: After reviewing the comments, we are finalizing a post-TDAPA addon payment adjustment amount of $0.4601 for Korsuva® that would be included in the calculation of the post-TDAPA add-on payment adjustment amount for all four quarters of CY 2025. Additionally, we are presenting an estimated post-TDAPA add-on payment adjustment amount of $0.0096 for Jesduvroq, which would be included in the calculation of the post-TDAPA add-on payment adjustment amount for the fourth quarter of CY 2025. As discussed later in this section of the final rule, this presented post-TDAPA add-on payment adjustment amount for Jesduvroq will be updated in a CR once we have a full year's worth of utilization data available for the analysis.

a. Proposal To Publish Post-TDAPA Add-On Payment Adjustment Amounts After the Final Rule in Certain Circumstances

As discussed in the CY 2024 ESRD PPS final rule (88 FR 76393) and codified at 42 CFR 413.234(g), we have finalized a post-TDAPA add-on payment adjustment, which is based on the most recent year of utilization data and is calculated annually in each rulemaking cycle. Under § 413.234(g)(1), CMS bases the post-TDAPA add-on payment adjustment calculation on the most recent 12-month period of utilization for the new renal dialysis drug or biological product and the most recent available full calendar quarter of ASP data. However, when a drug or biological product begins its TDAPA period in the fourth quarter of a CY, and, therefore, would be included in the post-TDAPA add-on payment adjustment calculation beginning in the fourth quarter 2 CYs later, there would likely not be a full year's worth of utilization data available at the time of proposed or final rulemaking for that CY due to the time-lag associated with collecting and processing utilization data for the final rule. For example, at the time of rulemaking for last year's ESRD PPS final rule, we had data available through June 2023 when calculating the post-TDAPA add-on payment adjustment amount for Korsuva® (88 FR 73697). However, for a drug or biological product that began its TDAPA period in October of the prior year, data from October through June would only represent 9 months of data. We believe it is important to have a full year's utilization data when determining the post-TDAPA add-on payment adjustment amount so that the post-TDAPA add-on payment adjustment appropriately captures the utilization of the drug or biological product as required by § 413.234(g)(1).

We proposed that when there is insufficient data at the time of rulemaking, we will publish the post-TDAPA add-on payment adjustment amount via CR once we have a full 12 months of data. Specifically, we will publish the post-TDAPA add-on payment adjustment amount in a CR under the following circumstances: (1) a drug or biological product is ending its TDAPA period during the CY, and therefore under § 413.234(c)(1) will begin being included in the post-TDAPA add-on payment adjustment amount calculation during that CY; and (2) that drug or biological product does not have at least 12 full months of utilization data at the time the final rule is developed. Under this proposal, we would still include an estimated post-TDAPA add-on payment adjustment amount in the proposed rule and update that estimated amount in the final rule, but we would note that the estimated amount presented in the final rule is subject to change. We note that the final post-TDAPA add-on payment adjustment amount published after the final rule could be higher or lower than the estimated amount presented in the final rule. We do not anticipate having less than a full year's utilization data at the time of rulemaking for drugs and biological products that begin receiving TDAPA payments in quarters other than the fourth quarter of the year; however, should such an instance arise, we would similarly publish the post-TDAPA add-on payment adjustment amount in a CR once 12 months of utilization data are available. We would indicate the quarterly release CR in which we intend to publish the final post-TDAPA add-on payment adjustment amount.

For CY 2025, there is one TDAPA drug, Jesduvroq, which is ending its TDAPA period in CY 2025 and for which, at the time of proposed rulemaking, we did not anticipate having a full 12 months' worth of utilization data at the time of final rulemaking. As such, we stated that under this proposal we would indicate in the final rule that we intend to publish the post-TDAPA add-on payment adjustment amount for CY 2025 for Jesduvroq once we have a full year of utilization data. We generally intend to publish this updated post-TDAPA add-on payment adjustment amount two calendar quarters prior to the end of the TDAPA period, as this would allow for sufficient time to gather and analyze a year's worth of utilization data. We stated that for this drug, and for any drug or biological product that begins its TDAPA period in the fourth quarter of a CY, we would generally publish the post-TDAPA add-on payment adjustment amount at the beginning of the second quarter of the last CY of that drug or biological product's TDAPA period (that is, two

calendar quarters before the drug is included in the post-TDAPA add-on payment adjustment amount). However, should circumstances arise that prevent us from calculating a post-TDAPA add-on payment adjustment amount at that time, we would publish the final post-TDAPA add-on payment adjustment amount at a later time.

We noted that this approach to publishing the post-TDAPA add-on payment adjustment amount calculation would not impact any drug or biological product that has at least one full year's worth of utilization data at the time when the analysis for the final rule is developed, nor would it impact any drug or biological product that is already included in the post-TDAPA add-on payment adjustment calculation for a given CY. We do not intend to routinely update post-TDAPA add-on payment adjustment amounts quarterly, as we believe this will make it more difficult for ESRD facilities to estimate payments. However, for drugs or biological products that lack a full year's worth of utilization data at the time when the analysis for the final rule is developed, we believe it is appropriate to take this additional step to ensure that their post-TDAPA add-on payment adjustment is based on 12 months of utilization data as required by § 413.234(g)(1).

We invited public comment on our proposal to update post-TDAPA add-on payment adjustment amounts after the final rule is published in situations where 12 months of utilization data is not available at the time of the analysis calculated for the ESRD PPS final rule. We did not receive any comments on this proposal.

Final Rule Action: We are finalizing our proposal to publish the post-TDAPA add-on payment adjustment amount after the final rule in certain circumstances, as we believe it is most consistent with § 413.234(g)(1), which requires that the post-TDAPA add-on payment adjustment amount be calculated using 12 months of utilization data.

7. Inclusion of Oral-Only Drugs Into the ESRD PPS Bundled Payment

a. Background

Section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. Section 1881(b)(14)(B) of the Act defines renal dialysis services, and subclause (iii) of that section states that these services include other drugs and biologicals [36] that are furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, and any oral equivalent form of such drug or biological.

When we implemented the ESRD PPS in 2011 (75 FR 49030), we interpreted this provision as including not only injectable drugs and biological products used for the treatment of ESRD (other than ESAs and any oral form of ESAs, which are included under clause (ii) of section 1881(b)(14)(B) of the Act), but also all oral drugs and biological products used for the treatment of ESRD and furnished under title XVIII of the Act. We also concluded that, to the extent oral-only drugs or biological products used for the treatment of ESRD do not fall within clause (iii) of section 1881(b)(14)(B) of the Act, such drugs or biological products would fall under clause (iv) of that section, and constitute other items and services used for the treatment of ESRD that are not described in clause (i) of section 1881(b)(14)(B) of the Act.

We finalized and issued payment policies for oral-only renal dialysis service drugs or biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053). In that rule, we defined renal dialysis services at § 413.171 as including drugs and biological products with only an oral form. We also finalized a policy to delay payment for oral-only drugs under the ESRD PPS until January 1, 2014. Accordingly, we codified the delay in payment for oral-only renal dialysis service drugs and biological products at § 413.174(f)(6), and provided that payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form would be incorporated into the ESRD PPS payment rates effective January 1, 2014, once we had collected and analyzed adequate pricing and utilization data. Since oral-only drugs are generally not a covered service under Medicare Part B, this delay of payment under the ESRD PPS also allowed coverage to continue under Medicare Part D for those beneficiaries with such coverage.

In the CY 2011 ESRD PPS proposed rule (74 FR 49929), we noted that the only oral-only drugs that we identified were phosphate binders and calcimimetics, specifically, cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride, and sevelamer carbonate. All of these drugs fall into the ESRD PPS functional category for bone and mineral metabolism.

Since then, the Congress has acted three times to further delay the inclusion of oral-only renal dialysis service drugs and biological products in the ESRD PPS. Specifically, as discussed in section II.A.1 of this final rule, ATRA in 2013, as amended by PAMA in 2014, and amended by ABLE in 2014, ultimately delayed the inclusion of oral-only drugs into the ESRD PPS until January 1, 2025.

Section 217(c)(1) of PAMA also required us to adopt a process for determining when oral-only drugs are no longer oral-only and to incorporate them into the ESRD PPS bundled payment. Section 217(a)(2) of PAMA further amended section 632(b)(1) of ATRA by requiring that, in establishing payment for oral-only drugs under the ESRD PPS, the Secretary must use data from the most recent year available. In the CY 2016 ESRD PPS proposed rule (80 FR 37839), we noted that when the existing oral-only drugs (which were, at that time, only phosphate binders and calcimimetics) were determined no longer to be oral-only drugs, we would pay for them using the TDAPA. We stated that this would allow us to collect data reflecting current utilization of both the oral and injectable or intravenous forms of the drugs, as well as payment patterns and beneficiary co-pays, before we add these drugs to the ESRD PPS bundled payment.

In 2017, when an injectable calcimimetic became available, CMS issued a Change Request[37] to add all calcimimetics, including oral and injectable forms, to the ESRD PPS bundled payment beginning in CY 2018. CMS paid the TDAPA for calcimimetics for a period of 3 years (CY 2018 through CY 2020). When the TDAPA period ended, we went through rulemaking (85 FR 71410) to increase the ESRD PPS base rate beginning in CY 2021 to incorporate the cost of calcimimetics.

Most recently, in the CY 2023 ESRD PPS final rule (87 FR 67185 through 67186), we finalized a revision to the regulatory definition of an oral-only drug, effective January 1, 2025, to clarify our longstanding policy by specifying that an oral-only drug has no injectable functional equivalent. The effective date of this revised definition will coincide

[36] As discussed in the CY 2019 ESRD PPS final rule (83 FR 56922), we began using the term ''biological products'' instead of ''biologicals'' under the ESRD PPS to be consistent with FDA nomenclature. We use the term ''biological products'' in this final rule except where referencing specific language in the Act or regulations.

[37] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm10065.pdf* and *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2018downloads/r1999otn.pdf.*

with the January 1, 2025, incorporation of oral-only drugs into the ESRD PPS under § 413.174(f)(6). The revised definition of oral-only drugs reflects that drugs with similar end-action effects are treated as equivalent under the ESRD PPS, consistent with our approach to designating drugs into ESRD PPS functional categories.

b. Current Policy for Oral-Only Drugs in CY 2025

Existing regulations at § 413.174(f)(6) state that effective January 1, 2025, oral-only drugs will be paid for under the ESRD PPS. Although oral-only drugs are excluded from the ESRD PPS bundled payment until January 1, 2025, they are currently recognized as renal dialysis services as defined in regulation at § 413.171. Accordingly, CMS is planning to incorporate oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, using the TDAPA, as described in the CY 2016 ESRD PPS final rule (80 FR 69027) and subsequent rules.

As we stated in the CY 2023 ESRD PPS final rule (87 FR 67180), if an injectable equivalent or other form of administration of phosphate binders were to be approved by FDA prior to January 1, 2025, the phosphate binders would no longer be considered oral-only drugs and would no longer be paid for outside the ESRD PPS. We stated that we would pay for the oral and any non-oral version of the drug using the TDAPA under the ESRD PPS for at least 2 years, during which time we would collect and analyze utilization data. We stated that if no other injectable equivalent (or other form of administration) of phosphate binders is approved by the FDA prior to January 1, 2025, we would pay for these drugs using the TDAPA under the ESRD PPS for at least 2 years beginning January 1, 2025. CMS will use the same process that it used for calcimimetics to incorporate phosphate binders into the ESRD PPS beginning January 1, 2025. CMS discussed its process for incorporating calcimimetics in CMS Transmittal 1999, dated January 10, 2018, and in MLN Matters Number: MM10065.[38] [39] We stated that pricing for phosphate binders under the TDAPA would be based on pricing methodologies available under section 1847A of the Act. A new renal dialysis drug or biological product is paid for using the TDAPA, which is based on 100 percent of ASP. If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. In such cases, CMS will undertake rulemaking to modify the ESRD PPS base rate, if appropriate, to account for the cost and utilization of phosphate binders in the ESRD PPS bundled payment.

We note that on October 17, 2023, a new oral phosphate lowering agent received FDA marketing approval. According to the FDA-approved labeling for this drug, XPHOZAH® (tenapanor) is indicated to reduce serum phosphorus in adults with chronic kidney disease who are on dialysis as add-on therapy in patients who have an inadequate response to phosphate binders or who are intolerant of any dose of phosphate binder therapy. CMS has identified XPHOZAH® to be a renal dialysis service because it is used to treat or manage a condition associated with ESRD, per its approved indication. XPHOZAH® tablets are taken orally, usually twice a day with meals. CMS has also determined that XPHOZAH® meets the current regulatory definition of an oral-only drug as defined at § 413.234(a), and therefore, in accordance with § 413.174(f)(6), is not paid for under the ESRD PPS until January 1, 2025. Consistent with policies adopted in the CY 2016 and CY 2023 ESRD PPS final rules (see 80 FR 69025 and 87 FR 67183), XPHOZAH® will be included in the ESRD PPS effective January 1, 2025, using the drug designation process under § 413.234.

As set forth in § 413.174(f)(6), effective January 1, 2025, payment to an ESRD facility for renal dialysis service drugs and biological products with only an oral form furnished to ESRD patients will be incorporated within the prospective payment system rates established by CMS in § 413.230, and separate payment will no longer be provided. As noted earlier in this section, we have recently published operational guidance, including information about the TDAPA amount, HCPCS codes, and ASP reporting requirements and timelines for phosphate binders at *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf*. We note that we will use the same process that we used for calcimimetics to incorporate phosphate binders into the ESRD PPS beginning January 1, 2025, and that we will not be following this process for any other oral drugs or biological products. Manufacturers would need to apply for a HCPCS code and the TDAPA for any other oral drugs or biological products to be eligible for the TDAPA.

Finally, we note that the TDAPA amount is not applied to claims for renal dialysis services provided to beneficiaries with acute kidney injury.[40] When ESRD facilities were paid the TDAPA for calcimimetics and the latter were incorporated into the ESRD PPS bundled payment for patients with ESRD, the TDAPA was not paid for claims for renal dialysis services provided to beneficiaries with acute kidney injury. Similarly, ESRD facilities will not be paid the TDAPA for phosphate binders for renal dialysis services provided to beneficiaries with acute kidney injury. This is discussed below in section III.E of this final rule.

We note that for any other oral-only drugs, such as XPHOZAH®, we will apply our drug designation process as we do for all new renal dialysis drugs and biological products, consistent with § 413.234 and the policy finalized in CY 2016 ESRD PPS final rule (80 FR 69027) and reiterated in the CY 2023 ESRD PPS final rule (87 FR 67180).

c. Operational Considerations Related to the Incorporation of Oral-Only Drugs

In the CY 2011 ESRD PPS final rule (75 FR 49043), we explained that there were certain advantages to delaying the implementation of payment for oral-only drugs and biological products under the ESRD PPS. These advantages included allowing ESRD facilities additional time to make operational changes and logistical arrangements to furnish oral-only renal dialysis service drugs and biological products to their patients.

In November 2023, in accordance with section 632(d) of ATRA, the Government Accountability Office (GAO) published a Report to Congressional Committees titled, ''End-Stage Renal Disease: CMS Plans for including Phosphate Binders in the Bundled Payment.'' (GAO–24–106288).[41] The report summarized the current status of payment for the phosphate binders as well as identifying areas of operational concerns. These include challenges related to hiring the staff needed for ESRD facilities to provide phosphate binders to patients, complexities relating to system updates needed to accommodate the volume and broad array of phosphate binders, and costs related to dispensing, storage, and

[38] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2018Downloads/R1999OTN.pdf.*

[39] *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10065.pdf.*

[40] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/mm102811.pdf* and *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/R1941OTN.pdf.*

[41] *https://www.gao.gov/assets/d24106288.pdf.*

transportation. The considerations identified in the GAO report generally align with the comments we have received on past ESRD PPS proposed rules. The GAO also interviewed dialysis organization representatives who stated that they are preparing to make the anticipated adjustments needed to dispense the phosphate binders.

With respect to considerations related to staffing, we note that the ESRD PPS includes payment for staffing related to the provision of renal dialysis services. We believe there are several strategies that ESRD facilities could employ to efficiently use available staff time to provide phosphate binders. There are parallels between the administration of phosphate binders and the administration of oral calcimimetics, which are also typically taken every day. First, we expect that patients with ESRD generally receive treatment for at least 3 hours per session, typically three times per week. We believe that during this treatment window there is generally staff availability to provide the patient with pre-packaged medication, which we note could include medication for multiple days. Second, ESRD facilities could maximize the efficiency of staff time by mailing the prescriptions, to the extent that doing so is consistent with state pharmacy laws. For example, the GAO report identified that one large dialysis organization only mails oral prescriptions to patients' homes, while others mail the medication to either the ESRD facility or the patient's home. Third, the GAO report identified that some ESRD facilities contract with outside pharmacies rather than operating their own pharmacy. By contracting with outside pharmacies, ESRD facilities could reduce or avoid the need to hire additional pharmacists and pharmacy staff to manage the volume of prescriptions.

Another challenge identified by the dialysis organizations was the complexity of dispensing phosphate binders because of the broad array of phosphate binders and the high volume of pills.[42] We acknowledge there are six common types of phosphate binders as compared to only one type of calcimimetics. The GAO report also noted that unlike calcimimetics, phosphate binders are typically taken with every meal and snack. We note that although Medicare will begin paying for phosphate binders under the ESRD PPS beginning January 1, 2025, we are not establishing any requirements regarding how or where patients take these medications. These decisions are made and will continue to be made by the patient, nephrologist, and care team.

We recognize that updates may be required to ESRD facilities' systems, including electronic medical records, billing systems, and inventory management systems to accommodate new procedures for dispensing phosphate binders. As we previously noted, we initially delayed the incorporation of oral-only drugs into the ESRD PPS in 2011, in part to allow ESRD facilities to make such operational changes and logistical arrangements. In addition, we have provided operational guidance on the CMS website at *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf* that addresses HCPCS coding, billing, and price information. We expect that ESRD facilities will be able to make these system changes in advance of January 1, 2025.

As discussed in the CY 2025 ESRD PPS proposed rule, dialysis organizations have expressed concerns surrounding CMS using ASP to determine the TDAPA amount added to the ESRD PPS base rate for phosphate binders, which they believe does not adequately provide for dispensing cost.[43] Under current TDAPA policy, CMS intended to pay the TDAPA based on 100 percent of ASP for phosphate binders for at least 2 years. However, as noted in the CY 2025 ESRD PPS proposed rule (89 FR 55797), CMS recognized that updates may be required to ESRD facilities' systems, including electronic medical records, billing systems, and inventory management systems to accommodate new procedures for dispensing phosphate binders. In addition, we recognized the high percentage of ESRD beneficiaries that have at least one phosphate binder prescription and the large volume of phosphate binder prescriptions and stated that we were considering whether it may be appropriate to make additional payment to account for incremental operational costs in excess of 100 percent of ASP, such as dispensing fees, when paying the TDAPA for phosphate binders. Unlike drugs and biological products for which payment is already included in the ESRD PPS base rate, including all other drugs and biological products in existing functional categories, dispensing fees and other costs are not currently included in the ESRD PPS base rate for phosphate binders. Therefore, in the CY 2025 ESRD PPS proposed rule, we also stated that we were considering whether a potential change in TDAPA amount policy for phosphate binders to account for such costs would be consistent with the TDAPA policy as finalized in the CY 2019 and CY 2020 ESRD PPS final rules (83 FR 56948 and 84 FR 60673 through 60676). In the proposed rule, we noted one potential example we could consider would be paying 106 percent of ASP for 2 years as we did for calcimimetics. As discussed in the CY 2011 ESRD PPS final rule, the amounts added to the ESRD PPS base rate for oral drugs at that time were based on data from Part D, which included dispensing fees (75 FR 49043). We solicited comments on the extent to which 100 percent of ASP is an appropriate TDAPA amount for phosphate binders and whether there are any costs associated with the inclusion of phosphate binders into the ESRD PPS bundled payment that may not be accounted for by 100 percent of ASP. In the proposed rule we noted that CMS may finalize a change in the TDAPA amount for phosphate binders after considering comments on this topic.

As noted earlier, we have issued guidance[44] about the process we will use for paying the TDAPA for the phosphate binders and for their incorporation into the ESRD PPS bundled payment. This guidance addresses several key topics including billing information, information about the discarded drug policy, and information for manufacturers about reporting timelines for ASP data.

We invited public comment on the TDAPA payment methodology for the January 1, 2025, incorporation of oral-only drugs in the ESRD PPS. Approximately 162 commenters including LDOs; provider advocacy organizations; nonprofit dialysis associations; coalitions of dialysis organizations; a network of dialysis organizations; professional organizations; long-term care pharmacy association; ESRD facilities; ESRD beneficiaries, a trade association and pharmaceutical manufacturers, along with MedPAC, commented on the TDAPA payment methodology for the January 1, 2025, incorporation of oral-only drugs in the ESRD PPS. Of the 162 comments on oral-only drugs, we received 22 responses directly pertinent to the TDAPA methodology for the January 1, 2025, incorporation of oral-only drugs in the ESRD PPS. The remaining comments were out-of-scope, including 133 form letters, of which approximately 110 were from a unique

[42] Ibid.

[43] Ibid.

[44] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd* and *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf.*

submitter. The following is a summary of the public comments received on these proposals and our responses.

Comment: Multiple commenters expressed appreciation that CMS recognized the operational concerns and associated costs that were raised by ESRD facilities in the 2023 GAO report.[45] However, they expressed concern that CMS does not fully understand the costs and burdens associated specifically with staff time and dispensing of these drugs. Numerous commenters expressed concerns regarding the incremental operational costs and burden of incorporating phosphate binders into the ESRD PPS bundled payment. The commenters' concerns included, but were not limited to, distribution fees, mailing fees, storage fees, and increases in labor costs.

Response: CMS thanks the commenters for their appreciation and for sharing concerns regarding the costs and burden of incorporating phosphate binders into the ESRD PPS bundled payment. CMS has addressed these specific concerns in the responses to comments that follow in this rule. CMS recognizes that the introduction of oral-only medications into the ESRD PPS bundle can present some new logistic challenges. CMS is recognizing these costs through the modification to the TDAPA amount for phosphate binders in this final rule. In accordance with section 1881(b)(14)(B) of the Act, § 413.171 defines renal dialysis services to include oral-only renal dialysis services drug and biologicals. Oral-only renal dialysis service drugs and biological products were included in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044). At that time CMS finalized a policy to delay payment for these drugs under the ESRD PPS until January 1, 2014, to allow ESRD facilities to plan for the logistic challenges like those interested parties note in their comments. Legislation further delayed this date to January 1, 2025, and CMS ultimately updated the regulations at 42 CFR 413.174(f)(6) to finalize the date of the incorporation of oral-only drugs into the ESRD PPS bundled payment as January 1, 2025. CMS believes that the passage of over a decade since implementation of the ESRD PPS has provided sufficient time for interested parties to make the operational changes and logistical arrangements needed to furnish oral-only renal dialysis service drugs and biological products to their patients.

Comment: Numerous commenters stated that CMS should finalize the payment of a dispensing fee to account for such incremental operational costs when phosphate binders are added to the ESRD PPS bundled payment. They stated that the dispensing of oral medications to be taken daily will result in incremental operational costs and that these costs and dispensing fees are not included in the ESRD PPS base rate. An LDO and a coalition of dialysis organizations noted that every dialysis provider likely will implement a process that is most cost effective and efficient based on their footprint, organizational structure, patient population and other specific circumstances. Commenters stated that while the processes and procedures may vary by ESRD facility, every ESRD facility will incur distribution, storage, and staff expenses that are not accounted for in the ASP data, and this is an important distinction from the current processes related to calcimimetics. These other costs are discussed in the comments and responses that follow.

Response: In the CY 2025 ESRD PPS proposed rule, CMS recognized the high percentage of ESRD beneficiaries that have at least one phosphate binder prescription and the large volume of phosphate binder prescriptions and noted that we were considering whether it may be appropriate to make additional payment to account for incremental operational costs in excess of 100 percent of ASP, such as dispensing fees, when paying the TDAPA for phosphate binders. We stated that unlike drugs and biological products for which payment is already included in the ESRD PPS base rate, including all other drugs and biological products in existing ESRD PPS functional categories, dispensing fees and other costs are not currently included in the ESRD PPS base rate for phosphate binders (89 FR 55797). CMS believes that payment for the incremental operational costs, such as distribution fees, mailing fees, storage fees, and increases in labor costs incurred by the ESRD facilities for the provision of phosphate binders should align with resource use; that is, ESRD facilities' outlay to provide the phosphate binders to the Medicare beneficiaries. In lieu of a dispensing fee, as discussed later in this section, we are finalizing a flat rate increase to the proposed 100 percent of ASP TDAPA amount for phosphate binders.

Comment: Coalitions of dialysis organizations commented that distribution costs, both dispensing fees and mailing fees, are not included in 100 percent of ASP. An LDO stated that CMS suggested that ESRD facilities can implement efficiencies by having phosphate binder prescriptions mailed to the patient's home to the extent possible under state pharmacy laws. They noted, however, that this still represents a new cost to ESRD facilities that is not accounted for in a drug's ASP. One commenter who is a pharmacy solutions company stated that the range of dispensing fees tends to be $5 to $30 for any given dispense, and incremental operational costs might include costs associated with call centers and pharmacists to receive prescriptions from ESRD facilities, as well as the internal processing costs associated with converting that into fillable medications. The commenter also stated that there is labor associated with the actual fulfillment of oral medications, which includes both quality control such as operational checks, and despite automation there is additional regulatory burden and oversight that is applied to mail order pharmacies. They stated that all these activities will result in incremental operational costs. The commenter stated that it is reasonable to expect that ESRD facilities, depending on their size and scale, might pay more than what would be incurred in mailing fees to dispense oral medications through a pharmacy. Commenters noted that these types of distribution costs exist regardless of whether the oral-only drugs are dispensed from a retail or mail or central pharmacy.

Multiple commenters stated that the ESRD facilities will be paying pharmacy charges to obtain the drugs through them. Commenters expressed concern that ESRD facilities will incur additional costs that should not be theirs to shoulder. A non-profit dialysis association noted that increased payment for these incremental operational costs is important, particularly now when according to the commenter ESRD facilities are at a financial breaking point. The commenter noted that the logistics involved with getting the phosphate binders to a patient can be more expensive than the drugs themselves. They stated that these costs are even greater when beneficiaries are based in rural communities, putting their ESRD facilities at an even greater disadvantage.

An organization of pediatric nephrologists supported the TDAPA amount based on 100 percent of ASP for oral phosphate binders. While the organization appreciated that adding

[45] ''End-Stage renal Disease: CMS Plans for Including Phosphate Binders in the Bundled Payment.'' (GAO–24–106288, Nov. 2023).

oral-only drugs to the bundled payment will improve patient access, they are concerned that these drugs are expensive, and pediatric centers will not be able to afford them. The organization stated that pediatric patients with kidney disease are mainly dialyzed in pediatric hospitals, which are not able to get bulk pricing deals for these drugs. By adding oral-only drugs to the ESRD PPS bundled payment without an appropriate increase in payment, the organization stated that there will be a huge cost to the pediatric hospitals that they cannot absorb. The commenter identified additional concerns about access, as these are not first-line drugs for pediatrics and there is often significant prior authorization involved in procuring these drugs for pediatric patients. They stated that the provision of phosphate binders for the pediatric ESRD population would include compounding charges and dispensary costs.

Several commenters noted that there will be mailing fees either in terms of obtaining drugs from pharmacies or sending the drugs directly to the patient's home, which is where they are taken. The pharmacy solutions company stated that the home delivery of medications is preferred by beneficiaries. The commenter predicted that most dialysis providers will rely on mail order or shipping from a central pharmacy to their clinics for distribution; others may rely on local retail pharmacies. The commenter stated that for home delivery, each prescription must be shipped to a patient's home through a carrier like the United States Postal Service, FedEx, UPS, etc. Thus, each dispense incurs an additional expense of $3 to $25 depending on weight and shipping method. The commenter also noted that given the number of types of phosphate binders used per patient, and the sheer volume of pills needed, there will be increased shipping costs previously unaccounted for in the ESRD PPS base rate for oral phosphate binders. A coalition of dialysis providers stated that shipping costs alone are expected to be significant, as pills must be packaged to ensure the medication is not damaged during transit, and shipping costs are likely to escalate year over year, as will the contract costs with mail-order pharmacies.

Drug manufacturers encouraged CMS to finalize a change in the TDAPA amount to 106 percent of ASP for phosphate binders. They stated that 100 percent of ASP does not consider the substantial cost for dispensing oral-only drugs particularly for the high volume of pills associated with phosphate binders, which a large majority of Medicare ESRD beneficiaries utilize. An LDO and a coalition of dialysis organizations commented on the distribution of phosphate binders to a subpopulation of patients with housing instability, for whom mailing medications to a home is not an option. Based on an assessment of the LDO's patient population, as well as internal and external assets and capabilities in efficiently ordering and distributing a large volume of oral drugs, they assessed that mailing medications to patient homes, arguably the least burdensome process for facility staff, is viable for only a subset of their population. Because many patients have unstable housing situations, the LDO stated that they cannot rely on mail order for every patient.

Multiple commenters noted that all these distribution options will incur new costs previously unaccounted for in the original underlying bundled payment and that are not covered by 100 percent of ASP, including additional staff time and facility infrastructure costs. Unlike the current process used for calcimimetics, staff will be required to accept and store individual prescriptions for each patient. An LDO stated phosphate binders currently flow through retail and mail order pharmacies, and that they will continue to flow through those channels when the payment changes from Part D to Part B. The LDO suggested that it would be appropriate for CMS to adjust the TDAPA payment amount to recognize Part B pharmacy supply fees paid for oral drugs paid as part of a physician's service, or in this case as part of the renal dialysis service.

Response: CMS thanks the commenters for sharing the challenges accompanying the complexity of dispensing phosphate binders because of the broad array of phosphate binders and the high volume of pills. We acknowledge there are six common types of phosphate binders as compared to only one calcimimetic. CMS also acknowledges the range of dispensing fees for the high volume of phosphate binders required to manage ESRD patients, along with the impact of potentially higher pharmacy supply fees on the rural community. We understand the concerns expressed by the commenters about ASP, and that small ESRD facilities may be unable to negotiate the lower drug prices attributed to volume, and inaccessibility to supply chain discounts. These unique challenges of the high volume of phosphate binders that ESRD facilities must provide to beneficiaries would be magnified by a higher cost-to-payment ratio for the smaller ESRD facilities. We recognize that unstable housing situations with some ESRD beneficiaries would affect the distribution of phosphate binders through mail order, which may be a preferred way for ESRD facilities to manage this process. In consideration of the incremental operational costs that will be incurred by the ESRD facilities, as noted later in this section, CMS has decided to finalize an increase to the current 100 percent of ASP calculation of the TDAPA amount paid to ESRD facilities for the inclusion of phosphate binders.

Comment: A coalition of dialysis organizations noted that ESRD facilities will need to update information technology systems to facilitate these changes. Changes are required to update electronic medical records, billing systems, and inventory management. The commenter also stated that e-prescribing is also a complex process that involves interactions with state regulatory authorities and that ESRD facilities will need to stand-up or expand their internal ability to engage with e-prescribing systems and contract with e-prescribing platforms to facilitate this policy change for phosphate binders. The coalition stated that all these changes represent both significant up-front costs and investments as well as ongoing administrative requirements to ensure operational connectivity and seamless delivery to the beneficiary. The commenter stated that ASP does not cover any of information technology costs for ESRD facilities to distribute phosphate binders to beneficiaries.

Response: CMS acknowledges that there will be changes needed in the IT systems for ESRD facilities to accommodate the updates and methodological changes accompanying the inclusion of the phosphate binders in the ESRD PPS. These changes and updates affect electronic medical records, billing systems, and inventory management systems. However, since publication of the CY 2016 ESRD PPS final rule, our existing regulations at § 413.174(f)(6) have stated that effective January 1, 2025, oral-only drugs, which includes phosphate binders, will be paid for under the ESRD PPS. As previously discussed, we initially delayed the incorporation of oral-only drugs into the ESRD PPS in 2011, in part to allow ESRD facilities to make such operational changes and logistical arrangements. In addition, we have provided detailed operational guidance on the implementation of the TDAPA policy as it pertains to phosphate binders to ensure that facilities have clear instructions on compliance and payment processes to facilitate a smooth

transition,[46] which addresses HCPCS coding, billing, and price information for phosphate binders. We expect that ESRD facilities will be able to make these system changes in advance of January 1, 2025. CMS will continue to issue operational guidance as necessary for the smooth implementation of the incorporation of phosphate binders into the ESRD PPS bundled payment. As discussed later in this section, CMS is finalizing an increase in the TDAPA amount for phosphate binders, which may help to offset the costs associated with the logistic steps that the commenter described.

Comment: Coalitions of dialysis organizations, a professional organization of nephrologists, a drug manufacturer and a health care system noted that supporting the provision of a significant volume of pills to patients along with the storage costs associated with maintaining the drugs at the ESRD facility if the decision is to distribute the drugs to patients during their dialysis treatment sessions is an additional cost to the ESRD facility. An LDO stated that the storage and distribution of oral calcimimetic medications are different from what they would be with phosphate binders. Commenters noted that because there is one oral calcimimetic medication, and half of their patient population on calcimimetic treatment (approximately 25 percent) receives this drug three times per week chairside, the storage and distribution processes are much simpler. They stated that ESRD facilities can maintain a supply of calcimimetics with relatively low burden compared to phosphate binders. The commenters stated that with more than 80 percent of ESRD patients being prescribed phosphate binders, and with more than six different types of oral phosphate binders and various dosages of each, phosphate binders represent a 225 percent relative increase over, and addition to, the percent of patients to whom the ESRD facilities are currently delivering calcimimetics. The coalition stated that the scale of operational requirements needed to deliver calcimimetics simply pales in comparison to what will be required to deliver phosphate binders to beneficiaries through the ESRD PPS.

The commenters also noted that because of the size of the pills and the quantity required for each prescription, most ESRD facilities are not equipped to store and dispense this volume of oral medication. They stated that phosphate binders represent an exponential increase in the volume of pills dialysis providers will need to acquire, distribute, store, and manage for their patients each month and year. The relative difference between managing 360 pills per year per patient for cinacalcet as compared with 3,240 pills per year per patient for calcium carbonate is 800 percent.

An LDO stated that the ESRD PPS bundled payment might have included storage administration fees for drugs that were previously separately billable (largely intravenous agents) when CMS established the bundled payment. However, they noted that the claims data CMS analyzed at that time omitted these oral medications. The LDO commented that it is incorrect to assume that the storage costs and dispensing fees for intravenous agents, which represent the vast majority of dialysis-provided drugs accounted for when the bundled payment was created, are equivalent to the administration and mailing costs associated with oral-only medications. A coalition of dialysis organizations stated that while their member ESRD facilities have increased their familiarity with dispensing oral drugs since the inception of the ESRD PPS, the difference between distributing several hundred pills to 25 percent of their patients each year and distributing thousands of large pills to 80 percent of the ESRD facilities' patients each year requires a significant expansion of their pharmaceutical distribution operations on a massive scale. The commenter stated that the ESRD facilities cannot simply repurpose existing systems to meet this goal—they must build, rebuild, and significantly expand the scale of their operations to accommodate a vastly larger number of patients taking exponentially more pills than they have ever provided before. The development, maintenance, and ongoing clinical management of these processes represent significant costs to ESRD facilities, which are not covered by setting the TDAPA for phosphate binders at 100 percent of ASP.

The LDO commented that intravenous agents and oral-only drugs differ in several respects. Most notably, intravenous agents are usually administered to patients while on dialysis. Thus, there is centralized shipping and administration of those products. In contrast, the commenter stated, under state and other pharmacy laws, a significant number of the oral-only drugs will be shipped and dispensed directly to the patient's home. This delivery model incurs fixed costs, such as shipping and administration fees, which differ from those associated with the previously separately billable intravenous drugs.

A coalition of dialysis organizations stated that ESRD facilities would also have to construct or install on-site storage with appropriate temperature controls and security measures compliant with state pharmacy laws and requirements. If the patient misses or changes their appointment, or if the delivery of their prescription is delayed by the shipping carrier, this process breaks down. The coalition stated that CMS's suggestion regarding labor allocation for in-center distribution of phosphate binders does not address the needs of patients using home dialysis, is not simple, and is not without costs. The commenter stated that having an ESRD facility staff member hand a patient their pre-packaged medication is the final step in a long, complex, and costly process. They stated that none of those costs will be supported if CMS sets the TDAPA amount for phosphate binders at 100 percent of ASP.

A non-profit treatment and research center stated that given the difficulties associated with dispensing these medications in the ESRD facility, these facilities may have to restrict the formulary of available medications, which may mean that some patients have difficulty accessing the optimal medication for them. A health care system stated that because of significant cost considerations, they are concerned that ESRD facilities may limit patient choice by offering fewer phosphate binders based on the cost to facilities.

In their comment, MedPAC refers to their comment in the CY 2019 proposed rule that stated that the ASP + 6 percent policy that is applied to many Part B drugs was developed to reimburse physicians for the cost of drugs that they purchase directly and commonly administer in their offices. MedPAC also stated that while the ASP payment policy never stated what cost the ''+6 percent'' was intended to cover, they noted that reimbursing dialysis facilities is considerably different from reimbursing physicians. First, the variation in physicians' purchasing power, whether they practice solo, as part of a group, or in a health system, is likely to result in considerably more variation in the acquisition price for a drug compared to the acquisition prices for dialysis facilities. If the intent of the ''+6 percent'' was to address acquisition price variation, MedPAC stated that they believe that rationale is diminished for dialysis facilities. MedPAC also stated that the TDAPA amount is in addition to the ESRD PPS base rate, which already includes payment for the cost of storage and administration of

[46] *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf.*

ESRD-related drugs. Therefore, if the intent of the ''+6 percent'' was to address storage and administration costs, MedPAC believes these costs are already addressed through the ESRD PPS bundled payment and do not contribute to the rationale for paying 106 percent of ASP for the TDAPA.

Response: We agree with MedPAC that the 106 percent of ASP percent policy was developed to pay physicians for the cost of drugs and that the TDAPA is an add-on payment adjustment to the ESRD PPS base rate, which already accounts for the cost of storage and administration of renal dialysis drugs. However, CMS recognizes the unique costs associated with the provision of phosphate binder drugs and believes it is appropriate to consider a potential change in the TDAPA payment policy for these drugs. CMS believes it is appropriate to make an incremental addition to the TDAPA amount to specifically account for incremental operational costs in excess of 100 percent of ASP for furnishing phosphate binders, such as distribution fees, mailing fees, excess storage fees, and increases in labor costs. Unlike other drugs and biological products for which payment is already included in the ESRD PPS base rate, including all other drugs and biological products in existing ESRD PPS functional categories, these incremental operational costs, such as security of medications in storage, are not currently included in the ESRD PPS base rate for phosphate binders. We noted this in the analysis conducted to establish the base rate in the CY 2011 ESRD PPS final rule, and we did not include phosphate binders in that analysis due to a lack of data (75 FR 49043). CMS is making a provision for a fixed additional amount for each monthly claim that includes phosphate binders, which will increase the TDAPA amount to account for these unaddressed incremental operational costs in CY 2025 and CY 2026.

Regarding the concern about the difficulties associated with dispensing phosphate binders in the ESRD facility, and the risk that these facilities may have to restrict the formulary of available medications, which may mean that some patients have difficulty accessing the optimal medication for them, we believe that physicians and their patients should make the decision together on the appropriate form of the drug for treatment. It is not our intent to interfere with that decision making process. As the number of drugs within each ESRD PPS functional category increases and market share competition from the manufacturers is a factor, we anticipate easier access, more choices in care, and lower prices. We acknowledge that payment policies may have unintended consequences as identified by the commenters. However, it is our expectation that ESRD facilities will follow the physician's plan of care for the patient. Under the ESRD facility CfCs (for example, §§ 494.70(a)(12) and 494.90(a)(3)), if a physician determines that a particular phosphate binder is clinically best for a particular patient, the ESRD facility is obligated to make that drug available to the patient. In the CY 2011 ESRD PPS final rule, we specifically stated that we expect ESRD facilities to provide the appropriate medications, at the appropriate dosage, based upon individual patient needs. We expect the patient's nephrologist and the interdisciplinary team to identify medication needs in accordance with the individual patient's plan of care (75 FR 49038). CMS will be closely monitoring drug utilization at the beneficiary and facility level for these types of issues.

Comment: Coalitions of dialysis organizations, a professional organization of nephrologists and drug manufacturers commented that complying with state pharmacy laws for the distribution of phosphate binders is an additional cost. For example, these commenters noted that some states, like Alabama and Arkansas, do not allow ESRD facilities to distribute oral drugs directly to the patients, so there are additional contracting costs incurred. An LDO commented that ESRD facilities are limited by state rules in their ability to maintain a stock of medications that are dispensed to patients for consumption at home. They stated that CMS's recommendation that ESRD facilities could provide the patient with prepackaged medication when they are at the facility is not aligned with the reality of how ESRD facilities operate. They also stated that since they are not licensed to package medications, they will need to pay pharmacies to provide the medication so it can be distributed by registered nurses in their ESRD facilities to their patients. This fee is not included in the ASP, and the commenter stated that they will incur additional costs.

Another coalition of dialysis organizations commented that ESRD facilities are working diligently to stand up contracting and procurement agreements with manufacturers, distributors, mail-order pharmacies, and other entities to facilitate these changes to the payment system. The coalition notes that each provider must ensure compliance with federal rules as well as state pharmacy laws, which can vary significantly and prevent providers from having uniform policies and protocols across the country, creating inefficiencies that cannot be mitigated. Whether standing-up or significantly expanding these operations from their current, limited state to manage the phosphate binders, the coalition noted that ESRD facilities will need to invest in significant legal, administrative, and compliance staff resources to initiate and continuously maintain these operations going forward. The coalition also stated that some of their members noted that they will also need to help beneficiaries understand the limitations based on state pharmacy laws of what they can and cannot address with them about their prescription in the facility, as many state pharmacy laws require questions about prescriptions to be answered only by the pharmacist or prescribing clinician.

An organization of pediatric nephrologists stated that pediatric hospitals providing pediatric dialysis often do not have a license to dispense for Medicare.

A trade association stated that the dispensing flexibilities of pre-packaged mailed medications that extend to community-dwelling beneficiaries or contracting with external pharmacies to furnish the medications not dispensed during an in-center dialysis session, may not apply to those beneficiaries in long-term care facilities (LTCs), due to Federal or State nursing home regulations. In addition, this trade association stated that furnishing the oral-only phosphate binder medications to beneficiaries receiving home dialysis in a nursing facility will create excessive burdens on facility staff to establish ''work-around'' processes to intake, store, and dispense these oral-only dialysis medications in a manner different than their standard operating procedures for all other residents. The trade association wrote that such ''work-arounds'' increase the risk for missed medication administration and increase LTC provider operating costs, which may disincentivize providers from offering in-center dialysis room, akin to a ''den'' in a private home, or home dialysis services within the LTC facility, thereby limiting beneficiary care options.

A coalition of dialysis organizations stated that CMS should ensure that other providers, such as SNFs, are notified of forthcoming changes to the ESRD PPS regarding the provision of phosphate binders and work with those providers to ensure a smooth transition. Coalitions of dialysis organizations and a nephrology nurses association requested additional guidance from CMS regarding the complexity of

phosphate binder management for ESRD patients in the SNF setting. A trade association also requested that CMS address how ESRD and LTC facilities should address the unique operational considerations related to the incorporation of oral-only drugs into the ESRD PPS when the beneficiary's current home is a LTC facility. The association requested CMS to explain how the oral-only phosphate binder medications for Medicare dialysis patients should be made available to the LTC provider in a manner that complies with the Federal and State LTC provider regulations, whether it be from the ESRD facility, mail delivery or through an LTC pharmacy. The same commenters wanted to know if assurances will be provided that the costs of these medications directly related to the ESRD benefit and services will not be passed on to the SNF. Finally, the commenter questioned what, if any, are the documentation needs and requirements to be exchanged between the SNF and the ESRD facility.

Response: CMS expects that facilities should be prepared logistically for the inclusion of phosphate binders in the ESRD PPS bundled payment, given that the regulation establishing the current effective date was codified in 2016. This would include the logistics and contractual agreements for distributing the phosphate binders, whether in-center or for those patients receiving home dialysis, any need for increased storage due to the number of pills, and efficient use of ESRD facility labor. CMS is planning to hold at least two open door forums to inform interested parties about ESRD PPS policy and answer questions related to implementation of the incorporation of phosphate binders into the ESRD PPS bundled payment. In addition, CMS has a payment mailbox for incoming questions regarding the ESRD PPS payment policies. That mailbox address is: *ESRDPAYMENT@cms.hhs.gov*.

Regarding the commenter's concerns about pediatric hospitals' licensure to dispense phosphate binders, we believe the commenter is referring to regulations that prevent certain hospital pharmacies from providing drugs to patients to take home. We note that we expect ESRD facilities would contract with a pharmacy as necessary, and this would be the case for hospital-based ESRD facilities as well. Some hospitals may not have outpatient pharmacies, as would most freestanding ESRD facilities, but would be able to contract with a pharmacy to make phosphate binders available to patients. We note that the additional $36.41 increase to the TDAPA amount for phosphate binders would be intended cover incremental operational costs associated with such a contract.

CMS expects that LTC facilities will ensure that the current procedures they are using to supply oral drugs, such as calcimimetics, comply with the Federal and State LTC facility regulations. Accordingly, the same process should be followed for phosphate binders. In accordance with the statutory definition of renal dialysis services at section 1881(b)(14)(B)(iii) of the Act, § 413.171 defines phosphate binders as a renal dialysis service. Renal dialysis services have always been included within the scope of the Part A extended care benefit under section 1861(h)(7) of the Act that provides for coverage of those services (not specified elsewhere in section 1861(h)) that are generally furnished by, or under arrangements made by, SNFs. However, dialysis services described under section 1861(s)(2)(F) of the Act may be unbundled when furnished by an outside dialysis supplier. Given this, the SNF rarely bills separately for renal dialysis services. Rather, such services are billed for separately under the Medicare Part B dialysis benefit by the outside supplier. The incorporation of oral only drugs did not change the existing ESRD facility CfCs or associated guidance for providing home dialysis services in a LTC facility. Currently, CMS does not plan to update the QSO 18–24 guidance. As explained in QSO 18–24, collaborative care planning and delineated division of responsibilities is critical to the successful implementation of a patient's dialysis plan of care.[47] Listed below are the clinical areas that should be addressed in an agreement between an ESRD facility and LTC facility when home dialysis services are provided to residents of a LTC facility. This is not an exhaustive list, nor does it represent mandatory elements of a written agreement. This guidance is a resource for dialysis facilities to refer to prior to furnishing home dialysis care to nursing home residents. Guidance on clinical areas that should be addressed in an agreement include:

- Methods for enabling timely communication and collaboration between the ESRD facility and nursing home care team;
- Ensuring a safe and sanitary environment where the dialysis treatments occur;
- Ensuring active participation of the nursing home care team in the development and implementation of an individualized care plan;
- Delineation of patient monitoring responsibilities before, during, and after each treatment, ensuring any state scope-of-practice laws and limitations are adhered to when delineating responsibilities;
- Processes that ensure a review of the qualifications, training, competency verification, and monitoring of all personnel, patients, and caregivers (family members or friends) who administer dialysis treatments in the nursing home;
- Procedures for preparing nursing home staff to appropriately address and respond to dialysis-related complications and provide emergency interventions, as needed; and
- Procedures to make sure that all equipment necessary for the resident's dialysis treatment is available and maintained in working condition.

Comment: A trade association questioned if CMS intends to update the QSO–18–24–ESRD guidance prior to implementation to assure that both the ESRD facility and the LTC provider clearly understand what may need to be updated in their agreements, policies and procedures, and training needs resulting from the revised payment methodologies and the potential shift in how these oral-only phosphate binder medications are made available to the LTC provider.

Response: The incorporation of oral-only drugs under the ESRD PPS will not change the existing ESRD facility CfCs or associated guidance for providing home dialysis services in a LTC facility. Currently, CMS does not plan to update the QSO 18–24 guidance. As explained in QSO 18–24, collaborative care planning and delineated division of responsibilities is critical to the successful implementation of a patient's dialysis plan of care.

Comment: A non-profit treatment and research center stated that there will be difficulty managing these medications for patients residing in nursing homes whether for short-term rehabilitation or as long-term residents. They stated that nursing homes have existing processes for obtaining medication for their patients which does not include obtaining it from ESRD facilities. The ESRD facilities will need to collaborate with any nursing facility in which their patients reside to arrange for the delivery of the medication. Further, the commenter stated that the nursing homes will ask for payment for the time their staff spend in providing the medication to the patient. They will need to have a pharmacist deliver the medication to the nurse caring for a

[47] *https://www.cms.gov/files/document/qso-18-24-esrd-revised.pdf.*

patient and then the nurse will have to provide the medication to the patient as prescribed.

Response: As noted previously, renal dialysis services have always been included within the scope of the Part A extended care benefit under section 1861(h)(7) of the Act that provides for coverage of those services (not specified elsewhere in section 1861(h)) that are generally furnished by, or under arrangements made by, SNFs. However, dialysis services described under section 1861(s)(2)(F) of the Act may be unbundled when furnished by an outside dialysis supplier. Therefore, LTCs can provide renal dialysis services, including provision of phosphate binders, to their residents in an ''under arrangement'' agreement with an ESRD facility.[48] Any payment arrangements, such as payment for the LTC staff time, with the ESRD facilities would involve contractual arrangements with the ESRD facility and the LTC facility. Alternatively, if the LTC is a Medicare-certified dialysis facility, it can provide renal dialysis services.

Comment: A coalition of dialysis organizations, a professional organization of nephrologists, a drug manufacturer, and a health care system all stated that adjusting drug supplies when a physician changes a patient's prescription to another product (which often occurs) is a cost not covered by 100 percent of ASP. In a comment from an LDO, they stated that their data suggests that relative to calcimimetics, phosphate binder prescriptions change frequently. They noted that approximately 23 percent of patients on a phosphate binder have a change in their prescription each month. The commenters stated that assuming mail delivery is used for appropriate patients, ESRD facilities will incur the cost of delivery, which in some cases may be more than once per month depending on the rate of prescription changes.

Response: CMS recognizes that there may be changes in the patient's prescription for phosphate binders to address the patient's side-effects from a current phosphate binder or to adjust following the results of laboratory testing. As a cost control measure, ESRD facilities could adjust the prescribed amounts to avoid additional mailing fees or could negotiate deeper discounted pricing from mail service pharmacies for long term, chronic therapies such as phosphate binder prescriptions. In the CY 2016 ESRD PPS final rule (80 FR 69033), we discussed our existing policy since the inception of the ESRD PPS that all renal dialysis service drugs and biological products prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities, and the units reported on the monthly claim must reflect the amount expected to be taken during that month. We stated that ESRD facilities should use the best information they have in determining the amount expected to be taken in a given month, including fill information from the pharmacy and the patient's plan of care. CMS notes that Medicare does not pay for drugs that are not in single-use packaging that have been dispensed and discarded. As noted in an October 2022 review article about mineral bone disorders in kidney disease patients, decisions about the use and dose of specific phosphate binders should be based on progressive or persistent hyperphosphatemia.[49] Additionally, changes in phosphate binder prescriptions most often occur in patients with ESRD who are new to dialysis[50] and may have higher costs. CMS provides an onset adjustment of 32.7 percent, which is a Medicare payment adjustment for patients with ESRD who are eligible for Medicare during their first 120 days of chronic renal dialysis. As noted in the CY 2011 ESRD PPS proposed rule (74 FR 49952) the higher costs of the new patients may be due to stabilization of the patient's condition, along with administrative and labor costs associated with the patients being new to dialysis.

Comment: A coalition of dialysis organizations and a health care system disagreed with the language in the proposed rule that suggested there would be no additional labor cost incurred when phosphate binders are added to the ESRD PPS bundled payment. The commenters stated that they anticipate that adding new duties associated with the distribution of phosphate binders will take significant time away from existing patient care activities. As a result, many ESRD facilities may find themselves having to hire additional health care professionals and other staff to maintain the same level of care provided today. The coalition and health care facility also stated that ESRD facilities continue to face significant labor costs and, while the tight labor market has abated somewhat, hiring additional staff remains a significant expense. An LDO noted that CMS suggested that ESRD facilities can efficiently use staff time by providing patients with pre-packaged medication that would include medications for multiple days. However, the LDO, along with a coalition of ESRD facilities commented that this represents a new cost to ESRD facilities that is not accounted for in a drug's ASP. They commented that what CMS presents as a simple solution is the end-result of a complex system that will require a significant up-front and ongoing investments of resources and staff time. To execute CMS's suggestion, the commenters noted that ESRD facilities need to contract with a pharmacy to dispense, fill, and ''pre-package'' the medication and arrange for delivery to the facility in advance of each patient's scheduled appointment. Facility staff would need to receive, inventory, store, and manage medication for all their patients on-site and then ensure that all pharmacy processes are coordinated with scheduled patient appointments. The LDO stated that under Part B, phosphate binders will continue to be distributed through pharmacies whether those prescriptions are mailed to the patient or to the facility. Regardless of where the patient receives the prescription (facility or home), the burden of managing oral phosphate binders through the facility affects every member of the staff. The LDO stated that the ESRD facility staff will need to manage medication orders, call in new prescriptions, conduct medication management, maintain delivery logs when prescriptions are delivered to the facility, review and maintain refill requests, educate patients on usage, and manage disposal of unused oral medications. Because many patients will lose the low-income subsidy and other beneficiary protections in Part D, the LDO noted, some facility staff time will now be dedicated to assisting patients who have trouble affording their medications.

A non-profit treatment and research center stated that not only are there costs incurred when their registered nurses dispense the medications to the patients, provide counseling about the medications and answer any questions patients may have, but the nurses will be taken away from their current patient care responsibilities to perform these functions, which the commenters noted will negatively impact the patients under their care. A health care system

[48] *https://www.cms.gov/Medicare/Medicare-Contracting/ContractorLearningResources/Downloads/ja0435.pdf.*

[49] *Int. J. Mol. Sci.* 2022, *23*(20), 12223; *https://doi.org/10.3390/ijms232012223*, Mineral Bone Disorders in Kidney Disease Patients: The Ever Current Topic.

[50] Expert Opinion on Drug Safety, 2022, 21(7); *https://doi.org/10.1080/14740338.2022.2044472*. An update on phosphate binders for the treatment of hyperphosphatemia in chronic kidney disease patients on dialysis: a review of safety profiles.

also stated that increasing the number of pharmacies will increase the administrative cost of providing services and the complexity of tracking the drugs for the ESRD facility.

The LDO stated that while approximately 25 percent of their patient population is on calcimimetic therapy, whereas approximately 70 to 80 percent of their population is on phosphate binder therapy, CMS cannot assume that because ESRD facilities are managing calcimimetics, the infrastructure is in place to manage phosphate binders. They stated that there will be a significant amount of staff time devoted to managing phosphate binders through the ESRD facility, which will almost certainly be required to hire additional staff to reduce the burden on clinical staff. The LDO stated that these areas represent the ongoing costs to providers and do not include startup costs of building storage capacity and upgrading IT systems to accommodate changed workflow and new business functions.

A coalition of dialysis organizations expressed the importance of medication management with ESRD patients, as they may have multiple co-morbidities and polypharmacy, and there is a potential for medication-related errors. This makes continuity of care and medication management systems important. They stated that CMS does not cover ESRD facilities' ongoing expenses to provide medication management for the phosphate binders.

Response: CMS has carefully considered the operational considerations and costs raised in the comments. With respect to considerations for ESRD facility staffing, CMS notes that the ESRD PPS includes payment for staffing related to the provision of most renal dialysis services. However, we acknowledge that there are some areas such as IT synchronization and the advancements in the delivery systems that had not been considered, when establishing both the ESRD PPS base rate and the current policy for TDAPA payments at 100 percent of ASP. These costs were considered in formulating the increased TDAPA payment which is intended to account for incremental operational costs associated with furnishing phosphate binders. CMS does believe there are several strategies that ESRD facilities could employ to efficiently use available staff time to provide phosphate binders. There are parallels between the administration of phosphate binders and the administration of oral calcimimetics, which are also typically taken every day. First, we expect that patients with ESRD generally receive treatment for at least 3 hours per session, typically three times per week. We believe that during this treatment window there is generally staff availability to provide the patient with pre-packaged multiple-day doses of their medication (should state law allow). Second, ESRD facilities could maximize the efficiency of staff time by mailing the prescriptions, to the extent that doing so is consistent with state pharmacy laws. For example, the GAO report identified that one large dialysis organization only mails oral prescriptions to patients' homes, while others mail the medication to either the ESRD facility or the patient's home. Third, the GAO report identified that some ESRD facilities outsource labor by contracting with outside pharmacies rather than operating their own pharmacy. By contracting with outside pharmacies, ESRD facilities could reduce or avoid the need to hire additional pharmacists and pharmacy staff to manage the volume of prescriptions. CMS acknowledges that these suggestions may not be fully applicable for LTC or SNF facilities. CMS will continue to engage and communicate with these facilities to ensure continuity of care and will continue to monitor patient outcomes under this policy change.

Comment: A coalition of dialysis organizations stated that while ESRD facilities and clinical teams, such as dietitians, are involved in the current management of bone and mineral metabolism and hyperphosphatemia, the process is currently managed under the auspices of the prescribing physician working within the formulary confines of the beneficiary's Part D plan or other source of drug coverage, which is managed largely outside of the ESRD facility. Migration of phosphate binders from Part D to Part B imposes new clinical administrative responsibility on ESRD facilities to develop clinical protocols and formularies, educate their clinician partners and clinical staff, and manage ongoing clinical evaluation and monitoring to ensure they are meeting the needs of our patients on an ongoing basis to manage a class of drugs for which they were previously not responsible. The coalition stated that the development, maintenance, and ongoing clinical management of these processes represent significant costs to ESRD facilities to hire and continuously employ clinical leaders across ESRD facilities and educate and train clinical staff on evolving educational protocols and educate beneficiaries on complex clinical issues. They noted that although ESRD facilities certainly already employ many clinicians, the expansion of the bundled payment to include phosphate binders represents an expansion of the duties their clinical teams need to undertake, which will result in an expansion of their clinical teams. They stated that ASP would not cover any of these clinical operations expenses required for ESRD facilities to take on the responsibility of managing the phosphate binders for ESRD patients.

Response: As discussed in the CY 2016 ESRD PPS final rule (80 FR 69010), we issued sub-regulatory guidance that instructs ESRD facilities to include all composite rate drugs and biological products furnished to the beneficiary on the monthly claim form (Change Request 8978, issued December 2, 2014). In CY 2015 ESRD PPS final rule (79 FR 66149 through 66150), we discussed the drug categories that we consider to be used for the treatment of ESRD with the expectation that all of those drugs and biological products would be reported on the claim. Along with capturing cost to align payment with resource use, we expected that ESRD facilities would be aware of all renal dialysis service drugs and biological products being taken by their dialysis patients in the event of a medical adverse event during dialysis. In addition, the ESRD QIP includes measures for coordination of care in the Care Coordination domain, which accounts for 30 percent of an ESRD facility's Total Performance Score. The QIP also includes a reporting measure for dialysis events. We have heard from interested parties that they are aware of and manage, with the patient's physician, the drugs and biological products taken by their ESRD patients. Therefore, CMS does not believe that the management of phosphate binders done in conjunction with the ESRD patient's physician, represents a new clinical administrative responsibility.

CMS will continue monitoring beneficiary utilization of phosphate binders, as well as beneficiary health outcomes that might be related to phosphate binder treatment, as it includes these drugs in the bundled payment. In addition, CMS is monitoring these metrics across beneficiary characteristics, including race or ethnicity and dual eligibility status, to ensure that vulnerable populations are not harmed by this change.

Comment: A coalition of dialysis organizations commented on the ESRD facilities' responsibility to educate ESRD beneficiaries on an ongoing basis. They stated that the migration of Medicare payment for phosphate binders from Part D to Part B would be a significant change for beneficiaries.

For some, this change would start with ensuring they understand that their phosphate binders will now be managed by their ESRD facility rather than through their local pharmacy. However, the commenter noted that some beneficiaries may experience a change in their recommended prescription related to the change from their prior drug coverage and will need clinical, dietary, and social work education in support of that change.

Response: Under the CfCs for ESRD facilities (73 FR 20480), the standard for patient education located at § 494.90(d) mandates that the plan of care include education and training for patients and family members or caregivers or both, in aspects of the dialysis experience and dialysis management, which includes medications they are taking. The plan of care would include a change in a patient's recommended prescription and would include the need for clinical, dietary, and social work education in support of that change. ESRD beneficiary education is a longstanding CfC requirement.

Comment: An LDO expressed appreciation of CMS's interest in exploring options for paying providers for costs in addition to the drug acquisition costs and acknowledgement that drug dispensing fees were included in the original bundling of oral drugs in 2011. An interested party requested that CMS consider the incremental operational costs involved when adding phosphate binders to the ESRD bundled payment, noting that the current proposal does not account for these costs, which could lead to increased financial strain on ESRD facilities. The commenter stated that a fair dispensing fee or a similar mechanism should be implemented to cover these additional expenses.

An LDO and a health care system requested CMS to consider that payment at 100 percent of ASP is inconsistent with Part B drug payment generally, where providers are typically paid at 106 percent of ASP percent or receive additional dispensing fees for certain drugs. Numerous commenters agreed that CMS should finalize the TDAPA payment for phosphate binders at 106 percent of ASP, rather than 100 percent of ASP, to account for additional facility incremental operational costs. One LDO stated that they strongly believe the savings CMS will obtain from including these drugs in the ESRD PPS bundled payment will cover the additional costs associated with appropriately recognizing dispensing and other incremental operational costs. The non-profit dialysis organization also recommended that beginning January 1, 2025, CMS should begin collecting and analyzing data to inform a mid-year correction to the TDAPA amount if data suggest that 106 percent of ASP is insufficient.

MedPAC commented that CMS should maintain its existing TDAPA policy to incorporate oral-only phosphate binders into the ESRD PPS. The commission wrote that in their comment in the CY 2019 ESRD PPS proposed rule, they stated that the 106 percent of ASP policy that is applied to many Part B drugs was developed to reimburse physicians for the cost of drugs that they purchase directly and commonly administer in their offices.[51] MedPAC stated that while the ASP payment policy never stated what cost the ''+6 percent'' was intended to cover, they noted that payment to ESRD facilities is considerably different from payment to physicians. MedPAC stated that the variation in physicians' purchasing power, whether they practice solo, as part of a group, or in a health system, is likely to result in considerably more variation in the acquisition price for a drug compared to the acquisition prices for ESRD facilities. If the intent of the ''+6 percent'' was to address acquisition price variation, MedPAC believed that rationale was diminished for ESRD facilities. In their comment letter, MedPAC referenced their comment on the CY 2019 ESRD PPS proposed rule, that setting the TDAPA at 100 percent of ASP appears to be a well-founded policy. Further, they stated that as CMS explained when the agency reduced the TDAPA amount for calcimimetics in CY 2020 from 106 percent of ASP to 100 percent of ASP, setting the payment level with the average sales price of the drug limits the financial burden on beneficiaries and taxpayers.

Response: As discussed previously, CMS agrees with MedPAC that the 106 percent of ASP policy was developed to reimburse physicians for the cost of drugs and that the TDAPA is an add-on payment adjustment to the ESRD PPS base rate, which already accounts for the cost of storage and administration of renal dialysis drugs and biological products. However, we also recognize that there are incremental operational costs with inclusion of phosphate binders into the ESRD PPS, that were not factored into the original payment policy. As described later in this section, CMS is making a provision for an increase in the calculation of the amount for the TDAPA for phosphate binders through a flat rate addition for two years to account for these unforeseen incremental operational costs.

Comment: A hospital association requested that CMS pay ESRD facilities for the costs associated not only with drug acquisition, but also with storing, managing and distributing oral drugs that are not consumed with the treatment. An LDO noted that in the proposed rule, CMS suggests that payment for phosphate binders at 106 percent of ASP may be appropriate for the 2-year TDAPA period. The LDO and a drug manufacturer agreed that this approach would be consistent with CMS policy for calcimimetics and would also be consistent with Part B drug payment policies generally. However, a non-profit treatment and research center stated that for some phosphate binder medications like sevelamer and calcium acetate, the 6 percent above ASP likely will not cover the costs they will have to pay to the pharmacy, much less the costs incurred when their registered nurses dispense the medications to the patients, provide counseling about the medications and answer any questions patients may have.

To maintain consistency with the treatment of calcimimetics during their first 2 years of TDAPA, to align with the way Medicare pays for drugs and biological products under the Hospital Outpatient PPS's pass-through payment policy, and to minimize administrative burden on CMS and ESRD facilities, multiple commenters recommend that CMS adopt the methodology outlined in section 1847A of the Act, which sets payment at the 106 percent of ASP; if ASP is not available, the payment is based on the Wholesale Acquisition Cost (WAC). Alternatively, an LDO urged CMS to use the flat rate part B supply fee for oral drugs under the Physician Fee Schedule as a precedent to provide the same payment adjustment for oral Part B renal dialysis drugs.

MedPAC opposed the TDAPA amount based on 106 percent of ASP for phosphate binders in their comment and noted that when CMS reduced the TDAPA amount for calcimimetics in CY 2020 from 106 percent of ASP to 100 percent of ASP, MedPAC stated that CMS explained that setting the payment amount at 100 percent of ASP of the drug limits the financial burden on beneficiaries and taxpayers.

Response: Consistent with our discussion in the CY 2020 ESRD PPS final rule (84 FR 60675), we continue to

[51] Medicare Payment Advisory Commission.2018. MedPAC comment on CMS's proposed rule on the end-stage renal disease payment system for CY 2019. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-letters/08312018_esrd_cy2019_dme_medpac_comment_v2_sec.pdf.*

believe that 100 percent of ASP is a reasonable basis for payment for the TDAPA for new renal dialysis drugs and biological products that fall within an existing functional category, because there are already dollars in the per treatment base rate for the new drug's respective functional category. We further believe 100 percent of ASP is a reasonable basis for the TDAPA amount for new renal dialysis drugs and biological products that do not fall within an existing functional category because the ESRD PPS base rate has dollars built in for administrative complexities and overhead costs for drugs and biological products. However, we note that the original analysis in the CY 2011 ESRD PPS final rule excluded phosphate binders, which are a longstanding renal dialysis service, and their associated costs, so a higher payment amount to capture these additional costs would be warranted. In addition, we believe the 106 percent of ASP payment could induce ESRD facilities to choose the higher priced phosphate binders for the higher payment rate. As detailed below, CMS is increasing the TDAPA amount for phosphate binders for two years in an amount similar to 106 percent of ASP to pay for the additional incremental operational costs of phosphate binder inclusion in the ESRD PPS while striking a balance between accessibility and efficiency and economy for the Medicare program.

Comment: Numerous commenters stated that CMS should adopt a dispensing fee using a rate of 106 percent of ASP for phosphate binders to align the ESRD PPS policies with those applied to other Medicare providers. They stated that both the Medicare Part D and Medicaid programs provide for dispensing fees. Under Part D, they noted that the dispensing fees are set through negotiations between the plan and pharmacy. Medicaid amounts are significantly higher and in the range of $9 to $12 per prescription, which the commenter noted would translate into a $0.69 to $0.92 per treatment amount in the context of the ESRD PPS, according to an analysis cited by the commenter. The commenters also noted that in accordance with section 1861(s) of the Act, Medicare Part B includes a $24 dispensing fee, which would be approximately $1.85 per treatment in the ESRD PPS context. Additionally, the commenters stated that according to the Medicare Claims Processing Manual, Chapter 17, § 90.4, CMS also provides a dispensing fee to hospital outpatient departments (HOPD) and ambulatory surgical centers (ASC), but relies upon 106 percent of ASP rather than a flat rate. The commenters stated that CMS decided to maintain the 106 percent of ASP policy in the HOPD and ASC settings after conducting a multi-year analysis of hospital cost reports. This analysis sought to determine the average overhead costs associated with providing drugs to patients, and CMS decided to adopt 106 percent of ASP as the payment amount. The commenters indicated that even though in the context of some HOPD/ASC products the add-on may result is higher payment amounts, CMS adopted this approach because of its administrative simplicity. Similarly, in these settings, the commenters stated that CMS also has adopted 106 percent of ASP as the basis for paying for separately payable non-pass-through drugs. One criterion a drug must meet to receive this separate payment is that the cost exceeds $135 per day.

The commenters stated that adopting a 106 percent of ASP policy as the basis of a dispensing fee rate would also align with the treatment of drugs in these other payment systems. They indicated that one analysis of phosphate binders demonstrates that the increase in per treatment payment for a 30-day supply of a phosphate binder could range from $1.46 to $8.03. The commenters stated that these amounts are not significantly different than those CMS finds acceptable in the HOPD/ASC setting or the other dispensing fee programs.[52]

The commenters requested that CMS adopt the 106 percent of ASP policy that it relies upon in other parts of the Medicare program, which the commenters described as straightforward and transparent.

Response: As CMS stated in the CY 2020 ESRD PPS final rule (84 FR 60676), we believe moving from pricing methodologies available under section 1847A of the Act, (106 percent of ASP) to 100 percent of ASP for all new renal dialysis drugs and biological products regardless of whether they fall within an ESRD PPS functional category strikes a balance between the increase to Medicare expenditures (subsequently increasing beneficiary co-insurance) and addressing stakeholder concerns discussed in section II.B.1.e of the CY 2019 ESRD PPS final rule (83 FR 56932). As an example of how the flat addition to the TDAPA amount would impact beneficiary copayment when compared to 106 percent of ASP, if a beneficiary's monthly utilization for a given phosphate binder totaled $1,000 (100 percent of ASP) + $36.41= $1,036.41, the beneficiary co-pay would be $207.28. However, if the same phosphate binder were to be paid a TDAPA amount derived from 106 percent of ASP ($1,000 * 1.06 = $1,060), then the beneficiary's copay would be $212 ($1,060 * 0.20 = $212). During the CY 2024 ESRD PPS rulemaking cycle, CMS indicated that it preferred to adopt policies that are less complex and more transparent. As noted later in this section of the preamble, we are finalizing the incorporation of a flat-rate add-on amount to the TDAPA, as allowed by section 1881(b)(14)(D)(iv) of the Act, for phosphate binders, which we believe reflects a similarly transparent and straightforward approach. We believe this fixed addition to the TDAPA amount for phosphate binders is relatively simple while being more predictable and more transparent than the requested 106 percent of ASP methodology, because ESRD facilities would not have their additional payment based on the ASP of the drug prescribed. Additionally, this fixed increase methodology would achieve many of the benefits described by commenters without incentivizing use of higher-cost phosphate binders.

Comment: Commenters generally agreed that payment of 100 percent of ASP would be insufficient to cover the incremental operational costs of including phosphate binders in the ESRD PPS bundled payment. In their comments letters, both MedPAC (citing their 2023 Report to Congress)[53] and LDOs have recognized the inherent incentives that a percentage-based payment policy creates in encouraging use of higher cost drugs when less expensive therapeutic alternatives are available.

A coalition for dialysis organizations recognized that utilizing 106 percent of ASP ties the value of the dispensing fee to ASP, which may present issues where ESRD facility incremental operational costs exceed 6 percent of ASP. They stated that they understand why some other payment systems have instead provided fixed dispensing fees that are intended to reimburse for incremental operational costs independent of ASP and arrive at the fixed dispensing fee through different mechanisms, including some that are set in statute.

Although MedPAC did not support setting the TDAPA amount at 106 percent of ASP to account for dispensing fees, which are intended to cover reasonable costs that are directly

[52] MedPAC. *Report to the Congress: Outpatient Dialysis Services* (Mar. 2024).

[53] Medicare Payment Advisory Commission.2023. *Report to the Congress: Medicare and the health care delivery system.* Washington, DC:MedPAC.

related to providing the drug,[54] MedPAC did state in the comment that there is no consensus on the original intent of the percentage add-on to ASP. MedPAC stated that if CMS elects to include a dispensing fee in the TDAPA for phosphate binders, the agency should examine the dispensing fees for phosphate binders paid under Part D to assess if such data are appropriate to use under the ESRD PPS, noting that, in 2021, the median Part D dispensing fee was $0.50 per claim for the six common types of phosphate binders furnished to beneficiaries on dialysis. In their comment letter, the Commission indicated that it has also found that under Part D, dispensing fees for generic drugs are typically a fixed dollar amount (that is, not always related to the price of the product), and that similar to dispensing fees paid in the commercial sector, Part D plans typically pay dispensing fees of $1 per claim or less.[55] As an alternative to 106 percent of ASP, the LDOs, coalitions of dialysis organizations and the professional association of nephrologists would also support, and there is precedent for, a flat rate addition to the ASP. One LDO recommended a flat fee instead of a percentage of the cost of the medication. The LDO stated that dispensing expenses do not fluctuate based on the cost of the medication. The commenter estimated that dispensing fees would be roughly $11 and shipping fees would be approximately $15 per prescription. Other commenters stated that for certain conditions, Medicare Part B covers outpatient prescription drugs and biological products when they are part of a physician's service or used with covered durable medical equipment. For those drugs, Medicare Part B pays pharmacies a supply fee for each prescription. The commenters referred to 42 CFR 414.1001 and stated that pharmacies are paid $24 for the first 30-day period, and $16 for each subsequent 30-day period. On a per treatment basis, this would equate to approximately $1.23 to $1.85 when a patient receives 13 treatments in a month. Commenters suggested that CMS should recognize that under Part B, ESRD facilities will be required to pay for these pharmacy services.

Response: CMS has reviewed all of the comments regarding implementation of the inclusion of phosphate binders in the ESRD PPS bundled payment. In the CY 2016 ESRD PPS final rule, we stated that for at least 2 years we will pay for the existing oral-only drugs—phosphate binders and calcimimetics—using the TDAPA, which will be calculated based on the payment methodologies under section 1847A of the Act (80 FR 69027), which can include 106 percent of ASP. Following finalization of the CY 2016 ESRD PPS final rule, the regulation at § 413.234(c)(2) stated the TDAPA is paid until sufficient claims data for rate setting analysis for the new injectable or intravenous product is available, but not for less than two years. In the CY 2019 ESRD PPS final rule CMS stated that to balance the price controls inherent in any PPS we believe that we needed to take numerous issues into consideration to revise the basis for TDAPA payment. These issues included the use of the best available data, the avoidance of use of the highest price drugs for higher payment, and cost-sharing for beneficiaries. We noted that we are, and will continue to be, conscious of ESRD facility resource use and recognize the financial barriers that may be preventing uptake of innovative new drugs and biological products.

Therefore, we proposed to revise § 413.234(c) under the authority of section 1881(b)(14)(D)(iv) of the Act, to reflect that we would base the TDAPA payments on 100 percent of ASP instead of the pricing methodologies available under section 1847A of the Act (which includes 106 percent of ASP)(83 FR 56943–56944).

As we discussed previously, we believe that a flat increase to the TDAPA amount for phosphate binders would be most appropriate. We believe an increase in the payment adjustment amount that approximates 6 percent of ASP would provide the appropriate payment for incremental operational costs associated with ESRD facilities furnishing phosphate binders. We considered the differences in the availability of data for calculating the appropriate TDAPA amount for calcimimetics and phosphate binders. Prior to the TDAPA payment for calcimimetics in CY 2018, only those ESRD beneficiaries with Part D had access to the oral calcimimetic, Sensipar, but there was no utilization data for the injectable calcimimetic, Parsabiv, which would serve as a substitute for the oral calcimimetic. However, CMS was able to obtain data on phosphate binder utilization among ESRD PPS beneficiaries who had Part D coverage for phosphate binders to estimate expenditures, and there is no injectable phosphate binder for which we do not have utilization data. Therefore, with the knowledge of utilization of phosphate binders in Part D, coupled with the percentage of ESRD PPS beneficiaries who do not have Part D coverage, we believe we have adequate data to be able to calculate an appropriate amount to pay the TDAPA for phosphate binders for at least two years. Taking into account the estimates that were put forth by the commenters for the incremental operational costs to the ESRD facilities for supplying the phosphate binders to the ESRD facilities, along with our use of the Part D data, we have determined that a fixed amount derived from 6 percent of ASP of a monthly weighted average of the six most common phosphate binders based on past Part D utilization data best aligns payment with resource use and mitigates the incentive to use of the most expensive phosphate binders to obtain higher TDAPA payment and ultimately a higher dollar addition to the ESRD PPS base rate at the end of the TDAPA period. This aligns with the commenters' suggestions of using a flat rate adjustment instead of 106 percent of ASP. We are finalizing a flat rate increase to the TDAPA amount for phosphate binders, derived from 6 percent of the weighted average of Medicare expenditures for phosphate binders per month under Part D, for the first two years of TDAPA payment to ESRD facilities. The CY 2025 flat rate increase to the TDAPA amount will be $36.41. This payment adjustment is included for every monthly ESRD PPS claim that includes phosphate binders. We will consider changes to this amount through future rulemaking if appropriate; for example, this amount could be recalculated derived from the best available updated data for the second year of TDAPA payment for phosphate binders, potentially utilizing data from Part B.

Additionally, we are finalizing regulatory language at 413.234(c)(4), which states that we would pay an increased amount through the TDAPA for phosphate binders for two years. The increase to the TDAPA amount would be the equivalent of the monthly weighted average of 6 percent of ASP, calculated for each of the first two years of TDAPA payment for the phosphate binders.

Comment: Coalitions of dialysis organizations, a professional organization of nephrologists and a non-profit treatment and research center

[54] Under 42 CFR 423.100, dispensing fees are costs incurred at the point of sale in excess of the ingredient cost of a covered Part D drug. Dispensing fees include pharmacy costs such as checking insurance status, performing quality assurance, physical delivery, special packaging, and salaries of pharmacists and other pharmacy workers as well as the costs associated with maintaining the pharmacy facility and acquiring and maintaining technology and equipment.

[55] The Commission's calculation is based on Part D prescription drug event data from CMS. According to our stakeholder interviews, this amount is in line with most commercial insurance. *https://www.medpac.gov/wpcontent/uploads/2023/10/Generic-prices-Part-D-April-2024-SEC.pdf.*

stated that, due to the 2 percent reduction in Medicare FFS payments under sequestration, 100 percent of ASP equates to roughly ASP minus 1.6 percent, which the commenters stated does not cover the cost of acquiring phosphate binders. They commented that many medium and small ESRD facilities do not have the economies of scale and must purchase drugs at a significant percentage above the ASP. As a result, 100 percent of ASP is actually less than the acquisition cost of these drugs and will have a negative financial impact on these ESRD facilities. A non-profit treatment and research center noted that since the ASP is reduced by 1.6 percent because of the sequestration cuts, the gap between resource use and payment is even greater. A professional organization of dialysis providers and an LDO stated that Medicare only pays 80 percent of costs. For patients who are dual eligible receiving Medicaid, this remaining 20 percent goes unreimbursed, which, following sequestration, equates to 78.4 percent. Similar results would occur for patients without a secondary insurance if they are unable to pay the remaining 20 percent cost-sharing amount. An LDO asserted that for patients without secondary insurance, only 60 percent of the nonpayment is covered by bad debt.

Response: We appreciate the commenters' concerns about payment adequacy; however, we noted that these concerns generally fall outside the scope of ESRD PPS policy. Sequestration is a mandatory spending reduction that affects Medicare Part B payments broadly, including payments under the ESRD PPS.[56] Reductions in Medicare payments due to sequestration fall outside the scope of the ESRD PPS policy and are required under the Budget Control Act of 2011 (BCA; P.L. 112–25). In addition, the 20 percent beneficiary copayment amount is required by statute, and we did not propose any changes to this amount. Section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. In general, many Part B services are subject to a payment structure that requires beneficiaries to be responsible for a 20 percent coinsurance after the deductible (and Medicare pays 80 percent). With respect to renal dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(A) of the Act, Medicare pays 80 percent of the total amount per treatment and the individual pays 20 percent (74 FR 50005). Some dual eligible beneficiaries could have their coinsurance reimbursed via Medicaid in some circumstances.[57]

Similarly, we did not propose any changes to the ESRD PPS bad debt policy, which is also dictated by statute. For instance, we have long interpreted Title I, section 153(b)(4) of MIPPA as providing that bad debt payments are available only for covered services under the composite rate.[58] In addition, section 1861(v)(1) of the Act, implemented at §§ 413.89 & 413.215(b), imposes certain reductions in the amount of bad debts otherwise treated as allowable costs which are attributable to deductibles and coinsurance amounts. Currently, general requirements and policies for payment of bad debts attributable to unpaid Medicare deductibles and co-insurance are found in chapter 3 of the Provider Reimbursement Manual, Part 1 (PRM) (CMS Pub. 15–1) and cost reporting worksheets and instructions in the PRM Part 2 (CMS Pub. 15–2).

We acknowledge that some ESRD facilities may pay more or less than ASP for renal dialysis drugs and biological products that they purchase, since ASP represents an average, but we note that payment of the TDAPA based on ASP is consistent with the principles of prospective payment underlying the ESRD PPS more broadly. As stated earlier in this final rule, we are finalizing an increase to the TDAPA amount for phosphate binders to account for certain administrative costs not included in the ESRD PPS base rate, but this increase is not intended to account for sequestration costs, beneficiary copayment amounts, or bad debts.

Comment: Coalitions of dialysis organizations requested that CMS address what they consider to be a gap in the current Medicare guidance to support including phosphate binders into the ESRD PPS bundled payment. Specifically, regarding the reporting of oral drugs, the coalition notes that the current Medicare Benefit Policy Manual states that for oral or other forms of renal dialysis drugs that are filled at the pharmacy for home use, ESRD facilities should report one line item per prescription, but only for the quantity of the drug expected to be taken during the claim billing period.[59] A non-profit treatment and research center stated that patients will be given all of their medications at one time, presumably a few days before the start of a new month. They noted that if a patient misplaces the medication, they will need to obtain a new supply from the ESRD facility. Since the ESRD facility is not paid for the lost medication, the lost medication will cost the ESRD facility significant money. The commenter also stated that the doses prescribed for these medications depend on blood tests which are performed monthly, typically during the mid-week dialysis treatment of the first week of the month. The results become available a few days later and are then reviewed by nephrologists who may prescribe dose changes in phosphate lowering medication or may prescribe a different phosphate lowering medication. In that case, the ESRD facility would have to provide the patient an additional supply of medication and would have to pay additional fees to the pharmacy. In the event the medication is changed, the facility would again not be paid for the unused medication. A professional organization of nephrologists stated that ESRD facilities absorb the costs of unused medications when patients are hospitalized, transfer to other facilities, die, or receive a kidney transplant. A coalition of dialysis providers provided additional illustrative examples of when the current payment policy does not work financially for ESRD facilities, including patient hospitalization or when the patient is on vacation over 30 days, patient death and changes in ESRD facility. To align the reporting and payment with similar provisions for hospitals and skilled nursing facilities (SNFs), coalitions of dialysis organizations referred to the Medicare Claims Processing Manual, Chapter 17, § 90.4 and requested that CMS require reporting on claims of one of the following:

- Both the quantity of the drug expected to be taken during the claim billing period and any unused quantity of drug that was prescribed under a prescription that was later revised.
- The total amount of the drug provided during the claim billing period.

The coalition of dialysis providers claimed that these changes would alleviate the financial losses to ESRD

[56] A general description of Medicare sequestration from the Congressional Research Service is available at *https://sgp.fas.org/crs/misc/R45106.pdf.*

[57] *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/medicare_beneficiaries_dual_eligibles_at_a_glance.pdf.*

[58] See the November 17, 2004 Decision of the Administrator (*https://www.cms.gov/Regulations-and-Guidance/Review-Boards/OfficeAttorneyAdvisor/Downloads-3/2004-D43.pdf*) and Medicare Benefit Policy Manual, Chapter 11, § 80 (*https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c11.pdf*).

[59] Medicare Benefit Policy Manual Chapter 11—End Stage Renal Disease § 20.3.C.

facilities. The commenter stated that these changes do not need to be included in the CY 2025 final rule but can be done through guidance prior to the end of CY 2024 to apply to the forthcoming inclusion of phosphate binders in the ESRD PPS bundled payment to limit unnecessary losses for an already strained payment system. The commenter also stated that making these changes to the billing rules is also necessary for CMS to have accurate utilization data of the phosphate binders during the TDAPA period for the purpose of future rate setting exercises. The commenter believes that without these changes, not only will ESRD facilities experience real-time losses due to circumstances outside their control, but those losses will be baked into depressed utilization data used to update the base rate after the end of the TDAPA period for the phosphate binders, locking those losses into the ESRD PPS in perpetuity. In addition, the commenter noted that other providers, including hospitals, pharmacies and skilled nursing facilities, are all permitted by Medicare to submit claims for the full prescription dispensed in good faith to the beneficiary. They requested that CMS align the ESRD PPS billing policies with that of other health care providers rather than imposing what they characterized as unique and unnecessary burdens on a fragile payment system serving the most vulnerable patients.

Response: CMS thanks the commenters for their recommendations. Per the regulation at § 413.198(b)(5), each ESRD facility must submit data and information of the types and in the formats established by CMS for the purpose of estimating patient-level and facility-level variation in resource use involved in furnishing renal dialysis services. At § 413.198(b)(5)(ii), this includes information reported on ESRD PPS claims about the total number of billing units (or the expected number of billing units), for renal dialysis drugs and biological products provided to beneficiaries for use while receiving home dialysis services as defined in § 413.217(b), which includes home dialysis services, support, and equipment as identified in § 410.52, to be included in the ESRD PPS effective January 1, 2011.

As we noted previously in this section, in the CY 2016 ESRD PPS final rule (80 FR 69033), we discussed our existing policy since the inception of the ESRD PPS that all renal dialysis service drugs and biological products prescribed for ESRD patients, including the oral forms of renal dialysis injectable drugs, must be reported by ESRD facilities, and the units reported on the monthly claim must reflect the amount expected to be taken during that month. We did not propose a change to the reporting requirements regarding the drugs expected to be taken during the claim billing period and any unused quantity of that drug that was prescribed under a prescription that was later revised, along with the total amount prescribed during the billing period. However, we thank the commenter for their suggestions and will take the commenter's suggestions into consideration in future rulemaking. Discarded drugs or biological products that are not in single use containers or single dose packaging are not billable under the ESRD PPS.[60] Similarly, we believe it would be most appropriate to make a future modification to the ESRD PPS base rate, if warranted, based on actual phosphate binder utilization and not discarded amounts. We expect that ESRD facilities will employ strategies to reduce discarded amounts of phosphate binders, which best serves the interest of efficient resource use and is consistent with the goals of the ESRD PPS.

Comment: A coalition of dialysis organizations recommended that CMS should amend the cost reports and update billing and payment policies in advance of the TDAPA period for phosphate binders. The current ESRD Facility Cost Report revision includes one line item for the TDAPA and one line item for the TPNIES. At the time this was implemented, there was only one drug receiving the TDAPA and one supply item receiving the TPNIES. At present and in the coming years, the commenter expects there will be multiple drugs and devices receiving the TDAPA and the TPNIES in the same year. The commenter stated that CMS and other policymakers would find it important and useful to be able to track costs associated with individual products receiving the TDAPA and TPNIES rather than have them reported in the aggregate. The commenter recommended that CMS add several line items for each of the TDAPA and TPNIES reporting sections and provide instructions that each product receiving the TDAPA or the TPNIES are to be reported separately on their distinct line-items. The commenter stated that CMS should also ensure that ESRD facilities have clear instructions for reporting the TDAPA for phosphate binders during the TDAPA period and that facilities have clear instructions for reporting the phosphate binders after they are bundled into the base rate after the end of the TDAPA period. The commenter stated that it is imperative that CMS amend the cost report and instructions in advance of the launch of the TDAPA period and end of the TDAPA period to ensure the integrity of dialysis facility cost reporting.

Further, the coalition requested CMS to make changes to billing procedures to make it easier for ESRD facilities to identify the correct TDAPA and TPNIES payments to report on the cost report. At present, they state that when CMS pays a claim that includes the TDAPA or TPINIES, ESRD facilities simply receive one payment for the adjusted base rate plus the TDAPA or TPNIES amount. The TDAPA or TPNIES is not indicated on a separate line item by CMS. The coalition stated that while the ESRD PPS is a bundled payment system with a standardized base rate, most claims are adjusted based on a dozen patient and facility characteristics. As a result, the commenter stated that to accurately report TDAPA and TPNIES payments on the Cost Report, ESRD facilities need to crosswalk each reimbursement to relevant patient claims or medical records to identify those for whom TDAPA or TPNIES payment was requested, then determine if and at what amount the TDAPA or TPNIES was paid, noting that the TDAPA and TPNIES payment amount fluctuates over the course of the year, and then report those figures on the cost report on an ESRD facility basis. For some ESRD facilities this is a manual, and not an automated exercise. The commenter requested that CMS amend billing and payment procedures to flag TDAPA and TPNIES payments separately on an itemized report so that ESRD facilities can more effectively and efficiently identify and flag these items for accurate reporting onto the Cost Report.

Response: CMS thanks the commenters for their suggestions regarding the cost reports. We are currently evaluating changes to the ESRD PPS cost reports and will take these suggestions into consideration for future cost report modifications.

Comment: A drug manufacturer questioned why the phosphate-lowering agent XPHOZAH® is receiving disparate treatment from phosphate binders with respect to the TDAPA. The drug manufacturer stated that they view CMS as treating XPHOZAH® similar to a phosphate binder for the purposes of inclusion in the ESRD PPS bundled payment, but different from a phosphate

[60] In the CY 24 ESRD PPS final rule, we finalized a new policy to require the use of the JW or JZ modifier on claims to track discarded amounts of single-dose container and single-use package renal dialysis drugs and biological products paid for under the ESRD PPS, effective January 1, 2025 (88 FR 76346, 76383–76386).

binder for the purposes of a potential increase to the ESRD PPS base rate after the end of the TDAPA period.

Response: Existing Medicare regulations state that effective January 1, 2025, oral-only drugs will be paid for under the ESRD Prospective Payment System (PPS). Although oral-only drugs are not included in the ESRD PPS bundled payment until January 1, 2025, they are currently recognized as renal dialysis services as defined in regulation. Accordingly, CMS is planning to incorporate oral-only drugs into the ESRD PPS bundled payment beginning January 1, 2025, using the TDAPA, as described in the calendar year (CY) 2016 ESRD PPS final rule (80 FR 69027) and subsequent rules. In the CY 2022 ESRD PPS final rule (87 FR 67179) we stated that we finalized and issued the payment policies for oral-only renal dialysis service drugs or biological products in the CY 2011 ESRD PPS final rule (75 FR 49038 through 49053). In that rule we defined renal dialysis services at § 413.171 as including other drugs and biologicals that are furnished to individuals for the treatment of ESRD and for which payment was made separately prior to January 1, 2011, under Title XVIII of the Act, including drugs and biologicals with only an oral form. Although we included oral-only renal dialysis service drugs and biologicals in the definition of renal dialysis services in the CY 2011 ESRD PPS final rule (75 FR 49044), we also finalized a policy to delay payment for these drugs under the ESRD PPS until January 1, 2014. In the CY 2011 ESRD PPS proposed rule (74 FR 49929), we noted that the only oral-only drugs that we identified were phosphate binders and calcimimetics, specifically, cinacalcet hydrochloride, lanthanum carbonate, calcium acetate, sevelamer hydrochloride, and sevelamer carbonate. All of these drugs fall into the ESRD PPS functional category for bone and mineral metabolism. In the manufacturer's press release on October 17, 2023, they noted that XPHOZAH® is a phosphate-lowering therapy, and it is not a phosphate binder.[61]

As for the commenter's concern regarding CMS's treatment of XPHOZAH® with respect to a potential increase in the ESRD PPS base rate after the end of the TDAPA period, we note that we have been consistent in treating XPHOZAH® as an oral-only drug that is considered included in the ESRD PPS base rate because it falls within the bone and mineral metabolism ESRD PPS functional category. XPHOZAH® is a renal dialysis service under the definition at § 413.171 and is to be included in the ESRD PPS bundled payment effective January 1, 2025, according to § 413.174(f)(6). Any other oral renal dialysis drug or biological product without an injectable equivalent or other form of administration would also be included in the ESRD PPS bundled payment effective January 1, 2025. We note that XPHOZAH®, should it apply for the TDAPA, would receive the same consideration and treatment as other renal dialysis drugs and biological products in existing ESRD PPS functional categories which are considered included in the ESRD PPS base rate. In the CY 2016 ESRD PPS final rule we explained that we would modify the ESRD PPS base rate after the end of the TDAPA period only for calcimimetics and phosphate binders, but that we would not follow this process for any other potential future oral-only drugs in the bone and mineral functional category or any other functional category, as calcimimetics and phosphate binders were the only two drugs for which 2007 utilization data was available at the time the ESRD PPS base rate was first developed for which payment was delayed (80 FR 69025). In particular, the intention behind CMS's policy is that funds would be added to the base rate to account for phosphate binders because the costs associated with phosphate binders would have been included in the initial calculation of the base rate in CY 2011 if not for CMS's (and subsequently congress') decision to temporarily delay their inclusion. However, the delay was always with the intention that the costs would eventually be included in the ESRD PPS base rate. This is not true of other drugs or biological products that were not in use in the timeframe analyzed for the initial development of the ESRD PPS base rate, but that are considered included in the base rate because they fall within an existing functional category.

From a policy perspective, the ESRD PPS bundled rate is intended to encourage efficient resource use, and CMS therefore only would add funds, if appropriate, to the base rate for drugs that have a new function not accounted for when the initial base rate was developed or, in the case of calcimimetics and phosphate binders, that were intended to be included at the time the base rate was first developed but were temporarily excluded. As discussed previously, XPHOZAH® is not a phosphate binder (nor is it a calcimimetic), so under our established methodology it would be treated in the same way as all other new drugs (80 FR 69027). We note that any specific considerations regarding modification of the ESRD PPS base rate to account for phosphate binders, such as whether to incorporate data from drugs or biological products with a similar end-action effect that may be a substitute for phosphate binders, will be made through notice and comment rulemaking in the future. We will consider the commenter's suggestions related to how the ESRD PPS treats new renal dialysis drugs and biological products in existing functional categories which are considered included in the base rate for potential future rulemaking related to TDAPA and other payment policies under the ESRD PPS.

Comment: Some commenters expressed support for a delay for the inclusion of either oral-only drugs and biological products or phosphate binders, in the ESRD PPS bundled payment. We received 110 form letters from unique submitters that did not relate to policies proposed in the CY 2025 ESRD PPS proposed rule, but rather expressed support for -draft legislation that would delay the inclusion of certain oral-only drugs and biological products into the ESRD PPS bundled payment. One drug manufacturer requested CMS refrain from incorporating phosphate-lowering therapies into the ESRD PPS in January 2025. The drug manufacturer suggested that CMS should respond to stakeholder concerns regarding access issues and public health data on harms to patients.

Response: We did not propose any changes to § 413.174(f)(6) to modify the date of the incorporation of the oral-only drugs into the ESRD PPS. We note that in the CY 2011 ESRD PPS final rule we stated that the delay in incorporating oral-only drugs into the ESRD PPS bundled payment would allow additional time to address several issues including the following: the determination of oral-only drug pricing and utilization; adequate beneficiary education; assessment of potential problems which may arise in connection with the provision of oral drugs prior to the system's expansion to include oral-only drugs; analysis regarding the ability of ESRD facilities to provide oral-only ESRD drugs; and, evaluation of indicators applicable to the monitoring of certain patient conditions treated with oral-only drugs, such as bone loss and mineral metabolism associated with the provision of calcimimetics and

[61] *https://ir.ardelyx.com/news-releases/news-release-details/fda-approves-xphozahr-tenapanor-first-class-phosphate-absorption.*

phosphate binders, which could assist in determining the impact of the fully bundled ESRD PPS, and any unintentional consequences that might ensue, on quality of care (75 FR 49043 through 49044). CMS has actively been engaged in addressing the aforementioned issues since that rule was finalized 13 years ago in preparation for inclusion of the oral-only drugs into the ESRD PPS. Our data analysis has shown that because not all ESRD PPS beneficiaries have had Part D coverage some have lacked equal access to either calcimimetics or phosphate binders. Inclusion in the ESRD PPS bundled payment provides patients access to all the drugs and biological products in all the ESRD PPS functional categories, including those included in the bone and mineral metabolism functional category, averting potential harm to those Medicare beneficiaries currently lacking access to some of those drugs and biological products.

Comment: A coalition for dialysis organizations recommended that CMS should align MA and ESRD PPS policies in advance of the TDAPA period for phosphate binders and future inclusion of phosphate binders in the ESRD PPS base rate to ensure MA beneficiaries will receive necessary medication.

Response: With respect to MA, per section 1852(a)(1) of the Act and its implementation regulations (42 CFR 422.100 and 422.101(a)), Medicare Advantage organizations (MAOs) must cover items and services, including drugs, for which benefits are available under Parts A and B in the Traditional Medicare program, subject to limited exclusions. We note that phosphate binders are not subject to the limited exclusions at section 1852(a)(1) of the Act and, therefore, must be covered by MAOs. Specifically, in accordance with section 1852(a)(1) if the Act and 42 CFR 422.100 and 422.101(a), and as noted in [62] section 10.4 of chapter 4 of the Medicare Managed Care Manual,[63] MAOs must provide coverage of, by furnishing, arranging for, or making payment for, generally all services that are covered by Part A and Part B of Medicare and that are available to beneficiaries residing in the plan's service area. Services may be provided outside of the service area of the plan if the services are accessible and available to enrollees. In addition, with respect to coverage of Traditional Medicare benefits such as Part B drugs, MAOs must comply with applicable Medicare statutes, regulations, national coverage determinations (NCDs) and local coverage determinations (LCDs) of Medicare contractors with jurisdiction for claims in the geographic area in which services are covered under the MA plan (42 CFR 422.101(b)). In general, an MA plan that offers Part D benefits (MA–PD) must determine whether payment for the drug is allocated under Parts B or D, consistent with Traditional Medicare and Part D program drug coverage policies (see Appendix C, Attachment II, Question 5 of Chapter 6 [64] Medicare Prescription Drug Benefit Manual for additional detail). Concerning how Part D sponsors will determine whether a drug is covered under Part B, it is important to keep in mind that in most cases Part B drug coverage should not impact payment decisions by Part D sponsors since Part B coverage is generally in a provider setting or physician's office rather than for drugs dispensed at a pharmacy. A Part D sponsor cannot deny payment for a particular drug on the basis that it is covered under Part B in some instances and Part D in others unless there is Part B coverage as the drug is prescribed and dispensed or administered in that particular instance. The fact that a claim is received for a drug that is sometimes covered by Part B is not a basis for denial since the Part D sponsor would have to determine whether the drug is being prescribed and dispensed or administered on the basis under which Part B coverage is available. This will generally involve interaction between the Part D sponsor and the Medicare Part B contractor with jurisdiction in that geographic area for that drug. Regarding new drugs, as decisions are made nationally or by individual A/B MAC contractors, this information will be available on the CMS and contractor websites. MA–PD coordinated care plans must coordinate all benefits administered by the plan with respect to drugs for which payment as so prescribed and dispensed or administered to an individual may be available under Part A or Part B, or under Part D (42 CFR 422.112(b)(7)). As a result of the rules and regulations described here, MAOs must cover oral-only ESRD drugs under their plans, as these are drugs under Part B and are not subject to the limited exclusions under section 1852(a)(1) of the Act.

Final Rule Action: After consideration of all the comments received, we agree with commenters that there are additional costs associated with ESRD facilities furnishing phosphate binders that are not currently included in the ESRD PPS base rate and that were not addressed when the ESRD PPS base rate was developed in CY 2011. This differentiates phosphate binders from other drugs and biological products in existing ESRD PPS functional categories, which justifies a change to the TDAPA policy, as phosphate binders were excluded from the analysis performed for the CY 2011 ESRD PPS final rule due to a lack of data available at the time of rulemaking. Consistent with past policies, we consider drugs and biological products in existing ESRD PPS functional categories to be included in the ESRD PPS base rate. The ESRD PPS base rate includes money for the costs, such as dispensing fees, associated with furnishing other drugs (in existing functional categories) paid for using the TDAPA. We are finalizing to pay the TDAPA for phosphate binders at 100 percent of ASP, increased by a fixed amount calculated at an amount that we believe most appropriately approximates 6 percent of ASP. For CY 2025, as utilization data and ASP reporting are currently unavailable, we are finalizing to use the weighted average of Medicare expenditures for phosphate binders per month under Part D for all phosphate binders used in a month, based on estimates for CY 2025 phosphate binder utilization using utilization patterns in CY 2023 among Part D eligible beneficiaries. For CY 2025, this amount is $36.41, which will be added to any monthly claim for which there is a TDAPA payment for phosphate binders. For CY 2025 and 2026, the TDAPA amount for a phosphate binder is based on 100 percent of ASP plus an additional amount based on 6 percent of per-patient phosphate binder spending derived from utilization and cost data.

We are finalizing two changes to § 413.234(c) to codify this change in TDAPA policy for phosphate binders. First, we are amending paragraph (c) to note that we would not pay the TDAPA at 100 percent of ASP in this circumstance by adding in language which reads ''except as provided in paragraph (c)(4) of this section.'' Second, we are adding paragraph (c)(4) which reads: ''For calendar years 2025 and 2026, the transitional drug add-on payment adjustment amount for a phosphate binder is based on 100 percent of ASP plus an additional amount based on 6 percent of per-patient phosphate binder spending derived from utilization and cost data.'' As discussed previously, for calendar year 2025, the additional amount is estimated based on the weighted

[63] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/chapter4-final-may2012_0.pdf*

[64] *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

average of Medicare expenditures for phosphate binders per month under Part D for all phosphate binders used in a month, derived from estimates for CY 2025 phosphate binder utilization using utilization patterns in CY 2023 among Part D eligible beneficiaries. . We intend to reevaluate this amount in rulemaking next year; for example, for calendar year 2026, we may consider updating the additional amount quarterly derived from the actual phosphate binder utilization and ASP reported under Medicare Part B in the most recently available quarter, if appropriate.

d. Expected Impact of Incorporation of Oral-Only Drugs

We anticipate that the incorporation of oral-only drugs into the ESRD PPS will increase access to these drugs for beneficiaries. We estimate that there will be an increase in Medicare spending as a result of this increase in access. Specifically, CMS has been monitoring and analyzing data regarding beneficiary access to Medicare Part D drugs; increases in expenditures for renal dialysis drugs paid under Medicare Part D; health equity implications of varying access to Medicare Part D drugs among patients with ESRD; and ESRD facility behavior regarding drug utilization. We have seen that incorporating Medicare Part D drugs into the ESRD PPS has had a significant positive effect of expanding access to such drugs for beneficiaries who do not have Medicare Part D coverage, with significant positive health equity impacts. For example, based on the results of our ESRD PPS monitoring analyses, in December 2017, prior to incorporation of calcimimetics into the ESRD PPS bundled payment, utilization was at 28.97 percent for African American/Black beneficiaries but went up to 35.31 percent in January 2018 and eventually to 39.04 percent in at the end of the TDAPA period for calcimimetics in December 2021. This 10.07 percentage point increase in utilization reflects the significant access improvement for African American/Black beneficiaries of incorporating formerly oral-only drugs into the ESRD PPS.

Lastly, as part of the preparation for the inclusion of phosphate binders into the ESRD PPS, CMS has monitored Part D utilization of, and spending for, phosphate binders. We have developed budgetary estimates of the changes in Medicare Part B and Part D spending, which are discussed in section VII.C.1 of this final rule.

8. Changes to the Low-Volume Payment Adjustment (LVPA)

a. Background on the LVPA

Section 1881(b)(14)(D)(iii) of the Act provides that the ESRD PPS shall include a payment adjustment that reflects the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services, and for payment for renal dialysis services furnished on or after January 1, 2011, and before January 1, 2014, such payment adjustment shall not be less than 10 percent. Therefore, the ESRD PPS provides a facility-level payment adjustment to ESRD facilities that meet the definition of a low-volume facility.

Under § 413.232(b), a low-volume facility is an ESRD facility that, based on the submitted documentation: (1) furnished less than 4,000 treatments in each of the 3 cost reporting years (based on as-filed or final settled 12-consecutive month costs reports, whichever is most recent, except as specified in paragraphs (g)(4) and (5)) preceding the payment year; and (2) has not opened, closed, or received a new provider number due to a change in ownership (except where the change in ownership results in a change in facility type or as specified in paragraph (g)(6)) in the 3 cost reporting years (based on as-filed or final settled 12-consecutive month cost reports, whichever is most recent) preceding the payment year.

In addition, under § 413.232(c), for purposes of determining eligibility for the LVPA, the number of treatments considered furnished by the ESRD facility equals the aggregate number of treatments furnished by the ESRD facility and the number of treatments furnished by other ESRD facilities that are both under common ownership with, and 5 road miles or less from, the ESRD facility in question. To receive the LVPA, an ESRD facility must submit a written attestation statement to its Medicare Administrative Contractor (MAC) confirming that it meets the requirements as specified in § 413.232 and qualifies as a low-volume ESRD facility. For purposes of determining eligibility for the LVPA, ''treatments'' mean total hemodialysis equivalent treatments (Medicare and non-Medicare). For peritoneal dialysis patients, one week of peritoneal dialysis is considered equivalent to three hemodialysis treatments (80 FR 68994). Section 413.232(e) generally imposes a yearly November 1 deadline for attestation submissions unless extraordinary circumstances justify an exception and specifies exceptions for certain years where the deadline is in December or January. The November 1 attestation timeframe provides 60 days for a MAC to verify that an ESRD facility meets the LVPA eligibility criteria (76 FR 70236). The ESRD facility would then receive the LVPA for all the Medicare-eligible treatments in the payment year. Once an ESRD facility is determined to be eligible for the LVPA, a 23.9 percent increase is applied to the ESRD PPS base rate for all treatments furnished by the ESRD facility (80 FR 69001).

In the CY 2011 ESRD PPS final rule (75 FR 49118 through 49125), we finalized the methodology used to target the appropriate population of ESRD facilities that were low-volume facilities based on a treatment threshold. After consideration of public comments, we originally established an 18.9 percent adjustment for ESRD facilities that furnish less than 4,000 treatments annually and indicated that this increase to the base rate would encourage small ESRD facilities to continue providing access to care.

In the CY 2016 ESRD PPS proposed rule (80 FR 37819), we analyzed ESRD facilities that met the definition of a low-volume facility under § 413.232(b) as part of the updated regression analysis and found that these ESRD facilities still had higher costs compared to other ESRD facilities. A regression analysis of low-volume facility claims from CYs 2012 and 2013 and cost report data indicated a multiplier of 1.239; therefore, we proposed an updated LVPA adjustment factor of 23.9 percent in the CY 2016 ESRD PPS proposed rule (80 FR 37819) and finalized this policy in the CY 2016 ESRD PPS final rule (80 FR 69001). This update was implemented budget neutrally alongside numerous other changes to the case-mix and facility-level adjusters. In CY 2022, 352 ESRD facilities received the LVPA. Using the most recent available data for CY 2023, the number of ESRD facilities receiving the LVPA was 330.

In the CY 2021 ESRD PPS final rule (85 FR 71443), we finalized a policy to allow ESRD facilities flexibility for LVPA eligibility due to the COVID–19 Public Health Emergency (PHE). Under § 413.232(g)(4), for purposes of determining ESRD facilities' eligibility for payment years 2021, 2022, and 2023, we only considered total dialysis treatments for any 6 months of their cost-reporting period ending in 2020. In the CY 2024 ESRD PPS final rule (88 FR 76344), we finalized changes to the LVPA regulation at § 413.232 that allow ESRD facilities affected by disasters and other emergencies to qualify for

exceptions to certain eligibility requirements for the LVPA. Facilities may close and reopen if they experience an emergency, or they may temporarily exceed the 4,000-treatment threshold if they take on additional patients displaced by an emergency and still qualify for the LVPA.

(1) Current Issues and Concerns

As discussed in the CY 2025 ESRD PPS proposed rule, interested parties, including MedPAC and the GAO,[65] have recommended that we make refinements to the LVPA to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas.[66] These groups and other interested parties have also expressed concern that the strict treatment count used to determine eligibility introduces a ''cliff-effect'' that may incentivize ESRD facilities to restrict their patient caseload to remain below the 4,000 treatments per year for the LVPA threshold.[67]

We considered several changes to the LVPA eligibility criteria to address the concerns that interested parties, including the GAO and MedPAC, raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. Specifically, these interested parties requested that we take into consideration the geographic isolation of an ESRD facility within the LVPA methodology. Section 1881(b)(14)(D)(iii) of the Act requires that the LVPA must reflect the extent to which costs incurred by low-volume facilities (as defined by the Secretary) in furnishing renal dialysis services exceed the costs incurred by other facilities in furnishing such services. Our analysis found that isolated low-volume facilities do not face higher costs than other low-volume facilities. Therefore, we stated in the CY 2025 ESRD PPS proposed rule that we do not believe that this requested change reconciles with the central statutory requirements and limitations for the LVPA, and we stated that we are considering alternative approaches, including potentially addressing this issue through a new payment adjustment separate from the LVPA based on section 1881(b)(14)(D)(iv) of the Act. We noted in the proposed rule that we are analyzing claims and cost data regarding dialysis treatment levels and cost to inform options for potentially tailoring our methodology to meet the requirements of the statute, while simultaneously collecting additional data on geographic isolation of ESRD facilities. The ESRD PPS has separate facility-level payment adjustments for low-volume facilities, as set forth in 42 CFR 413.232, and facilities in rural areas, as set forth in § 413.233. To avoid overlap with these existing facility-level adjustments, we stated that we are analyzing the impact of potentially creating a new payment adjustment and considering innovative methodological options, such as the local dialysis need methodology on which we requested information in the CY 2024 ESRD PPS proposed rule (88 FR 42441 through 42445).

In addition, interested parties expressed that the eligibility criteria for the LVPA are very explicit and leave little room for flexibility in certain circumstances (85 FR 71442). Some also viewed the attestation process as burdensome to ESRD facilities and believed it may discourage participation by small ESRD facilities with limited resources that would otherwise qualify for the LVPA.[68] Given these concerns, we considered alternative approaches to the LVPA that would reduce burden, remove negative incentives that may result in gaming, and better target ESRD facilities that are critical for beneficiary access.

CMS's contractor has held three Technical Expert Panels (TEPs) to discuss potential refinements to the ESRD PPS.[69] During the 2018, 2019, and 2020 TEPs, panelists, including representatives from ESRD facilities, independent researchers, patient advocates, and representatives from professional associations and industry groups (86 FR 36397), discussed limitations of the current LVPA methodology and potential alternatives. In the CY 2022 ESRD PPS proposed rule, we included a RFI to inform LVPA payment reform (86 FR 36398 through 36399). All fourteen responses to the CY 2022 ESRD PPS RFI for LVPA wrote in support of either eliminating or revising the current LVPA or rural facility adjustment.[70] One small dialysis organization within a large non-profit health system responded that it is reliant upon the LVPA and the rural facility adjustment and supports both adjustments, albeit with modifications. MedPAC renewed its support for a new Low-Volume and Isolated (LVI) adjustment with a recommendation for a three-tiered approach for treatment thresholds, which would incorporate geographic isolation into its methodology and may disincentivize gaming. MedPAC called upon CMS to provide clear and timely criteria for ESRD facility eligibility and ensure the LVPA methodology is transparent. In concurrence with MedPAC, a coalition of dialysis organizations, three large dialysis organizations (LDOs), a non-profit kidney organization, and a provider advocacy coalition commented that the rural facility adjustment should be eliminated and a LVI methodology should be adopted, as they considered a methodology based upon census tracts to be both complicated and lacking transparency. Numerous commenters wrote in support of a tiered adjustment to mitigate the cliff effect and gaming. Commenters raised concerns regarding the reliance of the census tract methodology used by the rural facility adjustment upon 'driving time' as a data measure, noting this presents legitimate equity issues. ESRD facilities that have relied upon both the LVPA and rural payment adjustments to remain operational expressed opposition to elimination of either adjustment.[71]

In the CY 2022 ESRD PPS proposed rule LVPA RFI, we sought input on alternative approaches to the LVPA methodology (86 FR 36398 through 36399).[72] Specifically, we requested input on—(1) whether a distinction other than census tract information should be considered; and (2) what criteria should be used to determine the threshold(s) of adjusted latent demand (in treatment counts) which determine LVPA eligibility. Additionally, we explored the LVI adjustment that MedPAC recommended in its June 2020 Report to Congress. Under the LVI methodology, a determination that a facility is low volume and isolated would be based on that facility's distance from the nearest facility and its total treatment volume. Regarding the LVI methodology, we requested input on the concerns for facilities that would lose the LVPA under the LVI methodology and the potential for gaming within the LVI methodology. In

[65] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun20_ch7_reporttocongress_sec.pdf.*

[66] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[67] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[68] *https://www.cms.gov/files/document/end-stage-renal-disease-prospective-payment-system-technical-expert-panel-summary-report-april-2021.pdf.*

[69] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.*

[70] *https://www.cms.gov/files/document/cy-2022-esrd-pps-rfi-summary-comments.pdf.*

[71] The materials from the TEPs and summary reports can be found at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/educational_resources.*

addition, we requested input regarding the extent that the LVI methodology captures more isolated (and most often rural) facilities, and whether a separate rural facility adjustment should be maintained. As previously discussed, our most recent analysis of cost report data does not support the claim that isolated low-volume ESRD facilities face higher costs than non-isolated ESRD facilities; therefore, the LVI methodology would not adhere to the statutory requirement for the LVPA set forth at section 1881(b)(14)(D)(iii) of the Act.

(2) CY 2024 RFI on Potential Changes to the LVPA

In the CY 2024 ESRD PPS proposed rule (88 FR 42430 through 42544), we issued a RFI regarding several possible modifications to the current LVPA methodology.[73] We provided commenters the option of maintaining a single LVPA threshold, establishing LVPA tiers, or utilizing a continuous function. We received 23 comments in response to the RFI, all of which had differing opinions. A coalition of dialysis organizations recommended a two-tiered approach, while MedPAC reiterated their support for a LVI adjustment. A common theme among a handful of comments was concern about administrative burden and transparency regarding the methodology that is chosen. Most commenters believed that the issue of payment cliffs is substantial, but many did not believe any of the options presented in the RFI could successfully eliminate gaming completely. CMS will continue to consider these comments to potentially inform future rulemaking.

(3) CY 2024 RFI on the Rural Facility Adjustment

We have considered several changes to the LVPA eligibility criteria to address the concerns that the GAO and MedPAC raised about targeting LVPA payments to ESRD facilities that are necessary to protect access to care and are not located near other ESRD facilities. As previously discussed, we do not believe the suggestion to consider facilities' geographic isolation reconciles with the central statutory requirements and limitations for the LVPA, and we are considering alternative approaches, including potentially addressing this issue through a new payment adjustment separate from the LVPA based on section 1881(b)(14)(D)(iv) of the Act.

The LVPA and rural adjusters currently result in increased payments to some geographically isolated ESRD facilities, but these adjusters do not specifically target geographically isolated ESRD facilities. Interested parties, including MedPAC and the GAO, have recommended that CMS make refinements to the LVPA and rural adjusters to better target ESRD facilities that are critical to beneficiary access to dialysis care in remote or isolated areas. The GAO and MedPAC, among others, have also raised concerns about targeting LVPA payments to ESRD facilities that are not located near other ESRD facilities to protect access to care.

In the CY 2024 ESRD PPS proposed rule's LVPA RFI (88 FR 42441 through 42445), we solicited comments on a potential new payment adjustment that accounts for isolation, rurality, and other geographical factors, including local dialysis need (LDN). The LDN methodology, as described in the CY 2024 ESRD PPS proposed rule (88 FR 42430 through 42544), would consider LDN instead of basing payment strictly upon a rural designation, as provided for by §§ 413.233 and 413.231(b)(2). In the CY 2024 ESRD PPS proposed rule's LVPA RFI, we suggested the utilization of census tracts to identify geographic areas with low demand, then calculating latent demand by multiplying the number of beneficiaries near (''near'' was defined by driving time to ESRD facilities) an ESRD facility by the average number of treatments for ESRD beneficiaries. The threshold to qualify for the LVPA could then be applied by determining the amount of adjusted latent demand. The ESRD facilities that fall below the threshold would be eligible. The statutory requirements for the LVPA under section 1881(b)(14)(D)(iii) of the Act generally would not allow for CMS to account for geographic isolation outside of the extent to which low-volume facilities face higher costs in furnishing renal dialysis services than other facilities, and preliminary analysis found that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. Because of this, the LDN methodology would be implemented under the authority in section 1881(b)(14)(D)(iv) of the Act, which states that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate.

We received 23 comments in response to the LVPA RFI, all of which had differing opinions.[74] Some commenters supported eliminating the rural adjuster and reallocating its funds to either the LVPA or to a new adjustment that considers LDN. Others stated the rural facility adjustment should be removed, and those dollars be incorporated into one of the tiered LVPA methodologies. Many commenters noted that a LVPA, a rural facility adjustment, and a possible LDN-based adjustment would be redundant. A coalition of dialysis organizations stated that CMS's reliance on zip codes to identify rural facilities is no longer an adequate proxy for facilities in need, and cited data that many rural facilities enjoy a large patient count and positive profit margins. Other commenters supported the rural facility adjustment, explaining that it was especially appropriate in conjunction with a modified LVPA methodology, since under the options presented by CMS in the RFI, many facilities would experience significant decreases in payment. They claimed that the additional funds provided by the rural facility adjustment would protect against the closure of rural facilities. Several commenters expressed concern about administrative burden and transparency in a general sense, no matter the methodology chosen.

Generally, commenters were opposed to a payment adjustment based on the LDN methodology, reiterating many of the concerns raised during the 2020 TEP. A coalition of dialysis organizations voiced the concern that the LDN methodology would take away providers' ability to make financial decisions about their operations, since they would not be able to predict their eligibility for the LDN payment adjustment nor the amount they would receive. They maintained that the LDN may not target the appropriate facilities and could provide opportunities for gaming. The coalition also claimed that the central issue faced by these facilities is low patient count, which they stated that the LDN methodology would not recognize, and thus the adjustment could be provided to facilities that are isolated, but have high patient counts, and are not in need of an additional payment adjustment. A coalition of dialysis organizations and a non-profit dialysis association both stated that the current LVPA provision to aggregate the treatments of facilities under common ownership that are not at least 5 miles apart is an important feature that discourages gaming, one that is not included in the LDN methodology. Furthermore, the coalition noted that the LDN methodology would lack stability, given that patient location varies over time. MedPAC suggested that if the LDN were adopted, CMS should ensure that the methodology is transparent; for example, making the

[74] *https://www.cms.gov/files/document/cy-2024-esrd-pps-lvpa-rfi-summary-comments.pdf.*

specifications and results for the regression equation available on CMS's website and in the **Federal Register**. In addition, MedPAC stated that CMS should note how often the model would be updated, discuss how census tract populations changing over time would affect the stability of the adjustment, and how the approach would address MedPAC's anticipated increase in home dialysis use.

In addition to the questions outlined in the CY 2024 ESRD PPS proposed rule LVPA RFI, as discussed in the CY 2025 ESRD PPS proposed rule, CMS has also considered incorporating isolation criteria into the rural facility adjustment, where payment of the adjustment could be limited to ESRD facilities that are isolated from other ESRD facilities, or a higher adjustment could be applied for isolated rural facilities than for non-isolated rural facilities. Alternatively, the current rural facility adjustment could be replaced by an adjustment based solely on isolation. We noted that recent analysis has confirmed that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. This analysis aligns with suggestions from various commenters, including MedPAC, to refine or remove the rural facility adjustment to better target ESRD facilities that are critical to beneficiary access and are likely not being adequately targeted under the current methodology. However, we noted that many ESRD facilities which receive the rural facility adjustment are critical to patient access and that these ESRD facilities may be relying on the additional payment from the rural facility adjustment for the coming years. As discussed in section II.B.2.f.(2) of this final rule, we proposed to implement a phase-out policy for ESRD facilities that lose the rural facility adjustment as a result of being redesignated from a rural area to an urban area in the most recent CBSA delineations. We are not finalizing any other changes to the rural facility adjustment in this final rule.

b. Tiered LVPA Methodology

The goals of the ESRD PPS (including the LVPA) are to align resource use with payment, advance health equity, and protect access to renal dialysis services for vulnerable beneficiaries in underserved communities, including rural and isolated communities, by increasing payments to certain ESRD facilities in these areas to align with their higher costs. As noted in the CY 2016 ESRD PPS final rule (80 FR 68967 through 69077), we aim to target the benefit of the LVPA to facilities that serve the access needs of patients in remote locations. In the CY 2022 ESRD PPS final rule (86 FR 61874 through 62026), we detailed our commitment to achieving equity in health care outcomes for our beneficiaries using the definition of equity set forth in Executive Order 13985,[75] which places emphasis on individuals who belong to underserved communities. In the CY 2023 ESRD PPS proposed rule RFI (87 FR 38464 through 38586), we reiterated our commitment to achieving equity in health care and noted that we aim to align ESRD facility resource use with payment. Recent feedback from interested parties indicates that the current LVPA payment structure may lead some ESRD facilities to treat fewer patients to avoid a payment cliff. Proposing a revised methodology that would reduce the incentive for gaming, as the GAO described, would help advance health equity by removing the incentive for some ESRD facilities to limit access to renal dialysis services. We would expand access through payments that incrementally align resource use with payment to ESRD facilities that furnish different volumes of treatment.

In the CY 2025 ESRD PPS proposed rule, we proposed to refine the LVPA methodology to include two tiers based on treatment volume with different payment adjustments for each tier. This methodology would be similar to the methodology described in the CY 2024 ESRD PPS proposed rule RFI (88 FR 42430 through 42544), but with methodological changes to improve consistency in an ESRD facility's tier assignment from year to year.

We analyzed cost report data from ESRD facilities to develop the tiered thresholds and adjustment amounts for the proposed LVPA. This analysis used a logarithmic regression model that controls for various geographical and facility level characteristics, including facility type and region, to estimate cost differences based on treatment volume. We also simulated attestation patterns by excluding a stratified random sample of ESRD facilities who are eligible for LVPA payment but do not submit LVPA attestations. This step allowed us to account for the fact that a portion of ESRD facilities that were within the treatment volume threshold routinely did not attest to meeting the LVPA requirements for other reasons. We analyzed numerous different potential tiered payment structures based on this analysis, where the estimated cost for the tier uses the upper bound of the treatment count for that tier. Based on the results of this analysis, we proposed a two-tiered approach; we believe the two-tiered approach is appropriate because it strikes a balance between simplicity for ESRD facilities, sufficiently large tiers to allow for treatment volume variation from one year to the next, and payment adequacy for current low-volume facilities, particularly those with the lowest volume.

Table 9 presents our proposed two-tiered LVPA methodology, which is based on data from ESRD facility cost reports such that the reporting periods include some part of the period between January 1, 2020, to December 31, 2022 (that is, beginning or ending during these 3 CYs). We noted that we have required budget neutrality for any change to the LVPA methodology, so any proposed changes to the LVPA cannot increase or decrease total estimated ESRD PPS payments; therefore, the two sets of potential adjustment factors in Table 9 would be implemented budget-neutrally. The second column presents the unscaled adjusters, which if implemented, would cause the ESRD PPS base rate to be reduced by a factor of 0.999262, or approximately $0.20, to achieve budget neutrality. The third column presents the adjusters scaled down by a factor of 0.815 to maintain the LVPA payment amount under the existing methodology of $26.7 million based on the expected CY 2025 LVPA payments. Using the scaled adjusters would maintain budget neutrality without lowering the ESRD PPS base rate.

[75] 86 FR 7009 (January 25, 2021). *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

TABLE 9: Proposed LVPA Methodology with Two Tiers

Tier	LVPA Adjusters without Scaling	LVPA Adjusters with Scaling	Number of Eligible CMS Certification Numbers (CCNs)
Tier 1 (less than 3,000)	34.9%	28.4%	202
Tier 2 (3,000 – 3,999)	22.2%	18.1%	128

The adjustment factors in the second column are derived from the regression explained previously. These results indicate that facilities which furnish less than 3,000 treatments have costs that are 34.9 percent higher than non-low-volume facilities, and facilities that furnish between 3,000 and 3,999 treatments have costs that are 22.2 percent higher. The adjustment factors in the third column, which are scaled down, reflect the same relationship between the two tiers of low-volume facilities and non-low-volume facilities.

We explained that we believe a two-tier scaled approach is appropriate because it would increase payments to facilities with the lowest volume while keeping payment changes contained within the LVPA. In CY 2016 ESRD PPS final rule (80 FR 68972 through 69004) when we last updated the LVPA adjustment factor, we also updated most of the facility-level and case-mix adjusters. At that time, it was appropriate to apply a budget-neutrality factor that represented all of the changes to the facility-level and case-mix adjusters. However, we only proposed changes to the LVPA in the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843) and believed it would be most appropriate to contain the changes within the current LVPA by applying a scaling factor to the LVPA adjusters.

We also analyzed a three-tiered option that would include a tier for ESRD facilities furnishing between 4,000 and 5,000 treatments, which is presented in Table 10. As noted previously, we considered both scaled and unscaled adjustment factors, with both maintaining budget neutrality. Our analysis showed that the scaled, three-tiered option would reduce payments for facilities furnishing less than 3,000 treatments as compared to both the current LVPA methodology and the proposed two-tiered scaled methodology. Because payments for facilities furnishing between 4,000 and 5,000 treatments would increase, payments for the lowest-volume facilities would need to decrease to maintain budget neutrality, which we did not believe would align with the goals of the LVPA outlined previously. We explained that if we were to propose a three-tiered option, we believe budget neutralizing the base rate rather than scaling the adjustment factors would better align with these goals. Our analysis shows that an unscaled three-tiered adjustment would result in a $0.99 reduction to the base rate. We sought comment on our proposed scaled, two-tier proposal and on the alternative three-tier LVPA structure. We noted that, should this alternative be finalized, we would make changes to § 413.232(b)(1) to reflect the increased LVPA threshold of 5,000. As discussed further in the next subsection, we also proposed to determine an ESRD facility's LVPA tier based on the median treatment count volume of the last three cost-reporting years, rather than using a single year treatment count. Therefore, expanding LVPA eligibility to ESRD facilities that furnished fewer than 5,000 treatments in each of the past three cost-reporting years would also increase the number of ESRD facilities that would qualify for tier 1 and tier 2, since ESRD facilities which furnished between 4,000 and 4,999 treatments in one of the past 3 years and fewer than 4,000 (or 3,000 for tier 1) in the other 2 years could qualify in these tiers.

TABLE 10: Alternative LVPA Methodology with Three Tiers

Tier	LVPA Adjusters without Scaling	LVPA Adjusters with Scaling	Number of Eligible CCNs
Tier 1 (less than 3,000)	34.9%	16.2%	257
Tier 2 (3,000 – 3,999)	22.2%	10.3%	224
Tier 3 (4,000 – 4,999)	14.2%	6.6%	166

c. Final Changes to the LVPA for CY 2025

We proposed a two-tiered LVPA using the scaled adjusters presented in the second column of Table 9. ESRD facilities that fall into the first tier (those that furnish fewer than 3,000 treatments) would receive a payment adjustment of 28.4 percent. Those that fall in the second tier (those that furnish 3,000 or more treatments but fewer than 4,000 treatments) would receive a payment adjustment of 18.1 percent. Outside of the change to the LVPA amount, this change would not impact how the LVPA is applied to ESRD PPS payments.

We stated that one potential complication with a tiered approach to the LVPA is that there would still be payment cliffs present between the tiers. This may discourage ESRD facilities from increasing their treatment volume in a given year, especially if it is uncertain whether the ESRD facility's treatment volume in future years will stay at the increased level. To address this, we proposed to determine an ESRD facility's LVPA tier based on the median treatment count volume of the last three cost-reporting years, rather than using a single year treatment count. This methodology would smooth payments over years, increasing stability and predictability in payments to low-volume facilities. We also proposed that, should a facility receive an exception under § 413.232(g)(5) in one or more of the past three cost-reporting years, the median treatment count of the unaffected cost-reporting years would be used to make the facility's tier determination. We note that the median of two numbers is the average of those numbers, and the median of one number is that number. In the case that a facility does not have cost-reporting data from the last 3 years that are unaffected by a disaster or other emergency, we would assign the facility to a tier based on their last full year of unaffected treatment volume, assuming all LVPA eligibility criteria are met.

We stated that we believe that the proposed median treatment approach would promote stability, especially for facilities whose treatment counts are on the margins of a tier. We also believe that the proposed smoothing methodology for determining the treatment volume tier for which an ESRD facility qualifies is better than the alternative of using the highest tier (in terms of treatment volume) for which an ESRD facility has qualified in each of the past years. For example, if we used the highest tier of the last 3 years and a facility furnishes 3,500 treatments in one of the past 3 years, it would be categorized as tier 2 even if it furnished fewer than 3,000 treatments in the other 2 years. We believe that the proposed smoothing would mitigate the introduction of a cliff-effect within the tiers.

By contrast, under the proposed smoothing methodology, if the cost-reporting data indicated that the facility furnished 2,500, 2,999, and 3,500 treatments in the 3 years preceding the payment year, the median tier would be identified (tier 1 in this case), and the facility would (in the proposed two-tier system with scaling) receive a 28.4 percent payment adjustment for all of the treatments furnished during the payment year. We expect that any higher or lower payments from year to year under this policy would balance out over time without putting additional burden on the MACs. The structure of the proposed scaled, two-tier LVPA methodology is presented in Table 9, and the structure of the alternative three-tier unscaled LVPA methodology is presented in Table 10. For the purposes of comparison, we have included the scaled and unscaled version of both of the potential LVPA structures.

We noted that we did not propose any changes to the methodology for determining eligibility for the LVPA under § 413.232(b)(1), as the purpose of this change is to better allocate payments within the LVPA, not to expand the LVPA to facilities that have furnished more than 4,000 treatments in one of the past three cost-reporting years. We would continue to determine eligibility for the LVPA based on a facility's treatment count in each of the three cost-reporting years preceding the payment year as set forth in § 413.232(b)(1) and would not consider the median treatment count over that period for purposes of determining eligibility. Likewise, we did not propose any changes to § 413.232(g)(5), which allows for an exception to the requirement at § 413.232(b)(1) in the case of a disaster or other emergency. In the CY 2011 ESRD PPS final rule (75 FR 49030 through 49214), we stated that we believe a 3-year waiting period serves as a safeguard against facilities that have the opportunity to take a financial loss in establishing facilities that are purposefully small. In response to the CY 2024 ESRD PPS proposed rule RFI (88 FR 42430 through 42544), several interested parties commented that they believe CMS should maintain the 3-year attestation to determine eligibility for the LVPA, as it is an important safeguard against gaming. In addition, if we were to use the median tier methodology to determine LVPA eligibility, we estimate that the adjustment factors would decrease, because the scaling factor used to maintain budget neutrality within the LVPA would be smaller to account for a larger amount of ESRD facilities qualifying for the LVPA.

We stated that, if finalized, the proposed median treatment count methodology for determining an eligible ESRD facility's LVPA tier would improve the stability and predictability of the LVPA by basing tier determination on the median treatment count of the last 3 years as opposed to the treatment count for each of the last 3 years, where facilities could be disqualified from a higher adjustment based on marginal changes. The proposed tiered smoothing methodology would also better align payment with resource use by minimizing the impact of the payment cliff between the LVPA tiers in a transparent and reproducible fashion. We solicited comments on each aspect of our proposal: (1) the tiered structure of the LVPA; (2) using the median treatment count volume to determine the LVPA payment tier for ESRD facilities that are eligible for the adjustment; and (3) the scaling of the adjusters to maintain LVPA payments at the same level. As previously discussed, we also considered an alternative three-tiered structure, which would have the effect of reducing the base rate by $0.99. We solicited comments on whether this alternative methodology could be more appropriate than the proposed methodology.

We invited public comment on our proposal to change the LVPA methodology to include two tiers, use the median treatment count volume to determine the LVPA payment tier for eligible facilities, and to scale the adjusters to maintain budget neutrality without lowering the ESRD PPS base rate. Approximately 12 commenters including a non-profit dialysis organization, a non-profit kidney organization, multiple large dialysis organizations, a provider advocacy organization, a non-profit organization of ESRD networks, a non-profit kidney care alliance, a coalition of dialysis organizations, a small dialysis organization within a large non-profit health system, and MedPAC commented on the proposed changes to the LVPA methodology. The following is a summary of the public comments received on these proposals and our responses.

Comment: Several commenters supported CMS's proposed changes to the LVPA methodology, agreeing that introducing two tiers would help reduce

the burden of payment cliffs. Some of these commenters encouraged CMS to continue refining the LVPA as more data becomes available, and to continue evaluating the impact of creating additional tiers. Nearly all commenters expressed support for our proposal to use the median treatment count volume to determine the LVPA payment tier for eligible facilities.

Response: We thank commenters for their support and dedication to advancing health equity and protecting access to renal dialysis services for vulnerable beneficiaries. CMS will continue to monitor the ESRD PPS LVPA methodology to ensure that payments are appropriately aligned with resource use and adequately target low-volume facilities and make refinements, if appropriate, through rulemaking.

Comment: Some commenters cited analysis suggesting that CMS may have underestimated the number of facilities projected to furnish more than 3,000 treatments during CY 2025 in the CY 2025 impact file [76] and expressed concern that the adjuster amounts CMS calculated for both tier structures described in the CY 2025 ESRD PPS proposed rule may be inaccurate. Many of these commenters were also concerned that the two- and three-tiered structures presented in the proposed rule had the same adjusters despite a greater number of ESRD facilities qualifying for the LVPA under the three-tiered structure.

Response: The dialysis treatment counts reported in the impact tables in Addendum B represent Fee-For-Service (FFS) treatments furnished by each facility during 2023. LVPA tier assignment is based on facility size, which encompasses all treatments (Medicare FFS, MA, or non-Medicare) furnished during CYs 2020, 2021, and 2022, including treatments by ESRD facilities under common ownership and located within a 5-driving mile radius. The CY 2023 facility size information was considered separately from the FFS treatment during our analysis.

The two- and three-tier LVPA structures in the CY 2025 ESRD PPS proposed rule appear identical as both represent estimates of expected cost differentials derived from a common model that measures association between facility size and cost. The adjusters from the common model are stable because they are based on the overall relationship between cost and volume, not on the number of tiers into which facilities are divided. These estimates appear in the second columns of Tables 9 and 10 in this final rule. However, once facilities are assigned to a category and payment budget neutrality is applied, the adjusters for the two- and three-tier proposals diverge, as shown by the third columns in each respective table where the adjustment factors are scaled to maintain total LVPA payments at the same level.

Comment: Several interested parties expressed concern that the facilities in the second tier under the proposed two-tier LVPA methodology (furnishing between 3,000 and 3,999 treatments per year) would receive a lower adjustment compared to the current LVPA policy.

Response: We maintain our belief that a two-tier scaled approach is appropriate, as it replaces a one-size-fits all approach with one where payments more closely align with cost while keeping payment changes contained within the population of LVPA facilities. Maintaining budget neutrality in this manner when transitioning to a tiered structure necessitates payment adjustments that differ from the current adjuster at each tier. Therefore, it is unavoidable that the tier 2 LVPA facilities receive a lower LVPA adjustment factor under the tiered system while holding total LVPA payments at the same level.

We also maintain our belief that it is appropriate to implement a scaled approach as opposed to a budget neutrality factor applied to all ESRD PPS payments. We reiterate that when we last updated the LVPA adjustment factor in the CY 2016 ESRD PPS final rule (80 FR 68972 through 69004), we also updated most of the facility-level and case-mix adjusters and applied a budget neutrality factor that represented all of those changes. Since we only proposed changes to the LVPA in the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), we noted that it would be most appropriate to contain the changes within the current LVPA by applying a scaling factor to the LVPA adjusters.

Comment: MedPAC supported the proposal for a two-tier LVPA for existing ESRD facilities as well as maintaining budget neutrality with respect to the current LVPA policy but expressed multiple concerns about extending the LVPA to new ESRD facilities. MedPAC suggested that the two-tier proposal is an improvement over the current policy, but that they ultimately support a statutory change that would replace both the LVPA and the rural facility adjustment with a single payment adjustment that considers distance to the next nearest facility and treatment volume. MedPAC stated that such an adjustment would eliminate extra payments to low-volume facilities in close proximity to another facility and high-volume rural facilities.

Response: CMS appreciates the support expressed by MedPAC for the proposed changes to the LVPA methodology and its input on future refinements that could preserve access to renal dialysis services. CMS also shares MedPAC's concerns about extending the LVPA to new ESRD facilities, as this could result in decreased payment to the lowest-volume ESRD facilities. As we discussed in the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), CMS aims to align resource use with payment, advance health equity and protect access to renal dialysis services for vulnerable beneficiaries in underserved communities, including rural and isolated communities, by increasing payments to certain ESRD facilities in these areas to align with their higher costs. We acknowledge MedPAC's continued support for an LVPA that incorporates geographic isolation but reiterate that such an adjustment would not be consistent with the statutory requirements for the LVPA unless geographic isolation is found to influence the extent to which low-volume ESRD facilities face higher costs, and we agree that such an adjustment would require a statutory change.

Comment: Multiple commenters once again called for the elimination of the rural facility adjustment and for its funds to be allocated to support a more robust LVPA, either within the current bounds of eligibility or to include ESRD facilities that furnish up to 6,000 treatments per year. Many of these commenters reiterated their support for MedPAC's LVI methodology and noted several concerns regarding the three-tier model presented by CMS in the CY 2025 ESRD PPS proposed rule. Some commenters stated that the three-tier model presented by CMS would cause substantial overlap between facilities receiving the LVPA and the rural facility adjustment, and that a large number of rural facilities are high-volume to an extent that may not warrant additional payment.

Response: In the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), CMS noted that recent analysis has confirmed, in general, that low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. This analysis broadly aligns with suggestions from various commenters, including MedPAC, to refine or remove the rural

[76] The CY 2025 impact file can be found in Addendum B of the proposed rule.

facility adjustment to better target ESRD facilities that are critical to beneficiary access and are likely not being adequately targeted under the current methodology. However, CMS found that, on treatment weighted basis, over 65 percent of rural providers have no other providers in a 5-driving mile distance, and that this fraction increases to 83 percent for providers eligible for both the rural facility adjustment and the LVPA. These findings indicate that the overlapping payments for both the LVPA and rural facility adjustments are primarily going to small and isolated providers and align with our belief that many ESRD facilities which receive the rural facility adjustment are critical to patient access and may be relying on the additional payment from the rural facility adjustment for the coming years. We are not finalizing any changes to the rural facility adjustment at this time, but we are open to considering potential refinements to the definition of a rural ESRD facility in the future by considering alternate rural designations. Any future changes would consider the impact on rural ESRD facilities. Additionally, we note that the rural facility adjustment for the ESRD PPS is relatively small compared to other payment systems, at 0.8 percent, and that the suggested elimination of this adjustment would only account for about one third of the budget neutrality adjustment required for our alternative 3-tiered adjustment, which would expand the LVPA to ESRD facilities that furnish up to 5,000 treatments per year. Therefore, the funds currently associated with the rural facility adjustment would not be able to ''pay for'' expanding the LVPA to the commenter's suggested 6,000 treatment volume threshold without a significant budget neutrality reduction to the ESRD PPS base rate.

CMS also reiterates that because payments for facilities furnishing between 4,000 and 5,000 treatments would increase under the three-tier methodology presented in the proposed rule, payments for the lowest-volume facilities would need to decrease to maintain budget neutrality, and we do not believe this would align with the goals of the LVPA. We thank the commenters who presented analysis demonstrating why the three-tier methodology we presented may yield decreased payment to the lowest-volume facilities and how alternative methodologies, including MedPAC's LVI methodology, could potentially yield more equitable payment distribution to LVPA-eligible facilities. CMS intends to consider the provided analyses to inform future notice and comment rulemaking pertaining to the LVPA methodology.

Comment: A small dialysis organization within a large non-profit health system commented asking for additional clarification regarding the median tier calculation in the instance where a facility receives an exception for taking on additional patients due to a disaster or emergency.

Response: In the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), we proposed that, should a facility receive an exception under § 413.232(g)(5) in one or more of the past three cost-reporting years, the median treatment count of the unaffected cost-reporting years would be used to make the facility's tier determination. We noted that the median of two numbers is the average of those numbers, and the median of one number is that number. In the case that a facility does not have cost-reporting data from the last 3 years that are unaffected by a disaster or other emergency, we would assign the facility to a tier based on their last full year of unaffected treatment volume, assuming all LVPA eligibility criteria are met. For example, if cost-reporting data indicated that an ESRD facility furnished 2,500, 2,999, and 4,500 treatments in the 3 years preceding the payment year, but received an exception under § 413.232(g)(5) during the year it furnished 4,500 treatments, the median treatment count from the two prior years (2,500 and 2,999) would be used determine the facility's LVPA tier, which would place the facility in tier 1 under the proposed two-tier methodology. The facility would then receive a 28.4 percent payment adjustment for all of the treatments furnished during the payment year.

Comment: Some interested parties commented that it is necessary to conduct analysis of the Pacific territories separately from the general Pacific census region to consider the unique costs that are exclusive to small island economies. The commenters cited air freight shipping costs, operational costs for utilities, limited availability of local healthcare professionals, and a lack of economies of scale as factors that may be raising the per-treatment costs across the Pacific territories. The interested parties acknowledged that CMS is barred from accounting for geographic isolation outside of the extent to which low-volume facilities face higher costs in furnishing renal dialysis services than other facilities, but claimed that CMS may have concluded that low-volume facilities that are rural, isolated, or located in low-demand areas generally did not have higher costs than low-volume ESRD facilities overall without adequately considering the unique situation of the Pacific territories. The commenters urged CMS to refine the LVPA to better target isolated ESRD facilities such as those in the Pacific islands and requested the Secretary to consider exercising the authority provided under section 1881(b)(14)(D)(iv) to establish other payment adjustments for the Pacific territories in the case that CMS is unable to better target these facilities due to statutory constraints.

Response: In the CY 2024 ESRD PPS proposed rule's LVPA RFI (88 FR 42441 through 42445), we solicited comments on a potential new payment adjustment that accounts for isolation, rurality, and other geographical factors, including local dialysis need (LDN). CMS stated that the statutory requirements for the LVPA under section 1881(b)(14)(D)(iii) of the Act generally would not allow for CMS to account for geographic isolation outside of the extent to which low-volume facilities face higher costs in furnishing renal dialysis services than other facilities, and preliminary analysis found that, in general, low-volume facilities that are rural, isolated, or located in low-demand areas did not have higher costs than low-volume ESRD facilities overall. Because of this, we clarified that the LDN methodology could only be implemented under the authority in section 1881(b)(14)(D)(iv) of the Act, which states that the ESRD PPS may include such other payment adjustments as the Secretary determines appropriate. Commenters were generally opposed to the LDN methodology for a variety of factors, and many supported MedPAC's LVI methodology in place of the existing LVPA and rural facility adjustments. The statute generally would not permit MedPAC's approach recommending payment directed at isolated facilities under the LVPA, and our preliminary analysis shows that the funds from the rural adjuster alone cannot support a third LVPA tier while maintaining budget neutrality and without decreasing payment to the lowest volume facilities. CMS is committed to achieving equity in healthcare outcomes for our beneficiaries, and we reiterate that the statutory requirement for the LVPA requires it reflect the extent to which low-volume ESRD facilities face higher costs. We intend to continue to evaluate whether geographic isolation is associated with higher costs for low-volume ESRD facilities and, should we find such evidence, we would be able to

consider alternative methodologies to the LVPA similar to MedPAC's LVI in potential future rulemaking. Should our future analysis show that isolated, low-volume ESRD facilities incur greater costs than other low-volume ESRD facilities, we would consider, if appropriate, making further refinements to the LVPA methodology through rulemaking. We recognize that the U.S. Pacific Territories are uniquely isolated compared to mainland ESRD facilities, so a different set of isolation criteria may apply distinctly to these ESRD facilities and, should they have higher costs than other LVPA facilities, support incorporating such isolation criteria into the LVPA under the current statute. However, we do not believe it would be appropriate to define isolation criteria based on predetermined ESRD facilities that we believe should be considered isolated. Additionally, as there are relatively few ESRD facilities in the U.S. Pacific Territories, any isolation criteria which would only identify these ESRD facilities would likely be very restrictive and not appropriate to be applied to the ESRD PPS overall. Therefore, we do not believe it would be most appropriate to address the higher costs that the commenter described through the LVPA. We intend to further consider the unique challenges and costs which are faced by ESRD facilities in the U.S Pacific Territories, and other similarly isolated places, and address these challenges and costs, if warranted, through an appropriate payment mechanism, such as an adjustment under section 1881(b)(14)(D)(iv), in potential future rulemaking.

CMS appreciates the unique challenges that ESRD facilities in the U.S. Pacific Territories face and the higher costs that might accompany them. However, we note that the LVPA is generally not constructed to account for factors outside of the costs that ESRD facilities incur as a result of furnishing a small number of treatments. CMS has also noted that there are ESRD facilities that may be eligible for the LVPA but have not submitted attestations to their MACs. CMS encourages these facilities to attest for purposes of the LVPA as we continue to consider appropriate ways to support Pacific Territory facilities that are critical to beneficiary access to renal dialysis services.

Final Rule Action: After considering the comments, we are finalizing as proposed the scaled two-tier LVPA methodology, where ESRD facilities that fall into the first tier will receive a payment adjustment of 28.9 percent and those that fall in the second tier will receive a payment adjustment of 18.3 percent. The structure of this methodology can be found in Table 11. We are also finalizing as proposed the tiered smoothing methodology, where an ESRD facility's LVPA tier will be determined based on the median treatment count volume of the last three cost-reporting years, rather than using a single year treatment count.

TABLE 11: Final LVPA Methodology with Two Tiers

Tier	LVPA Adjusters with Scaling	Number of Eligible CMS Certification Numbers (CCNs)
Tier 1 (less than 3,000)	28.9%	202
Tier 2 (3,000 – 3,999)	18.3%	128

We note that the final LVPA adjusters under the two-tier methodology are marginally different from those presented in the CY 2025 ESRD PPS proposed rule. The final LVPA adjusters presented in Table 11 reflect the use of more recent claims data in our analysis for this final rule, which results in changes to the scaling factor used to maintain total estimated LVPA payments at the same amount.

CMS reiterates that we did not propose and are not finalizing any changes to the methodology for determining eligibility for the LVPA under § 413.232(b)(1), as the purpose of the finalized changes is to better allocate payments within the LVPA, not to expand the LVPA to facilities that have furnished more than 4,000 treatments in one of the past three cost-reporting years. We will continue to determine eligibility for the LVPA based on a facility's treatment count in each of the three cost-reporting years preceding the payment year as set forth in § 413.232(b)(1) and would not consider the median treatment count over that period for purposes of determining eligibility. Likewise, we did not propose and are not finalizing any changes to § 413.232(g)(5), which allows for an exception to the requirement at § 413.232(b)(1) in the case of a disaster or other emergency.

d. Summary of RFI on Improving the LVPA for New ESRD Facilities

In the CY 2025 ESRD PPS proposed rule (89 FR 55760 through 55843), we sought comment on several approaches to modifying the LVPA methodology to ensure that payments are accurately aligned with resource use, adequately target low-volume facilities, and strive for healthcare equity for ESRD beneficiaries. We issued an RFI to seek feedback from the public on potential changes to the LVPA eligibility criteria, including the potential modification of the 3-year cost-reporting data requirement, and what commenters believe would be the best way for a new low-volume ESRD facility to demonstrate or attest that it expects to be low-volume. We also sought information regarding the potential implementation of a reconciliation process for ESRD facilities that fail to furnish a low enough treatment volume to qualify for the LVPA or their predicted tier. We also questioned commenters about the cost differences for providers of low-volume home dialysis and providers of low-volume in-center dialysis, and whether the

LVPA be an appropriate pathway to support the provision of home dialysis through increased payment. In particular, we sought input and responses to the following considerations, requests, and questions:

- Whether the LVPA or another adjustment, such as the LDN methodology discussed earlier, would be the most appropriate payment pathway to support access to renal dialysis services in areas that do not currently have sufficient capacity to furnish these services to all Medicare beneficiaries.
- What would be the most appropriate way or ways for a new ESRD facility to demonstrate or attest that it expects to be low-volume?
- The potential for future reconciliation process as an appropriate accommodation for new ESRD facilities.
- Whether a reconciliation process would be an effective tool for making appropriate payments to existing ESRD facilities that have three or more years of cost reporting data.
- Would a reconciliation process be operationally straightforward and understandable for an ESRD facility that has opened in the past 3 years?
- Would a reconciliation process make it more difficult for ESRD facilities to plan and budget for future payment years? Is this outweighed by the potential benefit of earlier access to the LVPA for these new facilities?
- Would it be useful or feasible to implement a reconciliation process for ESRD facilities that have not opened in the past 3 years but, for whatever reason, may have furnished a low enough treatment volume to qualify for the LVPA?
- Could the LVPA be changed in any way to better support ESRD facilities opening in underserved areas? Are there any costs specific to low-volume facilities for which the current LVPA does not account?
- How are the costs for providers of low-volume home dialysis different from the costs for providers of low-volume in-center dialysis? Could the LVPA be an appropriate pathway to support the provision of home dialysis through increased payment?

We did not receive any new feedback in response to our RFI regarding LVPA eligibility or the attestation process for new ESRD facilities. A handful of commenters reiterated their stance from the CY 2024 ESRD PPS RFI on the LVPA. Some commenters thanked CMS for our consideration of public comments as we continue to refine the LVPA methodology. We received one comment from an LDO in response to our RFI regarding the cost differences for low-volume home dialysis versus in-center dialysis providers. The comment explained that staffing dynamics make the 4,000-treatment LVPA threshold inapplicable for home dialysis programs but cautioned that a home dialysis-specific LVPA threshold may not address the challenges faced by low-volume home programs as the treatment aggregation mechanism within the LVPA disqualifies many of these programs due to their proximity to commonly owned in-center programs.

We thank the commenters for their detailed and thoughtful comments, including those who responded to the RFI. While we are not responding to these comments in this CY 2025 ESRD PPS final rule, we intend to take them into consideration for future rulemaking and future policy development.

C. Transitional Add-On Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) Applications and Technical Changes for CY 2025

1. Background

In the CY 2020 ESRD PPS final rule (84 FR 60681 through 60698), we established the transitional add-on payment adjustment for new and innovative equipment and supplies (TPNIES) under the ESRD PPS, under the authority of section 1881(b)(14)(D)(iv) of the Act, to support ESRD facility use and beneficiary access to these new technologies. For additional background on the TPNIES we refer readers to the CY 2024 ESRD PPS final rule (88 FR 76410 through 76412).

As indicated in § 413.236(c) CMS includes the summary of each TPNIES application and our analysis of the eligibility criteria for each application in the annual ESRD PPS proposed rule and announces the results in the annual ESRD PPS final rule. Because we did not receive any applications for the TPNIES for CY 2025, no TPNIES application summaries, CMS analyses, or results have been included in this final rule.

2. Technical Changes to § 413.236(b)(4) and § 413.236(c)

As part of the TPNIES eligibility requirements in § 413.236(b)(4), a covered equipment or supply must have a complete HCPCS Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) items and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular CY. We have identified a minor error in § 413.236(b)(4). Specifically, we inadvertently transposed the words orthotics and prosthetics within the DMEPOS acronym. The acronym was intended to read durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) instead of durable medical equipment, orthotics, prosthetics and supplies (DMEPOS).

As described in the HCPCS Level II Coding Procedures, HCPCS Level II is a standardized coding system that is used primarily to identify drugs, biologicals and non-drug and non-biological items, supplies, and services not included in the CPT® code set jurisdiction, such as ambulance services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used outside a physician's office.

While the HCPCS level II Coding Procedures include DMEPOS as an example of items for which HCPCS Level II codes are established, we believe that the phrase non-drug and non-biological items more broadly reflects all items, supplies, and services for which HCPCS Level II codes are established and aligns with the HCPCS Level II coding procedures on the CMS website. Therefore, we proposed a technical change at § 413.236(b)(4) to remove the reference to the phrase durable medical equipment, orthotics, prosthetics and supplies (DMEPOS) and replace it with the phrase non-drug and non-biological items. We are also adding the word supplies. These technical changes would better reflect the broader category of non-drug and non-biological item coding in the HCPCS Level II Coding Procedures available on the CMS website.[77]

We did not receive any comments on our proposed technical changes to § 413.236(b)(4). We are finalizing the technical changes as proposed at § 413.236(b)(4) and also finalizing the corresponding edit at § 413.236(c) for the same reasons that we identified for the proposed edit.

D. Continuation of Approved Transitional Add-On Payment Adjustments for New and Innovative Equipment and Supplies for CY 2025

In this section of the final rule, we identify any items previously approved for the TPNIES and for which payment

[77] Healthcare Common Procedure Coding System (HCPCS) Level II Coding Procedures. Available at: *https://www.cms.gov/medicare/coding/medhcpcsgeninfo/downloads/2018-11-30-hcpcs-level2-coding-procedure.pdf.* Accessed on January 16, 2024.

is continuing for CY 2025. As described in the CY 2024 ESRD PPS final rule, no new items were approved for the TPNIES for CY 2024 (88 FR 76431). As such there are no items previously approved for the TPNIES for which payment is continuing in CY 2025.

E. Continuation of Approved Transitional Drug Add-On Payment Adjustments for CY 2025

Under § 413.234(c)(1), a new renal dialysis drug or biological product that is considered included in the ESRD PPS base rate is paid the TDAPA for 2 years. In July 2023, CMS approved Jesduvroq (daprodustat) for the TDAPA under the ESRD PPS, effective October 1, 2023. Implementation instructions are specified in CMS Transmittal 12157, dated July 27, 2023, and available at: *https://www.cms.gov/files/document/r12157cp.pdf.*

In April 2024, CMS approved DefenCath® (taurolidine and heparin sodium) for the TDAPA under the ESRD PPS, effective July 1, 2024. Implementation instructions are specified in CMS Transmittal 12628, dated May 9, 2024, and available at: *https://www.cms.gov/files/document/r12628CP.pdf.*

Table 12 identifies the two new renal dialysis drugs for which the TDAPA payment period as specified in § 413.234(c)(1) will continue in CY 2025: Jesduvroq (daprodustat) that was approved for the TDAPA effective in CY 2023 and DefenCath® (taurolidine and heparin sodium) that was approved for the TDAPA effective in CY 2024. Table 12 also identifies the products' HCPCS coding information as well as the payment adjustment effective dates and end dates.

TABLE 12: Continuation of Approved Transitional Drug Add-On Payment Adjustments

HCPCS Code	Long Descriptor	Payment Adjustment Effective Date	Payment Adjustment End Date
J0889	Daprodustat, oral, 1 mg, (for ESRD on dialysis)	10/1/2023	9/30/2025
J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	7/1/2024	6/30/2026

Comment: One commenter recommended that CMS monitor anemia outcomes with hypoxia-inducible factor prolyl hydroxylase inhibitor (HIF–PHI) versus erythropoiesis stimulating agent (ESA) therapy.

Response: We thank the commenter for the recommendation and note that Jesduvroq (daprodustat) is a HIF–PHI.[78] CMS engages in ongoing monitoring and analysis of the ESRD PPS to identify trends in beneficiary health outcomes. An overview of the ESRD PPS claims-based monitoring program is provided on the CMS website.[79] CMS will continue the claims-based monitoring in CY 2025, inclusive of all drugs approved for the TDAPA. CMS intends to monitor anemia and cardiovascular outcomes among beneficiaries using Jesduvroq (daprodustat) and ESAs.

[78] Jesduvroq Prescribing Information. Accessed October 10, 2024. Available at: *https://gskpro.com/content/dam/global/hcpportal/en_US/Prescribing_Information/Jesdvroq/pdf/JESDUVROQ-PI-MG.PDF.*

[79] ESRD Prospective Payment System (ESRD PPS) Claims-Based Monitoring Program-Overview of 2010–2022 Claims-Based Monitoring Program. Accessed September 13, 2024. Available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/esrdpayment/esrd-claims-based-monitoring.*

III. Final CY 2025 Payment for Renal Dialysis Services Furnished to Individuals With AKI

A. Background

The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

In the CY 2017 ESRD PPS final rule, we finalized several coverage and payment policies to implement subsection (r) of section 1834 of the Act and the amendments to section 1861(s)(2)(F) of the Act, including the payment rate for AKI dialysis (81 FR 77866 through 77872 and 77965). We interpret section 1834(r)(1) of the Act as requiring the amount of payment for AKI dialysis services to be the base rate for renal dialysis services determined for a year under the ESRD PPS base rate as set forth in § 413.220, updated by the ESRD bundled market basket percentage increase factor minus a productivity adjustment as set forth in § 413.196(d)(1), adjusted for wages as set forth in § 413.231, and adjusted by any other amounts deemed appropriate by the Secretary under § 413.373. We codified this policy in § 413.372 (81 FR 77965).

B. Public Comments and Responses on the Proposal To Allow Medicare Payment for Home Dialysis for Beneficiaries With AKI

1. Background

In the CY 2017 ESRD PPS final rule, we indicated that we did not expect beneficiaries with AKI to dialyze at

home; therefore, the home dialysis benefit was not extended to beneficiaries with AKI (81 FR 77870). There were commenters who advocated for beneficiaries to have the option to dialyze in a home setting, particularly those beneficiaries who started peritoneal dialysis (PD) in the hospital and desired to continue PD after discharge. However, other commenters indicated that beneficiaries with AKI needed close supervision during dialysis. Additionally, some commenters indicated that dialysis for AKI is a short-term treatment, and beneficiaries would not have time to learn to administer a home therapy. Therefore, we finalized the AKI payment policy in the CY 2017 ESRD PPS final rule as proposed without extending the AKI benefit to home dialysis beneficiaries. We indicated that we would gather data on the AKI beneficiary population and the extent of home training necessary to safely self-administer dialysis in the home, and that we would consider the use of home dialysis for beneficiaries with AKI in the future as we find that it may be beneficial for subsets of beneficiaries.

In past years we have received comments regarding the site of renal dialysis services for Medicare beneficiaries with AKI, with the most recent comments received in response to the CY 2024 ESRD PPS proposed rule to update to the AKI dialysis payment rate (88 FR 76433). We have monitored data for beneficiaries with AKI and researched data in journal articles discussing the potential to expand dialysis for beneficiaries with AKI to a home setting, as noted in the CY 2017 ESRD PPS final rule (81 FR 77871).

In the CY 2017 ESRD PPS final rule, we clarified that the ESRD Facility CfCs apply to ESRD facilities, not to ESRD beneficiaries, and noted that the ESRD facility CfCs would be the appropriate regulatory location for standards addressing care provided to beneficiaries with AKI in ESRD facilities. We finalized a policy that our CfCs would not need to be revised to address the provision of dialysis treatment to beneficiaries with AKI (81 FR 77871 through 77872).

In December 2020, CMS's data contractor held a TEP that considered data related to utilization review and cost of AKI treatments since 2017. The TEP solicited input regarding how reported costs align with realized costs of treatment for beneficiaries with AKI. During the TEP, participants suggested that we extend Medicare payment for beneficiaries with AKI to allow them to dialyze in a home setting. Additionally, the TEP indicated that beneficiaries with AKI could benefit from different treatment regimens. The TEP noted that more frequent, gentler dialysis with a lower ultrafiltration rate would be a viable option for some beneficiaries. Members of the panel commented on the similar treatment frequencies observed for beneficiaries with AKI and ESRD, stating that the payment system is currently constructed to facilitate the standard treatment plan for beneficiaries with AKI. Panelists recommended that the ESRD PPS should be flexible in terms of number of treatments for beneficiaries with AKI, so that those who need more frequent treatments are not impeded from receiving them. Panelists related instances of hospitals starting a patient on PD, which can be done frequently in the home setting, only to convert the patient to a more standard treatment regimen such as three in-center hemodialysis treatments per week before discharging the patient to a dialysis facility. Panelists also advocated that we provide Medicare payment for beneficiaries with AKI to be treated at home.

We solicited comments regarding potentially modifying the site of renal dialysis services for beneficiaries with AKI and payment for AKI in the home setting as a RFI in the CY 2022 ESRD PPS proposed rule (86 FR 36322, 36408). We received 16 comments from LDOs, patient advocacy groups, professional organizations, small dialysis organization within a large non-profit health system, and non-profit organizations. Most of the comments favored providing a payment option for beneficiaries with AKI to dialyze in a home setting; however, some commenters expressed concerns about doing so. A small dialysis organization within a large non-profit health system indicated that beneficiaries with AKI may have chronic kidney disease at a lesser stage, such as, Stage 3 or Stage 4 chronic kidney disease (CKD) rather than ESRD; however, the AKI makes dialysis necessary. This commenter noted that if the AKI were to cause the beneficiary's underlying Stage 3 or Stage 4 CKD to progress to ESRD in the future, training them to use a home modality during the AKI episode could prepare the patient for a home modality if they are diagnosed as having ESRD. One LDO indicated there is evidence that PD, which is typically used in the home setting, is associated with better preservation of residual kidney function compared to hemodialysis. A national organization of beneficiaries and kidney health care professionals advocated that PD may be learned quickly, reduces rapid hemodynamic changes that may potentiate kidney injury and impede recovery, and does not require a high-risk central venous catheter to provide treatment. We note that these comments are specific to PD as a treatment modality; however, when considering such a policy we would include payment for both PD and hemodialysis (HD) in the home setting for beneficiaries with AKI, consistent with our payment policy for home dialysis for patients with ESRD.

Most recently, as noted in the CY 2024 ESRD PPS final rule (88 FR 76433), we received 10 public comments on our proposal to update the payment rate for renal dialysis services furnished to individuals with AKI. Commenters included a coalition of dialysis organizations, a non-profit dialysis organization, a trade association, a renal product development company, and multiple large dialysis organizations. Most of the commenters requested that we allow payment for beneficiaries with AKI to select home dialysis modalities by changing the current policy, even though it was not proposed in the CY 2024 ESRD PPS proposed rule.

In the CY 2025 ESRD PPS proposed rule, we acknowledged there have been concerns in the past regarding the safety of beneficiaries with AKI dialyzing at home (89 FR 55806). However, we explained that we carefully reviewed the totality of the information and evidence presented to the agency and now recognize that current information regarding beneficiaries with AKI dialyzing in a home setting supports more frequent dialysis at a lower ultrafiltration rate. We stated that the ability to dialyze at a lower ultrafiltration rate supports a decrease in hemodynamic fluctuation and the complications associated with it, which in turn support recovery of kidney function.

2. Technical Analysis

In the CY 2025 ESRD PPS proposed rule, we noted that although there is only limited research regarding the use of home dialysis for the treatment of AKI, several studies support the use of home dialysis to generally improve access to dialysis and provide care that better meets patient needs (89 FR 55806 through 55807). We noted that many of the studies related to home dialysis in the AKI patient population use PD as the treatment modality, which we explained is consistent with comments received during the December 2020 TEP and comments received during rulemaking as noted previously. Additionally, we stated that data from the United States Renal Data System (USRDS) Annual Data Report (ADR),

indicated the percentage of incident dialysis patients performing home HD was only 0.4 percent in 2021, and a significant majority of dialysis patients performing home dialysis chose PD.[80] We stated that we believe the choice of a home modality would be comparable in the beneficiary population for those with AKI as those initiating chronic maintenance dialysis for ESRD. However, we affirmed that payment would be provided for either modality of home dialysis. For example, PD was used frequently for patients during the COVID–19 PHE due to challenging situations such as supply shortages, staffing shortages, and limited surgical availability for the placement of a venous access. In the proposed rule, we noted that a multicenter, retrospective, observational study of 94 patients who received acute PD in New York City in the spring of 2020 indicated that rapid deployment of acute PD was feasible. We stated that the rates of death and renal recovery were like those of patients with AKI requiring kidney replacement therapy (KRT) in other cohorts. Of those who were discharged on dialysis, four were discharged on PD, and one was discharged on HD.[81]

We further noted that the International Society for Peritoneal Dialysis (ISPD) reiterated in the 2020 guidelines, updated from the 2014 guidelines for PD in AKI, that PD should be considered a suitable modality for treatment of AKI in all settings. This was a strong recommendation from the ISPD based on evidence rated at the second highest level used by ISPD.[82] Researchers found little to no difference between PD and hemodialysis in all-cause mortality, recovery of kidney function, or infection as a complication.[83] We noted that this finding was augmented by an article that reviewed the resurgence of PD for the treatment of AKI since the COVID–19 PHE. The article listed cost effectiveness, low infrastructure requirements, ease of staff training, and more rapid recovery of renal function as benefits to the use of PD to treat AKI. We identified a survey of nephrologists from three international conferences which reported that 50.8 percent and 36.4 percent of respondents stated that PD was suitable for treating AKI in the wards and ICU, respectively. We found that PD is the predominant therapy used to treat pediatric patients with AKI, and until the mid to late 1990s was the predominant therapy to treat adults with AKI, but the use of this therapy has waned since the advent of pump driven continuous kidney replacement therapy.[84]

We noted that most studies regarding recovery of kidney function in patients with AKI were based around hospitalized patients. We further noted that there were very limited studies suggesting that self-care dialysis can yield faster recovery of kidney function; however, the results were not conclusive.[85] We identified that one study of hospitalized patients with AKI indicated that a median of 10 patients recovered kidney function more quickly utilizing PD.[86] We noticed another study of hospitalized patients with AKI that indicated that while the recovery of kidney function was similar in PD and HD (28 and 26 percent) there was a significantly shorter time to the recovery of kidney function for patients with AKI that utilized PD.[87]

We identified additional information from CMS AKI monitoring data, in which we found that current provision of AKI dialysis is very similar to the provision of ESRD dialysis. Data noted in the 2021 Quarter 4 public use file (PUF)[88] for AKI showed that hemoglobin for beneficiaries with ESRD averaged 10.6 gm/dL while the average hemoglobin for beneficiaries with AKI averaged 9 gm/dL. Although the data further suggested that beneficiaries with AKI were less likely to be prescribed an ESA than patients with ESRD, we identified research that indicated that patients using PD have a lower rate of anemia that those using HD. Additionally, patients receiving PD require lower doses of ESAs and iron than patients receiving HD.[89] We observed that this might indicate that dialyzing in a home environment could be effective to manage anemia in beneficiaries with AKI more appropriately, as the USRDS ADR indicated incident patients with ESRD typically choose PD as a home modality over home HD.[90] We stated that we believed that beneficiaries with AKI would make similar choices. Furthermore, the AKI PUF data showed that approximately 8 percent of beneficiaries with ESRD experienced incidences of fluid overload, while beneficiaries with AKI experienced episodes for which congestive heart failure was reported within 30, 60, and 90 days (which can be related to fluid overload) at rates of around 42 percent, 50 percent, and 53 percent, respectively.[91] This data was concerning because fluid overload in beneficiaries with AKI can be detrimental to recovering kidney function. Additionally, this data supported conclusions drawn from an article involving the review of 1754 patients with AKI requiring dialysis. The article indicated that treatment protocols for patients with AKI were like those of incident ESRD patients despite the underlying differences in treatment goals. The article further indicated that most patients with AKI who recovered had discontinued dialysis without ever having been weaned from their initial dialysis prescription, suggesting there may be substantial opportunity to wean dialysis sooner.[92] We continue to support the significant need to individualize the treatment of every kidney patient, but particularly beneficiaries with AKI, as this omission could result in a missed opportunity to recover kidney function.

We stated that we believed the proposal to provide payment for beneficiaries with AKI to dialyze in a home setting aligns closely with the CMS Strategic Pillars[93] of expanding access, engaging the ESRD community by being responsive to TEPs and RFIs, and driving innovation to promote patient centered care. We did not have utilization data for beneficiaries with AKI using a home modality available, but we used the USRDS ADR, which indicated that disparities currently exist for self-care dialysis in the home setting for the ESRD beneficiary population, with fewer African American/Black and Hispanic beneficiaries choosing a home dialysis modality. Additionally, fewer Medicare and Medicaid dual eligible

[80] Annual Data Report | USRDS (*nih.gov*), *https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis.*

[81] *https://www.sciencedirect.com/science/article/pii/S0085253821004567.*

[82] *https://journals.sagepub.com/doi/10.1177/0896860820970834.*

[83] *https://pubmed.ncbi.nlm.nih.gov/29199769/.*

[84] *https://academic.oup.com/ckj/article/16/2/210/6696026.*

[85] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4594060/.*

[86] *https://onlinelibrary.wiley.com/doi/pdfdirect/10.1111/1744-9987.12660.*

[87] *https://www.sciencedirect.com/science/article/pii/S0085253815528664.*

[88] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-prospective-payment-system-esrd-pps-overview-claims-based-monitoring-program.*

[89] *https://academic.oup.com/ckj/article/16/12/2493/7210548.*

[90] Annual Data Report | USRDS (*nih.gov*), *https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis.*

[91] *https://www.cms.gov/medicare/payment/prospective-payment-systems/end-stage-renal-disease-esrd/esrd-prospective-payment-system-esrd-pps-overview-claims-based-monitoring-program.*

[92] *https://journals.lww.com/jasn/abstract/2023/12000/initial_management_and_potential_opportunities_to.9.aspx.*

[93] *https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan.*

beneficiaries choose a home dialysis modality.[94] We noted that the ability for beneficiaries with AKI to choose self-care dialysis in a home setting would offer a pathway to reduce these current disparities (insofar as the AKI population mirrors the ESRD beneficiary population) by promoting access to treatment, as well as removing a disparity in care between AKI beneficiaries and ESRD beneficiaries. We continue to believe it is crucial that the policy revisions to payment for AKI renal dialysis consider health equity and the effects on underserved populations. We identified that the rate of AKI was about 81 percent higher among African American/Black beneficiaries than among White beneficiaries.[95] We noted that we had reviewed comments and concerns from interested parties and agreed that home dialysis could benefit beneficiaries with AKI. We noted that issues with fluid management could be managed with more frequent, gentler modalities, such as PD. We stated that we trusted that providing an avenue to expand treatment modalities would encourage individualized and patient-centered treatment plans for beneficiaries with AKI, for example, addressing anemia and ESA management. We will continue to monitor outcomes for beneficiaries with AKI with the expectation that AKI PUF are being reviewed in quality improvement efforts by ESRD facilities that provide services to beneficiaries with AKI.

3. Home Dialysis Benefit for Beneficiaries With AKI

As we explained in the CY 2025 ESRD PPS proposed rule (89 FR 55806), we did not extend the home dialysis benefit to beneficiaries with AKI when we initially implemented the benefit (81 FR 77870). However, as discussed in the proposed rule (89 FR 55806 and 55807), we reviewed AKI monitoring data that showed the outcomes for anemia, ESA use, and fluid management are not necessarily reflective of the specific, individualized care, and close supervision by qualified staff currently required during the in-center dialysis process. We further noted that research demonstrated the use of PD correlated with positive outcomes for fluid management and a lower rate of anemia with less utilization of ESAs and iron. In the proposed rule we indicated that research related to home dialysis in the AKI patient population has primarily discussed results using PD as the modality; however, we would provide payment for either PD or HD as a home modality. We noted our goal was for beneficiaries with AKI to receive the necessary care to improve their condition, recover kidney function, and be weaned from dialysis treatment. We also noted that the literature exhibits a high correlation between the use of PD treatment for beneficiaries with AKI and positive outcomes for fluid management, infection rates, mortality, and recovery of kidney function.[96] Additionally, we reviewed research that demonstrated that the use of PD to manage the care of beneficiaries with AKI as a result of COVID–19 was successful and that beneficiaries who had successfully begun a treatment regime that could transition from the hospital to a home modality should not have to change treatment to an in-center treatment modality.

We proposed, based on the current research we cited (89 FR 55806 through 55807), to extend the home dialysis benefit as defined at 42 CFR 410.52 to beneficiaries with AKI for either PD or HD. As discussed in section III.C.1 of this final rule, we proposed that the payment amount for home dialysis for AKI beneficiaries would be the same as the payment amount for in-center dialysis for AKI beneficiaries, consistent with payment parity within the ESRD PPS. This payment amount would be the ESRD PPS base rate, adjusted for geographic area, as described in section III.C.2 of this final rule. Additionally, as discussed in section III.C.3 of this final rule, we proposed to extend the training add-on payment adjustment for home and self-dialysis training in the same amount as for patients with ESRD, on a budget neutral basis. We proposed to revise § 413.373, which currently states ''The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act,'' by adding paragraph (a) before ''The payment rate'' that reads ''CMS applies the wage-adjusted add-on per treatment adjustment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims that include such training.'' We proposed to move the current language to paragraph (b) with a technical revision to add ''of the Act'' after ''section 1834(r)''. Furthermore, as discussed in section III.D of this final rule, we proposed changes to the ESRD facility CfCs that would accommodate the provision of home dialysis for beneficiaries with AKI and help ensure safe and high-quality care for Medicare beneficiaries in this setting.

We proposed to amend § 410.52 to provide Medicare payment for the treatment of patients with AKI in the home setting. We proposed to revise § 410.52 to read ''Medicare Part B pays for the following services, supplies, and equipment furnished to a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter in his or her home:'' by striking the words ''an ESRD patient'' after ''to'' and adding the words ''a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter'' after ''to''. We also proposed to revise § 413.374(a) to read: ''The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act, including home services, supplies, and equipment, and self-dialysis.''

We invited public comment on our proposal for extending the home dialysis benefit to beneficiaries with AKI. Approximately 27 commenters including LDOs; regional health systems; a home dialysis services provider; a coalition of dialysis organizations; a provider advocacy organization; a non-profit dialysis association; an advocacy group for people living with a serious illness; a non-profit organization of ESRD networks; a non-profit organization for environmental health and justice; a professional organization of pediatric nephrologists; a professional organization of nephrologists; a home dialysis stakeholder alliance; a national organization of patients and kidney health care professionals; a hospital association; a non-profit kidney care alliance; a non-profit kidney organization; device manufacturers; a patient-led dialysis organization; and ESRD patients commented on the proposed regulation. The following is a summary of the public comments received on these proposals and our responses.

Comment: Many commenters were overwhelmingly in favor of the proposal to extend the home dialysis benefit to beneficiaries with AKI. The commenters agreed that while evidence is limited, experience from the COVID–19 PHE supports modifying payment policy to ensure home modalities would be available for appropriate patients with AKI. A patient with ESRD spoke to the

[94] *https://usrds-adr.niddk.nih.gov/2023/end-stage-renal-disease/2-home-dialysis.*

[95] Annual Data Report | USRDS (*nih.gov*), *https://usrds-adr.niddk.nih.gov/2023/chronic-kidney-disease/4-acute-kidney-injury.*

[96] *https://pubmed.ncbi.nlm.nih.gov/29199769/.*

importance the proposal would have in empowering beneficiaries, in reducing their travel burden, and in enhancing their general quality-of-life. A LDO expressed they were ''excited,'' and a home dialysis services provider expressed their ''enthusiastic support'' for the proposed policy change. Some commenters indicated that the proposal is an important step forward in mitigating health disparities. Additionally, some commenters expressed that providing patients with AKI access to home modalities, particularly PD, could support recovery of kidney function because of positive clinical outcomes. A few commenters spoke about the quality-of-life benefits and the positive move toward patient-centered care the proposal could generate. One commenter agreed that there are safety concerns surrounding home dialysis for beneficiaries with AKI, but that these can be mitigated with appropriate training. Finally, some commenters indicated that training beneficiaries with AKI for a home dialysis modality could be beneficial if the beneficiary did not recover kidney function and progressed to having ESRD.

Response: CMS appreciates the support from commenters for the proposal to extend the home dialysis benefit with appropriate training to beneficiaries with AKI. We agree with commenters that extending the home dialysis benefit with appropriate training to beneficiaries with AKI could advance positive outcomes for beneficiaries who choose a home dialysis modality.

Comment: A hospital association expressed confusion about the frequency of care received by chronic maintenance home dialysis patients and by extension the frequency of care a patient with AKI could receive in the home setting. Additionally, the same commenter indicated concern that the proposed rule does not include treatment of transplant patients with late graft recovery in the AKI definition.

Response: A beneficiary with AKI and their health care provider would still determine the best frequency of care. CMS would provide payment for home dialysis treatments furnished to AKI beneficiaries at the ESRD PPS base rate determined for the year under section 1881(b)(14) of the Act, as statutorily required at section 1834(r)(1) of the Act. In the CY 2011 ESRD PPS final rule CMS explained that home dialysis treatments are paid the same rate as in-center treatments (75 FR 49058). Additionally, CY 2011 ESRD final rule provided an explanation that a week of home dialysis is converted into three equivalent in-center HD treatments. In the CY 2017 ESRD PPS final rule we stated that there is no weekly limit on the number of dialysis treatments that will be paid for beneficiaries with AKI (81 FR 77867). AKI is defined statutorily at section 1834(r)(2) of the Act. CMS cannot change the definition of AKI to include beneficiaries who have had a kidney transplant that experience late graft recovery. Beneficiaries that have had a transplant are still covered under the ESRD benefit for three years post-transplant. Therefore, the beneficiary that had a transplant could dialyze in an outpatient ESRD facility under the ESRD benefit.

Comment: One commenter questioned how to use CPT codes such as 90945 (Dialysis procedure other than hemodialysis) and 90947 (Dialysis procedure other than hemodialysis requiring repeated evaluations by a physician or other qualified health care professional, with or without substantial revisions of dialysis prescription) when billing for home dialysis rather than in-center.

Response: We refer the commenter to the Medicare Claims Processing Manual Chapter 8 § 170, which indicates that codes 90935, 90937, 90945, or 90947 are only used if the place of service on the claim is an inpatient hospital. This is because all physicians' outpatient renal-related services are included in payment made under the monthly capitation payment.[97]

Final Rule Action: After consideration of the comments received, we are finalizing our proposal to extend the home dialysis benefit to beneficiaries with AKI, as proposed. Accordingly, we are finalizing our proposal to revise § 410.52 to read: ''Medicare Part B pays for the following services, supplies, and equipment furnished to a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter in his or her home.'' We are also finalizing our proposal to revise § 413.374(a) to read: ''The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act, including home services, supplies, and equipment, and self-dialysis.''

[97] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf.*

C. Annual Payment Rate Update for CY 2025

1. CY 2025 AKI Dialysis Payment Rate

The payment rate for AKI dialysis is the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act, which is the finalized ESRD PPS base rate, including the applicable annual market basket update, geographic wage adjustments, and any other discretionary adjustments, for such year. We note that ESRD facilities could bill Medicare for non-renal dialysis items and services and receive separate payment in addition to the payment rate for AKI dialysis. As discussed in section II.B.4 of this final rule, the final ESRD PPS base rate is $273.82, which reflects the application of the CY 2025 wage index budget-neutrality adjustment factor of 0.988600 and the CY 2025 ESRDB market basket percentage increase of 2.7 percent reduced by the productivity adjustment of 0.5 percentage point, that is, 2.2 percent. Accordingly, we are finalizing a CY 2025 per treatment payment rate of $273.82 (($271.02 × 0. 988600) × 1.022 = $273.82) for renal dialysis services furnished by ESRD facilities to individuals with AKI. Additionally, we have applied a $0.00 budget neutrality adjustment to the AKI per treatment base rate as discussed in section III.C.3 of this final rule to address the training add-on payment adjustment for home dialysis modalities in the AKI beneficiary population. We did not receive specific comments related to the CY 2025 AKI dialysis payment rate. We discuss general comments on the ESRD PPS base rate in section II.B.4 of this final rule, and we discuss comments related to the budget neutrality reduction to the AKI payment rate to account for the training add-on payment adjustment in section III.C.3 of this final rule.

2. Geographic Adjustment Factor

Under section 1834(r)(1) of the Act and regulations at § 413.372, the amount of payment for AKI dialysis services is the base rate for renal dialysis services determined for a year under section 1881(b)(14) of the Act (updated by the ESRDB market basket percentage increase and reduced by the productivity adjustment), as adjusted by any applicable geographic adjustment factor applied under section 1881(b)(14)(D)(iv)(II) of the Act. Accordingly, we apply the same wage index under § 413.231 that is used under the ESRD PPS. As discussed in section II.B.2.b of this final rule, we are finalizing a new ESRD PPS wage index methodology, which utilizes BLS OEWS

data and freestanding ESRD facility cost report data. We proposed to use this same methodology when adjusting AKI dialysis payments to ESRD facilities, consistent with our historical practice of using the ESRD PPS wage index for AKI dialysis payments. The AKI dialysis payment rate is adjusted by the wage index for a particular ESRD facility in the same way that the ESRD PPS base rate is adjusted by the wage index for that ESRD facility (81 FR 77868). Specifically, we apply the wage index to the labor-related share of the ESRD PPS base rate that we utilize for AKI dialysis to compute the wage adjusted per-treatment AKI dialysis payment rate. We also apply the wage index policies regarding the 0.600 wage index floor (87 FR 67161 through 67166) and the 5 percent cap on wage index decreases (87 FR 67159 through 67161) to AKI dialysis payments to ESRD facilities. ESRD facilities would utilize the same staff to provide renal dialysis services to and educate beneficiaries with AKI as those beneficiaries with ESRD. Therefore, utilizing the same wage index methodology would be appropriate in accordance with § 413.372, which addresses the payment rate for AKI dialysis and refers to § 413.231 for the wage adjustment. As stated previously, we are finalizing a CY 2025 AKI dialysis payment rate of $273.82, adjusted by the ESRD facility's wage index. We did not receive specific comments related to the CY 2025 AKI geographic adjustment factor. We discuss general comments related to the new ESRD PPS wage index methodology in section II.B.2 of this final rule.

3. Other Adjustments to the AKI Payment Rate

Section 1834(r)(1) of the Act also provides that the payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r)) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act. As discussed in the previous section of this final rule, we proposed to extend AKI dialysis payment to home dialysis.

As we explained in the CY 2025 ESRD PPS proposed rule (89 FR 55807), we considered our existing payment policies for home dialysis for beneficiaries with ESRD in implementing payment for home dialysis in the AKI patient population. In the CY 2011 ESRD PPS final rule, we explained that although we included payments for providing training to beneficiaries in computing the ESRD PPS base rate, we agreed with commenters that we should pay for home dialysis training as a training add-on payment adjustment under the ESRD PPS to account for the cost of providing training to beneficiaries on the use of home dialysis modalities. Thus, we finalized the home dialysis training add-on payment adjustment of $33.44 per treatment as an additional payment made under the ESRD PPS when one-on-one home dialysis training is furnished by a nurse for either hemodialysis or peritoneal dialysis training and retraining (75 FR 49063). We clarified our policy on payment for home dialysis training again in the CY 2013 ESRD PPS final rule, in which we stated that training costs are included in the ESRD PPS base rate; however, we also provide a training add-on payment adjustment for each home and self-dialysis training treatment furnished by a Medicare-certified home dialysis training facility (77 FR 67468). We explained in the CY 2017 ESRD PPS final rule that it is not the intent of the training add-on payment adjustment to reimburse a facility for all of the training costs furnished during training treatments. Rather, the single ESRD PPS base rate, all applicable case-mix and facility-level adjustments, as well as the add-on payment should be considered the Medicare payment for each training treatment and not the training add-on payment alone (81 FR 77854).

In the CY 2025 ESRD PPS proposed rule we considered making payment for home dialysis for beneficiaries with AKI under the ESRD PPS base rate without a training add-on payment adjustment for home modality training (89 FR 55807). As we noted in section III.A. of the final rule, the ESRD PPS base rate upon which the AKI dialysis payment rate is established contains monies for training related costs. However, we stated in the proposed rule (89 FR 55809) that we are concerned that not providing a home and self-dialysis training add-on payment adjustment for AKI dialysis may limit access to home dialysis care for the AKI beneficiary population. As previously noted, incorporation of an adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act into AKI dialysis payments must be done on a budget neutral basis for payments under section 1834(r) of the Act. Therefore, we stated that establishing a training add-on payment adjustment for training for home and self-care dialysis could have an impact on the AKI base rate.

As discussed in the proposed rule, we reviewed options for applying budget neutrality to a home and self-dialysis training add-on payment adjustment for beneficiaries with AKI. We considered applying a budget neutrality adjustment factor by reducing the AKI dialysis payment rate amount (which is based on the ESRD PPS base rate and is then adjusted for wages according to § 413.372) for renal dialysis services provided to patients with AKI to account for the training add-on payment adjustment. We provided an example for a potential calculation based on ESRD PPS data in the proposed rule (89 FR 55809). Additionally, we noted our concern that a decrease in the AKI dialysis payment rate to account for the home dialysis training add-on payment adjustment might create a disincentive for ESRD facilities to treat beneficiaries with AKI. We welcomed comments regarding budget neutralizing the home dialysis training add-on payment adjustment and solicited comments on other venues where beneficiaries might receive training for a home dialysis modality (89 FR 55809).

We proposed, in accordance with section 1834(r)(1) of the Act and § 413.373, to extend the home and self-dialysis training add-on payment adjustment under § 413.235(c) to payments for renal dialysis services provided to beneficiaries with AKI using a home modality. We proposed to make payment for a home and self-dialysis training add-on payment adjustment at the same amount currently applicable under the ESRD PPS of $95.60 with a limit of 15 training treatments for PD and a limit of 25 training treatments for HD per patient excluding retraining sessions (75 FR 49063). Additional information regarding the maximum number of training treatments for which CMS provides payment under the ESRD PPS is located in the Medicare Claims Processing Manual.[98] We requested data, either actual or estimated, regarding the number of training sessions provided to beneficiaries with AKI and the number of beneficiaries with AKI using a home modality (89 FR 55809) to use this information to make a determination on a training add-on payment adjustment in the CY 2025 ESRD PPS final rule or in future rulemaking for subsequent years.

We invited public comment on our proposal for a payment adjustment for training of beneficiaries with AKI that elect to dialyze in a home setting. Approximately 27 commenters including LDOs; a coalition of dialysis organizations; a regional health system; a provider advocacy organization; a non-profit dialysis association; and a

[98] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c08.pdf.*

home dialysis stakeholder alliance commented on the proposed payment adjustment for training of beneficiaries with AKI that elect to dialyze in a home setting. The following is a summary of the public comments received on these proposals and our responses.

Comment: Several commenters stated concerns regarding budget neutrality. The commenters indicated that they believe the home dialysis training add-on payment adjustment was previously budget neutralized in the ESRD PPS CY 2017 final rule. Additionally, they stated that they believe ESRD facilities that have provided services to beneficiaries with AKI have been underpaid since the budget neutralization in the CY 2017 ESRD PPS final rule. A few of the commenters indicated that beneficiaries with AKI that progressed to ESRD would already have received training for home dialysis and would not need to receive training as a beneficiary with ESRD. They believed this satisfied the budget neutrality requirement. Additionally, some commenters urged that CMS delay implementation of budget neutrality for these training add-on payment adjustments for AKI beneficiaries until sufficient data was collected on home utilization in the AKI beneficiary population.

Response: We appreciate the concerns of commenters that believe the training add-on payment adjustment was previously budget neutralized and therefore budget neutrality should not be a factor in this rule. We find that interpretation to be inconsistent with the statute because it would result in increased total AKI payments for CY 2025 relative to what they would be if CMS did not incorporate the training add-on payment adjustment. CMS rejected this premise in the ESRD PPS CY 2017 final rule where we indicated we interpret the payment rate for AKI to be the finalized base payment rate for ESRD, as the statute was clear that the payment rate for AKI dialysis must be the ESRD PPS base rate determined for a year under section 1881(b)(14) of the Act (81 FR 77867). CMS is compelled by section 1834(r)(1) of the Act to apply budget neutrality to the AKI payment to maintain total payments under section 1834(r) of the Act when incorporating an adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

CMS appreciates the commenters that expressed that training beneficiaries with AKI for home dialysis would offset the training for the beneficiaries who progress to ESRD. However, the beneficiaries who progress to ESRD would be eligible for the onset add-on payment adjustment, since both the training add-on payment adjustment and onset add-on payment adjustment cannot be applied at the same time (75 FR 49063). Furthermore, we would not rule out that some beneficiaries with AKI might require retraining after their disease progresses to ESRD. We do not believe that training beneficiaries to perform self-dialysis would create budget neutrality if their disease should progress to ESRD. Additionally, we appreciate the commenter who suggested that budget neutrality be delayed until sufficient data was collected. However, this would not be consistent with our general interpretation of statutes requiring budget neutrality, such as section 1834(r)(1) of the Act, as payments would increase for CY 2025. Generally, when we implement policies within the ESRD PPS budget neutrally, we do so based on estimates for the rulemaking year rather than retrospectively, and we do not adjust such adjustment post-hoc. For example, when we implemented the LVPA in CY 2011 we applied a budget-neutrality adjustment factor to the CY 2011 ESRD PPS base rate which accounted for all budget-neutral payment adjustments, including the LVPA, by holding total estimated payments for CY 2011 constant (75 FR 49194). Because this downward adjustment to the CY 2011 ESRD PPS base rate carried forward into future years (in which the base rate is only increased by the applicable annual market basket increase), it continues to offset the spending associated with those budget-neutral payment adjustments in future years as well.

Comment: Several commenters expressed concern that CMS had over-estimated the utilization of home modalities in the AKI beneficiary population. These commenters believe that providers and patients would need time to receive education about beneficiaries with AKI receiving dialysis in a home setting and that growth would be slow. These commenters believe that because of the over-estimation of utilization there is the potential to disincentivize ESRD facilities from providing services to beneficiaries with AKI. Additionally, some of the commenters indicated that CMS had over-estimated the number of training sessions that would be required for beneficiaries with AKI to successfully manage a home modality. These commenters indicated that initial training for a home dialysis modality may be provided while the beneficiary is hospitalized. They indicated that beneficiaries with AKI would likely only require 5 to 6 training sessions to successfully manage a home dialysis modality.

Response: We appreciate the commenters that provided information regarding CMS's estimation of utilization in the CY 2025 ESRD PPS proposed rule (89 FR 55809). We agree with commenters that the majority of beneficiaries with AKI who choose a home dialysis modality likely will be those that transition from the hospital utilizing PD as their home treatment modality. Additionally, we agree that utilization of home modalities for beneficiaries with AKI will be dependent on education to providers and patients. We have reviewed the available data considering these comments and have made revisions to the calculation for budget neutrality. After considering the comments on the use of PD for AKI, we have determined that it would be more reasonable to estimate utilization for home AKI based on in-center PD utilization. We found that from 2017 through 2023, there were 10 beneficiaries with AKI that received PD in-center. For the calculation of budget neutrality, this is approximately 2 beneficiaries with AKI per year receiving PD. As we agree with commenters that beneficiaries with AKI likely will receive partial training in the hospital to manage the home dialysis modality, we will estimate 6 training treatments for beneficiaries with AKI transitioning to a home modality. Lastly, as the training add-on payment adjustment would be adjusted by the wage index for the ESRD facility furnishing the training, we will multiply the training add-on payment adjustment amount of $95.60 by the average wage index for AKI, which is 1.0204. Using this data, we could estimate a cost of training to be $1170.60 ($2 \times 6 \times \$95.60 \times 1.0204$) or $0.0042. ($1170.60/279,000) per AKI treatment. Since the per treatment budget neutrality estimate would round to $0.00, we believe that applying this amount of reduction to the AKI base payment will be negligible. While budget neutrality was applied to the AKI base rate for home training for beneficiaries with AKI, we note that the actual amount of the reduction to the AKI payment per treatment rounds to $0.00, and therefore the AKI CY 2025 base rate would be $273.82 ($273.82 − $0.00) using this estimate. We plan to monitor data related to AKI including the uptake of home dialysis. We may revisit the calculation for budget neutrality as appropriate in the future.

Comment: One commenter suggested that training within a nursing facility should be paid only if the patient was

transitioning to home dialysis outside of the nursing facility.

Response: We note the commenter addressed concerns regarding training of beneficiaries with AKI in nursing facilities. CMS addressed this in the ESRD PPS CY 2011 final rule. Nursing caregivers at nursing facilities are not paid through the ESRD PPS (75 FR 49057). Therefore, training provided by nursing caregivers at nursing facilities would not be paid through the ESRD PPS. A nursing home resident that is independently performing home dialysis treatments would be eligible for a training add-on adjustment if there is the expectation the beneficiary can successfully complete the training and perform self-dialysis.

Final Rule Action: We are finalizing our proposal to extend a payment adjustment for training of beneficiaries with AKI that elect to dialyze in a home setting, beginning January 1, 2025. Specifically, we are finalizing our proposal to provide a payment for home dialysis training and home dialysis modalities for beneficiaries with AKI, with certain changes to the proposed methodology for calculating budget neutrality. As discussed previously, we are finalizing the requirement for a per-treatment budget neutrality reduction of $0.00 ($1146.84/279,000) which would be applied to the AKI base payment rate. We are codifying this requirement in regulation at § 413.373. As discussed in section III.C.3. of this final rule, we are finalizing the addition of a wage-adjusted training add-on payment adjustment per treatment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims. Furthermore, we are codifying in regulation at § 410.52, as discussed in section III.C.3. of this final rule, to provide Medicare payment for the treatment of patients with AKI in the home setting.

D. AKI and the ESRD Facility Conditions for Coverage

1. Statutory and Regulatory Background

ESRD is a kidney impairment that is irreversible and permanent. Dialysis is a process for cleaning the blood and removing excess fluid artificially with special equipment when the kidneys have failed. People with ESRD require either a regular course of dialysis or kidney transplantation to live. Given the high costs and absolute necessity of transplantation or dialysis for people with failed kidneys, Medicare provides health care coverage to qualifying individuals diagnosed with ESRD, regardless of age, including coverage for kidney transplantation, maintenance dialysis, and other health care needs. Acute kidney injury (AKI) is different than ESRD; it is an acute decrease in kidney function due to kidney damage or kidney failure that may require dialysis. Unlike people with ESRD, most individuals with AKI who require dialysis are expected to regain kidney function within three months. People with either ESRD or AKI can receive outpatient dialysis services from Medicare-certified ESRD facilities, also called dialysis facilities.

The Medicare ESRD program became effective July 1, 1973, and initially operated under interim regulations published in the **Federal Register** on June 29, 1973 (38 FR 17210). In the July 1, 1975, **Federal Register** (40 FR 27782), we published a proposed rule that proposed to revise sections of the ESRD requirements. On June 3, 1976, the final rule was published in the **Federal Register** (41 FR 22501). Subsequently, the ESRD Amendments of 1978 (Pub. L. 95–292), amended title XVIII of the Social Security Act (the Act) by adding section 1881. Sections 1881(b)(1) and 1881(f)(7) of the Act further authorize the Secretary to prescribe health and safety requirements (known as conditions for coverage or CfCs) that a facility providing dialysis and transplantation services to dialysis patients must meet to qualify for Medicare payment. In addition, section 1881(c) of the Act establishes ESRD Network areas and Network organizations to assure that dialysis patients are provided appropriate care. The ESRD facility CfCs were first adopted in 1976 and comprehensively revised in 2008 (73 FR 20369). The Trade Preferences Extension Act of 2015 (TPEA) (Pub. L. 114–27) was enacted on June 29, 2015, and amended the Act to provide coverage and payment for dialysis furnished by an ESRD facility to an individual with AKI. Specifically, section 808(a) of the TPEA amended section 1861(s)(2)(F) of the Act to provide coverage for renal dialysis services furnished on or after January 1, 2017, by a renal dialysis facility or a provider of services paid under section 1881(b)(14) of the Act to an individual with AKI. Section 808(b) of the TPEA amended section 1834 of the Act by adding a subsection (r) to provide payment, beginning January 1, 2017, for renal dialysis services furnished by renal dialysis facilities or providers of services paid under section 1881(b)(14) of the Act to individuals with AKI at the ESRD PPS base rate, as adjusted by any applicable geographic adjustment applied under section 1881(b)(14)(D)(iv)(II) of the Act and adjusted (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under section 1881(b)(14)(D) of the Act that the Secretary elects.

Medicare pays for routine maintenance dialysis provided by Medicare-certified ESRD facilities, also known as dialysis facilities. To gain certification, the State survey agency or CMS-approved accrediting organization performs an on-site survey of the facility to determine if it meets the ESRD facility CfCs at 42 CFR part 494. If a survey indicates that a facility is in compliance with the conditions, and all other Federal requirements are met, CMS then certifies the facility as qualifying for Medicare payment. Medicare payment for outpatient maintenance dialysis is limited to facilities meeting these conditions. As of March 2024, there are approximately 7,700 Medicare-certified dialysis facilities in the United States,[99] providing dialysis services and specialized care to people with ESRD; 3,700 of which provide home dialysis services, including training and support.[100]

The ESRD facility CfCs found at 42 CFR part 494, consist of the health and safety standards that all Medicare participating dialysis facilities must meet. These standards set baseline requirements for patient safety, infection control, care planning, staff qualifications, record keeping, and other matters to ensure that all patients with kidney failure receive safe and appropriate care. In addition, the CfCs require patients to be informed about all treatment modalities (hemodialysis or peritoneal dialysis) and settings (home dialysis modalities or in-facility hemodialysis) (§ 494.70(a)(7)). A dialysis facility that is certified to provide services to home patients must ensure that home dialysis services are at least equivalent to those provided to in-facility patients and meet all applicable conditions of § 494.100. The patient's interdisciplinary team must oversee training of the home dialysis patient, the designated caregiver, or self-dialysis patient before the initiation of home dialysis or self-dialysis (as defined in § 494.10). Dialysis facilities monitor home dialysis by documenting adequate comprehension of the training; retrieving and reviewing complete self-monitoring data and other information at least every two months; and

[99] *https://qcor.cms.gov/active_nh.jsp?which=7&report=active_nh.jsp.*

[100] *https://qcor.cms.gov/active_nh.jsp?which=7&report=active_nh.jsp.*

maintaining this information in the patient's medical record.

In the CY 2017 ESRD PPS final rule (81 FR 77834), we clarified that ESRD facility CfCs apply to ESRD facilities, not to people with ESRD, and noted that the ESRD facility CfCs would be the appropriate regulatory location for standards addressing care provided to beneficiaries with AKI in ESRD facilities. While the language of the ESRD facility CfCs does not directly address treatment of beneficiaries with AKI, we believe that the current ESRD facility requirements are sufficient to ensure that such patients are dialyzed safely. For example, infection control protocols are the same for any individual receiving hemodialysis, regardless of the cause or likely trajectory of their kidney disfunction. For the areas in which care and care planning may differ, such as frequency of certain patient assessments, we note that the CfCs set baseline standards and do not limit additional or more frequent services that may be necessary for beneficiaries with AKI receiving temporary dialysis as they recover kidney function.

During the development of the CY 2017 ESRD PPS final rule, we did not anticipate that beneficiaries with AKI would be candidates for home dialysis due to the likely short-term duration of treatment and the unique needs of AKI. Therefore, we did not propose to extend the home dialysis benefit to beneficiaries with AKI at that time (81 FR 77870). The initial concerns about the appropriateness of dialysis at home for individuals with AKI have been allayed by the existing scientific evidence of the effectiveness of that modality in this population. By revising the CfCs to facilitate beneficiaries with AKI utilizing home dialysis, we would increase patient options for renal replacement treatment beyond in-center hemodialysis and better empower these patients to make decisions about their care. We encourage readers to refer to the CY 2025 ESRD PPS proposed rule for this detailed discussion (CMS–1805–P).

2. Provisions of the Proposed Regulations and Analysis and Response to Public Comments

In response to the proposed rule, we received 22 comments pertaining to the expansion of home dialysis for AKI patients, with 6 comments specifically mentioning the conforming changes to the CfCs. Commenters included patient care organizations, dialysis facilities, and individual patients. To support treatment location choices for individuals with AKI requiring dialysis and to align with the coverage changes, we proposed conforming changes throughout the ESRD facility CfCs at 42 CFR part 494. We noted that the phrase ''ESRD patients'' is exclusive of beneficiaries with AKI, while phrase ''kidney failure'' is inclusive of people whose kidney function is inadequate such that dialysis is necessary to maintain or prolong life. This can be a temporary (AKI) or permanent (ESRD) condition. Accordingly, we proposed to amend the definitions of home dialysis and self-dialysis at §§ 494.10, 494.70(c)(1)(i), and 494.130 introductory text by removing the descriptor ''ESRD.'' In addition, we proposed to amend the following requirements: §§ 494.70(a)(1) and (10) and 494.80 introductory texts by revising the phrase ''ESRD'' to say ''kidney failure;'' § 494.90(b)(4) by revising the phrase ''ESRD care'' to say ''dialysis care;'' § 494.100(a)(3)(i) by revising the phrase ''management of ESRD'' to say ''management of their kidney failure;'' § 494.120 introductory text by revising the phrase ''serve ESRD patients'' to say ''serve patients with kidney failure;'' and lastly § 494.170 introductory text by revising the phrase ''provider of ESRD services'' to say ''provider of dialysis services.''

Comment: All the comments expressed support for the expansion of coverage for home dialysis to beneficiaries with AKI, with a couple specifically agreeing with the conforming changes in the CFCs. Commenters cited many benefits including choosing hours that work best for the patient, reducing travel burden (especially for patients in rural areas), and saving on healthcare costs. In addition to increasing access to home dialysis for all AKI patients, commenters indicated that they believe this policy supports our goal to expand home dialysis services for those AKI patients that proceed to ESRD. Commenters stated that the provision would reduce health disparities associated with home dialysis services. Commenters agreed that ''patient'' and ''kidney failure'' are the appropriate terminology for the CfCs to encompass both ESRD & AKI patients.

One commenter shared concerns about the safety of getting dialysis at home for what will generally be a short or limited period. Another commenter requested clarification on application of this policy to residents of long-term care facilities.

Response: We thank commenters for their support and taking the time to respond. We believe that patients with AKI are medically complex, and the clinical decision regarding the next stage of treatment should be evaluated by a physician or other licensed advanced practitioner and agreed upon mutually among the patient, care partners, and physician. Importantly, the entire armamentarium of treatment options must be available to provide the most patient-centered care and allow for the best outcomes. This policy aligns with the broader goals of patient-centered care and individualized treatment plans. We believe the current CfCs for home dialysis services provide sufficient training, education, and safety standards for AKI patients to safely dialyze at home, regardless of the duration of the services. We view home therapies as supervised care that is of at least similar quality and intensity to in-center hemodialysis and highlight our commitment to ensuring the success of all patients with AKI, regardless of whether they are receiving dialysis in the home or in a hemodialysis facility. Additionally, the home dialysis CfCs are applicable to home dialysis suppliers who provide such services in long-term care settings, since these locations are considered to be a patient's home. The Quality, Safety and Oversight Group (QSOG) has published sub-regulatory guidance (QSO–18–24–ESRD) that addresses patients receiving home dialysis services in nursing homes. This guidance is applicable to AKI patients receiving home dialysis services in LTC facilities.

Final Rule Action: We are finalizing our proposal to amend the ESRD facility CfCs to be inclusive of patients with AKI, without modification. For the reasons discussed in section III.B. of this final rule, we are extending coverage of home dialysis services to beneficiaries with AKI, allowing them flexibility in choosing their preferred treatment modality (hemodialysis vs. peritoneal dialysis) and location (in-center vs. home). Since the ESRD facility CfCs apply to ESRD facilities as a whole, not to solely to their patients with ESRD, we are providing clarifying revisions to the CfCs to align with the final coverage changes.

3. Expected Impact

Beneficiaries with AKI requiring dialysis represent a small subset of individuals treated in outpatient dialysis facilities. Specifically, around 12,000 patients will be eligible for this optional service.[101] Expanding coverage to include beneficiaries with AKI will not present any changes in burden on ESRD facilities or establish new information collections subject to the Paperwork Reduction Act.

[101] USRDS Annual Data Report 2023.

E. Clarification About Medicare Payment for Phosphate Binders for Beneficiaries With AKI

In the CY 2025 ESRD PPS proposed rule, we did not propose any policies related to payment for phosphate binders for beneficiaries with AKI during the period beginning January 1, 2025, when these drugs will be incorporated into the ESRD PPS and paid for using the TDAPA. While we did not receive any public comments on this topic, we are taking the opportunity in this final rule to provide clarity on this issue.

Under our longstanding policy, we have not applied any ESRD PPS adjustments to the AKI payment amount, other than the wage index adjustment. When we established the AKI benefit in the CY 2017 ESRD PPS final rule, we adopted regulations at § 413.372, which specify that only the adjustment for wages as set forth in § 413.231 shall apply to the amount of payment for AKI dialysis services. We also finalized regulations at § 413.373, which state that any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act that may be applied to the payment for AKI dialysis services is applied on a budget neutral basis for payments under section 1834(r). We stated in the CY 2017 ESRD PPS final rule that we were not adjusting the payment amount by any other factors at that time but indicated that we would potentially do so in future years (81 FR 77868). In that same final rule, we further explained that we finalized a policy to pay separately for all items and services that are not part of the ESRD PPS base rate. We explained that once we have substantial data related to the AKI population and its associated utilization, we would determine the appropriate steps toward further developing the AKI payment rate (81 FR 77868).

In the CY 2018 ESRD PPS final rule, a commenter requested that we clarify whether the TDAPA applies to AKI renal dialysis services. In response, we stated that we would issue additional program guidance that would address the application of the TDAPA to AKI services and other billing guidance. We stated that if we determine that it is appropriate for the TDAPA to apply to AKI services, we would consider that to be a substantive payment policy, which would be established through notice and comment rulemaking (82 FR 50756). CMS subsequently issued guidance [102] [103] which clarified that ESRD facilities would not be responsible for furnishing calcimimetics to individuals with AKI while calcimimetics were being paid for under the TDAPA. We further explained that Sensipar (HCPCS code J0604) remained payable under Medicare Part D for AKI beneficiaries until the costs were rolled into the ESRD PPS bundled payment, at which point it would transition to the bundled payment amount. With regard to Parsabiv (HCPCS code J0606), we stated that this drug was not indicated for AKI and therefore no bills should be submitted for Parsabiv in the AKI population.

We believe that with respect to Medicare payment for phosphate binders for beneficiaries with AKI, it is appropriate to maintain the same policy which applied for calcimimetics during the period in which they were paid for using the TDAPA under the ESRD PPS. Section 1834(r) of the Act requires that any adjustments made to the AKI payment amount under 1881(b)(14)(D) of the Act, other than the applicable geographical adjustment factor applied under subparagraph (D)(iv)(II) of the Act, must be applied on a budget neutral basis for payments under section 1834(r) of the Act. Because the TDAPA is a non-budget neutral add-on payment adjustment under section 1881(b)(14)(D)(iv) of the Act, we do not believe that it is appropriate to apply the TDAPA to claims for AKI dialysis under section 1834(r) of the Act. More specifically, if we were to apply the TDAPA to AKI payments, we believe that section 1834(r) of the Act would require us to apply a budget neutrality adjustment factor, which would reduce the AKI dialysis payment rate and be contrary to the policy objective of the TDAPA to provide additional payment for certain new renal dialysis drugs and biological products.

We also believe that consistent with our policy for calcimimetics during CY 2018 through CY 2020, allowing phosphate binders to remain separately payable under Part D for beneficiaries with AKI that have a Part D medically-accepted indication meets the requirements under section 1834(r) of the Act and the requirements under § 413.374(a) to make payment under the AKI dialysis payment rate for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act. We have not interpreted these statutory and regulatory requirements to apply to renal dialysis drugs and biological products that are not considered included in the ESRD PPS base rate. Specifically, we note that oral-only drugs are renal dialysis services under subparagraph (B) of section 1881(b)(14) of the Act; however, we have not paid for these drugs as part of the AKI dialysis payment rate, because they were not included in the ESRD PPS base rate. If we had interpreted section 1834(r) of the Act and § 413.374(a) to require payment under the AKI dialysis payment rate for oral-only renal dialysis drugs and biological products, then we would have been required to include payment for these drugs in the AKI dialysis payment rate before payment was included under the ESRD PPS, which we believe would have conflicted with the statutory requirements of ATRA, as amended by PAMA, and amended by ABLE, which ultimately delayed the inclusion of oral-only drugs into the ESRD PPS until January 1, 2025. Rather, we have interpreted the requirements of section 1834(r) of the Act and § 413.374(a) to provide a single payment for those renal dialysis services that are considered included in the ESRD PPS base rate. Consistent with that interpretation, as discussed earlier in this final rule, we explained in sub-regulatory guidance that oral calcimimetics remained separately payable under part D for AKI beneficiaries until they were incorporated into the ESRD PPS base rate.

For this CY 2025 ESRD PPS final rule, we are clarifying that we are maintaining the same policy for phosphate binders provided to beneficiaries with AKI that we applied to calcimimetics. That is, we are clarifying that ESRD facilities will not be responsible for furnishing phosphate binders to individuals with AKI while phosphate binders are being paid for using the TDAPA under the ESRD PPS. As discussed in section II.B.7 of this final rule, CMS published guidance containing information about the HCPCS codes for phosphate binders at *https://www.cms.gov/files/document/including-oral-only-drugs-esrd-pps-bundled-payment.pdf*. None of the drugs described by these HCPCS codes is indicated for patients with AKI, and therefore we do not expect these drugs will be provided for the treatment of AKI and billed for on AKI claims. To the extent that phosphate binders are provided to AKI beneficiaries other than for the treatment of their AKI, such as for preexisting chronic kidney disease, they will remain separately payable

[102] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2017downloads/r1941otn.pdf.*

[103] *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/mm102811.pdf.*

under Part D for beneficiaries with AKI that have a Part D medically-accepted indication until they are incorporated into the ESRD PPS base rate. We believe this policy will provide appropriate payment for phosphate binders furnished to beneficiaries with AKI.

IV. Updates to the End-Stage Renal Disease Quality Incentive Program (ESRD QIP)

A. Background

For a detailed discussion of the ESRD QIP's background and history, including a description of the Program's authorizing statute and the policies that we have adopted in previous final rules, we refer readers to the citations provided at IV.A of the CY 2024 ESRD PPS final rule (88 FR 76433). We have also codified many of our policies for the ESRD QIP at 42 CFR 413.177 and 413.178.

B. Updates to Requirements Beginning With the PY 2027 ESRD QIP

1. PY 2027 ESRD QIP Measure Set

In the proposed rule, we proposed to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure, a comprehensive measure on which facilities are scored for each payment year using one set of performance standards, with a Kt/V measure topic comprised of four individual Kt/V measures, beginning with PY 2027 (89 FR 55814 through 55815). We also proposed to remove the National Healthcare Safety Network (NHSN) Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027 (89 FR 55815 through 55816). Table 12 of the proposed rule summarized the previously finalized and proposed updated measures that we would include in the PY 2027 ESRD QIP measure set (89 FR 55813). As discussed in IV.B.2 and IV.B.3 of this final rule, we are finalizing our updates to the PY 2027 ESRD QIP measure set as proposed. We describe the finalized PY 2027 ESRD QIP measure set in Table 13, which includes the previously finalized measures and the measures we are finalizing in this final rule. In the proposed rule, we stated that the technical specifications for current measures that would remain in the measure set for PY 2027 can be found in the CMS ESRD Measures Manual for the 2024 Performance Period (89 FR 55812).[104] We also noted that the proposed technical specifications for the measures in the proposed Kt/V measure topic can be viewed at *https://www.cms.gov/medicare/quality/end-stage-renal-disease-esrd-quality-incentive-program/technical-specifications-esrd-qip-measures*. Finally, we stated that if the Kt/V measure topic is finalized, these specifications will be included in the CMS ESRD Measures Manual for the 2025 Performance Period.

TABLE 13: Finalized PY 2027 ESRD QIP Measure Set

Consensus-Based Entity[105] (CBE) #	Measure Title and Description
0258	In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) Survey Administration, a clinical measure Measure assesses patients' self-reported experience of care through percentage of patient responses to multiple survey questions.
2496	Standardized Readmission Ratio (SRR), a clinical measure Ratio of the number of observed unplanned 30-day hospital readmissions to the number of expected unplanned 30-day readmissions.
Based on CBE #2979	Standardized Transfusion Ratio (STrR), a clinical measure Ratio of the number of observed eligible red blood cell transfusion events occurring in patients dialyzing at a facility to the number of eligible transfusions that would be expected.
Based on CBE #0323, #0321, #2706, and #1423*	(Kt/V) Dialysis Adequacy Measure Topic, a clinical measure topic Four measures of dialysis adequacy where K is dialyzer clearance, t is dialysis time, and V is total body water volume. The individual Kt/V measures would be adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V.
2978	Hemodialysis Vascular Access: Long-Term Catheter Rate clinical measure Measures the use of a catheter continuously for 3 months or longer as of the last hemodialysis treatment session of the month.
1454	Hypercalcemia, a reporting measure Proportion of patient-months with 3-month rolling average of total uncorrected serum or plasma calcium greater than 10.2 mg/dL.
1463	Standardized Hospitalization Ratio (SHR), a clinical measure Risk-adjusted SHR of the number of observed hospitalizations to the number of expected hospitalizations.
Based on CBE #0418	Clinical Depression Screening and Follow-Up, a clinical measure Facility reports in ESRD Quality Reporting System (EQRS) one of four conditions for each qualifying patient treated during performance period.
Based on CBE #1460	National Healthcare Safety Network (NHSN) Bloodstream Infection (BSI) in Hemodialysis Patients, a clinical measure

[104] *https://www.cms.gov/files/document/esrd-measures-manual-v91.pdf.*

[105] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

Consensus-Based Entity[105] (CBE) #	Measure Title and Description
	The Standardized Infection Ratio (SIR) of BSIs will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.
N/A	Percentage of Prevalent Patients Waitlisted (PPPW), a clinical measure Percentage of patients at each facility who were on the kidney or kidney-pancreas transplant waitlist averaged across patients prevalent on the last day of each month during the performance period.
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities (MedRec), a reporting measure Percentage of patient-months for which medication reconciliation was performed and documented by an eligible professional.
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP), a reporting measure Percentage of HCP who are up to date on their COVID-19 vaccination.
N/A	Facility Commitment to Health Equity, a reporting measure Facilities will receive two points each for attesting to five different domains of commitment to advancing health equity for a total of ten points.
N/A	Screening for Social Drivers of Health, a reporting measure Percentage of patients at a dialysis facility who are 18 years or older screened for all five health-related social needs (HRSNs) (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety).
N/A	Screen Positive Rate for Social Drivers of Health, a reporting measure Percentage of patients at a dialysis facility who are 18 years or older screened for all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety), and who screened positive for one or more of the HRSNs.

*We are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with the Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this final rule. We note that, although the Kt/V Dialysis Adequacy Measure Topic is not endorsed by the CBE, the four individual Kt/V measures that are included in the measure topic are CBE-endorsed.

**We are finalizing our proposal to remove the NHSN Dialysis Event reporting measure beginning with PY 2027, as discussed in section IV.B.3 of this final rule.

2. Replacement of the Kt/V Dialysis Adequacy Comprehensive Clinical Measure With a Kt/V Dialysis Adequacy Measure Topic Beginning With the PY 2027 ESRD QIP

Section 1881(h)(2)(A)(i) states that the ESRD QIP must evaluate facilities based on measures of dialysis adequacy. Beginning with the PY 2027 ESRD QIP, we proposed to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure, a single comprehensive measure on which facility performance is calculated using one set of performance standards for each payment year, with a Kt/V Dialysis Adequacy Measure Topic, a measure topic comprising four individual Kt/V measures on which facility performance is calculated using performance standards for each individual Kt/V measure (89 FR 55814 through 55815).[106] In the CY 2025 ESRD PPS proposed rule, we proposed to remove the Kt/V Dialysis Adequacy Comprehensive clinical measure under § 413.178(c)(5)(i)(E), which is Measure Removal Factor 5 (a measure that is more strongly associated with desired patient outcomes for the particular topic becomes available), and proposed to replace it with the proposed Kt/V Dialysis Adequacy Measure Topic, which consists of four individual Kt/V measures. Under this proposed update, we stated that the individual Kt/V measures would be adult hemodialysis (HD) Kt/V, adult peritoneal dialysis (PD) Kt/V, pediatric HD Kt/V, and pediatric PD Kt/V (89 FR 55814).

By replacing the current Kt/V Dialysis Adequacy Comprehensive clinical measure with four separate measures, we noted that we would be able to assess Kt/V performance more accurately based on whether the patient is an adult or child and what type of dialysis modality the patient is receiving. We also proposed to score the four measures as a Kt/V Dialysis Adequacy Measure Topic and to limit the total weight of that topic to 11 percent of the total performance score (TPS), which we stated is the weight of the current Kt/V Dialysis Adequacy Comprehensive clinical measure. We noted that these proposals would continue to maintain Kt/V measurement as an important part of the quality of care assessed by the ESRD QIP (89 FR 55814). Facilities are eligible to receive an individual Kt/V measure score if they treat at least 11 eligible patients using the modality addressed by that particular measure. For example, a facility treating at least 11 eligible pediatric HD patients during the applicable performance period would be scored on the Kt/V Pediatric HD measure. In the proposed rule, we stated that we would calculate a facility's measure topic score by first calculating the facility's performance on each of the Adult HD Kt/V, Adult PD Kt/V, Pediatric HD Kt/V, and Pediatric PD Kt/V measures, as applicable, using the applicable achievement threshold, benchmark, and improvement threshold for the payment year (89 FR 55814). Second, we would calculate the total number of eligible patients for weighting each of these measure scores to calculate a single measure topic score. We would calculate this total number by summing all eligible patients included in the denominator for each individual measure. Third, we would calculate the weighted score for each

[106] For further information related to the Kt/V Dialysis Adequacy Comprehensive clinical measure, we refer readers to 77 FR 67487 through 67490, 79 FR 66197 through 66198, and 80 FR 69053 through 69057.

measure within the measure topic by dividing the number of patients included in the denominator for each individual measure by the total number of eligible patients for all of the measures within the measure topic and multiplying by the respective measure score. Finally, we would add the weighted measure scores together and round them to the nearest integer. An example of how we would calculate the measure topic score for a facility that treats the minimum number of patients to be eligible for scoring on all four of the measures is provided below.

Measure	Measure Score	# Patients in denominator	Weighted Score
Kt/V Adult HD	8	60	8 * (60/125) = 3.84
Kt/V Adult PD	6	30	6 * (30/125) = 1.44
Kt/V Pediatric HD	9	15	9 * (15/125) = 1.08
Kt/V Pediatric PD	5	20	5 * (20/125) = 0.80

Kt/V Topic Score= 3.84+1.44+1.08+0.80 = 7.16, which rounds to **7**.

We noted in the proposed rule that a facility would not need to be eligible for scoring on all four individual measures to receive a measure topic score (89 FR 55814). For example, a facility that exclusively treats adult HD patients and, for that reason, is eligible to be scored on only the Kt/V Adult HD measure would receive a topic score that is the same score as its individual Kt/V measure score. We stated that the proposed measure topic scoring considers both a facility's individual ESRD patient population and the treatment modalities it offers, and then weights its performance on the topic proportionately to its overall ESRD patient population. As a result, we believe that a facility's measure topic score will be more reflective of its actual performance among its patient population and offered modalities than its current Kt/V Dialysis Adequacy Comprehensive clinical measure score, which is a composite assessment that blends the Kt/V measure data of all patients treated at that facility.

We noted that we previously adopted a Kt/V Dialysis Adequacy Measure Topic that included three of the four measures that we were now proposing to include in the topic (adult HD Kt/V, adult PD Kt/V, and pediatric HD Kt/V) in the CY 2013 ESRD PPS final rule (77 FR 67487 through 67490). In the CY 2015 ESRD PPS final rule (79 FR 66197 through 66198), we updated the Kt/V Dialysis Adequacy Measure Topic to include the pediatric PD Kt/V measure as well. In the CY 2016 ESRD PPS final rule (80 FR 69053 through 69057), we replaced the Kt/V Dialysis Measure Topic with the current Kt/V Dialysis Adequacy Comprehensive clinical measure, which assesses the percentage of all patient-months for both adult and pediatric patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the performance period. This change allowed more facilities to be eligible for measure scoring, which in turn allowed us to evaluate the care provided to a greater proportion of ESRD patients.

At the time we finalized the Kt/V Dialysis Adequacy Comprehensive clinical measure, three facilities were eligible for scoring on the pediatric HD Kt/V measure, six facilities were eligible for scoring on the pediatric PD Kt/V measure, 1,402 facilities were eligible for scoring on the adult PD Kt/V measure, and 6,117 facilities were eligible for scoring on the adult HD Kt/V measure. Given the relatively low numbers of facilities eligible for scoring on the pediatric HD Kt/V, pediatric PD KT/V, and adult PD Kt/V measures at that time, we adopted the Kt/V Dialysis Adequacy Comprehensive clinical measure to help ensure that data reflecting those patient populations contributed to facilities' total performance scores. Since the CY 2016 ESRD PPS final rule, however, we noted that Kt/V measure data (using the PY 2024/CY 2022 ESRD QIP eligible facility list, CY 2022 EQRS data, and CY 2022 claims data) indicates that more facilities are treating greater numbers of pediatric HD patients and pediatric PD patients, as well as greater numbers of adult PD patients, and therefore would be eligible to be scored on the individual measures based on an 11-patient case minimum (89 FR 55815). For example, there are now 21 pediatric HD facilities and 28 pediatric PD facilities with at least 11 qualifying patients. We stated that this shows a 600 percent increase in facilities eligible to be scored on the pediatric HD Kt/V measure, and a 366 percent increase in facilities eligible to be scored on the pediatric PD Kt/V measure, since the CY 2016 ESRD PPS final rule (89 FR 55815). Additionally, there are now 2,538 facilities eligible for scoring on the adult PD Kt/V measure, an 81 percent increase since the CY 2016 ESRD PPS final rule. By contrast, we noted that the number of facilities eligible for scoring on the adult HD Kt/V measure has increased by 14 percent during that same period of time.

In light of the increase in the proportions of pediatric HD patients, pediatric PD patients, and adult PD patients being treated at ESRD facilities since the time we adopted the Kt/V Dialysis Adequacy Comprehensive clinical measure, we have determined that it is appropriate and more reflective of facility performance to reintroduce the Kt/V Dialysis Adequacy Measure Topic in the ESRD QIP. In addition, we stated in the proposed rule that the proposed measure topic scoring methodology will more accurately capture facility performance with respect to dialysis adequacy because it assesses those facilities based on performance standards tailored according to Kt/V measurements that reflect ESRD patient age and treatment modality (89 FR 55815).

We noted that the proposed replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic would also not affect a facility's measure data reporting requirements. A facility would continue to report the same Kt/V measure data into EQRS and Medicare claims as it would for the current Kt/V Dialysis Adequacy Comprehensive clinical measure. However, under the proposed Kt/V Dialysis Adequacy Measure Topic, the measure data would be used to score the facility on four individual Kt/V measures, as applicable based on their

ESRD patient population and treatment modalities.

In the proposed rule, we stated that the proposed replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic would also advance the CMS National Quality Strategy Goals by scoring facilities on measure data that more accurately reflects the quality of care provided to different kinds of ESRD patients on different treatment modalities (89 FR 55815). We noted that the proposed Kt/V Dialysis Adequacy Measure Topic would allow us to evaluate dialysis adequacy in adult HD patients, adult PD patients, pediatric HD patients, and pediatric PD patients by scoring facilities in a way that accounts for differences in patient populations and treatment modalities. Therefore, this proposed update would ensure that a facility's performance on the measure topic more accurately reflects the quality of care provided by the facility.

We welcomed public comment on this proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic consisting of an adult HD Kt/V measure, an adult PD Kt/V measure, a pediatric HD Kt/V measure, and a pediatric PD Kt/V measure, for the PY 2027 ESRD QIP and subsequent years. The comments we received, and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to remove the current Kt/V Dialysis Adequacy Comprehensive clinical measure and replace it with a Kt/V Dialysis Adequacy Measure Topic, noting that the measure topic will more accurately reflect a facility's performance based on different patient populations and treatment modalities. Several commenters expressed the belief that the proposed Kt/V Dialysis Adequacy Measure Topic will provide a more nuanced assessment of dialysis adequacy which will enhance the accuracy and relevance of quality assessments within the program. A few commenters also expressed support for the proposed Kt/V Dialysis Adequacy Measure Topic, noting that the current Kt/V Dialysis Adequacy Comprehensive clinical measure lacks transparency in terms of performance regarding patient population or dialysis modality, and also masks underlying social disparities in dialysis adequacy. A commenter expressed support for the proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic, noting that it does not change the current Kt/V data reporting requirements so there is minimal administrative burden associated with the proposed change.

Response: We thank the commenters for their support.

Comment: A few commenters expressed support for the proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with the four individual Kt/V Dialysis Adequacy measures. A commenter expressed appreciation that the proposed update would align with other publicly reported data programs.

Response: We thank the commenters for their support.

Comment: A commenter expressed support for the inclusion of the pediatric HD Kt/V Dialysis Adequacy measure and the pediatric PD Kt/V Dialysis Adequacy measure, noting that including these measures in the Kt/V Dialysis Adequacy Measure Topic will help account for meaningful differences between pediatric and adult patient populations.

Response: We thank the commenter for their support.

Comment: A few commenters recommended that CMS adopt the original reporting requirements that assessed performance at the individual measure level, noting that reporting facility performance on the individual Kt/V measures would provide greater transparency to patients, caregivers, and health care providers. These commenters believed that such reporting requirements would be consistent with the legislative intent underlying the statutory authority of the ESRD QIP. A different commenter expressed concern that the measure data is not sufficiently transparent and that patients would not be able to assess a facility's performance relative to their specific treatment modality.

Response: We believe that the Kt/V Dialysis Adequacy Measure Topic, consisting of an adult HD Kt/V measure, an adult PD Kt/V measure, a pediatric HD Kt/V measure, and a pediatric PD Kt/V measure, strikes a balance between scoring a facility on its overall quality of care related to Kt/V dialysis adequacy while also reflecting its performance on Kt/V dialysis adequacy specific to different patient populations and treatment modalities. We note that information regarding a facility's performance on the individual measures, as well as the resulting measure topic score, is provided during the preview period and in final reports shared with the facility. We believe that this approach to measuring dialysis adequacy will further incentivize improvement on dialysis adequacy performance standards, consistent with section 1881(h) of the Act. We also note that data regarding facility performance on individual Kt/V dialysis adequacy measures is available through Dialysis Facility Compare, which reports the Kt/V dialysis adequacy measures individually on Care Compare. We will continue to monitor the Kt/V Dialysis Adequacy Measure Topic as it is implemented to ensure that it is sufficiently transparent in a way that is meaningful to patients, caregivers, and health care providers.

Comment: A commenter recommended that CMS ensure that the new individual measures do not impose new administrative or reporting burdens on care providers that may divert resources away from patient care.

Response: As we stated in the CY 2025 ESRD PPS proposed rule, the replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic would not affect a facility's measure data reporting requirements, and therefore would not impose new administrative or reporting burdens on care providers (89 FR 55815). A facility would continue to report the same Kt/V measure data into EQRS and Medicare claims as it does for the current Kt/V Dialysis Adequacy Comprehensive clinical measure.

Comment: A commenter recommended including a measurement of residual kidney function (RKF) when appropriate in the determination of the HD Kt/V measure, noting the importance of taking RKF into account when assessing dialysis adequacy and the potential benefit to patient outcomes. Another commenter recommended that CMS adopt an alternate measure of dialysis adequacy for HD patients by looking at the percent of patients leaving dialysis at +/− 2 kg above/below their estimated dry weight.

Response: We thank the commenters for these recommendations and will take them into consideration for future updates. We consider the current HD Kt/V measure specifications to be sufficient for purposes of assessing dialysis adequacy among HD patients because these specifications reflect current clinical practices in dialysis adequacy measurement and assess measurable data that may incentivize improvement in quality of care provided to HD patients. However, we will continue to monitor the HD Kt/V dialysis adequacy measures and will also continue to monitor scientific advances in the field of ESRD care to assess appropriate alternative measures of dialysis adequacy for consideration in future rulemaking.

Comment: A commenter expressed concern regarding the use of Kt/V as a measure of dialysis adequacy for PD patients, noting that it may not be the most appropriate metric for patients who are new to dialysis or who have residual kidney function. This commenter recommended that CMS explore alternative measures of assessing dialysis adequacy for PD patients in future rulemaking.

Response: We thank the commenters for these recommendations and will take them into consideration for future updates. The current PD Kt/V measure considers residual kidney function as part of the measure calculation, and excludes patients who have been on ESRD treatment for less than 91 days as of the first day of the reporting month, which makes it an appropriate metric for all PD patients who have residual kidney function and have been on ESRD treatment long enough to be eligible for inclusion in the measure's calculations.[107] We consider the current PD Kt/V measure specifications to be sufficient for purposes of assessing dialysis adequacy among PD patients because these specifications reflect current clinical practices in dialysis adequacy measurement and assess measurable data that may incentivize improvement in quality of care provided to PD patients. However, we will continue to monitor the PD Kt/V dialysis adequacy measures for potential unintended consequences and will also continue to monitor scientific advances in the field of ESRD care to assess appropriate alternative measures of dialysis adequacy for PD patients for consideration in future rulemaking.

Comment: A few commenters expressed concern regarding the potential impact of the proposed Kt/V Dialysis Adequacy Measure Topic on home dialysis patients. A commenter expressed concern that the PD Kt/V measures could have unintentional consequences such as incentivizing in-center dialysis over home dialysis, which the commenter believed would result in diminished patient experience. A different commenter expressed concern that the proposed Kt/V Dialysis Adequacy Measure Topic will not sufficiently capture dialysis adequacy for home dialysis patients and recommended that CMS continue to explore ways to measure quality of care for home dialysis patients.

Response: For facilities offering both in-center dialysis and home dialysis treatment options, the Kt/V Dialysis Adequacy Measure Topic will more accurately reflect a facility's dialysis adequacy performance by differentiating between the Kt/V measure data of all patients treated at that facility and assessing facilities based on the Kt/V measurements according to ESRD patient age and treatment modality. Because of this differentiation, we expect that the Kt/V Dialysis Adequacy Measure Topic will better reflect the quality of care provided to patients on home dialysis, without incentivizing in-center hemodialysis over home dialysis. We expect that care providers will assess whether in-center hemodialysis or home dialysis would be more appropriate for a patient based on the patient's specific case and treatment plan. However, we will continue to monitor the Kt/V Dialysis Adequacy Measure Topic as it is implemented to assess the impact on the home dialysis patient population.

Comment: A few commenters did not support the proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic. A commenter expressed concern that the Kt/V Dialysis Adequacy Comprehensive clinical measure is topped out. This commenter stated that replacing the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic comprised of individual Kt/V Dialysis Adequacy measures will not be effective because the commenter believed that those individual measures are also topped out, and therefore recommended changing the current Kt/V Dialysis Adequacy Comprehensive clinical measure to a reporting measure instead. Another commenter recommended that, instead of the proposed update to measure Kt/V data by different modalities and patient ages, CMS should measure dialysis adequacy based on patient differences.

Response: We disagree with the commenter's assertion that the individual Kt/V measures are topped out and therefore would make the Kt/V Dialysis Adequacy Measure Topic ineffective as a measure of a facility's dialysis adequacy performance. Quality measures that have been in use for several years may reach a stage where meaningful differences and improvement in performance are no longer achievable. These measures are referred to as ''topped-out'' and considered for removal from CMS quality improvement or value-based purchasing programs such as the ESRD QIP. When developing proposals for the CY 2025 ESRD PPS proposed rule, we assessed the ESRD QIP measure set to identify any measures that may be appropriate for removal due to their topped-out status. Based on our analysis, the NHSN Dialysis Event reporting measure was the only measure that achieved topped-out status. Furthermore, a facility's score on the Kt/V Dialysis Adequacy Measure Topic, consisting of an adult HD Kt/V measure, an adult PD Kt/V measure, a pediatric HD Kt/V measure, and a pediatric PD Kt/V measure, would be unique to each facility based on its own patient populations and their specific treatment modalities. This approach takes patient differences into account when measuring dialysis adequacy.

Final Rule Action: After considering public comments, we are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic consisting of an adult HD Kt/V measure, an adult PD Kt/V measure, a pediatric HD Kt/V measure, and a pediatric PD Kt/V measure, for the PY 2027 ESRD QIP and subsequent years.

3. Removal of the NHSN Dialysis Event Reporting Measure From the ESRD QIP Measure Set Beginning With PY 2027

To ensure continued impact and effectiveness of our measure set on facility performance, we proposed to remove the NHSN Dialysis Event reporting measure beginning with PY 2027 (89 FR 55815). When we first adopted the NHSN Dialysis Event reporting measure in the CY 2012 ESRD PPS final rule (76 FR 70268 through 70269), we stated that reporting dialysis events to the NHSN by all facilities supports national goals for patient safety, including the reduction of Hospital Acquired Infections (HAIs). In the CY 2014 ESRD PPS final rule, we replaced the NHSN Dialysis Event reporting measure with the NHSN Bloodstream Infection (BSI) clinical measure (78 FR 72204 through 72207). We introduced the clinical version of the measure to hold facilities accountable for monitoring and preventing infections in the ESRD population, and to hold facilities accountable for their actual clinical performance on the measure. In the CY 2017 ESRD PPS final rule (81 FR 77879 through 77882), we reintroduced the NHSN Dialysis Event reporting measure to complement the NHSN BSI clinical measure as a way to incentivize facilities to report complete and accurate monthly dialysis event data in compliance with the NHSN Dialysis Event protocol.[108] In reintroducing the

[107] *https://www.cms.gov/files/document/esrd-measures-manual-v100.pdf.*

[108] For further information related to the NHSN Dialysis Event reporting measure, we refer readers

Continued

measure, we noted our concerns that facilities were not consistently reporting monthly dialysis event data, given the incentive to achieve high clinical performance scores on the NHSN BSI clinical measure. We stated that this may have been an unintended consequence of replacing the previous NHSN Dialysis Event reporting measure with the NHSN BSI clinical measure (81 FR 77879). Therefore, in the CY 2017 ESRD PPS final rule, we reintroduced the NHSN Dialysis Event reporting measure to be included in the ESRD QIP measure set along with the NHSN BSI Clinical Measure.

In the CY 2025 ESRD PPS proposed rule, we stated that, based on our analyses, facilities are consistently reporting monthly dialysis event data, and have been doing so for several years (89 FR 55815). In an assessment of ESRD QIP measure rate performance trends during PY 2020 through PY 2022, performance in the 5th percentile through the 100th percentile was 100 percent on the NHSN Dialysis Event reporting measure for all three performance years, meaning that most eligible facilities reported data on the measure for each of those years.[109] If most eligible facilities are reporting NHSN Dialysis Event measure data each year and measure performance levels at the 5th percentile and the 100th percentile are the same each year, then NHSN dialysis event data are now reported consistently and the measure is not likely to drive improvements in care.

We stated that our proposal to remove the NHSN Dialysis Event reporting measure is consistent with evolving the program to focus on a measure set of high-value, impactful measures that have been developed to drive care improvements for a broader set of ESRD patients (89 FR 55816). As such, we proposed to remove this measure from the ESRD QIP measure set under § 413.178(c)(5)(i)(A), which is Measure Removal Factor 1 (measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made). Although we believe that removing this measure would enable facilities to focus on the remaining measures in the ESRD QIP measure set, we noted that facilities would still be required to fully comply with the NHSN Dialysis Event protocol and report all dialysis event data, including BSI, for the NHSN BSI Clinical Measure.

We welcomed public comment on our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set, beginning with PY 2027. The comments we received, and our responses are set forth below.

Comment: Several commenters expressed support for the proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set, beginning with PY 2027. A few commenters expressed support for the proposed removal because the measure is unlikely to drive improvements in care due to consistent reporting and high compliance. A few commenters expressed the belief that removing the measure from the ESRD QIP measure set will allow dialysis centers to focus on impactful measures and meaningful improvements in care. A few commenters recommended that CMS continue to reduce the number of measures in the ESRD QIP and focus on incentivizing improvements in critical and meaningful quality measures. A commenter expressed support for the proposed removal of the NHSN Dialysis Event reporting measure because facilities will still be required to comply with NHSN dialysis event protocol for the NHSN BSI clinical measure. A different commenter expressed support for the proposed removal because it would align the ESRD QIP with other publicly reported data programs. Another commenter expressed support for the proposal to remove the NHSN Dialysis Event reporting measure because the commenter believed the measure created incentives to decrease reported events that would potentially negatively impact patient care.

Response: We thank the commenters for their support.

Comment: A few commenters did not support the proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set, beginning with PY 2027. A commenter recommended that CMS retain the NHSN Dialysis Event reporting measure, noting that facilities would still need to report the data to comply with Dialysis Event protocol as part of the NHSN BSI clinical measure and therefore removing the measure from the ESRD QIP would not alleviate facility burden. A different commenter expressed concern with the proposal to remove the NHSN Dialysis Event reporting measure, believing that the removal will lead to facilities underreporting adverse events and recommended retaining the measure to encourage and incentivize accurate reporting to NHSN.

Response: We thank the commenters for their feedback. Although we endeavor to minimize facility burden to the extent feasible, we proposed to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set because measure performance among the majority of ESRD facilities is so high and unvarying that meaningful distinctions in improvements or performance can no longer be made. Additionally, removing the NHSN Dialysis Event reporting measure would enable facilities to focus on the remaining measures in the ESRD QIP measure set. We do not anticipate that removing the NHSN Dialysis Event reporting measure from the ESRD QIP measure set will lead to underreporting, as facilities would still be required to fully comply with the NHSN Dialysis Event protocol and report all dialysis event data (that is, BSI, IV antimicrobial starts, and pus, redness, and swelling) for the NHSN BSI Clinical Measure.

Final Rule Action: After considering public comments, we are finalizing our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set, beginning with PY 2027.

4. Revisions to the Clinical Care and Reporting Measure Domains Beginning With the PY 2027 ESRD QIP

In the CY 2024 ESRD PPS final rule (88 FR 76481 through 76482), we finalized revisions to the ESRD QIP measure domains beginning with PY 2027. The measure domains and weights we finalized in the CY 2024 ESRD PPS final rule were depicted in Table 13a of the CY 2025 ESRD PPS proposed rule (89 FR 55816) and are depicted in this final rule in Table 14a.

to 76 FR 70268 through 70269 and 78 FR 72204 through 72207.

[109] Partnership for Quality Measurement. 2023 Measure Set Review (MSR): End Stage Renal Disease Quality Incentive Program (ESRD–QIP). September 2023. Available at: *https://p4qm.org/sites/default/files/2023-09/MSR-Report-ESRD-QIP-20230911.pdf.*

TABLE 14a: Previously Finalized PY 2027 ESRD QIP Measure Domains and Weights

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure	7.50
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Comprehensive measure	11.00
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain	**10.00**
Screening for Social Drivers of Health measure	1.43
Screen Positive Rate for Social Drivers of Health reporting measure	1.43
Facility Commitment to Health Equity reporting measure	1.43
Hypercalcemia reporting measure	1.43
MedRec reporting measure	1.43
NHSN Dialysis Event reporting measure	1.43
COVID-19 HCP Vaccination reporting measure	1.43

In the proposed rule, we proposed to revise the Clinical Care Domain beginning with PY 2027 to reflect our proposal to replace the Kt/V Comprehensive Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic, and to revise the measure weights in the Reporting Measure Domain to reflect our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set (89 FR 55816). Under our proposal, we stated that the weight of the Kt/V Dialysis Adequacy Topic would continue to be the same as the current weight of the Kt/V Dialysis Adequacy Comprehensive Measure, but that weight would be applied to a facility's measure topic score, instead of being applied, as it is now, to a facility's score on the single Kt/V Comprehensive Dialysis Adequacy Comprehensive clinical measure.

Given our proposal to remove the NHSN Dialysis Event reporting measure from the ESRD QIP beginning with PY 2027, we also proposed to update the individual measure weights in the Reporting Domain to accommodate the proposed new number of measures (89 FR 55816). Consistent with our approach in the CY 2023 ESRD PPS final rule, we proposed to assign individual measure weights to reflect the proposed updated number of measures in the Reporting Measure Domain so that each measure is weighted equally (87 FR 67251 through 67253). Although we proposed to change the number of measures and the weights of the individual measures in the Reporting Measure Domain, we did not propose to change the weight of any of the five domains. The measures that would be included in each domain, along with the proposed new measure weights, for PY 2027 were depicted in Table 13b of the CY 2025 ESRD PPS proposed rule (89 FR 55817). These measure domains and weights, which we are finalizing as proposed, are depicted in this final rule in Table 14b.

TABLE 14b: ESRD QIP Measure Domains and Weights for PY 2027

Measures by Domain	Measure Weight as Percent of TPS
Patient and Family Engagement Measure Domain	**15.00**
ICH CAHPS measure	15.00
Care Coordination Measure Domain	**30.00**
SHR clinical measure	7.50
SRR clinical measure	7.50
PPPW measure	7.50
Clinical Depression Screening and Follow-Up measure	7.50
Clinical Care Measure Domain	**35.00**
Kt/V Dialysis Adequacy Measure Topic*	11.00
Adult Hemodialysis (HD) Kt/V	
Pediatric Hemodialysis (HD) Kt/V	
Adult Peritoneal Dialysis (PD) Kt/V	
Pediatric Peritoneal Dialysis (PD) Kt/V	
Long-Term Catheter Rate clinical measure	12.00
STrR clinical measure	12.00
Safety Measure Domain	**10.00**
NHSN BSI clinical measure	10.00
Reporting Measure Domain**	**10.00**
Screening for Social Drivers of Health measure	1.67
Screen Positive Rate for Social Drivers of Health reporting measure	1.67
Facility Commitment to Health Equity reporting measure	1.67
Hypercalcemia reporting measure	1.67
MedRec reporting measure	1.67
COVID-19 HCP Vaccination reporting measure	1.67

*We are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this final rule.
** We are finalizing our proposal to remove the NHSN Dialysis Event reporting measure beginning with PY 2027, as discussed in section IV.B.3 of this final rule.

We welcomed public comment on these proposals to update the Clinical Care Measure Domain and Reporting Measure Domain. The comments we received, and our responses are set forth below.

Comment: A few commenters expressed support for the proposal to weight the Kt/V Dialysis Adequacy Measure Topic at 11 percent. A few commenters expressed appreciation that the weight appropriately reflects the statutorily required nature of the measure, while also allowing flexibility to assign more weight to other measures for which there is greater room for improvement. Another commenter expressed support for the proposed weight for the Kt/V Dialysis Adequacy Measure Topic because it is the same weight as the current Kt/V Dialysis Adequacy Comprehensive clinical measure.

Response: We thank the commenters for their support.

Comment: A few commenters expressed concern with the proposal to weight the Kt/V Dialysis Adequacy Measure Topic at 11 percent, believing that the proposed measure weight will disproportionately impact certain types of facilities. A commenter expressed concern that the proposed measure weight for the Kt/V Dialysis Adequacy Measure Topic disproportionately impacts home dialysis-only facilities, noting that they are not eligible for scoring on certain other measures. Another commenter recommended that CMS not limit the measure weight to 11 percent, and to only score pediatric facilities on pediatric-specific or cohort-neutral measures to ensure that the QIP is relevant to pediatric programs. This commenter expressed the belief that such steps are necessary to prevent unfair or inaccurate penalties based on ESRD QIP measures that are not relevant to the pediatric patient population.

Response: We thank the commenters for their feedback and appreciate their concerns. The Kt/V Dialysis Adequacy Measure Topic will more accurately reflect a facility's dialysis adequacy performance by differentiating between the Kt/V measure data of all patients treated at that facility and assessing facilities based on the Kt/V measurements according to ESRD patient age and treatment modality. Although facilities are only scored on measures they are eligible for based on their reported data, we acknowledge that home dialysis facilities and pediatric facilities may be

disproportionately impacted because they are not eligible to be scored on certain ESRD QIP measures due to their specific patient population. However, we have concluded that the importance of accurately measuring dialysis adequacy for home dialysis ESRD patients and pediatric ESRD patients to incentivize improvements in the quality of care provided to those patient populations outweighs possible concerns regarding potential disproportionate impacts. Because facilities are not scored on measures for which they are not eligible based on their reported data, their score reflects the quality of care provided to patients based on the measures for which they are eligible. We will continue to assess potential policies aimed at expanding measure eligibility for these facilities in future rulemaking.

Comment: A commenter requested that CMS limit the total weight of Kt/V measures to 11 percent because the commenter believed that the measure is topped out in many cases.

Response: In the CY 2025 ESRD PPS proposed rule, we proposed that the weight of the Kt/V Dialysis Adequacy Topic would be 11 percent, the same weight as the Kt/V Dialysis Adequacy Comprehensive Measure (89 FR 55816). Under our proposal, the total weight of the Kt/V measures would be 11 percent under the Kt/V Dialysis Adequacy Measure Topic.

Comment: A few commenters expressed concern that the weights of individual measures in the Reporting Measure Domain do not adequately reflect the burden associated with each measure's criteria and reporting requirements. A commenter recommended that the Reporting Measure Domain carry a higher weight to reflect the significance of the individual reporting measures, as well as the substantial burden associated with compliance.

Response: We take numerous factors into account when determining appropriate domain and measure weights, including clinical evidence, opportunity for improvement, clinical significance, and patient and provider burden (83 FR 56995 through 56996). We also consider (1) the number of measures and measure topics in a domain; (2) how much experience facilities have had with the measures and measure topics in a domain; and (3) how well the measures align with CMS's highest priorities for quality improvement for patients with ESRD (79 FR 66214). We assign weights to the measure domains based on the clinical value and meaningfulness of the measures to patients, and the burden of complying with individual measure requirements. We believe that the Reporting Measure Domain weights are appropriate to incentivize the provision of high-quality health care for all ESRD QIP measures.

Comment: A few commenters expressed the belief that the ESRD QIP's focus on meaningful measures should be reflected in the weights assigned to measure domains and individual measures. To ensure that the ESRD QIP takes a clinically driven approach to incentivizing improvement, a few commenters recommended that CMS work with organizations and care providers in the ESRD community to identify potential modifications to the individual measure weights. A few commenters expressed concern regarding the weighting distribution of individual measures relative to the growing number of measures in the ESRD QIP measure set. These commenters expressed the belief that there are too many individual measures within the ESRD QIP measure set, and that scoring facilities based on nearly 20 individual measures means that a facility's performance on each individual measure has little impact on the facility's overall score. A few commenters recommended that CMS reduce the ESRD QIP measure set by moving certain measures to Dialysis Facility Compare or by removing certain measures altogether where appropriate.

Response: We agree with commenters that the weights should reflect clinical value and meaningfulness to patients, which we took into account in developing our measure domains and individual measure weights. We expect that the measure domains and weights provide facilities with meaningful incentives to improve performance on measures that align with clinical value and importance to patients. We note that we have developed the ESRD QIP measure set specifically to ensure that facilities focus on the most relevant clinical topics that will lead to improved quality of care and better outcomes for patients. Although we aim to minimize facility burden as much as feasible, we disagree that reducing the number of measures in the ESRD QIP should be a goal, absent justification under our measure removal factors codified at § 413.178(c)(5)(i).

Final Rule Action: After considering public comments, we are finalizing our proposals to update the Clinical Care Measure Domain and Reporting Measure Domain, beginning with PY 2027 as proposed, and therefore, are finalizing the ESRD QIP measure domains and measure weights provided in Table 14b in this section of the final rule.

5. Performance Standards for the PY 2027 ESRD QIP

Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to the measures selected for the ESRD QIP for a performance period with respect to a year. The performance standards must include levels of achievement and improvement, as determined appropriate by the Secretary, and must be established prior to the beginning of the performance period for the year involved, as required by sections 1881(h)(4)(B) and (C) of the Act. We refer readers to the CY 2013 ESRD PPS final rule (76 FR 70277), as well as § 413.178(a)(1), (3), (7), and (12), for further information related to performance standards.

In the CY 2024 ESRD PPS final rule (88 FR 76480 through 76481), we set the performance period for the PY 2027 ESRD QIP as CY 2025 and the baseline period as CY 2023. In the proposed rule, we estimated the performance standards for the PY 2027 clinical measures in Table 14 using data from CY 2022, which was the most recent data available (89 FR 55818). We are updating these performance standards for all measures, using CY 2023 data, in this final rule, in Table 15.

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TABLE 15: Updated Performance Standards for the ESRD QIP Clinical Measures for PY 2027

Measure	Achievement Threshold (15th Percentile of National Performance)	Median (50th Percentile of National Performance)	Benchmark (90th Percentile of National Performance)
Vascular Access Type (VAT)			
Long-Term Catheter Rate	18.35%*	11.04%*	4.69%*
Kt/V Dialysis Adequacy Measure Topic**			
Adult Hemodialysis (HD) Kt/V	95.79%	98.34%	99.68%
Pediatric Hemodialysis (HD) Kt/V	81.25%	92.37%	100.00%
Adult Peritoneal Dialysis (PD) Kt/V	87.34%	94.85%	99.04%
Pediatric Peritoneal Dialysis (PD) Kt/V	66.49%	82.06%	95.18%
Standardized Readmission Ratio[a]	34.27*	26.50*	16.18
NHSN BSI	0.642	0.215	0
Standardized Hospitalization Ratio[b]	166.60*	129.14*	87.98*
Standardized Transfusion Ratio[b]	48.29*	26.19*	8.46
PPPW	8.12%*	16.73%*	33.90%*
Clinical Depression	88.21%	94.34%	100.00%
ICH CAHPS: Nephrologists' Communication and Caring	58.20%*	67.90%*	79.15%*
ICH CAHPS: Quality of Dialysis Center Care and Operations	55.68%	63.83%	74.22%
ICH CAHPS: Providing Information to Patients	74.49%*	81.09%*	87.80%*
ICH CAHPS: Overall Rating of Nephrologists	49.33%*	62.22%*	76.57%*
ICH CAHPS: Overall Rating of Dialysis Center Staff	51.78%	65.18%	79.68%
ICH CAHPS: Overall Rating of the Dialysis Facility	55.76%	69.69%	84.10%
*Values are the same final performance standards for those measures for PY 2026. In accordance with our longstanding policy, we are using those numerical values for those measures for PY 2027 because they are higher standards than the PY 2027 numerical values for those measures. **We are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with the Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this final rule.			

[a]Rate calculated as a percentage of hospital discharges
[b]Rate per 100 patient-years
Data sources: VAT measure: 2023 EQRS; SRR, SHR, STrR: 2023 Medicare claims; Kt/V: 2023 EQRS and 2023 Medicare claims; NHSN: 2023 CDC; ICH CAHPS: CMS 2023; PPPW: 2023 EQRS and 2023 Organ Procurement and Transplantation Network (OPTN); Clinical Depression: 2023 EQRS.

In addition, we summarize in Table 16 our requirements for successful reporting on our previously finalized reporting measures for the PY 2027 ESRD QIP.

TABLE 16: Requirements for Successful Reporting of ESRD QIP Reporting Measures for PY 2027

Measure	Reporting Frequency	Data Elements
MedRec	Monthly	• Date of the medication reconciliation. • Type of eligible professional who completed the medication reconciliation: o physician, o nurse, o advanced registered nurse practitioner (ARNP), o physician assistant (PA), o pharmacist, or o pharmacy technician personnel • Name of eligible professional
Hypercalcemia	Monthly	Total uncorrected serum or plasma calcium lab values
COVID-19 Vaccination Coverage Among HCP	At least one week of data each month, submitted quarterly	Cumulative number of HCP eligible to work in the facility for at least one day during the reporting period and who are up to date on their COVID-19 vaccination.
Facility Commitment to Health Equity	Annually	Domains to which facility must attest affirmatively: • Equity is a Strategic Priority • Data Collection • Data Analysis • Quality Improvement • Leadership Engagement
Screening for Social Drivers of Health	Annually	Number of eligible patients who were screened for all five HRSNs: • Food insecurity, • Housing instability, • Transportation needs, • Utility difficulties, or • Interpersonal safety.
Screen Positive Rate for Social Drivers of Health	Annually	Number of eligible patients with 'Yes' or 'No' (non-missing) screening responses for each of the five HRSNs.

6. Eligibility Requirements for the PY 2027 ESRD QIP

In the proposed rule, we proposed to update eligibility requirements as part of our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027 (89 FR 55819). Our previously finalized and proposed new minimum eligibility requirements are described in Table 16 of the CY 2025 ESRD PPS proposed rule (89 FR 55820) and provided in Table 17 of this final rule.

TABLE 17: Previously Finalized and Proposed New Eligibility Requirements for Scoring on ESRD QIP Measures Beginning with PY 2027

Measure	Minimum data requirements	CCN open date	Small facility adjuster
Kt/V Dialysis Adequacy Measure Topic: Adult HD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric HD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Adult PD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
Kt/V Dialysis Adequacy Measure Topic: Pediatric PD Kt/V (Clinical)*	11 qualifying patients	N/A	11-25 qualifying patients
VAT: Long-term Catheter Rate (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
Hypercalcemia (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
NHSN BSI (Clinical)	11 qualifying patients	Before October 1 prior to the performance period that applies to the program year.	11-25 qualifying patients
SRR (Clinical)	11 index discharges	N/A	11-41 index discharges
STrR (Clinical)	10 patient-years at risk	N/A	10-21 patient-years at risk
SHR (Clinical)	5 patient-years at risk	N/A	5-14 patient-years at risk
ICH CAHPS (Clinical)	Facilities with 30 or more survey-eligible patients during the calendar year preceding the performance period must submit survey results. Facilities would not receive a score if they do not obtain a total of at least 30 completed surveys during the performance period	Before October 1 prior to the performance period that applies to the program year.	N/A
Depression Screening and Follow-Up (Clinical)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
MedRec (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
PPPW (Clinical)	11 qualifying patients	N/A	11-25 qualifying patients
COVID-19 Vaccination Coverage Among HCP (Reporting)	N/A	Before September 1 of the performance period that applies to the program year.	N/A
Facility Commitment to Health Equity (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A
Screening for Social Drivers of Health (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A

Screen Positive Rate for Social Drivers of Health (Reporting)	11 qualifying patients	Before September 1 of the performance period that applies to the program year.	N/A

* We are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027, as discussed in section IV.B.2 of this final rule.
** We are finalizing our proposal to remove the NHSN Dialysis Event reporting measure beginning with PY 2027, as discussed in section IV.B.3 of this final rule.

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We welcomed public comment on these proposals to update the minimum eligibility requirements to reflect the proposed Kt/V Dialysis Adequacy Measure Topic. We did not receive any comments on our proposals to update the minimum eligibility requirements to reflect the Kt/V Dialysis Adequacy Measure Topic.

Final Rule Action: We are finalizing our proposals to update the minimum eligibility requirements to reflect the Kt/V Dialysis Adequacy Measure Topic, beginning with PY 2027 as proposed, and therefore, are finalizing the ESRD QIP eligibility requirements provided in Table 17 in this section of the final rule.

7. Payment Reduction Scale for the PY 2027 ESRD QIP

Under our current policy, a facility does not receive a payment reduction for a payment year in connection with its performance under the ESRD QIP if it achieves a TPS that is at or above the minimum TPS (mTPS) that we establish for the payment year. We have defined the mTPS in our regulations at § 413.178(a)(8).

Under § 413.177(a), we implement the payment reductions on a sliding scale using ranges that reflect payment reduction differentials of 0.5 percent for each 10 points that the facility's TPS falls below the mTPS, up to a maximum reduction of 2 percent. In the proposed rule, we stated that for PY 2027, we estimated using available data that a facility must meet or exceed an mTPS of 51 to avoid a payment reduction (89 FR 55821). We noted that the mTPS estimated in the proposed rule was based on data from CY 2022 instead of the PY 2027 baseline period (CY 2023) because CY 2023 data were not yet available. We presented the estimated payment reduction scale in Table 17 of the CY 2025 ESRD PPS proposed rule (89 FR 55821). We stated our intention to update and finalize the mTPS and associated payment reduction ranges for PY 2027, using CY 2023 data, in this CY 2025 ESRD PPS final rule. We have now finalized the payment reductions that will apply to the PY 2027 ESRD QIP using updated CY 2023 data. The mTPS for PY 2027 will be 51, and the finalized payment reduction scale is shown in Table 18.

TABLE 18: Updated Payment Reduction Scale for PY 2027 Based on the Most Recently Available Data

Total performance score	Reduction (%)
100-51	0%
50-41	0.5%
40-31	1.0%
30-21	1.5%
20-0	2.0%

C. Requests for Information (RFIs) on Topics Relevant to ESRD QIP

As discussed in the following sections, in the CY 2025 ESRD PPS proposed rule we requested information on two topics to inform future revisions to the ESRD QIP. First, we requested information regarding potential future modifications to the existing ESRD QIP scoring methodology to reward facilities based on their performance and the proportion of their patients who are dually eligible for Medicare and Medicaid (89 FR 55822). Second, we requested information regarding potential updates to the data validation policy to encourage accurate, comprehensive reporting of ESRD QIP data (89 FR 55822 through 55823).

In the CY 2025 ESRD PPS proposed rule, we noted that each of these sections in the proposed rule is a RFI only (89 FR 55821). In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), these general solicitations are exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

We stated that respondents are encouraged to provide complete but concise responses (89 FR 55821). These RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. These RFIs do not commit the United States Government to contract for any supplies or services or make a grant award. Further, we noted that we were not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders were advised that the United States Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor these RFI announcements for additional information pertaining to this request. We noted that we will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the United States Government to form a binding contract or issue a grant. We stated that information obtained as a result of these RFIs may be used by the United States Government for program planning on a non-attribution basis (89 FR 55822). Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. Finally, we noted that CMS may publicly post the comments received, or a summary thereof.

1. Request for Public Comment on Future Change to the Scoring Methodology To Add a New Adjustment That Rewards Facilities Based on Their Performance and the Proportion of Their Patients Who Are Dually Eligible for Medicare and Medicaid

Achieving health equity, addressing health disparities, and closing the performance gap in the quality of care provided to disadvantaged, marginalized, or underserved populations continue to be priorities for CMS as outlined in the CMS National Quality Strategy.[110] CMS defines ''health equity'' as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[111] We are working to advance health equity by designing, implementing, and operationalizing policies and programs that reduce avoidable differences in health outcomes.

The ESRD QIP adopted three new health-equity focused quality measures in the CY 2024 ESRD PPS final rule (88 FR 76437 through 76446; 76466 through 76480). Although commenters were generally supportive of the new measures, a few commenters recommended that the ESRD QIP take additional action to support facilities that treat patient populations with higher proportions of health-related social needs (HRSNs) (88 FR 76473). In the CY 2025 ESRD PPS proposed rule, we stated that we are considering updating our scoring methodology in future rulemaking to add Health Equity Adjustment bonus points to a facility's TPS that would be calculated using a methodology that incorporates a facility's performance across all five domains for the payment year and its proportion of patients with dual eligibility status (DES), meaning those who are eligible for both Medicare and Medicaid coverage (89 FR 55822).

In the 2016 Report to Congress on Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Programs, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) reported that beneficiaries with social risk factors had worse outcomes and were more likely to receive a lower quality of care.[112] Patients with DES experience significant disparities are also likely to be more medically complex and remain one of the most vulnerable populations.[113] [114] [115] DES remains the strongest predictor of negative health outcomes.[116]

We recently finalized a Health Equity Adjustment scoring policy for the Hospital Value-Based Purchasing (VBP) Program (88 FR 59092 through 59106) and the Skilled Nursing Facility (SNF) VBP Program (88 FR 53304 through 53316). These policies provide Health Equity Adjustment bonus points to top tier performing hospitals and SNFs with a high proportion of patients with DES, and each program's policy is tailored to meet the needs of the specific program. For example, in the Hospital VBP Program, the Health Equity Adjustment bonus is calculated based on a hospital's performance on each of the four measure domains and its proportion of patients with DES (88 FR 59095 through 59096). In the SNF VBP Program, the Health Equity Adjustment bonus is calculated based on a facility's performance on each measure and its proportion of patients with DES (88 FR 53309 through 53311).

Our policy for scoring performance on the ESRD QIP is codified at § 413.178(e). In the proposed rule, we requested public comment on potential future modifications to the existing scoring methodology to reward excellent care to underserved populations (89 FR 55822). We also noted that any Health Equity Adjustment bonus for the ESRD QIP would need to align with the Program's statutory requirements under section 1881(h) of the Act. We welcomed public comment on the following:

- Would a Health Equity Adjustment be valuable to the ESRD QIP?

++ If a Health Equity Adjustment would be valuable to the ESRD QIP, how should it be structured?

[110] Centers for Medicare & Medicaid Services. (2022) CMS National Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[111] Health Equity Strategic Pillar. Centers for Medicare & Medicaid Services. *https://www.cms.gov/pillar/health-equity*.

[112] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf*.

[113] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, And Functional Risk Factors In Medicare Spending For Dual And Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032*.

[114] Johnston, K.J., & Joynt Maddox, K.E. (2019). The Role of Social, Cognitive, and Functional Risk Factors in Medicare Spending for Dual and Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032*.

[115] Wadhera, R.K., Wang, Y., Figueroa, J.F., Dominici, F., Yeh, R.W., & Joynt Maddox, K.E. (2020). Mortality and Hospitalizations for Dually Enrolled and Nondually Enrolled Medicare Beneficiaries Aged 65 Years or Older, 2004 to 2017. *JAMA, 323*(10), 961–969. *https://doi.org/10.1001/jama.2020.1021*.

[116] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs*.

++ If a Health Equity Adjustment would not be valuable to the ESRD QIP, why not?

• Are there other approaches that the ESRD QIP could propose to adopt to effectively address healthcare disparities and advance health equity?

We received comments in response to this request for information and have summarized them here.

Comment: Many commenters provided feedback on a Health Equity Adjustment. Several commenters expressed support for a Health Equity Adjustment, believing that it would be valuable to the ESRD QIP. Several commenters noted that ESRD is more prevalent among patient populations with higher social risk factors or from lower socioeconomic status or communities of color and observed that a Health Equity Adjustment could help promote more equitable care by rewarding excellent performance to underserved populations. Several commenters expressed support for a Health Equity Adjustment specific to the ESRD QIP, believing that it will help to reduce disparities among facilities that treat a greater proportion of DES patients. A few of these commenters observed that a Health Equity Adjustment may help to mitigate the impact of payment reductions that may disproportionately impact facilities that care for a greater proportion of low-income patients. A few other commenters noted that many facilities require more resources and specific care expertise to meet the care needs relevant to this patient population, and that a Health Equity Adjustment may further incentivize parity among care providers by providing them with resources necessary to provide high quality care to a complex patient population. A commenter expressed support for adopting a bonus scoring methodology for a Health Equity Adjustment in the ESRD QIP, noting that such a framework would align with current Health Equity Adjustments implemented in IPPS, SNF VBP, and ETC Model.

A few commenters agreed that a Health Equity Adjustment would be valuable to the care providers and patients. These commenters recommended that CMS engage with organizations and care providers in the ESRD community to discuss potential Health Equity Adjustment options and related policies for inclusion in future rulemaking, which commenters believed would be helpful to ensure that a future Health Equity Adjustment is developed and implemented in a meaningful way.

Several commenters expressed support for structuring the Health Equity Adjustment as a bonus that is applied to a facility's TPS. A few commenters recommended adding a Health Equity Adjustment bonus to a facility's TPS based on its performance in each of the five measure domains included in the TPS, adjusted for the facility's proportion of socioeconomically disadvantaged patients. A few commenters recommended that a Health Equity Adjustment be calculated based on a facility's performance across select measure domains, rather than all 5 measure domains. A commenter noted that fewer dialysis facilities are eligible for scoring on ICH CAHPS due to measure eligibility requirements, and therefore recommended that CMS exclude the Patient & Family Engagement domain from the measure performance calculation for purposes of calculating the Health Equity Adjustment. Another commenter recommended that a facility's performance within each measure domain should be assessed independently, such that a facility may be eligible for Health Equity Adjustment bonus points based on its performance in each domain. This commenter recommended that facility performance is grouped into three tiers for each domain, and that eligibility for HEA points be calculated based on the facility's performance within a given domain's tertile. A different commenter recommended that CMS calculate potential Health Equity Adjustment bonus points based on a facility's performance in Coordination, Clinical Care, and Safety measure domains relative to the quintile of that domain score.

Several commenters offered recommendations regarding Health Equity Adjustment bonus application. A commenter recommended that a future Health Equity Adjustment policy be designed to award bonus points to facilities that serve greater proportions of underserved patient populations and have higher quality performance. A commenter recommended that CMS consider structuring the Health Equity Adjustment as a positive payment adjustment tied to improved health outcomes for DES patients, citing the health equity incentives in the ETC and IOTA models. Another commenter suggested that Health Equity Adjustment bonus points be awarded based on the percentage of patients from underserved populations treated at the facility. This commenter believed that this approach would help to ensure that facilities caring for patients in underserved communities have adequate resources, observing that such facilities are more likely to be impacted by payment penalties which may result in decreased ability to provide care to such patient populations.

A few commenters recommended that CMS apply a Health Equity Adjustment bonus to a facility's TPS in a way that would allow facilities to move to a lesser payment reduction tier or a zero-payment reduction tier, believing that such a methodology would support facilities serving greater proportions of DES patients. A commenter recommended that Health Equity Adjustment bonus points should be limited to a maximum of 10 points to appropriately reward facilities for delivering excellent performance to underserved populations while also not skewing the TPS or creating unintended incentives.

A commenter requested that any Health Equity Adjustment policy not require changes to the current process for calculating a facility's TPS or to the payment reduction scales. This commenter suggested the potential equity points be combined as a weighted average that uses the same weights as the TPS. The commenter recommended a methodology that included: (1) multiplying the measure performance scalar by a logistic exchange function representing the facility in the percent of DES patient-months, which would provide the pre-scaled Health Equity Adjustment bonus; (2) multiplying the pre-scaled Health Equity Adjustment bonus by 10 to scale the Health Equity Adjustment bonus for incorporation into the TPS; and (3) adding the Health Equity Adjustment points to the existing TPS for a maximum value of 100 points. Pursuant to this commenter's recommended framework, although facilities would be assessed against a modified TPS, the payment reduction scale would be set based on unmodified TPS ranges.

A few commenters recommended that a Health Equity Adjustment should be structured so that it is not budget neutral, and therefore would not negatively impact facilities that don't qualify for the Health Equity Adjustment bonus. A few commenters observed that potential unintended consequences may result from a Health Equity Adjustment in the ESRD QIP, due to the unique nature of the program. These few commenters observed that a Health Equity Adjustment within the ESRD QIP would likely result in a decrease in the number and size of payment reductions imposed and recommended that CMS should not seek to increase overall payment reductions through other policy changes.

A few commenters offered recommendations regarding potential grouping methodology for calculating eligibility for a Health Equity Adjustment. A commenter recommended that CMS group facilities into quartiles or quintiles to calculate eligibility for a Health Equity Adjustment bonus. This commenter noted that there are a greater number of eligible facilities in the ESRD QIP, as compared to other CMS programs that apply a Health Equity Adjustment. A different commenter recommended that CMS structure a ESRD QIP Health Equity Adjustment by grouping facility performance into three tiers for each Measure Domain, and that eligibility for Health Equity Adjustment bonus points be calculated based on the facility's performance within a given domain's tertile.

Several commenters provided recommendations regarding the applicable patient population used to determine a facility's eligibility for Health Equity Adjustment consideration. A few commenters recommended that a Health Equity Adjustment account for both Medicare fee-for-service patients as well as Medicare Advantage patients to accurately represent the proportion of the targeted patient population. A commenter recommended that, in addition to DES patients, CMS include Medicaid-only and uninsured patients in its definition of underserved patient population. Another commenter recommended that CMS expand the applicability of Health Equity Adjustment eligibility to include low-income subsidy recipients, noting potential different impacts for facilities in states that did not expand their Medicaid programs. A different commenter recommended that CMS award Health Equity Adjustment bonus points based on the percentage of DES patients as well as low-income subsidy patients treated at the facility, noting that this approach would be consistent with the ETC Model. Another commenter recommended that CMS set a minimum threshold of 20 percent DES patient population for Health Equity Adjustment eligibility, noting that such a threshold would be consistent with the SNF VBP scoring policy.

A few commenters expressed concern regarding potential unintended consequences that may result from a Health Equity Adjustment in the ESRD QIP. A few commenters expressed concern that a Health Equity Adjustment may create confusion by inflating or otherwise impacting a facility's TPS. A commenter noted that an adjustment to a facility's TPS based on a Health Equity Adjustment would create further confusion for patients seeking to understand the significance of a facility's publicly available TPS. A commenter observed that a Health Equity Adjustment may suggest that facilities with higher proportions of DES patients are held to a lower standard or that those patients are allowed to have poorer health outcomes. Another commenter noted that a Health Equity Adjustment may not be valuable to all ESRD facilities and recommended that CMS consider the potential impact on facilities in certain areas that may have limited resources. A different commenter expressed concern that a Health Equity Adjustment may result in unintended financial incentives and requested that CMS ensure that any Health Equity Adjustment policy continues to focus on advancing health equity. A commenter requested that CMS clarify how it anticipates measuring for health equity success.

A few commenters expressed concern that a Health Equity Adjustment may not be valuable to the ESRD QIP. A commenter observed that a Health Equity Adjustment may not be sufficient or appropriate for the ESRD QIP as a means to address health disparities. Another commenter expressed concern that a Health Equity Adjustment would not be valuable because the ESRD QIP is a penalty-only program that does not award bonuses.

A commenter recommended that the ESRD QIP adopt a peer grouping methodology, similar to the methodology used in the Hospital Readmissions Reduction Program (HRRP). This commenter expressed the belief that stratification into quintiles would promote competition among facilities within the same quintile and provide a more accurate comparison of facility performance that takes patient population into account.

Several commenters recommended other approaches that the ESRD QIP could propose to adopt to effectively address healthcare disparities and advance health equity. A few commenters recommended that the ESRD QIP adopt efforts that are more directly aimed at addressing health disparities. A commenter recommended that services aimed at navigating care coordination and HRSN-related needs be included as part of the quality care provided by ESRD facilities. This commenter noted that a facility that has staff trained in identifying and addressing such needs may help to mitigate the increased risk of poor outcomes for ESRD patients tied to unmet HRSNs. A different commenter expressed support for the three health equity measures recently added to the ESRD QIP, but expressed concern that the measures do little to directly address systemic health disparities and that facilities do not have the resources necessary to identify and facilitate solutions to address HRSNs. This commenter noted that, although collecting such data is essential, health disparities will persist in the absence of additional funding necessary to address these issues. Another commenter recommended that CMS explore policy approaches outside the ESRD QIP to reduce health disparities in the ESRD patient population, urging CMS to invest in structural and systemic capabilities that facilities require to comprehensively support the care needs of a complex patient population.

A commenter recommended that CMS consider restructuring the ESRD QIP to incorporate both negative and positive payment adjustments to incentivize high quality care and provide access to additional resources and support. This commenter expressed the belief that financial penalties do not necessarily facilitate improvement in quality of care, noting that such penalties also potentially reduce resources available to facilities that would benefit from them the most. Another commenter recommended that CMS continue to engage with the ESRD community to explore effective approaches to address health disparities and improve the quality of care provided to underserved populations.

A commenter recommended that CMS consider whether within-facility analysis is appropriate for addressing health disparities in the ESRD patient population, noting that the diversity of patient populations among different dialysis facilities often reflect the diversity of the population of the area which the facility is located. A different commenter recommended that CMS consider the role of patient autonomy and agency in developing future health equity measures, noting that individual patients may differ in their level of interest and engagement.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of our efforts to effectively address healthcare disparities and advance health equity. We will continue to take all concerns, comments, and suggestions into account for future development and expansion of our health equity-related efforts.

2. Request for Public Comment on Updating the Data Validation Policy for the ESRD QIP

One of the critical elements of the ESRD QIP's success is ensuring that the data submitted to calculate measure scores and TPSs are accurate. The ESRD QIP includes two types of data validation for this purpose: The EQRS data validation (OMB Control Number 0938–1289) and the NHSN validation (OMB Control Number 0938–1340). In the CY 2019 ESRD PPS final rule, we adopted the CROWNWeb (now EQRS) data validation as a permanent feature of the Program (83 FR 57003). In the CY 2020 ESRD PPS final rule, we adopted the NHSN data validation as a permanent feature of the Program (84 FR 60727). Under both data validation policies, we validate EQRS and NHSN data from a sample of facilities randomly selected for validation. If a facility is randomly selected for validation but does not submit the requested records, 10 points are deducted from the facility's TPS.

In the proposed rule, we requested public comment on ways to update the data validation policy to encourage accurate, comprehensive reporting of ESRD QIP data (89 FR 55823). We have reviewed data validation policies in other quality reporting programs such as the Hospital Inpatient Quality Reporting (IQR) Program (81 FR 57180) and the Hospital Outpatient Quality Reporting (OQR) Program (76 FR 74486). These programs have adopted data validation policies that require a hospital selected for data validation to achieve a 75 percent reliability or accuracy threshold to receive full credit for data validation reporting.

We welcomed comments on potential future policy proposals that would encourage accurate, comprehensive reporting for data validation purposes, such as introducing a penalty for facilities that do not meet an established reporting or data accuracy threshold, introducing a bonus for facilities that perform above an established reporting or data accuracy threshold, developing targeted education on data validation reporting, or requiring that a facility selected for validation that does not meet an established reporting or data accuracy threshold be selected again the next year.

We received comments in response to this request for information and have summarized them here.

Comment: A few commenters offered feedback on ways to reduce administrative burden associated with participating in data validation. A few commenters recommended that CMS focus on improving the data validation system because they believe that the current framework is too burdensome for facilities. A few commenters recommended that CMS prioritize enhancing the functionality of EQRS and NHSN systems to facilitate easier data submission and correction, which commenters believe will support more accurate and comprehensive reporting. A commenter suggested that CMS adopt advanced technologies such as artificial intelligence (AI) and machine learning algorithms to reduce burden associated with traditional reporting mechanisms. A few commenters noted that the current data validation system is burdensome on facilities due to compliance requirements and timeframes, which commenters observed may detract from the facility's ability to focus resources on providing quality care. A few commenters expressed concern that smaller facilities faced a disproportionately greater administrative burden to comply with the data validation process, and therefore recommended that CMS look into mitigating that burden. A commenter recommended that CMS mitigate the burden on smaller facilities by ensuring that the data validation policy reflect variability across facility types. A few commenters recommended that CMS extend the submission window because the 60-day compliance timeframe is often challenging due to staffing constraints, absences, and competing priorities. A few commenters recommended that, to reduce administrative burden and encourage comprehensive and accurate reporting, CMS establish and distribute a schedule outlining which facilities will be included in the validation study and when, to provide facilities with adequate notice. A commenter recommended that CMS also provide a more predictable schedule for survey requests. A few commenters recommended that CMS reduce survey frequency, noting that completing surveys twice a year is time-consuming and further constrains already limited staff resources. A few commenters observed that previous validation study results suggest a level of stability that reduces the need for annual re-measurement. A commenter recommended that CMS reduce the frequency of data validation surveys to every five years or reasonable intervals. A commenter noted that CMS has reported consistently high accuracy rates of data reporting by participating facilities, which the commenter believes is an indication that the current data validation policy is generating accurate, comprehensive reporting of QIP data. A commenter noted that reducing the frequency of validation studies would provide facilities additional time to understand data collection requirements and ensure the accuracy of submissions.

A few commenters suggested that CMS consider providing a bonus for facilities that perform above an established reporting or data accuracy threshold, but only if the funding for such bonus were not obtained by reducing payments to ESRD facilities. A commenter recommended that participation in data validation be voluntary and that participating facilities receive bonus points awarded to their TPS, rather than penalties for non-participation.

A few commenters requested that CMS share the results of previous data validation studies to inform their recommendations regarding the establishment of a reporting or data accuracy threshold. A commenter expressed concern with updating the data validation policy, noting that insufficient data validation information was publicly available to provide comment on future updates to the data validation policy at this time. A few commenters recommended greater transparency with regard to the results of the data validations surveys. A few commenters noted that such transparency will help facilities understand their results and support targeted education efforts, which will lead to more accurate ESRD QIP data submitted for validation. Although a commenter expressed support for targeted education, this commenter opposed mandatory re-selection of facilities that do not meet an established reporting or data accuracy threshold because commenter believes that selected facilities need to be chosen at random.

A few commenters recommended that any updates to the data validation system include robust due process protections that are similar to those provided through other audit programs operated by CMS. A commenter expressed the belief that due process policies will help to ensure the accuracy of data submitted by ensuring that there is opportunity to address potential issues with data submission and interpretation to ensure that facilities are not unfairly penalized.

Response: We appreciate all of the comments and interest in this topic. We believe that this input is very valuable in the continuing development of our efforts to encourage accurate, comprehensive reporting for data validation purposes. We will continue to take all concerns, comments, and

suggestions into account for future development and expansion of these efforts.

V. End-Stage Renal Disease Treatment Choices (ETC) Model

A. Background

Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of these programs. The purpose of the ETC Model is to test the effectiveness of adjusting certain Medicare payments to ESRD facilities and Managing Clinicians to encourage greater utilization of home dialysis and kidney transplantation, support ESRD Beneficiary modality choice, reduce Medicare expenditures, and preserve or enhance the quality of care. As described in the Specialty Care Models final rule (85 FR 61114), beneficiaries with ESRD are among the most medically fragile and high-cost populations served by the Medicare program. ESRD Beneficiaries require dialysis or kidney transplantation to survive, and the majority of ESRD Beneficiaries receiving dialysis receive hemodialysis in an ESRD facility. However, as described in the Specialty Care Models final rule, alternative renal replacement modalities to in-center hemodialysis, including home dialysis and kidney transplantation, are associated with improved clinical outcomes, better quality of life, and lower costs than in-center hemodialysis (85 FR 61264).

The ETC Model is a mandatory payment model. ESRD facilities and Managing Clinicians are selected as ETC Participants based on their location in Selected Geographic Areas—a set of 30 percent of Hospital Referral Regions (HRRs) that have been randomly selected to be included in the ETC Model, as well as HRRs with at least 20 percent of ZIP codes™ located in Maryland.[117] CMS excludes all United States Territories from the Selected Geographic Areas.

Under the ETC Model, ETC Participants are subject to two payment adjustments. The first is the Home Dialysis Payment Adjustment (HDPA), which is an upward adjustment on certain payments made to participating ESRD facilities under the ESRD Prospective Payment System (PPS) on home dialysis claims, and an upward adjustment to the Monthly Capitation Payment (MCP) paid to participating Managing Clinicians on home dialysis-related claims. The HDPA applies to claims with claim service dates beginning January 1, 2021, and ending December 31, 2023.

The second payment adjustment under the ETC Model is the Performance Payment Adjustment (PPA). For the PPA, we assess ETC Participants' home dialysis rates and transplant rates during a Measurement Year (MY), which includes 12 months of performance data. Each MY has a corresponding PPA Period—a 6-month period that begins 6 months after the conclusion of the MY. We adjust certain payments for ETC Participants during the PPA Period based on the ETC Participant's home dialysis rate and transplant rate, calculated as the sum of the transplant waitlist rate and the living donor transplant rate, during the corresponding MY.

Based on an ETC Participant's achievement in relation to benchmarks based on the home dialysis rate and transplant rate observed in Comparison Geographic Areas during the Benchmark Year, and the ETC Participant's improvement in relation to their own home dialysis rate and transplant rate during the Benchmark Year, we would make an upward or downward adjustment to certain payments to the ETC Participant. The magnitude of the positive and negative PPAs for ETC Participants increases over the course of the Model. These PPAs apply to claims with claim service dates beginning July 1, 2022 and ending June 30, 2027.

CMS has modified the ETC Model several times. In the CY 2022 ESRD PPS final rule, we finalized a number of changes to the ETC Model. We adjusted the calculation of the home dialysis rate (86 FR 61951 through 61955) and the transplant rate (86 FR 61955 through 61959) and updated the methodology for attributing Pre-emptive LDT Beneficiaries (86 FR 61950 through 61951). We changed the achievement benchmarking and scoring methodology (86 FR 61959 through 61968), as well as the improvement benchmarking and scoring methodology (86 FR 61968 through 61971). We specified the method and requirements for sharing performance data with ETC Participants (86 FR 61971 through 61984). We also made a number of updates and clarifications to the kidney disease patient education services waivers and made certain related flexibilities available to ETC Participants (86 FR 61984 through 61994). In the CY 2023 ESRD PPS final rule (87 FR 67136) we finalized further changes to the ETC Model. We updated the PPA achievement scoring methodology beginning in the fifth MY of the ETC Model, which began on January 1, 2023 (87 FR 67277 through 67278). We also clarified requirements for qualified staff to furnish and bill kidney disease patient education services under the ETC Model's Medicare program waivers (87 FR 67278 through 67280) and finalized our intent to publish participant-level model performance information to the public (87 FR 67280). In the CY 2024 ESRD PPS final rule (88 FR 76344) we finalized a policy whereby an ETC Participant may seek administrative review of a targeted review determination provided by CMS.

B. Provisions of the Proposed Rule

We proposed a modification to the definition of ESRD Beneficiary at 42 CFR 512.310 as that definition is used for the purposes of attributing beneficiaries to the ETC Model. As finalized in the Specialty Care Models final rule and codified at § 512.360, CMS retrospectively, that is, following a MY, attributes ESRD Beneficiaries and Pre-emptive Living Donor Transplant (LDT) Beneficiaries to an ETC Participant for each month during a MY. An ESRD Beneficiary may be attributed to an ETC Participant if the beneficiary has already had a kidney transplant and has a non-AKI dialysis or MCP claim less than 12 months after the beneficiary's transplant date and has a kidney transplant failure ICD–10 diagnosis code documented on any Medicare claim. Based on feedback from model participants, we became aware that the use of the ICD–10 code T86.12 to identify transplant failures may be incorrectly identifying beneficiaries for attribution to the ETC Model because a claim that is only coded with T86.12 may signify delayed graft function rather than a true transplant failure. To ensure that we are correctly identifying ESRD beneficiaries for the purposes of ETC Model ESRD Beneficiary attribution, we proposed to modify our definition of an ESRD Beneficiary at § 512.310. Our regulations currently define an ESRD Beneficiary as a beneficiary that meets either of the following criteria: (1) is receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney transplant up to and including the month in which the beneficiary receives a kidney transplant, or (2) has already received a kidney transplant and has a non-AKI dialysis or MCP claim at least 12-months after the beneficiary's latest transplant date; or less than 12-months after the beneficiary's latest transplant date and

[117] ZIP code™ is a trademark of the United States Postal Service.

has a kidney transplant failure diagnosis code documented on any Medicare claim. We proposed to modify the second criterion to specify that the beneficiary's latest transplant date must be identified by at least one of the following: (1) two or more MCP claims in the 180 days following the date on which the kidney transplant was received; (2) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or (3) indication of a transplant failure after the beneficiary's date of transplant based on data from the Scientific Registry of Transplant Recipients (SRTR). We proposed that if a beneficiary meets more than one of these criteria, that CMS will consider that beneficiary an ESRD Beneficiary for the purposes of ETC model attribution starting with the earliest month in which the transplant failure was recorded. In our analysis of the proposed methodology for identifying transplant failures, we found that the use of all three criterion correctly identified more true transplant failures than did the use of T86.12 alone.

We considered a proposal to modify the language at 42 CFR 512.310 that an ESRD Beneficiary is a beneficiary that has already received a kidney transplant and has a non-AKI or MCP dialysis claim less than 12 months after the beneficiary's latest transplant date with kidney transplant failure diagnosis code documented on any Medicare claim. We considered removing the last clause; in other words, removing the specification that that the beneficiary must have a kidney transplant failure diagnosis code documented on any Medicare claim. We did not propose this modification to the definition of an ESRD Beneficiary because doing so would preclude the possibility for a beneficiary to be attributed to the ETC Model for 12-months after a transplant, regardless of if the transplant failed. We were concerned that this scenario would reduce the number of attributed beneficiary-months that would be available for us to use to calculate the home dialysis and transplant rate for ETC Participants. We solicited comment on our proposal to modify the definition of an ESRD Beneficiary to more accurately identify beneficiaries that may be attributed to the ETC Model due to receiving a kidney transplant that fails within 12-months of its receipt.

Comment: We received four comments on this proposed policy and the alternative policy put forth for consideration, all expressing collective agreement on the methodology modification. Two Patient Advocacy Organizations agreed with our plan to modify these definitions as described and specifically agreed that if a beneficiary meets more than one of the amended criteria, then they should be considered an ESRD Beneficiary for the purposes of ETC model attribution starting with the earliest month in which the transplant failure was recorded. One commenter agreed with our decision to forgo the alternative policy to remove the specification that that the beneficiary must have a kidney transplant failure diagnosis code documented on any Medicare claim. One dialysis organization stated that they commend CMS' dedication to correctly identifying ESRD beneficiaries for attribution to the ETC Model. They believe the proposed clarification will help prevent beneficiaries with delayed graft function who have a claim coded with T86.12 from being incorrectly attributed to the ETC Model. The organization further encourages CMS to make needed refinements for the ETC Model's remaining duration and utilize its regulatory authority to mitigate penalties to physicians and dialysis providers.

Response: We appreciate the commenters' dedicated engagement with the design of the ETC Model and the methodology by which we assess transplant beneficiary attributions. However, we uncovered an inconsistency in the rule text between Paragraph 3 and Paragraph 4 of the proposed definition of an ESRD beneficiary. Paragraph 3 suggests that a kidney transplant failure would be identified from a beneficiary who has ''at least'' one of the following three criteria, whereas Paragraph 4 in the proposed rule states that if a beneficiary meets ''more than one'' of the criteria described in paragraphs (3)(i) through (iii) that they would then be considered an ESRD beneficiary. Given the specific comment from one interested party that expressed support for a beneficiary meeting more than one of the following criteria to be considered an ESRD Beneficiary for the purposes of ETC model attribution: (1) two or more MCP claims in the 180 days following the date on which the kidney transplant was received; (2) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or (3) indication of a transplant failure after the beneficiary's date of transplant based on data from the Scientific Registry of Transplant Recipients (SRTR), we plan to update the definition in paragraph three to resolve the inconsistency and delete the phrase ''at least one of the following''.

Final Decision: In consideration of the comments received, we are finalizing our proposed modification to the definition of ESRD Beneficiary at 42 CFR 512.310 as that definition is used for the purposes of attributing beneficiaries to the ETC Model with one modification. We will delete the phrase ''at least one of the following'' from the definition of kidney transplant failure in paragraph 3 so it reads, ''Has a kidney transplant failure less than 12 months after the beneficiary's latest transplant date as identified by''. Per paragraph 4 of the definition then, a beneficiary must meet more than one of the criteria laid out in paragraph 3 to qualify as having a kidney transplant failure.

C. Request for Information

1. Request for Information

In the Specialty Care Models final rule, we referenced a report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis that describes barriers to increased adoption of home dialysis including educational barriers, the need for home care partner support, the monthly visit requirement for the Monthly Capitation Payment (MCP) under the Physician Fee Schedule, variations in dialysis business practices in staffing allocation, lack of home clinic independence, and other restrictions resulting in the inefficient distribution of home dialysis supplies (85 FR 61265).[118] The National Kidney Foundation (NKF) Kidney Disease Outcomes Quality Initiative (KDOQI) controversies conference report, ''Overcoming Barriers for Uptake and Continued Use of Home Dialysis: An NKF–KDOQI Conference Report,'' describes clinical, operational, policy, and societal barriers to increased prescribing of and retention on home modalities. For example, lack of clinical confidence in prescribing home dialysis, lack of infrastructure, financial costs to patients associated with home modifications, the need for space to store home dialysis supplies, lack of housing, lack of appropriate education, care partner burnout, and patient fear of self-cannulation.[119]

[118] Golper TA, Saxena AB, Piraino B, Teitelbaum, I, Burkart, J, Finkelstein FO, Abu-Alfa A. Systematic Barriers to the Effective Delivery of Home Dialysis in the United States: A Report from the Public Policy/Advocacy Committee of the North American Chapter of the International Society for Peritoneal Dialysis. American Journal of Kidney Diseases. 2011; 58(6): 879–885.doi:10.1053/j.ajkd.2011.06.028.

[119] Chan, C.T., Collins, K., Ditschman, E.P., Koester-Wiedemann, L., Saffer, T.L., Wallace, E., & Rocco, M.V. (2020). Overcoming barriers for uptake and continued use of home dialysis: An NKF-Kdoqi Conference Report. American Journal of Kidney

Continued

Since the Specialty Care Models final rule was published, interested parties have spoken to us about challenges associated with increasing access to home dialysis, particularly among beneficiaries with lower socioeconomic status, who have lower rates of home dialysis and kidney transplantation than people with higher socioeconomic status. The ETC Model was designed to address these barriers; for example, CMS applied the Home Dialysis Payment Adjustment (HDPA) to assist dialysis organizations with overcoming market realities that impose substantial barriers to opening and sustaining home dialysis programs. The upside and downside risk associated with the Performance Payment Adjustment (PPA) are designed to be strong incentives for behavioral change towards increasing beneficiary access to home dialysis. In the CY 2022 ESRD PPS final rule, we finalized a policy whereby we stratify achievement benchmarks based on the proportion of attributed beneficiaries who are dual eligible for both Medicare and Medicaid or who receive the Low-Income Subsidy (LIS) (86 FR 61968). We also finalized the Health Equity Incentive (HEI), which rewards ETC Participant aggregation groups that demonstrate greater than 2.5 percentage points improvement on the home dialysis and transplant rate among dual eligible and LIS recipient beneficiaries from the Benchmark Year (BY) to the MY with a .5 increase in their improvement score (86 FR 61971).

Performance accountability in the ETC Model is scheduled to end on June 30, 2026. We are concerned that the end of performance accountability may reduce incentives for dialysis organizations to invest in access to home dialysis and address the challenges of the type we describe previously in this section. We were interested in hearing from interested parties regarding policies that the Innovation Center may consider specifically incorporating into any successor model to the ETC Model or that CMS may consider generally. Given the growth in ESRD beneficiaries choosing Medicare Advantage plans,[120] we were particularly interested in approaches CMS could take to improve beneficiary access to home dialysis modalities in Medicare Advantage.

We sought input on the following topics that may improve our understanding of other policy interventions that may increase access to high quality home dialysis within the context of Innovation Center models and across CMS.

1. How should any future Innovation Center model that incorporates home dialysis incorporate what the community has learned from the ETC Model?

2. What barriers to home dialysis could be addressed through the ESRD Prospective Payment System (PPS)? We request that commenters be as specific as possible.

3. What approaches could CMS consider to increase beneficiary access to home dialysis modalities in Medicare Advantage?

4. How should nephrologist payment from traditional, fee-for-service Medicare and from MAOs account for clinician-level barriers to prescribing and retaining patients on home modalities?

We received comments in response to this request for information and have summarized them here.

Comment: Inclusion of the Kidney Disease Education (KDE) Benefit. Several commenters expressed their belief in the usefulness of KDE as a tool for individuals with kidney failure to learn about their disease state and options for treatment. The commenters mentioned it is also well known that patients who receive early and accurate modality education, such as what is provided through KDE, are more likely to choose a home modality should their disease progress to ESRD. Commenters urge CMS to maintain the ETC's changes to the KDE program in any future models related to increasing home dialysis and waiving the 20 percent coinsurance.

Consideration of Pediatric Patients in Future Models. A professional society for pediatric nephrologists expressed appreciation for the exclusion of children under 18 from participation in the ETC Model. The commenter reiterated their belief of current model goals and further highlighted that young adults who continue to be treated by pediatric nephrologists once they turn 18 years old are a particularly complex group of patients. Of note, the commenter urged CMS to consider collaboration with representatives of the pediatric nephrology community on future models to incentivize home dialysis and transplantation.

Increased Access to New and Innovative Drugs. A non-provider industry-associated interested party noted that within various CMS hospital inpatient and outpatient models advanced by the Innovation Center, add-on payments for innovative new technologies and therapies are purposely excluded from episode expenditures to ensure that Medicare beneficiaries have consistent access to innovations that improve their care. The interested party encourages the Innovation Center to apply the same reasoning and approach under future kidney models.

Data and Quality Metrics. A dialysis organization encouraged CMS to reconsider the concept of comparing geographic areas in potential successor models. Additionally, the commenter and several patient advocacy organizations encouraged the inclusion of home dialysis measures with greater specificity, such as a home retention metric or optimal starts, and the development of a home dialysis patient satisfaction and experience measure. Similarly, for transplant, CMS was encouraged to consider removing metrics that run counter to beneficiaries' waitlisting, such as waitlist mortality, and consider adding metrics, such as referral to waitlist percentage and time from referral to waitlist. A commenter further highlighted future models with more efficient data sharing capabilities to access performance data would be a strength.

Increased Efforts Towards Transplantation. Several commenters provided recommendations on ways to effectively increase transplantation, such as the creation of a patient navigator program to improve patient experience of care in seeking transplants.

Social Drivers of Health. Several commenters expressed support of future models that test how additional resources and/or direct patient incentives aimed at addressing social drivers of health would impact the uptake of home modalities and ultimately whether quality of life is improved. Commenters reiterated previous recommendations that CMS work with HHS and the states to revise federal, state, and local fraud and abuse laws to support dialysis facilities and physicians in their efforts to help individuals with kidney failure address socio-economic barriers to home dialysis. A commenter also suggested some barriers contributing to the lower uptake of home dialysis in communities of color and underserved communities could be addressed by encouraging Medicare Advantage (MA) plans to apply the Special Supplemental Benefits for the Chronically Ill (SSBCI). The commenter suggested these benefits could be used to reduce barriers to

Diseases, 75(6), 926–934. *https://doi.org/10.1053/j.ajkd.2019.11.007.*

[120] Nguyen, K.H., Oh, E.G., Meyers, D.J., Kim, D., Mehrotra, R., & Trivedi, A.N. (2023). Medicare advantage enrollment among beneficiaries with end-stage renal disease in the first year of the 21st Century Cures Act. *JAMA, 329*(10), 810. *https://doi.org/10.1001/jama.2023.1426.*

home dialysis, such as copay assistance programs for necessary dialysis related medications, stipends for utility costs and necessary home modifications, assistance for care partners or respite when needed, and assistance in installing and paying for broadband internet.

Model Structure. Several commenters expressed their support for future models being voluntary and including more flexibilities for smaller providers, like the Comprehensive ESRD Choices (CEC) model. Additionally, stakeholders believe future models should have a financial structure based on anticipated savings to increase incentives and should include Medicare Advantage (MA) beneficiaries. Other commenters recommend a model that tests the impact of additional Medicare payments for a package of comprehensive care services to aid in investments in infrastructure and care management capabilities for dialysis providers.

Recurring Barriers Elevated by Patients and Caregivers. Commenters elevated recurring barriers shared by patients and caregivers that dialysis providers noted being limited in their capacity to address, such as the fear of abandonment and/or lack of real time support in the home, inadequate space in the home for equipment and supplies, and the lack of available in-home support staff. A commenter suggested the development of a Technical Expert Panel (TEP) to evaluate evidence from the IM–HOME1 framework for resolving the barriers that exist for home dialysis.

Incentivizing Peritoneal Dialysis (PD) Catheter Placement. Commenters elevated several barriers impacting timely PD catheter placement previously identified by CMS: (1) challenges scheduling operating room time in the hospital setting for PD catheter placement, (2) the need for additional training on PD catheter placement for both surgeons and interventional nephrologists, and (3) the lack of dedicated PD catheter insertion teams in the hospital setting who can immediately place catheters for patients who ''crash'' into dialysis and would benefit from urgent start PD. Commenters encourage CMS to develop a demonstration to test the impact of policy changes for equal reimbursement rates between PD catheter placement procedures and vascular access placement procedures. A patient advocacy organization recommended a bonus incentive payment for vascular surgeons, hospitals, and surgical centers, that would increase reimbursement for PD catheter placements and become equal with the reimbursements provided for Arteriovenous (AV) Fistula reimbursement.

Fraud and Abuse Laws. Two commenters recommended we remove certain barriers that they believe are created by the physician self-referral law, Anti-Kickback Statute (AKS), and beneficiary inducement laws. The commenters described various arrangements they believe may be prohibited by such laws but would be beneficial to care coordination, management of patient care and disease progression, and patient education.

Increased Data Transparency. Commenters strongly suggested that publicly accessible data is needed to ensure that beneficiaries with kidney failure who elect an MA plan maintain access to the care they need. CMS is encouraged to update MA data collection and reporting efforts to match other Medicare programs and better align incentives across the health care continuum.

Time and Distance Standards and Network Adequacy. Commenters urge CMS to reconsider requiring time and distance standards in MA, as described in regulations at 42 CFR 422.116, for dialysis facilities that were removed in 2020. Interested parties across the kidney community have noticed unintended consequences on patients-including home dialysis patients-as a result of this amended policy. Patients and interested parties report that some plans have such narrow networks that patients have difficulty accessing vascular access surgeons, nephrologists, or even a dialysis facility near their homes. Commenters further note other patients have been listed as inactive on transplant waitlists because MA plans have removed their center from the network.

Expanded Staff Training Requirements. A commenter noted that a big obstacle to home dialysis is the current training requirements that limit training to one patient at a time, and for that trainer be a Registered Nurse (RN). This leads to significant backlogs for training and deters potential patients. The national shortage of RNs limits the availability of trainers, and a core curriculum could be developed to train other professionals who could provide home dialysis training. CMS is further encouraged to create incentives to support new technologies that support mobile dialysis such that patients living in rural or remote parts of our country may have access to same standard of care as those that reside in a large urban area.

Medicare Advantage (MA) Benchmarks and Plan Finder Tools. Commenters note that CMS should ensure that corresponding adjustments in MA benchmarks for ESRD are made to reflect any adjustments in FFS ESRD payments. Additionally, commenters stated that CMS should reinforce statutory requirements that MA patients maintain access to the same services as Medicare FFS patients, including home dialysis. Despite statutory requirements, commenters reported that many MA organizations (MAOs) limit beneficiary access to in-network home dialysis, a treatment modality to which all Medicare beneficiaries should maintain equitable access. Commenters further highlight that the Medicare.gov Plan Finder is a useful tool from CMS that helps people find MA and Medicare Part D plans available in their area and should include information regarding the availability of home dialysis programs by MA plan. In doing so, CMS can shift the responsibility away from patients and onto MAOs to ensure they are communicating clearly their plans' offerings and whether enrollees will have access to a home dialysis program. Commenters also believe MA plans would be incentivized to prioritize home dialysis uptake if home dialysis penetration was included as a new quality marker, in addition to established standards that measure their performance against a set of quality measures determined by CMS.

Changes to Physician Payments for Referrals and Training. Interested parties believe that upstream incentive payments could serve as a benefit for those physicians doing particular work with patients in later CKD stages. CMS is also urged to consider providing a one-time incentive payment for referral to home dialysis—either PD or Home Hemodialysis (HHD). A complimentary policy change to the recommendations earlier, is the increased payment for HCPCS codes G0420 and G0421, which are used for individual face-to-face education services and group face-to-face education services related to CKD. Commenters note that the codes have not been meaningfully updated.

Commenters highlighted the payment system is currently underfunded by approximately 6.9 percent due to inadequate adjustments for inflation and may be insufficient to achieve the goal of 20 to 25 percent of patients receiving dialysis at home. Minor inflationary updates have not accounted for the increased demand for home training nurses and staffing intensive TCU programs. Technological advances, like remote patient monitoring and other digital tools could help to fill the gap. A commenter noted that a TEP convened in May 2020 concluded that

facilities spent between 7.5 and 8 hours training patients on home hemodialysis. CMS is encouraged to conduct an analysis to determine a more accurate number of hours per session needed for successful home dialysis training and subsequently revise the home dialysis training add-on payment amount to capture growing costs.

Interested parties have reported barriers to physician training in home dialysis modalities has led to a reluctance to prescribe these therapies in practice. Additionally, the home dialysis training service codes, CPT codes 90989 (for a completed course of home dialysis training) and 90993 (for a single training session when the course is not completed) have not been updated. These are unique service codes in that they do not have relative value units (RVUs) assigned to them but rather flat rates of $500 for 90989 and $20 per session for 90993. Stakeholders believe an adjustment of this fee to $1,500 to $2000 would be a step in the right direction for incentivizing the nephrologists to offer home modality to their patients. Additionally, stakeholders recommend that CMS issue a transmittal for Medicare Administrative Contractors (MACs) clarifying that home dialysis training via CPT codes 90989 and 90993 are covered services in the Medicare physician fee schedule.

Response: We appreciate all the comments on and interest in the topics. We note that several of the suggestions made by commenters are beyond the scope of CMS' rulemaking authority. Nonetheless, we highly value this input, as it is essential to deliberations on future model successors and ESRD policy development as we work to advance administration initiatives to expand access to home dialysis and increase transplantation efforts.

With respect to comments on fraud and abuse laws, thank you for the comments related to certain arrangements that facilitate value-based health care delivery and payment. We note that to the extent such arrangements create financial relationships for purposes of the physician self-referral law, we see no reason why the parties to the arrangements described by the commenters could not use existing exceptions to the physician self-referral law, including those for value-based arrangements, and why the financial relationships could not be structured to satisfy the requirements of an existing applicable exception. Also, CMS may determine that the AKS safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (42 CFR 1001.952(ii)) is available to protect remuneration exchanged pursuant to certain financial arrangements or patient incentives permitted under future models. Such determination, if any, would be set forth in documentation separately issued by CMS.

Final Decision: We intend to use comments received in response to this RFI to inform future policy development. CMS would propose any potential changes to payment policies through a separate notice and comment rulemaking.

2. Exemption of the RFI From the Paperwork Reduction Act Implementing Regulations

Please note, this is a RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the United States Government to contract for any supplies or services or make a grant award. Further, we did not seek proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the United States Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. Not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. Please note that we will not respond to questions about the policy issues raised in this RFI. We may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the United States Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the United States Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become United States Government property and will not be returned. We may publicly post the comments received, or a summary thereof.

VI. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ESRD QIP—Wage Estimates (OMB Control Numbers 0938–1289 and 0938–1340)

We refer readers to the CY 2024 ESRD PPS final rule for information regarding wage estimates and resulting information collection burden calculations used in this final rule (88 FR 76484 through 76485). To derive wage estimates in the CY 2025 ESRD PPS proposed rule, we used data from the United States Bureau of Labor Statistics' May 2022 National Occupational Employment and Wage Estimates for Medical Records

Specialists, who are responsible for organizing and managing health information data, are the individuals tasked with submitting measure data to the ESRD Quality Reporting System (EQRS) (formerly, CROWNWeb) and the Centers for Disease Control and Prevention's (CDC's) NHSN, as well as compiling and submitting patient records for the purpose of data validation (89 FR 55825). In the proposed rule, we noted that when this analysis was conducted, the most recently available median hourly wage of a Medical Records Specialist was $22.69 per hour.[121] In this final rule, we are updating the median hourly wage to $23.45 per hour, which reflects the most recently available data from the United States Bureau of Labor Statistics' May 2023 National Occupational Employment and Wage Estimates.[122] We also calculate fringe benefit and overhead at 100 percent. We adjusted these employee hourly wage estimates by a factor of 100 percent to reflect current HHS department-wide guidance on estimating the cost of fringe benefits and overhead. Using these assumptions, in the proposed rule we estimated an hourly labor cost of $45.38 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP (89 FR 55825). In this final rule, we are updating our previously estimated hourly labor cost to $46.90 as the basis of the wage estimates for all collections of information calculations in the ESRD QIP.

We used this wage estimate, along with updated facility and patient counts, to update our estimate for the total information collection burden in the ESRD QIP for PY 2027. We provide the re-estimated information collection burden associated with the PY 2027 ESRD QIP in section VI.C of this final rule.

B. Estimated Burden Associated With the Data Validation Requirements for PY 2027 (OMB Control Numbers 0938–1289 and 0938–1340)

We refer readers to the CY 2024 ESRD PPS final rule for information regarding the estimated burden associated with data validation requirements for PY 2027 (88 FR 76485 through 76486). In the CY 2024 ESRD PPS final rule, we estimated that the aggregate cost of the EQRS data validation for PY 2027 would be approximately $34,035 (750 hours × $45.38), or an annual total of approximately $113.45 ($34,035/300 facilities) per facility in the sample. In this final rule, we are updating the aggregate cost of EQRS data validation for PY 2027 to reflect updated wage estimates. Using the most recently available data, we estimate that the aggregate cost of the EQRS data validation for PY 2027 would be approximately $35,175 (750 hours × $46.90), or an annual total of approximately $117.25 ($35,175/300 facilities) per facility in the sample. The burden cost increase associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1289; Expiration date: November 30, 2025). In the CY 2024 ESRD PPS final rule and re-stated in the CY 2025 ESRD PPS proposed rule, we estimated that the aggregate cost of the NHSN data validation for PY 2027 would be approximately $68,070 (1,500 hours × $45.38), or a total of approximately $226.90 ($68,070/300 facilities) per facility in the sample (89 FR 55826). We are updating the aggregate cost of NHSN data validation to reflect updated wage estimates in this final rule. Based on the updated wage data, we estimate that the aggregate cost of the NHSN data validation for PY 2027 would be approximately $70,350 (1,500 hours × $46.90), or a total of approximately $234.50 ($70,350/300 facilities) per facility in the sample. While the burden hours estimate would not change, the burden cost updates associated with these requirements will be submitted to OMB in the revised information collection request (OMB control number 0938–1340; Expiration date: November 30, 2025).

C. Estimated EQRS Reporting Requirements for PY 2027 (OMB Control Number 0938–1289)

To estimate the burden associated with the EQRS reporting requirements (previously known as the CROWNWeb reporting requirements), we look at the total number of patients nationally, the number of data elements per patient-year that the facility would be required to submit to EQRS for each measure, the amount of time required for data entry, the estimated wage plus benefits applicable to the individuals within facilities who are most likely to be entering data into EQRS, and the number of facilities submitting data to EQRS. In the CY 2024 ESRD PPS final rule, we estimated that the burden associated with EQRS reporting requirements for the PY 2027 ESRD QIP was approximately $130.5 million for approximately 2,877,743 total burden hours (88 FR 76486).

We are finalizing changes to the ESRD QIP measure set in this final rule, but do not anticipate that any of these policies would affect the burden we have previously estimated for EQRS reporting requirements for PY 2027. Beginning with PY 2027, we are finalizing our proposal to replace the Kt/V Dialysis Adequacy Comprehensive measure with a Kt/V Dialysis Adequacy Measure Topic. However, we are not updating facility reporting requirements as part of that finalized policy. Additionally, although we are finalizing our proposal to remove one measure from the ESRD QIP measure set beginning with PY 2027, the measure removal would not impact EQRS reporting requirements on facilities. We provided the burden estimate for PY 2027 in the CY 2025 ESRD PPS proposed rule (89 FR 55826) and are updating the information collection burden to reflect updated wage estimates, along with updated facility and patient counts, in this final rule. In the CY 2025 ESRD PPS proposed rule, we estimated that the amount of time required to submit measure data to EQRS would be 2.5 minutes per element and did not use a rounded estimate of the time needed to complete data entry for EQRS reporting. We are further updating these estimates in this final rule. There are 136 data elements for 511,957 patients across 7,695 facilities, for a total of 69,626,152 elements (136 data elements × 511,957 patients). At 2.5 minutes per element, this would yield approximately 377.01 hours per facility. Therefore, the PY 2027 burden would be 2,901,090 hours (377.01 hours × 7,695 facilities). Using the updated wage estimate for a Medical Records Specialist, we estimate that the PY 2027 total burden cost would be approximately $136.1 million (2,901,090 hours × $46.90). The information collection request under the OMB Control Number: 0938–1289 will be revised and sent to OMB.

D. ESRD Treatment Choices Model

Section 1115A(d)(3) of the Act exempts Innovation Center model tests and expansions, which include the ETC Model, from the provisions of the PRA. Specifically, this section provides that the provisions of the PRA do not apply to the testing and evaluation of Innovation Center models or to the expansion of such models.

VII. Regulatory Impact Analysis

A. Statement of Need

1. ESRD PPS

On January 1, 2011, we implemented the ESRD PPS, a case-mix adjusted, bundled PPS for renal dialysis services

[121] *https://www.bls.gov/oes/2022/may/oes292072.htm.*

[122] *https://www.bls.gov/oes/current/oes292072.htm.*

furnished by ESRD facilities as required by section 1881(b)(14) of the Act, as added by section 153(b) of MIPPA (Pub. L. 110–275). Section 1881(b)(14)(F) of the Act, as added by section 153(b) of MIPPA, and amended by section 3401(h) of the Affordable Care Act (Pub. L. 111–148), established that beginning CY 2012, and each subsequent year, the Secretary shall annually increase payment amounts by an ESRD market basket percentage increase, reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. This final rule includes updates and policy changes to the ESRD PPS for CY 2025. These changes include a new wage index methodology which utilizes BLS data and reflects revised OMB CBSA delineations, a wage index budget-neutrality adjustment factor, an expansion to the ESRD PPS outlier list, methodological changes to the outlier calculation, updates to the TPNIES offset amount, updates to the post-TDAPA add-on payment adjustment amounts for Korsuva® and Jesduvroq, changes to the LVPA payment structure, and an increase to the calculation of the TDAPA for phosphate binders. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2025 for renal dialysis services furnished to ESRD beneficiaries.

This final rule also has several policy changes to improve payment stability and adequacy under the ESRD PPS. These include updates to the LVPA and payments for ESRD outlier services. We believe that each of these changes will improve payment stability and adequacy under the ESRD PPS.

2. AKI

This rule finalizes updates to the payment rate for renal dialysis services furnished by ESRD facilities to individuals with AKI. Additionally, we are extending Medicare payment for home dialysis to beneficiaries with AKI. As discussed in section III.C of this final rule, we also are applying the updates to the ESRD PPS base rate, wage index, and training add-on payment adjustment for home dialysis to the AKI dialysis payment rate. Failure to publish this final rule would result in ESRD facilities not receiving appropriate payments in CY 2025 for renal dialysis services furnished to patients with AKI in accordance with section 1834(r) of the Act.

3. ESRD QIP

Section 1881(h)(1) of the Act requires CMS to reduce the payments otherwise made to a facility under the ESRD PPS for a year by up to two percent if the facility does not satisfy the requirements of the ESRD QIP for that year. This rule finalizes updates for the ESRD QIP, which would remove the NHSN Dialysis Event reporting measure from the ESRD QIP measure set beginning with PY 2027 and replace the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027.

4. ETC Model

The ETC Model is a mandatory Medicare payment model tested under the authority of section 1115A of the Act, which authorizes the Innovation Center to test innovative payment and service delivery models expected to reduce Medicare, Medicaid, and CHIP expenditures while preserving or enhancing the quality of care furnished to the beneficiaries of such programs.

This final rule finalizes a change to the ETC Model, specifically to the methodology CMS uses to identify transplant failures for the purposes of defining an ESRD beneficiary and attributing an ESRD beneficiary to the ETC Model. As described in detail in section V.B of this final rule, we believe it is necessary, for the purposes of accuracy, to adopt this change to the ETC Model.

B. Overall Impact Analysis

We have examined the impacts of this final rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094, entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the 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). Executive Order 14094 amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1). Based on our estimates of the combined impact of the ESRD PPS, ESRD QIP, and ETC provisions in this final rule, OIRA has determined this rulemaking is significant under section 3(f)(1) of E.O. 12866. Accordingly, we have prepared a Regulatory Impact Analysis that presents the costs and benefits of the rulemaking to the best of our ability. Pursuant to Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act), OIRA has determined that this rule meets the criteria set forth in 5 U.S.C. 804(2). Therefore, OMB has reviewed this final regulation, and the Department has provided the following assessment of their impact.

1. ESRD PPS

We estimate that the final revisions to the ESRD PPS would result in an increase of approximately $260 million in Medicare payments to ESRD facilities in CY 2025. This includes $220 million associated with the payment rate update, the updated post-TDAPA add-on payment adjustment amounts, and continuation of the approved TDAPA as identified in Table 19. This also includes approximately $40 million for the additional TDAPA payment for operational costs in excess of 100 percent of ASP for phosphate binders, which is derived from 6 percent of per-patient phosphate binder spending based on utilization and cost data as discussed in section II.B.7.c. of this final rule. In addition, this amount includes, but is not impacted by, the following budget neutral changes to the ESRD PPS: updates to the outlier list, updates to the outlier methodology and thresholds, updates to the wage index methodology, updates to the OMB CBSA delineations, and changes to the LVPA.

Although the incorporation of oral-only renal dialysis drugs and biological products into the ESRD PPS in CY 2025 is provided for by existing regulations and is not impacted by this final rule, we estimate for reference that total ESRD PPS spending for phosphate binders will be approximately $870 million ($220 million in beneficiary coinsurance payments and $650 million in Medicare Part B spending) in CY 2025 for the original phosphate binder TDAPA payment at 100 percent of ASP; however we note that these drugs are currently being paid for under Medicare Part D, which we estimate will lead to a decrease in spending of approximately $690 million ($0 million in beneficiary premium offset and $690 million in Medicare Part D spending), for a net payment increase of approximately $180 million.

2. AKI

We estimate that the final updates to the AKI payment rate will result in an increase of approximately $2 million in Medicare payments to ESRD facilities in CY 2025.

3. ESRD QIP

We estimate that, as a result of our previously finalized policies and the policies we are finalizing in this final rule, the updated ESRD QIP will result in $17.9 million in estimated payment reductions across all facilities for PY 2027.

4. ETC Model

The change we are finalizing is the definition of an ESRD Beneficiary for the purposes of attribution in the ETC Model. This policy change is not expected to change the model's projected economic impact.

5. Summary of Impacts

We estimate that the combined impact of the policies finalized in this rule on payments for CY 2025 is $260 million based on the estimates of the updated ESRD PPS and the AKI payment rates. We estimate the impacts of the ESRD QIP for PY 2027 to be $136.1 million in information collection burden and $17.9 million in estimated payment reductions across all facilities. Finally, we estimate that the final methodology change to the ETC Model will not affect the model's projected economic impact described in the Specialty Care Models final rule (85 FR 61114) and in the CY2022 ESRD PPS final rule (86 FR 61874).

C. Detailed Economic Analysis

In this section, we discuss the anticipated benefits, costs, and transfers associated with the changes in this final rule. Additionally, we estimate the total regulatory review costs associated with reading and interpreting this final rule.

1. Benefits

Under the CY 2025 ESRD PPS and AKI payment, ESRD facilities will continue to receive payment for renal dialysis services furnished to Medicare beneficiaries under a case-mix adjusted PPS. We continue to expect that making prospective Medicare payments to ESRD facilities will enhance the efficiency of the Medicare program. Additionally, we expect that updating the Medicare ESRD PPS base rate and rate for AKI treatments furnished by ESRD facilities by 2.2 percent based on the final CY 2025 ESRDB market basket percentage increase of 2.7 percent reduced by the final CY 2025 productivity adjustment of 0.5 percentage point 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 delivering renal dialysis services. We estimate that overall payments under the ESRD PPS will increase by 2.7 percent as a result of the finalized policies in this rule.

2. Costs

a. ESRD PPS and AKI

We do not anticipate the provisions of this final rule regarding ESRD PPS and AKI rates-setting will create additional cost or burden to ESRD facilities.

b. ESRD QIP

We have made no changes to our methodology for calculating the annual burden associated with the information collection requirements for EQRS data validation (previously known as the CROWNWeb validation study) or NHSN data validation. Although we do not anticipate that the policies finalized in this final rule regarding ESRD QIP will create additional cost or burden to ESRD facilities for PY 2027, we are updating the estimated costs associated with the information collection requirements under the ESRD QIP, with updated estimates of the total number of ESRD facilities, the total number of patients nationally, wages for Medical Records Specialists or similar staff, and a refined estimate of the number of hours needed to complete data entry for EQRS reporting.

3. Transfers

We estimate that the updates to the ESRD PPS and AKI payment rates will result in a total increase of approximately $220 million in Medicare payments to ESRD facilities in CY 2025, which includes the amount associated with final updates to the outlier thresholds, and final updates to the wage index. This estimate includes an increase of approximately $2 million in Medicare payments to ESRD facilities in CY 2025 due to the updates to the AKI payment rate, of which approximately 20 percent is increased beneficiary coinsurance payments. We estimate approximately $180 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $40 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments because of this final rule.

We also estimate that the updates to the TDAPA payment policy for phosphate binders will result in an increase of approximately $40 million in Medicare payments to ESRD facilities in CY 2025, which includes approximately $30 million in transfers from the Federal Government to ESRD facilities due to increased Medicare program payments and approximately $10 million in transfers from beneficiaries to ESRD facilities due to increased beneficiary coinsurance payments.

4. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this ESRD PPS final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the ESRD PPS final rule, we assume that the total number of unique commenters on this year's ESRD PPS proposed rule, which was 191 for the CY 2025 ESRD PPS proposed rule, is equal to the number of individual reviewers of this final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed this year's proposed rule in detail, and it is also possible that some reviewers chose not to comment on the CY 2025 ESRD PPS proposed rule. For these reasons we determined that the number of past commenters would be a fair estimate of the number of reviewers of this final rule. We used a similar methodology for calculating the regulatory review costs in the CY 2025 ESRD PPS proposed rule; in that proposed rule we welcomed any comments on the approach in estimating the number of entities which would review that proposed rule and did not receive any direct responses.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final

rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of this proposal. We sought comments on this assumption.

Using the May 2023 wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing this rule is $129.28 per hour, including overhead and fringe benefits [123] (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed of 250 words per minute, we estimate that it will take approximately 260 minutes (4.33 hours) for the staff to review half of this final rule, which has a total of approximately 130,000 words. For each entity that reviews the rule, the estimated cost is $559.78 (4.33 hours × $129.28). Therefore, we estimate that the total cost of reviewing this regulation is $106,917.98 ($559.78 × 191).

[123] Calculated by multiplying the mean wage for medical and health service managers by 2 to account for overhead and fringe benefits.

5. Impact Statement and Table

a. CY 2025 End-Stage Renal Disease Prospective Payment System

(1) Effects on ESRD Facilities

To understand the impact of the changes affecting Medicare payments to different categories of ESRD facilities, it is necessary to compare estimated payments in CY 2024 to estimated payments in CY 2025. To estimate the impact among various types of ESRD facilities, it is imperative that the estimates of Medicare payments in CY 2024 and CY 2025 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this final rule, we used CY 2023 data from the Medicare Part A and Part B Common Working Files as of August 02, 2024, as a basis for Medicare dialysis treatments and payments under the ESRD PPS. We updated the 2023 claims to 2024 and 2025 using various updates. The final updates to the ESRD PPS base rate are described in section II.B.4 of this final rule. Table 19 shows the impact of the estimated CY 2025 ESRD PPS payments compared to estimated Medicare payments to ESRD facilities in CY 2024.

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TABLE 19: Impacts of the Final Changes in Medicare Payments to ESRD Facilities for CY 2025

Facility Type	Number of Facilities (A)	Number of Treatments (in millions) (B)	Routine Changes to Outlier Policy (C)	LVPA Changes (D)	Changes to TDAPA and Post-TDAPA Payments[1] (E)	Addition of Composite Rate Drugs to Outlier Services (F)	Wage Index Methodology Changes and updates to the CBSA delineations (G)	Total Percent Change[2] (H)
All Facilities	7,718	27.4	0.4%	0.0%	0.1%	0.0%	0.0%	2.7%
Type								
Freestanding	7,367	26.3	0.4%	0.0%	0.1%	0.0%	0.0%	2.6%
Hospital-based	351	1.1	1.4%	0.0%	0.1%	0.3%	0.4%	4.5%
Ownership Type								
Large dialysis organization	5,961	21.3	0.4%	0.0%	0.1%	0.0%	0.2%	2.8%
Regional chain	912	3.3	0.5%	0.0%	0.0%	0.0%	-0.3%	2.4%
Independent	485	1.7	0.6%	0.0%	0.1%	-0.1%	-1.9%	0.8%
Hospital-based	351	1.1	1.4%	0.0%	0.1%	0.3%	0.4%	4.5%
Unknown	9	0.0	0.6%	0.0%	0.1%	-0.2%	-2.2%	0.4%
Geographic Location								
Rural	1,245	3.8	0.4%	0.0%	0.1%	0.0%	1.7%	4.4%
Urban	6,473	23.6	0.4%	0.0%	0.1%	0.0%	-0.2%	2.4%
Census Region								
East North Central	1,191	3.7	0.4%	0.0%	0.1%	0.0%	0.0%	2.6%
East South Central	603	1.7	0.3%	0.0%	0.1%	0.0%	2.5%	5.1%
Middle Atlantic	872	3.5	0.6%	0.0%	0.1%	0.0%	-1.2%	1.5%
Mountain	438	1.5	0.3%	0.0%	0.1%	0.0%	1.6%	4.3%
New England	199	1.0	0.4%	0.0%	0.1%	0.0%	1.9%	4.6%
Pacific[3]	986	4.9	0.4%	0.0%	0.1%	-0.1%	-2.4%	0.2%
Puerto Rico and Virgin Islands	54	0.1	0.3%	0.0%	0.1%	-0.1%	2.6%	5.2%
South Atlantic	1,802	5.9	0.5%	0.0%	0.1%	0.0%	1.1%	3.8%
West North Central	477	1.5	0.5%	0.0%	0.1%	0.1%	-0.5%	2.4%
West South Central	1,096	3.5	0.4%	0.0%	0.0%	0.0%	1.3%	4.0%
Facility Size								
Less than 3,000 treatments	673	0.5	0.4%	0.8%	0.1%	0.2%	0.6%	4.3%
3,000 to 3,999 treatments	474	0.7	0.4%	-0.5%	0.1%	0.0%	0.4%	2.7%
4,000 to 4,999 treatments	540	1.0	0.4%	0.0%	0.1%	0.0%	0.7%	3.4%
5,000 to 9,999 treatments	2,928	8.2	0.4%	0.0%	0.1%	0.0%	0.7%	3.3%
10,000 or more treatments	3,103	17.0	0.5%	0.0%	0.1%	0.0%	-0.4%	2.3%

Unknown	0	0.0	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
Percentage of Pediatric Patients								
Less than 2%	7,621	27.2	0.4%	0.0%	0.1%	0.0%	0.0%	2.7%
Between 2% and 19%	34	0.2	0.5%	0.0%	0.1%	0.0%	1.3%	4.1%
Between 20% and 49%	7	0.0	0.1%	0.4%	0.1%	1.9%	0.1%	4.8%
More than 50%	56	0.0	-0.1%	0.0%	0.1%	0.6%	0.3%	3.0%

[1]This column includes the impact of the end of TDAPA payment for Jesduvroq and the final post-TDAPA add-on payment adjustment amount for Korsuva® and the presented post-TDAPA add-on payment adjustment amount for Jesduvroq (beginning October 1, 2025). This column does not include the TDAPA for phosphate binders.

[2] This column includes the impact of the final updates in columns (C) through (F) in Table 19, and of the final ESRDB market basket percentage increase for CY 2025 of 2.7 percent, reduced by 0.5 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category and column B indicates the number of dialysis treatments (in millions). The overall effect of the final routine updates to the outlier payment policy, including final changes to the inflation factors used for calculating MAP and FDL amounts described in section II.B.3 of this final rule, is shown in column C. For CY 2025, the impact on all ESRD facilities because of the final changes to the outlier payment policy would be an increase in estimated Medicare payments of approximately 0.4 percent.

Column D shows the effect of the final 2-tiered LVPA as described in section II.B.8 of this final rule. This adjustment is implemented in a budget neutral manner, so the total impact of this change will be 0.0 percent. However, there will be distributional impacts of this change, primarily increasing payments to facilities that furnish fewer than 3,000 treatments by 0.8 percent and lowering payments to ESRD facilities that furnish between 3,000 and 4,000 treatments by 0.5 percent. Because we are finalizing our proposal to use the scaled adjustment factors, the only impact of this policy is among ESRD facilities that are eligible for the LVPA.

Column E shows the effect of year-over-year payment changes related to the post-TDAPA add-on payment adjustment amounts as described in section II.B.6 of this final rule and current TDAPA payments. The post-TDAPA add-on payment adjustment will not be budget neutral, but the total impact on payment is 0.1 percent due to relatively low utilization of drugs for which we will pay this adjustment in CY 2025.

Column F reflects the impact of the expansion of outlier eligibility to formerly composite rate drugs. Overall, the changes to the outlier policy, including those reflected in column C of this table, are budget neutral insofar as we estimate that we will better hit the 1 percent target for outlier payments. These changes will increase payments for facilities that treat a higher proportion of exceptionally costly cases.

Column G reflects the effect of the finalized changes to the ESRD PPS wage index methodology, the adoption of the new OMB CBSA delineations, the continued application of the 5 percent cap on wage index decreases, and the rural transition policy as described in section II.B.2 of this final rule. This update will be budget neutral, so the total impact of this policy change is 0.0 percent. However, there will be distributional impacts of this change. The largest increase will be to ESRD facilities in Puerto Rico and the Virgin Islands, which would receive 2.6 percent higher payments because of the updated ESRD PPS wage index. The largest decrease would be for ESRD facilities in the Pacific Census region, which will receive 2.4 percent lower payments because of the updated ESRD PPS wage index and methodological changes.

Column H reflects the overall impact, that is, the effects of the outlier policy changes, LVPA changes, the post-TDAPA add-on payment adjustment amounts, the new wage index methodology, the new CBSA delineations, the rural transition policy, and the payment rate update as described in section II.B.4 of this final rule. The final ESRD PPS payment rate update for CY 2025 is 2.2 percent, which reflects the final ESRDB market basket percentage increase for CY 2025 of 2.7 percent and the productivity adjustment of 0.5 percentage point. We expect that overall ESRD facilities will experience a 2.7 percent increase in estimated Medicare payments in CY 2025. The categories of types of ESRD facilities in the impact table show impacts ranging from a 0.2 percent increase to a 5.2 percent increase in their CY 2025 estimated Medicare payments.

This table does not include the impact of the inclusion of oral-only drugs to the ESRD PPS as we are unable to calculate facility level estimates at this time, nor does it include the impacts of the increase to the TDAPA amount for phosphate binders as finalized in section II.B.7.c of this final rule. We cannot include the impact of this final change in Table 19 because we do not have the patient-level utilization data required to model facility-level uptake. As noted previously, the overall impact of this TDAPA increase is approximately $40 million. Furthermore, we note that the incorporation of oral-only renal dialysis drugs and biological products into the ESRD PPS beginning in CY 2025 is provided for by existing regulations and is not impacted by this final rule, other than the change in the TDAPA amount for phosphate binders. For public awareness, we estimate an increase in Medicare Part B spending of approximately $870 million in CY 2025, and a corresponding decrease in Medicare Part D spending of approximately $690 million in CY 2025, associated with payment for phosphate binders under the ESRD PPS.

(2) Effects on Other Providers

Under the ESRD PPS, Medicare pays ESRD facilities a single bundled payment for renal dialysis services,

which may have been separately paid to other providers (for example, laboratories, durable medical equipment suppliers, and pharmacies) by Medicare prior to the implementation of the ESRD PPS. Therefore, in CY 2025, we estimate that the ESRD PPS would have zero impact on these other providers.

(3) Effects on the Medicare Program

We estimate that Medicare spending (total Medicare program payments) for ESRD facilities in CY 2025 would be approximately $6.2 billion. This estimate considers a projected decrease in fee-for-service Medicare ESRD beneficiary enrollment of 2.1 percent in CY 2025.

(4) Effects on Medicare Beneficiaries

Under the ESRD PPS, beneficiaries are responsible for paying 20 percent of the ESRD PPS payment amount. As a result of the projected 2.7 percent overall increase in the CY 2025 ESRD PPS payment amounts, we estimate that there would be an increase in beneficiary coinsurance payments of 2.7 percent in CY 2025, which translates to approximately $40 million.

As we have previously noted, the incorporation of oral-only renal dialysis drugs and biological products into the ESRD PPS in CY 2025 is provided for by existing regulations and is not impacted by this final rule. For public awareness, we estimate an increase in beneficiary coinsurance payments of $230 million. As noted in section II.B.7 of this final rule, we anticipate that the inclusion of oral-only drugs in the ESRD PPS will increase access to these drugs for beneficiaries, particularly disadvantaged populations who currently do not have Part D coverage.

(5) Alternatives Considered

(a) Wage Index Changes

We considered, but did not finalize, a one-year delay to the implementation date for the new ESRD PPS wage index methodology. This delay would have allowed us further time to consider several potential methodological suggestions, including MedPAC's suggestions for smoothing across and variation within CBSAs. However, we have decided that such a delay is not appropriate, because we believe the new ESRD PPS wage index methodology is the best estimation available for the geographic variation in wages ESRD facilities face. We considered MedPAC's suggestions for the proposed rule and decided that they would introduce additional complexity and would involve parameters which could be seen as arbitrary for purposes of estimating wages for occupations related to furnishing renal dialysis services and involve lower-quality data sources. These alternatives would not have any specific impact on small entities as discussed in section VII.E of this final rule.

(b) Expansion of Outlier Eligibility

We considered only expanding outlier eligibility to drugs and biological products previously paid for under the TDAPA after the end of the TDAPA period. As discussed in section II.B.3.b of this final rule, we have instead decided to finalize to expand outlier eligibility to all drugs and biological products that were or would have been composite rate services prior to the inception of the ESRD PPS. We believe that this is appropriate because formerly composite rate drugs represent potentially significant costs which are not currently accounted for by the outlier adjustment. Furthermore, most of the commenters' concerns with the inclusion of composite rate drugs revolved around concerns that should we overestimate outliers in one year we would reduce the ESRD PPS base rate in future years, which is with a misinterpretation of our outlier policy. These alternatives would not have any specific impact on small entities as discussed in section VII.E of this final rule.

(c) TDAPA Amount for Phosphate Binders

We considered, but are not finalizing, paying the TDAPA for phosphate binders based on 106 percent of ASP, rather than the fixed addition to the TDAPA amount which we have finalized. Paying the TDAPA for phosphate binders at 106 percent of ASP for at least 2 years to mirror our TDAPA payment approach for the first 2 years for calcimimetics would have many of the same effects of the flat TDAPA increase we finalized, as we based the size of the flat increase off of 6 percent of TDAPA expenditures. However, as discussed in section II.B.7.c of this final rule, we believe that paying 106 percent of ASP could potentially incentivize ESRD facilities to prescribe higher-cost phosphate binders to receive additional payment. We note that our final policy, with respect to TDAPA payment for phosphate binders, would best support small entities, as discussed in section VII.E of this final rule, as we expect small entities would have less bargaining power than large entities in negotiating prices for phosphate binders.

(d) Changes to the LVPA

We considered, but did not finalize, a three tier LVPA which would be funded by eliminating the rural facility adjustment. This was a suggestion of several commenters who recommended the LVPA be expanded beyond the current 4,000 treatment volume threshold. However, our analysis found that the elimination of the rural facility adjustment would not provide nearly enough funds to establish a third LVPA tier, even if we were to lower the treatment volume threshold to 5,000 from the 6,000 suggested by commenters. As discussed in section II.B.8.c of this final rule, we are finalizing a two-tiered scaled LVPA in part because it would not lead to any budget neutrality reduction to the ESRD PPS base rate. In the proposed rule, we presented an alternative three-tiered LVPA which could be implemented by reducing the base rate, but commenters were generally not supportive of the idea. Although our proposal did not involve the elimination of the rural facility adjustment and the reallocation of those funds, we did not believe that commenters would support the proposal. Additionally, we believe that the rural facility adjustment is a useful tool which protects ESRD facilities in potentially vulnerable areas. The continued use of the rural facility adjustment likely benefits small entities, as discussed in section VII.E of this final rule, operating in rural areas. As discussed previously, eliminating the rural facility adjustment would not provide enough funds to fully cover the suggested approach, so such a policy would require budget neutrality reduction which would reduce payment to small entities that receive the LVPA.

b. Continuation of Approved Transitional Drug Add-On Payment Adjustments (TDAPA) for New Renal Dialysis Drugs or Biological Products for CY 2025

Two renal dialysis drugs for which the TDAPA was paid in CY 2024 will continue to be eligible for the TDAPA in CY 2025.

(1) Jesduvroq (Daprodustat)

On July 27, 2023, CMS Transmittal 12157 [124] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for Jesduvroq (daprodustat). The TDAPA payment period began on October 1, 2023, and will continue through September 30, 2025. As stated previously, TDAPA

[124] CMS Transmittal 12157, dated July 27, 2023, is available at: *https://www.cms.gov/files/document/r12157cp.pdf.*

payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

In the proposed rule, we based our impact analysis on the most current 72x claims data from November 2023, when utilization first appeared on the claims, through February 2024. During that timeframe, the average monthly TDAPA payment amount for Jesduvroq (daprodustat) was $23,075. In applying that average to each of the 9 remaining months of the TDAPA payment period in CY 2025, we estimated $207,675 in spending ($23,075 * 9 = $207,675) of which, approximately $41,535 ($207,675 * 0.20 = $41,535) would have been attributed to beneficiary coinsurance amounts.

Several commenters indicated that GlaxoSmithKline (GSK), Jesduvroq's manufacturer, is removing the drug from the market. The FDA's Orange Book [125] identifies Jesduvroq's marketing status as discontinued. GSK indicated that the change in marketing status does not reflect a change in availability or in FDA's approval of the product. GSK could not state definitively that there will be no TDAPA claims in CY 2025. Because we have no way of estimating how the change in Jesduvroq's marketing status will affect utilization, we have carried the proposed rule estimates forward unchanged. That is, we estimate $207,675 in spending, of which, approximately $41,535 will be attributed to beneficiary coinsurance amounts.

(2) DefenCath® (Taurolidine and Heparin Sodium)

On May 9, 2024, CMS Transmittal 12628 [126] implemented the 2-year TDAPA period specified in § 413.234(c)(1) for DefenCath® (taurolidine and heparin sodium). The TDAPA payment period began on July 1, 2024, and will continue through June 30, 2026. As stated previously, TDAPA payment is based on 100 percent of ASP. If ASP is not available, then the TDAPA is based on 100 percent of WAC and, when WAC is not available, the payment is based on the drug manufacturer's invoice.

As of the drafting of this final rule, DefenCath® was in the first few months of the TDAPA payment period. Complete claims data, upon which we could base CY 2025 Medicare impact estimates, was limited to the month of July 2024. Due to the limited timeframe of complete and available claims data, we believe that it would have been more appropriate to base Medicare impacts on cost and utilization volume estimates furnished by the manufacturer, recognizing that the manufacturer is most familiar with the market conditions affecting its products. We requested but did not receive utilization volume estimates from the manufacturer. Therefore, we based our impact analysis on the most current 72x claims data for the month of July 2024, when utilization first appeared on the claims. In July 2024, the average monthly TDAPA payment amount for DefenCath® was $2,118,827. In applying that average to each of the 12 months of the TDAPA payment period in CY 2025, we estimate $25,425,924 in spending ($2,118,827 * 12 = $25,425,924) of which, approximately $5,085,184 ($25,425,924 * 0.20 = $5,085,184) will be attributed to beneficiary coinsurance amounts.

c. Payment for Renal Dialysis Services Furnished to Individuals With AKI

(1) Effects on ESRD Facilities

To understand the impact of the finalized changes affecting Medicare payments to different categories of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is necessary to compare estimated Medicare payments in CY 2024 to estimated Medicare payments in CY 2025. To estimate the impact among various types of ESRD facilities for renal dialysis services furnished to individuals with AKI, it is imperative that the Medicare payment estimates in CY 2024 and CY 2025 contain similar inputs. Therefore, we simulated Medicare payments only for those ESRD facilities for which we can calculate both current Medicare payments and new Medicare payments.

For this final rule, we used CY 2023 data from the Medicare Part A and Part B Common Working Files as of August 02, 2024, as a basis for Medicare for renal dialysis services furnished to individuals with AKI. We updated the 2023 claims to 2024 and 2025 using various updates. The updates to the AKI payment amount are described in section III.C of this final rule. Table 20 shows the impact of the estimated CY 2025 Medicare payments for renal dialysis services furnished to individuals with AKI compared to estimated Medicare payments for renal dialysis services furnished to individuals with AKI in CY 2024.

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[125] FDA's Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations. Accessed September 26, 2024. Available at: *https://www.accessdata.fda.gov/scripts/cder/ob/results_product.cfm?Appl_Type=N&Appl_No=216951.*

[126] CMS Transmittal 12628, dated May 9, 2024, is available at: *https://www.cms.gov/files/document/r12628CP.pdf.*

TABLE 20: Impacts of the Final Changes in Medicare Payments for Renal Dialysis Services Furnished to Individuals with AKI for CY 2025

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change[1] (D)
All Facilities	5,082	282.6	0.1%	2.3%
Type				
Freestanding	4,974	277.8	0.1%	2.3%
Hospital-based	108	4.8	1.2%	3.4%
Ownership Type				
Large dialysis organization	4,216	233.7	0.2%	2.4%
Regional chain	568	30.4	0.0%	2.2%
Independent	189	13.6	-1.3%	0.8%
Hospital-based[2]	108	4.8	1.2%	3.4%
Unknown	1	0.1	4.3%	6.6%
Geographic Location				
Rural	826	44.7	1.7%	4.0%
Urban	4,256	237.9	-0.1%	2.1%
Census Region				
East North Central	835	44.4	0.2%	2.4%
East South Central	376	17.2	2.5%	4.8%
Middle Atlantic	575	31.9	-1.0%	1.2%
Mountain	314	20.9	0.4%	2.6%
New England	139	7.1	1.6%	3.8%
Pacific[3]	647	48.4	-2.1%	0.0%
Puerto Rico and Virgin Islands	4	0.1	-1.1%	1.0%
South Atlantic	1,197	67.6	1.5%	3.7%
West North Central	322	13.4	-0.4%	1.8%
West South Central	673	31.7	1.4%	3.7%
Facility Size				
Less than 3,000 treatments	204	6.6	0.2%	2.4%
3,000 to 3,999 treatments	247	9.7	0.4%	2.6%
4,000 to 4,999 treatments	320	13.1	0.8%	3.0%
5,000 to 9,999 treatments	2,032	104.4	0.8%	3.0%
10,000 or more treatments	2,279	148.8	-0.4%	1.8%

Facility Type	Number of Facilities (A)	Number of Treatments (in thousands) (B)	Wage Index Changes (C)	Total Percent Change[1] (D)
Unknown	0	0.0	0.0%	0.0%
Percentage of Pediatric Patients				
Less than 2%	5,068	282.1	0.1%	2.3%
Between 2% and 19%	12	0.5	0.8%	3.0%
Between 20% and 49%	1	0.0	0.6%	2.8%
More than 50%	1	0.0	0.5%	2.7%

[1] This column includes the impact of the updates in columns (C) as well as the impact of the wage index budget-neutrality adjustment factor in Table 20, and of the final ESRDB market basket percentage increase for CY 2025 of 2.7 percent, reduced by 0.5 percentage point for the productivity adjustment as required by section 1881(b)(14)(F)(i)(II) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

[2] Includes hospital-based ESRD facilities not reported to have large dialysis organization or regional chain ownership.

[3] Includes ESRD facilities located in Guam, American Samoa, and the Northern Mariana Islands.

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Column A of the impact table indicates the number of ESRD facilities for each impact category, and column B indicates the number of AKI dialysis treatments (in thousands). Column C shows the effect of the final CY 2025 wage index changes, including the changes to the ESRD PPS wage index methodology, the adoption of the new OMB CBSA delineations, the continued application of the 5 percent cap on wage index decreases, and the rural transition policy as described in section II.B.2.f.(2) of this final rule. We note the rural adjustment does not apply to beneficiaries with AKI, so this column only incorporates the budget neutrality factor associated with that policy.

Column D shows the overall impact, that is, the effects of the final wage index budget-neutrality adjustment factor, wage index updates, and the payment rate update of 2.2 percent, which reflects the final ESRDB market basket percentage increase for CY 2025 of 2.7 percent and the final productivity adjustment of 0.5 percentage point, as well as the training add-on budget neutrality reduction of $0.00. We expect that overall ESRD facilities will experience a 2.3 percent increase in estimated Medicare payments in CY 2025 for treatment of AKI beneficiaries. This table does not include any distributional impacts of payments to ESRD facilities associated with the extension of payment for AKI home dialysis or extension of the add-on payment adjustment for training for home and self-dialysis (outside of the budget-neutrality reduction, as discussed), as we are unable to estimate potential uptake at a facility level at this time. The categories of types of ESRD facilities in the impact table show impacts ranging from an increase of 0.0 percent to an increase of 3.8 percent in their CY 2025 estimated Medicare payments for renal dialysis services provided by ESRD facilities to individuals with AKI.

(2) Effects on Other Providers

Under section 1834(r) of the Act, as added by section 808(b) of TPEA, we are finalizing to update the payment rate for renal dialysis services furnished by ESRD facilities to beneficiaries with AKI. The only two Medicare providers and suppliers authorized to provide these outpatient renal dialysis services are hospital outpatient departments and ESRD facilities. The patient and his or her physician make the decision about where the renal dialysis services are furnished. Therefore, this change would have zero impact on other Medicare providers.

(3) Effects on the Medicare Program

We estimate approximately $70 million would be paid to ESRD facilities in CY 2025 because of patients with AKI receiving renal dialysis services in an ESRD facility at the lower ESRD PPS base rate versus receiving those services only in the hospital outpatient setting and paid under the outpatient prospective payment system, where services were required to be administered prior to the TPEA.

(4) Effects on Medicare Beneficiaries

Currently, beneficiaries have a 20 percent coinsurance obligation when they receive AKI dialysis in the hospital outpatient setting. When these services are furnished in an ESRD facility, the patients will continue to be responsible for a 20 percent coinsurance. Because the AKI dialysis payment rate paid to ESRD facilities is lower than the outpatient hospital PPS's payment amount, we expect beneficiaries to pay less coinsurance when AKI dialysis is furnished by ESRD facilities.

(5) Alternatives Considered

As we discussed in the CY 2017 ESRD PPS proposed rule (81 FR 42870), we considered adjusting the AKI payment rate by including the ESRD PPS case-mix adjustments, and other adjustments at section 1881(b)(14)(D) of the Act, as well as not paying separately for AKI specific drugs and laboratory tests. We ultimately determined that treatment for AKI is substantially different from treatment for ESRD, and the case-mix adjustments applied to ESRD patients may not be applicable to AKI patients, and as such, including those policies and adjustments is inappropriate. We

continue to monitor utilization and trends of items and services furnished to individuals with AKI for purposes of refining the payment rate in the future. This monitoring will assist us in developing knowledgeable, data-driven proposals.

As discussed in section III.B of this final rule, we are finalizing payment for AKI dialysis in the home setting, and as discussed in section III.C.3 of this final rule we will apply the home and self-dialysis training add-on payment adjustment for such services provided to AKI patients. We considered paying for AKI home dialysis without the training add-on adjustment; however, we were concerned that access to home dialysis for AKI beneficiaries could be negatively impacted in the absence of an add-on payment adjustment to support home dialysis training. These alternatives would not have any specific impact on small entities as discussed in section VII.E of this final rule.

d. ESRD QIP

(1) Effects of the PY 2027 ESRD QIP on ESRD Facilities

The ESRD QIP is intended to promote improvements in the quality of ESRD dialysis facility services provided to beneficiaries. The general methodology that we use to calculate a facility's TPS is described in our regulations at § 413.178(e).

Any reductions in the ESRD PPS payments as a result of a facility's performance under the PY 2027 ESRD QIP will apply to the ESRD PPS payments made to the facility for services furnished in CY 2027, consistent with our regulations at § 413.177.

For the PY 2027 ESRD QIP, we estimate that, of the 7,695 facilities (including those not receiving a TPS) enrolled in Medicare, approximately 36.9 percent or 2,750 of the facilities that have sufficient data to calculate a TPS would receive a payment reduction for PY 2027. Among an estimated 2,750 facilities that would receive a payment reduction, approximately 63 percent or 1,730 facilities would receive the smallest payment reduction of 0.5 percent. We are updating the estimated impact of the PY 2027 ESRD QIP that we provided in the CY 2024 ESRD PPS final rule (88 FR 76495 through 76497). Based on the policies finalized in this rule, the total estimated payment reductions for all the 2,750 facilities expected to receive a payment reduction in PY 2027 would be approximately $17,887,355. Facilities that do not receive a TPS do not receive a payment reduction.

Table 21 shows the updated overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP.

TABLE 21: Updated Estimated Distribution of PY 2027 ESRD QIP Payment Reductions

Payment Reduction	Number of Facilities	Percent of Facilities*
0.0%	4712	63.2%
0.5%	1730	23.2%
1.0%	760	10.2%
1.5%	177	2.4%
2.0%	83	1.1%

*233 facilities not scored due to insufficient data

To estimate whether a facility would receive a payment reduction for PY 2027, we scored each facility on achievement and improvement on several clinical measures for which there were available data from EQRS and Medicare claims. Payment reduction estimates were calculated using the most recent data available (specified in Table 22) in accordance with the policies finalized in this final rule. Measures used for the simulation are shown in Table 22.

TABLE 22: Data Used to Update the Estimated PY 2027 ESRD QIP Payment Reductions

Measure	Period of time used to calculate achievement thresholds, 50th percentiles of the national performance, benchmarks, and improvement thresholds	Performance period
ICH CAHPS Survey	Jan 2022-Dec 2022	Jan 2023-Dec 2023
SRR	Jan 2022-Dec 2022	Jan 2023-Dec 2023
SHR	Jan 2022-Dec 2022	Jan 2023-Dec 2023
PPPW	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Kt/V Dialysis Adequacy Measure Topic		
Adult HD Kt/V	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Pediatric HD Kt/V	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Adult PD Kt/V	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Pediatric PD Kt/V	Jan 2022-Dec 2022	Jan 2023-Dec 2023
VAT		
% Catheter	Jan 2022-Dec 2022	Jan 2023-Dec 2023
STrR	Jan 2022-Dec 2022	Jan 2023-Dec 2023
NHSN BSI	Jan 2022-Dec 2022	Jan 2023-Dec 2023
Clinical Depression	Jan 2022-Dec 2022	Jan 2023-Dec 2023

For all measures except the SHR clinical measure, the SRR clinical measure, the STrR measure, and the ICH CAHPS measure, measures with less than 11 eligible patients for a facility were not included in that facility's TPS. For the SHR clinical measure and the SRR clinical measure, facilities were required to have at least 5 patient-years at risk and 11 index discharges, respectively, to be included in the facility's TPS. For the STrR clinical measure, facilities were required to have at least 10 patient-years at risk to be included in the facility's TPS. For the ICH CAHPS measure, facilities were required to have at least 30 survey-eligible patients to be included in the facility's TPS. Each facility's TPS was compared to an estimated mTPS and an estimated payment reduction table consistent with the final policies outlined in section IV.B of this final rule. Facility reporting measure scores were estimated using available data from CY 2023. Facilities were required to have at least one measure in at least two domains to receive a TPS.

To estimate the total payment reductions in PY 2027 for each facility resulting from this final rule, we multiplied the total Medicare payments to the facility during the 1-year period between January 2023 and December 2023 by the facility's estimated payment reduction percentage expected under the ESRD QIP, yielding a total payment reduction amount for each facility.

Table 23 shows the updated estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2027. The table also details the distribution of ESRD facilities by size (both among facilities considered to be small entities and by number of treatments per facility), geography (both rural and urban and by region), and facility type (hospital based and freestanding facilities). Given that the performance period used for these calculations differs from the performance period we are using for the PY 2027 ESRD QIP, the actual impact of the PY 2027 ESRD QIP may vary significantly from the values provided here.

TABLE 23: Updated Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027

	Number of Facilities	Number of Treatments 2019 (in millions)	Number of Facilities with QIP Score	Number of Facilities Expected to Receive a Payment Reduction	Payment Reduction (percent change in total ESRD payments)
All Facilities	7,695	27.0	7,462	2,750	-0.27%
Facility Type:					
Freestanding	7,348	26.0	7,135	2,601	-0.26%
Hospital-based	347	1.0	327	149	-0.41%
Ownership Type:					
Large Dialysis	5,942	21.1	5,792	1,934	-0.22%
Regional Chain	908	3.3	881	343	-0.30%
Independent	461	1.6	444	319	-0.79%
Hospital-based (non-chain)	347	1.0	327	149	-0.41%
Unknown	37	0.0	18	5	-0.30%
Facility Size:					
Large Entities	6,850	24.4	6,673	2,277	-0.23%
Small Entities[1]	808	2.6	771	468	-0.63%
Unknown	37	0.0	18	5	-0.30%
Rural Status:					
1) Yes	1,245	3.8	1,209	373	-0.22%
2) No	6,450	23.2	6,253	2,377	-0.28%
Census Region:					
Northeast	1,069	4.4	1,033	393	-0.30%
Midwest	1,663	5.1	1,620	593	-0.27%
South	3,490	11.1	3,374	1,309	-0.28%
West	1,408	6.3	1,371	414	-0.21%
US Territories[2]	65	0.2	64	41	-0.41%
Census Division:					
Unknown	11	0.1	11	7	-0.50%
East North Central	1,188	3.6	1,155	449	-0.29%
East South Central	602	1.7	582	188	-0.22%
Middle Atlantic	870	3.4	836	334	-0.32%
Mountain	438	1.5	425	135	-0.22%
New England	199	1.0	197	59	-0.20%
Pacific	970	4.7	946	279	-0.21%
South Atlantic	1,793	5.9	1,737	698	-0.31%
West North Central	475	1.5	465	144	-0.23%
West South Central	1,095	3.5	1,055	423	-0.28%
US Territories[2]	54	0.1	53	34	-0.39%
Facility Size (# of total treatments)					
Less than 4,000 treatments	1,207	1.5	1,071	362	-0.31%
4,000-9,999 treatments	3,461	9.2	3,377	1,083	-0.23%
Over 10,000 treatments	3,027	16.3	3,014	1,305	-0.30%

[1]Small Entities include hospital-based and satellite facilities, and non-chain facilities based on EQRS.
[2]Includes American Samoa, Guam, Northern Mariana Islands, Puerto Rico, and Virgin Islands.

TABLE 24: Estimated ESRD QIP Aggregate Payment Reductions for Payment Years 2018 through 2027

Payment Year	Estimated Payment Reductions
PY 2027	$17,887,355
PY 2026	$15,990,524 (88 FR 76500)
PY 2025	$32,457,693 (87 FR 67297)
PY 2024	$17,104,031 (86 FR 62011)
PY 2023	$5,548,653 (87 FR 67297)
PY 2022	$0[127] (86 FR 62011)
PY 2021	$32,196,724 (83 FR 57062)
PY 2020	$31,581,441 (81 FR 77960)
PY 2019	$15,470,309 (80 FR 69074)
PY 2018	$11,576,214 (79 FR 66257)

(3) Effects on Medicare Beneficiaries

The ESRD QIP is applicable to ESRD facilities. Since the Program's inception, there is evidence of improved performance on ESRD QIP measures. As we stated in the CY 2018 ESRD PPS final rule, one objective measure we can examine to demonstrate the improved quality of care over time is the improvement of performance standards (82 FR 50795). As the ESRD QIP has refined its measure set and as facilities have gained experience with the measures included in the Program, performance standards have generally continued to rise. We view this as evidence that facility performance (and therefore the quality of care provided to Medicare beneficiaries) is objectively improving. We continue to monitor and evaluate trends in the quality and cost of care for patients under the ESRD QIP, incorporating both existing measures and new measures as they are implemented in the Program. We will provide additional information about the impact of the ESRD QIP on beneficiaries as we learn more by examining these impacts through the analysis of available data from our existing measures.

(4) Alternatives Considered

In section IV.B.2 of this final rule, we are finalizing the replacement of the Kt/V Dialysis Adequacy Comprehensive clinical measure with a Kt/V Dialysis Adequacy Measure Topic beginning with PY 2027. We considered not adopting this change. However, we concluded that replacing this measure was appropriate to ensure that facilities are scored on Kt/V measure data according to the individual facility's ESRD patient population and treatment modalities.

e. ETC Model

(1) Overview

The ETC Model is a mandatory payment model designed to test payment adjustments to certain dialysis and dialysis-related payments, as discussed in the Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), and the CY 2024 ESRD PPS final rule (88 FR 76344) for ESRD facilities and for Managing Clinicians for claims with dates of service from January 1, 2021, to June 30, 2027. The requirements for the ETC Model are set forth in 42 CFR part 512, subpart C. For the results of the detailed economic analysis of the ETC Model and a description of the methodology used to perform the analysis, see the Specialty Care Models final rule (85 FR 61114).

(2) Data and Methods

A stochastic simulation was created to estimate the financial impacts of the ETC Model relative to baseline expenditures, where baseline expenditures were defined as data from CYs 2018 and 2019 without the changes applied. The simulation relied upon statistical assumptions derived from retrospectively constructed ESRD facilities' and Managing Clinicians' Medicare dialysis claims, transplant claims, and transplant waitlist data reported during 2018 and 2019, the most recent years of complete data available before the start of the ETC Model. Both datasets and the risk-adjustment methodologies for the ETC Model were developed by the CMS Office of the Actuary (OACT).

Table 25 summarizes the estimated impact of the ETC Model when the achievement benchmarks for each year are set using the average of the home dialysis rates for year *t*-1 and year *t*-2 for the HRRs randomly selected for participation in the ETC Model. We estimate that the Medicare program would save a net total of $43 million from the PPA and HDPA between January 1, 2021, and June 30, 2027, less $15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $28 million in savings. This is consistent with the net impact to Medicare spending estimated for the CY 2022 ESRD PPS final rule, in which the net impact to Medicare spending was also estimated to be $28 million in savings (86 FR 62014 through 62016). The minor methodological change to the definition of an ESRD Beneficiary is not expected to change this estimate.

(3) Medicare Estimate—Primary Specification, Assume Rolling Benchmark

TABLE 25: Estimates of Medicare Program Savings (Rounded $M) for ESRD Treatment Choices (ETC) Model

	Year of Model							
	2021	2022	2023	2024	2025	2026	2027	6.5 Year Total*
Net Impact to Medicare Spending	15	9	-1	-9	-12	-19	-9	-28
Overall PPA Net & HDPA	14	7	-3	-11	-15	-22	-12	-43
Clinician PPA Downward Adjustment		-1	-2	-2	-3	-3	-2	-13
Clinician PPA Upward Adjustment		0	1	1	1	1	1	6
Clinician PPA Net		0	-1	-1	-2	-2	-1	-7
Clinician HDPA	0	0	0					0
Facility Downward Adjustment		-9	-20	-25	-31	-39	-21	-145
Facility Upward Adjustment		5	12	15	18	19	10	79
Facility PPA Net		-3	-8	-10	-14	-20	-11	-66
Facility HDPA	14	10	6					29
Total PPA Downward Adjustment		-9	-22	-27	-34	-43	-23	-158
Total PPA Upward Adjustment		6	13	16	19	21	11	84
Total PPA Net		-4	-9	-11	-15	-22	-12	-73
Total HDPA	14	10	6					30
Kidney Disease Patient Education Services Costs	0	1	1	1	1	1	1	5
HD Training Costs	1	1	1	1	2	2	2	10

In Table 25, negative spending reflects a reduction in Medicare spending, while positive spending reflects an increase. The results for this table were generated from an average of 400 simulations under the assumption that benchmarks are rolled forward with a 1.5-year lag. For a detailed description of the key assumptions underlying the impact estimate, see the Specialty Care Models final rule (85 FR 61353) and the CY 2022 ESRD PPS final rule (86 FR 60214 through 60216).

(4) Effects on the Home Dialysis Rate, the Transplant Rate, and Kidney Transplantation

The change finalized in this rule is not expected to impact the findings reported for the effects of the ETC Model on the home dialysis rate or the transplant rate described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017).

(5) Effects on Kidney Disease Patient Education Services and HD Training Add-Ons

The change finalized in this rule is not expected to impact the findings reported for the effects of the ETC Model on kidney disease patient education services and HD training add-ons described in the Specialty Care Models final rule (85 FR 61355) and the CY 2022 ESRD PPS final rule (86 FR 62017).

(6) Effects on Medicare Beneficiaries

Our decision to finalize changes to the definition of an ESRD Beneficiary for the purposes of attribution is not expected to impact the findings reported for the effects of ETC Model on Medicare beneficiaries. Further details on the impact of the ETC Model on ESRD Beneficiaries may be found in the Specialty Care Models final rule (85 FR 61357) and the CY 2022 ESRD PPS final rule (86 FR 61874).

(7) Alternatives Considered

Throughout this final rule, we have identified finalized changes to our policy and alternatives considered and provided information as to the likely effects of these alternatives and rationale for our changed policy.

The Specialty Care Models final rule (85 FR 61114), the CY 2022 ESRD PPS final rule (86 FR 61874), the CY 2023 ESRD PPS final rule (87 FR 67136), the CY 2024 ESRD PPS final rule (88 FR 76344), and the finalized policy herein address a model specific to ESRD. These rules provide descriptions of the requirements that we waive, identify the performance metrics and payment adjustments to be tested, and presents rationales for our changes, and where relevant, alternatives considered. For context related to alternatives previously considered when establishing and modifying the ETC Model we refer readers to section V.B. and to the previous citations.

D. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), we have prepared an accounting statement in Table 26 showing the classification of the impact associated with the provisions of this final rule.

TABLE 26: Accounting Statement: Classification of Estimated Transfers and Costs/Savings

ESRD PPS and AKI (CY 2025)	
Category	**Transfers**
Annualized Monetized Transfers	$210 million
Bearers of Transfer Gain	Medicare ESRD Facilities
Category	**Transfers**
Increased Beneficiary Co-insurance Payments	$50 million
Bearers of Transfer Gain	Medicare ESRD Facilities
ESRD QIP for PY 2027	
Category	Transfers
Annualized Monetized Transfers	$17.9 million
Bearers of Transfer Gain	Federal Government
ETC Model for July 1, 2022, through June 30, 2027	
Category	Transfers
Net Monetized Transfers	$28 million
Bearers of Transfer Gain	Federal Government

E. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. We do not believe ESRD facilities are operated by small government entities such as counties or towns with populations of 50,000 or less, and therefore, they are not enumerated or included in this estimated RFA analysis. Individuals and states are not included in the definition of a small entity. Therefore, the number of small entities estimated in this RFA analysis includes the number of ESRD facilities that are either considered small businesses or nonprofit organizations.

According to the Small Business Administration's (SBA) size standards, an ESRD facility is classified as a small business if it has total revenues of less than $47 million in any 1 year.[128] For the purposes of this analysis, we exclude the ESRD facilities that are owned and operated by LDOs and regional chains, which would have total revenues of more than $6.5 billion in any year when the total revenues for all locations are combined for each business (LDO or regional chain), and are not, therefore, considered small businesses. Because we lack data on individual ESRD facilities' receipts, we cannot determine the number of small proprietary ESRD facilities or the proportion of ESRD facilities' revenue derived from Medicare FFS payments. Therefore, we assume that all ESRD facilities that are not owned by LDOs or regional chains are considered small businesses. Accordingly, we consider the 485 ESRD facilities that are independent and 351 ESRD facilities that are hospital-based, as shown in the ownership category in Table 19, to be small businesses. These ESRD facilities represent approximately 11 percent of all ESRD facilities in our data set.

Additionally, we identified in our analytic file that there are 792 ESRD facilities that are considered nonprofit organizations, which is approximately 10 percent of all ESRD facilities in our data set. In total, accounting for the 369 nonprofit ESRD facilities that are also considered small businesses, there are 1,259 ESRD facilities that are either small businesses or nonprofit organizations, which is approximately 16 percent of all ESRD facilities in our data set.

As its measure of significant economic impact on a substantial number of small entities, HHS's practice in interpreting the RFA is to consider effects economically ''significant'' on a ''substantial'' number of small entities only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We did not receive any public comments on our regulatory impact analysis for small entities. As shown in Table 19, we estimate that the overall revenue impact of this final rule on all ESRD facilities is a positive increase to Medicare FFS payments by approximately 2.7 percent. For the ESRD PPS updates in this final rule, a hospital-based ESRD facility (as defined by type of ownership, not by type of ESRD facility) is estimated to receive a 4.5 percent increase in Medicare FFS payments for CY 2025. An independent facility (as defined by ownership type) is likewise estimated to receive a 0.8 percent increase in Medicare FFS payments for CY 2025. Among hospital-based and independent ESRD facilities, those furnishing fewer than 3,000 treatments per year are estimated to receive a 5.3 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 2.1 percent increase in Medicare FFS payments. Among nonprofit ESRD facilities, those furnishing fewer than 3,000 treatments per year are estimated to receive a 6.0 percent increase in Medicare FFS payments, and those furnishing 3,000 or more treatments per year are estimated to receive a 2.8 percent increase in Medicare FFS payments.

For AKI dialysis, we are unable to estimate whether patients would go to ESRD facilities, however, we have estimated there is a potential for $70 million in payment for AKI dialysis treatments that could potentially be furnished in ESRD facilities.

Based on the estimated Medicare payment impacts described previously, we believe that the change in revenue threshold will be reached by some categories of small entities as a result of the policies in this final rule. This analysis is based on the assumptions described earlier in this section of this final rule as well as the detailed impact analysis discussed in section VII.C of this final rule, which includes a discussion of data sources, general

[128] *http://www.sba.gov/content/small-business-size-standards.*

assumptions, and alternatives considered.

For the ESRD QIP, we estimate that of the 2,750 ESRD facilities expected to receive a payment reduction as a result of their performance on the PY 2027 ESRD QIP, 468 are ESRD small entity facilities. We present these findings in Table 21 (''Updated Estimated Distribution of PY 2027 ESRD QIP Payment Reductions'') and Table 23 (''Updated Estimated Impact of ESRD QIP Payment Reductions to ESRD Facilities for PY 2027''). Table 21 shows the updated overall estimated distribution of payment reductions resulting from the PY 2027 ESRD QIP. Table 23 shows the updated estimated impact of the ESRD QIP payment reductions to all ESRD facilities for PY 2027, and also details the distribution of ESRD facilities by size, geography, and facility type.

For the ETC Model, we do not anticipate any impact on ESRD facilities from our decision to finalize a change to the definition of an ESRD Beneficiary for the purposes of beneficiary attribution in the model. As previously stated, we estimate that the Medicare program would save a net total of $43 million from the ETC PPA and HDPA between January 1, 2021, and June 30, 2027, less $15 million in increased training and education expenditures. Therefore, the net impact to Medicare spending is estimated to be $28 million in savings.

Therefore, the Secretary has determined that this final rule will have a significant economic impact, reflecting a positive revenue increase, on a substantial number of small entities. This RFA section along with the RIA constitutes our final regulatory flexibility analysis.

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. We do not believe this final rule would have a significant impact on operations of a substantial number of small rural hospitals because most dialysis facilities are freestanding. While there are 108 rural hospital-based ESRD facilities, we do not know how many of them are based at hospitals with fewer than 100 beds. However, overall, the 108 rural hospital-based ESRD facilities would experience an estimated 5.9 percent increase in payments. Therefore, the Secretary has certified that this final rule will not have a significant impact on the operations of a substantial number of small rural hospitals.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2024, that threshold is approximately $183 million. We do not interpret Medicare payment rules as being unfunded mandates but simply as conditions for the receipt of payments from the Federal Government for providing services that meet Federal standards. This interpretation applies whether the facilities or providers are private, State, local, or Tribal. Therefore, this final rule does not mandate any requirements for State, local, or Tribal governments, or for the private sector.

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism, and have determined that it will not have substantial direct effects on the rights, roles, and responsibilities of State, local, or Tribal government.

H. Congressional Review Act

This final regulation is subject to the Congressional Review Act provisions of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 *et seq.*) and has been transmitted to the Congress and the Comptroller General for review.

VIII. Files Available to the Public

The Addenda for the annual ESRD PPS proposed and final rule will no longer appear in the **Federal Register**. Instead, the Addenda will be available only through the internet and will be posted on CMS's website under the regulation number, CMS–1805–F, at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/End-Stage-Renal-Disease-ESRD-Payment-Regulations-and-Notices*. In addition to the Addenda, limited data set files (LDS) are available for purchase at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/EndStageRenalDiseaseSystemFile*. Readers who experience any problems accessing the Addenda or LDS files, should contact CMS by sending an email to CMS at the following mailbox: *ESRDPayment@cms.hhs.gov*.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 23, 2024.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 494

Diseases, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 2. Section 410.52 is amended by revising paragraph (a) introductory text to read as follows:

§ 410.52 Home dialysis services, supplies, and equipment: Scope and conditions.

(a) Medicare Part B pays for the following services, supplies, and equipment furnished to a patient with ESRD or an individual with Acute Kidney Injury (AKI) as defined in § 413.371 of this chapter in his or her home:

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 3. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 4. Section 413.196 is amended by revising paragraph (d)(2) to read as follows:

§ 413.196 Notification of changes in rate-setting methodologies and payment rates.

* * * * *

(d) * * *

(2) The wage index using the most current wage data for occupations related to the furnishing of renal dialysis services from the Bureau of Labor Statistics and occupational mix data from the most recent full calendar year of Medicare cost reports submitted in accordance with § 413.198(b).

* * * * *

■ 5. Section 413.231 is amended by revising paragraph (a) to read as follows:

§ 413.231 Adjustment for wages.

(a) CMS adjusts the labor-related portion of the base rate to account for geographic differences in the area wage levels using an appropriate wage index (established by CMS) which reflects the relative level of wages relevant to the furnishing of renal dialysis services in the geographic area in which the ESRD facility is located.

* * * * *

■ 6. Section 413.234 is amended by revising paragraph (c) introductory text and adding paragraph (c)(4) to read as follows:

§ 413.234 Drug designation process.

* * * * *

(c) *Transitional drug add-on payment adjustment.* A new renal dialysis drug or biological product is paid for using a transitional drug add-on payment adjustment, which is based on 100 percent of average sales price (ASP), except as provided in paragraph (c)(4) of this section. If ASP is not available then the transitional drug add-on payment adjustment is based on 100 percent of wholesale acquisition cost (WAC) and, when WAC is not available, the payment is based on the drug manufacturer's invoice. Notwithstanding the provisions in paragraphs (c)(1) and (2) of this section, if CMS does not receive a full calendar quarter of ASP data for a new renal dialysis drug or biological product within 30 days of the last day of the 3rd calendar quarter after we begin applying the transitional drug add-on payment adjustment for the product, CMS will no longer apply the transitional drug add-on payment adjustment for that product beginning no later than 2-calendar quarters after we determine a full calendar quarter of ASP data is not available. If CMS stops receiving the latest full calendar quarter of ASP data for a new renal dialysis drug or biological product during the applicable time period specified in paragraph (c)(1) or (2) of this section, CMS will no longer apply the transitional drug add-on payment adjustment for the product beginning no later than 2-calendar quarters after CMS determines that the latest full calendar quarter of ASP data is not available.

* * * * *

(4) For calendar years 2025 and 2026, the transitional drug add-on payment adjustment amount for a phosphate binder is based on 100 percent of ASP plus an additional amount derived from 6 percent of per-patient phosphate binder spending based on utilization and cost data.

* * * * *

■ 7. Section 413.236 is amended by revising paragraphs (b)(4) and (c) to read as follows:

§ 413.236 Transitional add-on payment adjustment for new and innovative equipment and supplies.

* * * * *

(b) * * *

(4) Has a complete Healthcare Common Procedure Coding System (HCPCS) Level II code application submitted, in accordance with the HCPCS Level II coding procedures on the CMS website, by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for non-drug and non-biological items, supplies, and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year;

* * * * *

(c) Announcement of determinations and deadline for consideration of new renal dialysis equipment or supply applications. CMS will consider whether a new renal dialysis supply or equipment meets the eligibility criteria specified in paragraph (b) of this section and announce the results in the **Federal Register** as part of its annual updates and changes to the ESRD prospective payment system. CMS will only consider a complete application received by CMS by February 1 prior to the particular calendar year. FDA marketing authorization for the equipment or supply must occur by the HCPCS Level II code application deadline for biannual Coding Cycle 2 for non-drug and non-biological items, supplies, and services as specified in the HCPCS Level II coding guidance on the CMS website prior to the particular calendar year.

■ 8. Section 413.237 is amended by adding paragraph (a)(1)(vii) to read as follows:

§ 413.237 Outliers.

(a) * * *

(1) * * *

(vii) Renal dialysis drugs and biological products that are Composite Rate Services as defined in § 413.171.

* * * * *

■ 9. Section 413.373 is revised to read as follows:

§ 413.373 Other adjustments to the AKI dialysis payment rate.

(a) CMS applies the wage-adjusted add-on per treatment adjustment for home and self-dialysis training as set forth at § 413.235(c) to payments for AKI dialysis claims that include such training.

(b) The payment rate for AKI dialysis may be adjusted by the Secretary (on a budget neutral basis for payments under section 1834(r) of the Act) by any other adjustment factor under subparagraph (D) of section 1881(b)(14) of the Act.

■ 10. Section 413.374 is amended by revising paragraph (a) to read as follows:

§ 413.374 Renal dialysis services included in the AKI dialysis payment rate.

(a) The AKI dialysis payment rate applies to renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14) of the Act) furnished under Part B by a renal dialysis facility or provider of services paid under section 1881(b)(14) of the Act, including home services, supplies, and equipment, and self-dialysis.

* * * * *

PART 494—CONDITIONS FOR COVERAGE FOR END-STAGE RENAL DISEASE FACILITIES

■ 11. The authority citation for part 494 continues to read as follows:

Authority: 42 U.S.C. l302 and l395hh.

■ 12. Section 494.10 is amended by revising the definitions of ''Home dialysis'' and ''Self-dialysis'' to read as follows:

§ 494.10 Definitions.

* * * * *

Home dialysis means dialysis performed at home by a patient or caregiver who has completed an appropriate course of training as described in § 494.100(a).

Self-dialysis means dialysis performed with little or no professional assistance by a patient or caregiver who has completed an appropriate course of training as specified in § 494.100(a).

* * * * *

■ 13. Section 494.70 is amended by revising paragraphs (a)(1) and (10) and (c)(1)(i) to read as follows:

§ 494.70 Condition: Patients' rights.

* * * * *

(a) * * *

(1) Respect, dignity, and recognition of his or her individuality and personal needs, and sensitivity to his or her psychological needs and ability to cope with kidney failure;

* * * * *

(10) Be informed by the physician, nurse practitioner, clinical nurse specialist, or physician's assistant treating the patient for kidney failure of his or her own medical status as documented in the patient's medical record, unless the medical record contains a documented contraindication;

* * * * *

(c) * * *

(1) * * *

(i) How plans in the individual market will affect the patient's access to, and costs for the providers and suppliers, services, and prescription drugs that are currently within the individual's plan of care as well as those likely to result from other documented health care needs. This must include an overview of the health-related and financial risks and benefits of the individual market plans available to the patient (including plans offered through and outside the Exchange).

* * * * *

■ 14. Section 494.80 is amended by revising the introductory text to read as follows:

§ 494.80 Condition: Patient assessment.

The facility's interdisciplinary team consists of, at a minimum, the patient or the patient's designee (if the patient chooses), a registered nurse, a physician treating the patient for kidney failure, a social worker, and a dietitian. The interdisciplinary team is responsible for providing each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient's treatment plan and expectations for care.

* * * * *

■ 15. Section 494.90 is amended by revising paragraph (b)(4) to read as follows:

§ 494.90 Condition: Patient plan of care.

* * * * *

(b) * * *

(4) The dialysis facility must ensure that all dialysis patients are seen by a physician, nurse practitioner, clinical nurse specialist, or physician's assistant providing dialysis care at least monthly, as evidenced by a monthly progress note placed in the medical record, and periodically while the hemodialysis patient is receiving in-facility dialysis.

* * * * *

■ 16. Section 494.100 is amended by revising paragraph (a)(3)(i) to read as follows:

§ 494.100 Condition: Care at home.

* * * * *

(a) * * *

(3) * * *

(i) The nature and management of their kidney failure.

* * * * *

■ 17. Section 494.120 is amended by revising the introductory text to read as follows:

§ 494.120 Condition: Special purpose renal dialysis facilities.

A special purpose renal dialysis facility is approved to furnish dialysis on a short-term basis at special locations. Special purpose dialysis facilities are divided into two categories: vacation camps (locations that serve patients with kidney failure while the patients are in a temporary residence) and facilities established to serve patients with kidney failure under emergency circumstances.

* * * * *

■ 18. Section 494.130 is revised to read as follows:

§ 494.130 Condition: Laboratory services.

The dialysis facility must provide, or make available, laboratory services (other than tissue pathology and histocompatibility) to meet the needs of the patient. Any laboratory services, including tissue pathology and histocompatibility must be furnished by or obtained from, a facility that meets the requirements for laboratory services specified in part 493 of this chapter.

■ 19. Section 494.170 is amended by revising the introductory text to read as follows:

§ 494.170 Condition: Medical records.

The dialysis facility must maintain complete, accurate, and accessible records on all patients, including home patients who elect to receive dialysis supplies and equipment from a supplier that is not a provider of dialysis services and all other home dialysis patients whose care is under the supervision of the facility.

* * * * *

PART 512—RADIATION ONCOLOGY MODEL AND END STAGE RENAL DISEASE TREATMENT CHOICES MODEL

■ 20. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 21. Section 512.310 is amended by revising the definition of ''ESRD Beneficiary'' to read as follows:

§ 512.310 Definitions.

* * * * *

ESRD Beneficiary means a beneficiary who meets any of the following:

(1) Is receiving dialysis or other services for end-stage renal disease, up to and including the month in which the beneficiary receives a kidney transplant up to and including the month in which the beneficiary receives a kidney transplant.

(2) Has already received a kidney transplant and has a non-AKI dialysis or MCP claim at least 12 months after the beneficiary's latest transplant date.

(3) Has a kidney transplant failure less than 12 months after the beneficiary's latest transplant date as identified by:

(i) Two or more MCP claims in the180 days following the date on which the kidney transplant was received;

(ii) 24 or more maintenance dialysis treatments at any time after 180 days following the transplant date; or,

(iii) Indication of a transplant failure after the beneficiary's date of transplant based on data from the Scientific Registry of Transplant Recipients (SRTR) database.

(4) If a beneficiary meets more than one of criteria described in paragraphs (3)(i) through (iii) of this definition, the beneficiary will be considered an ESRD beneficiary starting with the earliest month in which transplant failure was recorded.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

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Part III

Federal Trade Commission

16 CFR Parts 801 and 803

Premerger Notification; Reporting and Waiting Period Requirements; Final Rule

FEDERAL TRADE COMMISSION

16 CFR Parts 801 and 803

RIN 3084–AB46

Premerger Notification; Reporting and Waiting Period Requirements

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission''), with the concurrence of the Assistant Attorney General, Antitrust Division, Department of Justice (''Assistant Attorney General'' or ''Antitrust Division'') (together the ''Agencies''), is issuing this final rule and Statement of Basis and Purpose (''SBP'') to amend the Premerger Notification Rules (the ''Rules'') that implement the Hart-Scott-Rodino Antitrust Improvement Act (''the HSR Act'' or ''HSR''), including the Premerger Notification and Report Form for Certain Mergers and Acquisitions (''Form'') and Instructions to the Notification and Report Form for Certain Mergers and Acquisitions (''Instructions''). The final rule requires parties to transactions that are reportable under the HSR Act to provide documentary material and information that are necessary and appropriate for the Agencies to efficiently and effectively conduct an initial assessment to determine whether the transaction may violate the antitrust laws and whether to issue a Request for Additional Information (''Second Request'') as provided by the HSR Act. In addition, the final rule implements certain requirements of the Merger Filing Fee Modernization Act of 2022 (''Merger Modernization Act'') and ministerial changes to the Rules as well as the necessary amendments to the Instructions to effect the final changes.

DATES: This rule is effective on February 10, 2025.

FOR FURTHER INFORMATION CONTACT: Robert Jones, Assistant Director, Premerger Notification Office, Bureau of Competition, Federal Trade Commission, 400 7th Street SW, Washington, DC 20024, or by telephone at (202) 326–3100.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

The Commission is amending and reorganizing the documentary material and information requirements for premerger notification required by the HSR Act, 15 U.S.C. 18a, (''notification'' or ''HSR Filing'' or ''Filing'') to improve the efficiency and effectiveness of premerger review and to implement changes mandated by the Merger Modernization Act, 15 U.S.C. 18b. The Act and the Rules require parties to certain mergers and acquisitions to submit a notification to the Agencies and to wait a short period of time before consummating the reported transaction. The reporting and waiting period requirements of the HSR Act are intended to enable the Agencies to determine whether a proposed merger or acquisition may violate the antitrust laws, including section 7 of the Clayton Act, 15 U.S.C. 18, if consummated and, when appropriate, to take appropriate law enforcement action prior to consummation to prevent a violation of the antitrust laws.

To advance the Clayton Act's goal of preventing undue consolidation or stopping it in its incipiency,[1] Congress passed the HSR Act to require mandatory premerger notification of some acquisitions. In particular, it charged the Agencies with reviewing the details of those proposed transactions in advance of consummation. The Agencies rely on information submitted in an HSR Filing to conduct a premerger antitrust risk assessment and to identify those transactions that require additional investigation to determine if they may harm competition, and thus violate the antitrust laws if consummated. The HSR Act requires that the parties not consummate their planned transaction while the Agencies conduct this assessment until the expiration of the statutory waiting period, which for most transactions is 30 days (15 days in the case of a cash tender offer or certain bankruptcy sales). During that short period of time, referred to as the initial waiting period, the Agencies review the information submitted in the parties' HSR Filings to identify those transactions that require a closer look, including through the collection of additional information from the acquiring and acquired persons or from third parties. If either agency determines during the initial waiting period to conduct an in-depth investigation of the transaction, section 7A(e) of the Clayton Act, 15 U.S.C. 18a(e), authorizes the Agencies to request additional information or documents from each party, which is referred to as a Second Request.[2] Issuing Second Requests extends the waiting period under the HSR Act for another 30 days (ten days in the case of a cash tender offer or certain bankruptcy sales) after the parties have substantially complied with the Second Requests. During this second waiting period, if the reviewing agency believes that a proposed transaction may violate the antitrust laws, it may seek an injunction in Federal district court to prohibit consummation of the transaction.

The Commission has administered the HSR Act's premerger notification program for over forty-five years, issuing an initial set of HSR Rules that took effect on September 5, 1978.[3] Since then, it has regularly updated these rules, with the concurrence of the Assistant Attorney General, pursuant to its mandate under 15 U.S.C. 18a(d), to require a premerger notification for each reportable acquisition that contains documentary material and information necessary and appropriate to enable the Agencies to determine whether the transaction is one that may violate the antitrust laws and proceed to an in-depth investigation through the issuance of Second Requests. In this rulemaking, the Commission is responding to several factors that make today's economic reality more challenging for conducting a premerger assessment with the limited information required by the current rules. Simply put, the economy of 2024 is different than it was in 1978 or 2000 and, in the Agencies' experience, the HSR Form has not kept pace with the realities of how businesses compete today. There is a higher degree of interconnectivity of businesses along the supply chain as well as with other companies that provide ancillary services. The focus of competitive interaction is not as obvious when companies that supply goods or services also generate revenues from other sources, such as data sales, and when even businesses in traditional sectors such as manufacturing generate significant revenues from the sale of associated services. The changing nature of competition makes it more difficult for the Agencies to identify existing business relationships that might be affected by the acquisition, including through non-price effects such as innovation competition, and that are not

[1] *See, e.g., Brown Shoe Co.* v. *United States,* 370 U.S. 294, 318 n.32 (1962).

[2] The FTC and DOJ share responsibility to enforce the antitrust laws and have established a protocol to clear the investigation of a transaction to one agency to avoid confusion and conserve public resources. The agency that receives clearance conducts the investigation and determines whether to issue Second Requests.

[3] The Commission commenced notice-and-comment rulemaking soon after the passage of the HSR Act and made extensive revisions to its proposed rules before issuing a final rule nearly two years later. *See* 41 FR 55488 (Dec. 20, 1976), 42 FR 39040 (Aug. 1, 1977), 43 FR 33450 (July 31, 1978), 43 FR 34443 (Aug. 4, 1978), 43 FR 36053 (Aug. 15, 1978). *See* Fed. Trade Comm'n & U.S. Dep't of Justice, Second Hart-Scott-Rodino Annual Report (FY 1978).

apparent from simply focusing on sales in output markets. In addition, changes in mergers and acquisition (''M&A'') activity, corporate structures, and investment strategies have rendered the current Form's focus on traditional corporate structures outdated, and often the Agencies are unable to determine which entities or individuals will be making competitive decisions post-merger.

These profound changes that have occurred over time have created or exposed significant gaps in the information generated for premerger review under the current HSR Rules. These gaps curtail the Agencies' ability to efficiently and effectively detect transactions that may violate the antitrust laws. To fill in these gaps and to directly respond to the passage of the Merger Modernization Act, the Commission relied on its experience and expertise to identify specific information that is necessary and appropriate to conduct effective premerger screening.

To initiate this rulemaking, the Agencies conducted a comprehensive review of the premerger notification process, relied on their experience collecting and reviewing data and documents during antitrust investigations, and considered the cumulative effects of changes in deal structure, investment strategies, and the competitive dynamics of the modern economy explained in more detail below. From this review, the Commission identified several information deficiencies in the current HSR Filing that prevent the Agencies from efficiently and effectively conducting a premerger assessment of reportable transactions to identify which ones may violate the antitrust laws. The Agencies compared documentary material and information they have received over the years during in-depth merger investigations with the information collected in HSR Filings and assessed whether having certain types of documentary material and information at the beginning of an investigation would have changed the Agencies' decision whether and how to investigate reportable transactions. These specific categories of information and documents, which are readily available to the merging parties, are not required by the current Rules, but would be highly probative to the initial antitrust screening of a transaction during the initial waiting period and thus are necessary and appropriate for that review. The information identified and required by this final rule will enable the Agencies to detect transactions that may violate the law in light of modern commercial realities and in furtherance of the statutory mandate to arrest trends toward concentration in their incipiency. The final rule also will allow the Agencies to identify potentially unlawful transactions more quickly and with greater accuracy, narrowing the scope of their investigations in some cases, and in others, reducing the need to conduct a more burdensome in-depth investigation by issuing Second Requests.

In June 2023, the Commission proposed amendments to address the information deficiencies under the existing HSR Rules in a Notice of Proposed Rulemaking (''NPRM'').[4] The Commission received approximately 721 comments.[5] The majority of commenters were individuals who expressed general support for the rulemaking or for more vigorous antitrust enforcement more broadly. Others opposed certain aspects of the proposed rule and some questioned the Commission's authority to make any adjustments. After careful consideration of the comments and as discussed in more detail below, the Commission has substantially narrowed the information requirements proposed in the NPRM. In the final rule, the Commission is not adopting several proposed requirements outright, including those related to:

- a timeline of key dates for closing the proposed transaction;
- creating organization charts for the purpose of filing a notification;
- information about other interest holders;
- drafts of submitted documents;
- information about employees;
- information about board observers;
- geolocation information;
- prior acquisitions involving entities with less than $10 million in sales or revenues, or consummated more than 5 years prior to filing; and
- information about steps taken to preserve documents or use of messaging systems.

For other proposals, the Commission has substantially modified its proposals to minimize where possible the costs to filers and third parties, yet still provide the Agencies with information that is necessary and appropriate for effective and efficient premerger review. Overall, these modifications significantly reduce the effort required to comply with the final rule as compared to the proposed rule and include:

- Creating a new category of ''select 801.30 transactions'' for which the cost of complying with the information requirements has been limited because of the low risk that the transaction may violate the antitrust laws;
- Eliminating several document requirements to reduce costs;
- Limiting some requirements to materials that already exist;
- Excusing the seller[6] from certain information requests if it would be duplicative of information received from the buyer;
- Limiting some requirements to cover only recent information;
- Providing definitions or clarifications to reduce uncertainty and improve filer compliance;
- Creating *de minimis* exceptions to reduce the costs of generating information that has little economic impact; and
- Making the provision of certain information contingent on the identification of a significant business relationship between the filing persons that is critical to assessing whether the transaction may violate the antitrust laws.

As modified, the final rule introduces necessary and appropriate updates to HSR information requirements to allow the Agencies to understand the reported transaction and conduct an initial antitrust assessment within the statutory timeframe and does so in a manner that aligns the associated costs with the likelihood that the transaction is one that presents antitrust risk. With more complete information that is targeted to disclose existing business relationships between the parties, the Agencies can determine whether and how to deploy their resources to further investigate potentially anticompetitive acquisitions prior to consummation. The final rule will also provide transparency for those contemplating a reportable transaction by describing the information the

[4] On June 29, 2023, the Commission published a Notice of Proposed Rulemaking, Premerger Notification; Reporting and Waiting Period Requirements, 88 FR 42178 (June 29, 2023) (hereinafter NPRM). On August 10, 2023, the Commission extended the comment period to receive public comments through September 27, 2023. 88 FR 54256. The comments on the NPRM (Doc. No. FTC–2023–0040) are available at *https://www.regulations.gov/docket/FTC-2023-0040/comments*.

[5] The Commission does not rely on any particular individual comment submission for its findings, but rather provides here (and throughout this final rule) examples of comments that were illustrative of themes that spanned many comments. The Commission's findings are based on consideration of the totality of the evidence, including its review of the empirical literature, its review of the full comment record, and its expertise and experience in identifying mergers that violate the antitrust laws.

[6] References to ''seller'' throughout refer to the acquired person, as defined in 16 CFR 801.2, regardless of whether or not the acquired person is actually a party to the transaction.

Agencies rely on to conduct their initial assessment of whether a transaction may violate the antitrust laws. The amendments will also reduce the current burden on third parties (such as customers and competitors of the merging parties) on whom the Agencies often rely to fill in many of the information gaps during the initial review period because of inadequacies in the current Rules.

With this rulemaking the Commission has closely tailored the burden of complying with the HSR Act to align as much as practicable with the risks of a law violation presented by the particular transaction. This alignment is consistent with the statutory purpose of premerger review, which is for the Agencies to determine which reported transactions may violate the antitrust laws during the brief period provided by the Act for an initial antitrust assessment. As a result, the final rule achieves the benefits associated with mandatory premerger review with an overall burden that is reasonable and consistent with the legislative purpose of the HSR Act.

II. Background

A. Premerger Review and the Implications for Merger Enforcement

Section 7 of the Clayton Act is, by its terms, forward-looking and predictive, focused on acquisitions whose effect ''may be substantially to lessen competition, or to tend to create a monopoly.'' [7] To better effectuate the Clayton Act's goal of preventing undue consolidation or stopping it in its incipiency, Congress passed the HSR Act to require mandatory premerger notification of some acquisitions, and charged the Agencies with reviewing the details of those proposed transactions in advance of consummation to determine whether they may violate the antitrust laws. In doing so, Congress fundamentally changed the way the Agencies enforce the nation's antitrust laws to prevent harmful consolidation.[8]

Congress specifically charged that the Commission engage in rulemaking to require information in the HSR Filing that is necessary and appropriate to detect acquisitions that may violate the antitrust laws. Section 18a(d)(1) of the HSR Act states that the Commission, by rule and in accordance with the Administrative Procedures Act, shall require that the notification contain such documentary material and information to determine whether the acquisition may, if consummated, violate the antitrust laws.[9] Relying on this explicit rulemaking authority, the Commission has adjusted those requirements over time to carry out the purposes of the Act.

In passing the HSR Act, Congress imposed mandatory premerger review only for certain large transactions, in part to ''improve and modernize antitrust investigation and enforcement mechanisms,'' [10] ''ease burdens on the courts by forestalling interminable post-consummation divestiture trials . . . [, and] advance the legitimate interests of the business community in planning and predictability.'' [11] The robust legislative history of the HSR Act makes plain that premerger review should focus on the likelihood that a reported transaction may violate the antitrust laws and that the Commission shall collect information to make that determination prior to consummation.[12] Consistent with Congressional mandate, the Agencies rely on notifications under the HSR Act to target their enforcement efforts to their best use in preventing undue consolidation by seeking to prohibit the consummation of acquisitions that violate the antitrust laws.

To focus the Agencies' screening and potential enforcement efforts on the mergers that are most likely to harm competition and consumers, Congress required notice in advance for the largest mergers and tasked the Agencies with conducting an assessment of the risk that the proposed acquisition may violate the antitrust laws. To perform this task, the Agencies must review thousands of filings each year and identify which ones should be targeted for an intensive investigation of their potential to violate the antitrust laws. This is a fact-intensive endeavor that requires a deep understanding of precedent and economic analysis. The Agencies employ lawyers, economists, technologists, accountants, and support staff to conduct premerger analyses of reported transactions in order to perform this critical task on behalf of the American public.

Nonetheless, transactions reported under the HSR Act are a small fraction of the total number of mergers and acquisitions that occur each year in the United States. Relying on commercial data on M&A activity and data from the Agencies' annual HSR reports, Table 1 shows that during the five-year period of FY 2018 to 2022, HSR filings represented a small percentage of overall deal activity in the United States, on average 16.5 percent a year.[13]

[7] 15 U.S.C. 18. *See Brown Shoe* v. *United States,* 370 U.S. 294, 317–18 (1962) (Congress provided authority for arresting mergers at a time when the trend to a lessening of competition in a line of commerce was still in its incipiency and assure courts had the power to brake the process of concentration at its outset and before it gathered momentum).

[8] *See* Peter W. Rodino, Jr., Statement on the 25th Anniversary of Hart-Scott-Rodino (2001), *https://www.ftc.gov/enforcement/premerger-notification-program/hsr-resources/pno-news-archive/statement-peter-w-rodino* (''Hart-Scott-Rodino was intended to give the anti-trust agencies two things: critical information about a proposed merger and time to analyze that information and prepare a case, if necessary. From what I hear, the legislation absolutely has transformed merger enforcement. Competition, as well as the consumer, has benefitted.'').

[9] 15 U.S.C. 18a(d)(1).

[10] S. Rep. No. 94–803, at 1 (1976).

[11] H.R. Rep. No. 94–1373, at 11 (1976). The HSR Act applies to acquisitions that met the statutory thresholds whether they are properly styled ''mergers'' and even if they do not result in a change of control. The terms ''mergers,'' ''acquisitions,'' and ''transactions'' are used interchangeably to refer to transactions for which an HSR filing is required.

[12] 15 U.S.C. 18a(d)(1).

[13] Using different commercially available data, the U.S. Government Accountability Office recently estimated that HSR filings during this same time frame averaged 15 percent of overall M&A activity. *See* U.S. Gov't Accountability Office, Defense Industrial Base: DOD Needs Better Insight into Risks from Mergers and Acquisitions 8 Fig. 1 (Oct. 2023) (GAO–24–106129), *https://www.gao.gov/assets/d24106129.pdf* (using Bloomberg data).

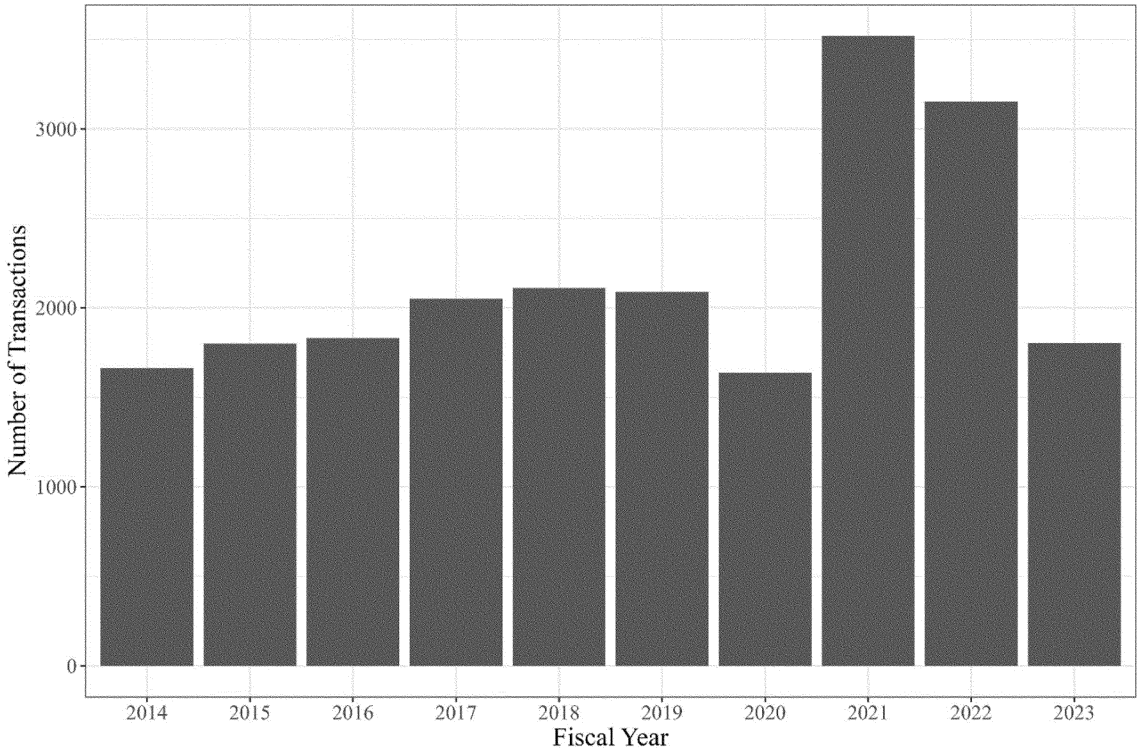
Table 1: M&A Transactions 2018 - 2022

	2018	2019	2020	2021	2022	Average
Total Number of Transactions[a]	13,366	13,696	12,828	19,099	15,734	**14,945**
Number of Reported Transactions[b]	2,111	2,089	1,637	3,520	3,152	**2,502**
Percentage	15.8%	15.3%	12.8%	18.4%	20.0%	**16.5%**

[a] Source: MergerStat Fact Set Review, M&A Announcements.
[b] Source: HSR Annual Reports for Fiscal Years 2018 - 2022, Figure 1.

While the Agencies investigate and ultimately seek to block only a small subset of reportable mergers each year, the challenges of administering mandatory premerger review have expanded and accelerated over time due to the changes in the nature of M&A activity discussed in detail below.

Figure 1: HSR Merger Transactions Reported Fiscal Years 2014 - 2023



As depicted in Figure 1, there was a recent spike in HSR-reportable transactions: in FY 2021, the Agencies reviewed HSR Filings for 3,520 transactions, over twice the number of the prior year's filings. In FY 2022, the Agencies reviewed 3,152 transactions. Although the pace of HSR Filings has recently moderated somewhat, the recent period of intense merger activity highlighted significant inefficiencies and deficiencies in current notification requirements that must be addressed so that the Agencies can direct their scarce resources to prevent those acquisitions most likely to cause widespread harm.[14]

The Commission is mindful of recent economic research that underscores the importance of adequate detection for effective merger enforcement. For instance, researchers posit that some firms appear to be employing strategies to avoid antitrust scrutiny of their anticompetitive deals, deliberately negotiating and structuring their deals to avoid premerger review (so-called

[14] Contrary to suggestions from some commenters, it is not practical for the Agencies to identify specific illegal transactions that they ''missed'' during their premerger review, nor is the Commission required to establish that as a predicate for invoking its statutory rulemaking authority under the HSR Act. *See Pharm. Rsch. & Mfrs. Am.* v. *FTC,* 790 F.3d 198, 199, 206 (D.C. Cir. 2015) (hereinafter *PhRMA*). Doing so would require a redirection of resources to investigate consummated mergers and away from resources devoted to premerger review. Instead, it is imperative that the Agencies ensure that they have the right information to address deficiencies that have emerged to undermine premerger review as an effective tool for detecting which transactions may violate the nation's antitrust laws.

stealth acquisitions),[15] or identifying acquisition targets at a nascent stage to buy them before they are valuable enough to require premerger review, sometimes solely for the purpose of preempting future competition (so-called ''killer acquisitions'').[16] One researcher concludes that merger enforcement falls by about 90 percent when transactions are not subject to premerger review.[17] Because most mergers are not subjected to premerger review, these strategies have contributed to a rise in aggregate concentration by stimulating mergers between competitors, with attendant negative effects on markups, private investment, and the share of output going toward profits.[18]

These studies support Congress' determination that premerger review is essential to effective enforcement of the antitrust laws and that without effective premerger review, there is inadequate detection of mergers that violate the law and cause harm.[19] While the Agencies can and do challenge acquisitions that are not reported under the HSR Act as well as consummated reported mergers that have caused harm, unwinding an illegal merger post-consummation still requires a significant investment of time and resources, and results in significant harm to market participants until unwound.[20] Even after the Agency succeeds in establishing a law violation, it may be difficult or impossible to restore the premerger state of competition, especially if the parties have commingled, sold, or closed assets, shared confidential information, or terminated key employees.[21] Moreover, the decision to pursue these time-consuming investigations involves opportunity costs, pitting the costs and benefits of challenging a consummated merger against devoting those enforcement resources to investigations into other potential antitrust violations, including investigations that may arise from HSR Filings.

To fulfill the Agencies' mandate to conduct quick yet effective premerger review of reported transactions, the Commission must make the best use of the tools Congress gave the Agencies to detect and prevent harmful acquisitions, including by requiring that the notification contain the documents and information that are necessary and appropriate for screening reportable mergers prior to consummation. Because premerger review is critically important to effective merger enforcement, the information contained in an HSR Filing must be fit for the purpose of determining whether a reported transaction may violate the antitrust laws in light of current market realities. Having the information necessary to make that assessment allows the Agencies to decide when and how to expend public resources to investigate and potentially challenge mergers. The final rule will enable the Agencies to engage in efficient and effective detection of illegal mergers that are subject to the HSR Act and thus is a reasonable exercise of the Commission's rulemaking authority under the HSR Act.

B. The Need for the Final Rule

The purpose of this rulemaking is to modernize the premerger review process in light of changing market dynamics, making adjustments that are necessary and appropriate to allow the Agencies to detect and prevent illegal mergers prior to consummation. The final rule also makes the process more efficient for filers, third parties, and the Agencies, shifting some of the burden of information collection and reporting to the merging parties (and away from third parties) and requiring the information needed for a preliminary antitrust assessment to be contained in the HSR Filing so that the Agencies have the full statutory review period to assess and confirm the information. Overall, the final rule addresses significant information gaps and asymmetries that have grown over time and undermined the Agencies' ability to conduct premerger review. In addition, this rulemaking implements requirements Congress imposed by passing the Merger Modernization Act, which broadened the scope of information the Agencies must collect as part of premerger review, including by requiring the collection of information about subsidies from foreign entities and governments of concern.

Due to changing commercial realities referenced above, the existing requirements for an HSR Filing leave significant gaps in the information available to the Agencies for conducting this assessment. Many of these gaps can be filled by information that the filing parties already have and often use in their own assessment of the transaction. Certain deficiencies in the existing reporting requirements prevent the Agencies from spotting problem areas that would justify a more in-depth investigation or, alternatively, from readily obtaining the facts needed to conclude that the transaction does not merit in-depth review prior to consummation. The rulemaking addresses these problems as well.

Based on the Agencies' extensive experience reviewing HSR Filings, transactions that present certain attributes are more likely to violate the antitrust laws and deserve further investigation. For instance, a merger of two firms that compete (or will soon compete) to provide goods or services to

[15] John Kepler et al., ''Stealth Acquisitions and Product Market Competition,'' 78 J. Fin. 2837 (2023); John M. Barrios & Thomas G. Wollmann, ''A New Era of Midnight Mergers: Antitrust Risk and Investor Disclosures'' (Nat'l Bureau of Econ. Rsch., Working Paper No. 29655, Jan. 2022), *https://www.nber.org/papers/w29655*; *see also* Colleen Cunningham et al., ''Killer acquisitions,'' 129 J. Political Econ. 649, 653 (2021) (killer acquisitions of overlapping targets bunch just below HSR threshold while there is no such pattern for non-overlapping acquisitions).

[16] Cunningham et al., *supra* note 15, at 653.

[17] *See* Comment of Thomas Wollmann, Doc. No. FTC–2023–0040–0680 at 1 n.2 (citing to Thomas G. Wollmann, ''Stealth Consolidation: Evidence from an Amendment to the Hart-Scott-Rodino Act,'' 1 a.m. Econ. Rev.: Insights 77–94 (2019) and Thomas G. Wollman, ''How to Get Away with Merger: Stealth Consolidation and Its Real Effects on US Healthcare'' (Nat'l Bureau of Econ. Rsch., Working Paper No. 27274, 2021)).

[18] Thomas G. Wollmann, ''Stealth Consolidation: Evidence from an Amendment to the Hart-Scott-Rodino Act,'' 1 a.m. Econ. Rev.: Insights 77–78 (2019) (hereinafter ''Stealth Consolidation'').

[19] *See id.* at 77 (post-2000, enforcement against newly exempt transactions dropped to nearly zero while mergers between competitors rose sharply, reflecting an endogenous response to reduced premerger scrutiny).

[20] In a recent example, the Commission ordered the unwinding of an illegal merger three years and two months after consummation. In December 2020, the Commission approved Otto Bock's divestiture of the assets of Freedom Innovations to another company to resurrect competition in the market for microprocessor prosthetic knees. *In re Otto Bock HealthCare N. Am., Inc.,* No. 9378 (F.T.C. Dec. 1, 2020). The Commission's effort to unwind Polypore's illegal acquisition of rival battery separator manufacturer Microporous required five years, during which an Eleventh Circuit decision upheld the Commission's divestiture order. *See* Press Release, Fed. Trade Comm'n, ''FTC Approves Polypore International's Application to Sell Microporous to Seven Mile Capital Partners; Sale Will Unwind Illegal 2008 Acquisition'' (Dec. 18, 2013), *https://www.ftc.gov/news-events/news/press-releases/2013/12/ftc-approves-polypore-internationals-application-sell-microporous-seven-mile-capital-partners-sale. See also* Debbie Feinstein, ''Un-consummated merger,'' Fed. Trade Comm'n Competition Matters blog (Dec. 18, 2013), *https://www.ftc.gov/enforcement/competition-matters/2013/12/un-consummated-merger.*

[21] Fed. Trade Comm'n, The FTC's Merger Remedies 2006–2012, 18–19 (2017) (report of the Bureaus of Competition and Economics) (less than one-quarter of consummated merger remedies successfully restored competition), *https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf.*

the same set of customers, or a merger involving a manufacturer and its main distributor that also distributes the products of competing manufacturers, may warrant closer scrutiny. On the other hand, if the Agencies can determine from review of an HSR Filing that a transaction does not present such attributes, the Agencies can more quickly and confidently determine that the transaction does not require a more in-depth review and may proceed to consummation.[22] However, the Agencies cannot make these determinations with confidence in the initial 15- or 30-day waiting period when the HSR Filings lack sufficient information about relevant premerger competitive relationships between the parties. By requiring the submission of such information, the final rule enables effective Agency decision-making during the initial 15- or 30-day waiting period.[23] The intention of the final rule is to make it possible for the Agencies to identify the most concerning transactions for more in-depth review, including through the issuance of Second Requests, and also to more quickly and confidently complete the review of those transactions that do not merit additional investigation and can proceed to closing at the end of the statutory waiting period.

The consequences of inadequate detection are revealed in a recent analysis of hospital mergers that were reported to the Agencies for premerger review co-authored by two economists from the Commission's Bureau of Economics.[24] The paper examined a set of consummated hospital mergers and measured the effect of each merger on prices. The study concluded that mergers not reportable under the HSR Act did not result in larger price increases than reportable mergers. In contrast, the authors found different outcomes among mergers that were subject to premerger review based on how much review the transaction received. Of the mergers reported to the Agencies, the largest average percentage price increase occurred for those mergers that received early termination of the initial waiting period. This suggests that the HSR Filings failed to provide sufficient information to trigger additional investigations that could have blocked these harmful mergers before they were consummated; instead, the filings resulted in early termination of the waiting period. While the study was not designed to test the impact of this rulemaking, the study supports the Commission's belief that there are information deficiencies with the current HSR Rules that prevent the Agencies from identifying mergers that may violate the antitrust laws.[25]

Hundreds of individuals submitted public comments to describe their own experiences in the aftermath of mergers and urge the antitrust agencies to do more to prevent the harmful effects of consolidation, including collecting more information in the HSR Filing. Examples of supportive comments from these individuals include the following:

- I was an employee at a mobile gaming company. . . . We went through acquisition after acquisition, to finally end up in a subsidiary of a big gaming multinational company. . . . There was a hiring freeze, there were layoffs in another subsidiary we had been affiliated with and then a month ago they cancelled our project and laid off all California employees. . . . Before the final acquisition, our company had 2 profitable games and was developing a third. After the acquisition there were harsh [Key Performance Indicators] for the new game and investment was cut back. Had our company been able to resist the wave of subsequent acquisitions, it is likely we would still be employed in a profitable and vibrant company that was able to compete on the marketplace.[26]
- I am a General Partner at a small Venture Capital firm. I support this proposal as I believe it will lead to increased transparency which benefits us all. . . . We are facing an oligopoly/monopoly crisis in this country/the world and it's important we strive for real competition. I believe this proposal will provide the government more information with which it can make sure our industries thrive.[27]
- As a retired person, I have noticed prices going up much more where a small group of suppliers have most of the market share. I see companies using near-monopoly power to stop employees from having unions. The only way the antitrust laws can be adequately enforced, is to insist that anyone proposing a merger provide full accurate information on what they are doing.[28]
- I work as a cybersecurity engineer. Leaving aside the economic concerns of monopolies, I want to bring up the security concerns of allowing unchecked mergers. Haphazard, rushed mergers increase the security risk across companies, as the engineering teams must stitch together the environments for disparate organizations quickly. . . . I look forward to these reporting requirements and I hope they cause companies to slow down and think of the knock-on effects of the mergers beyond the influx of cash and increased market power.[29]
- As an investor and financial advisor, I approve of the changes requiring more disclosure about the nature of mergers. The impacts of industry consolidation are important. . . . A thorough understanding of the purpose of mergers should help ensure that deals are not anti-competitive.[30]
- As a retired CPA and former business professor, I support these proposed changes to the HSR form. The government needs the additional information and greater clarity in order to carry out its responsibility to oversee and evaluate proposed mergers and acquisitions with a view to protecting

[22] Until 2020, the Agencies routinely granted early termination of the initial waiting period for certain transactions that did not warrant further action pursuant to 15 U.S.C. 18a(b)(2). In March 2020, in order to transition filers to an e-filing system that permitted the Agencies to continue to process filings during the COVID–19 pandemic, the Agencies temporarily suspended the discretionary granting of early termination. In February 2021, the Agencies once again suspended the granting of early termination in response to an unprecedented volume of transactions. *See* Press Release, Fed. Trade Comm'n, ''FTC, DOJ Temporarily Suspend Discretionary Practice of Early Termination'' (Feb. 4, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/02/ftc-doj-temporarily-suspend-discretionary-practice-early-termination*.

[23] The HSR Act provides for a shortened 15-day initial waiting period for reportable acquisitions by means of a cash tender offer or acquisitions subject to certain Federal bankruptcy provisions. 15 U.S.C. 18a(b)(1)(B); 11 U.S.C. 363(b)(2), as amended (1994). For these transactions, the second waiting period is also shorter, 10 days (as compared to 30 days for most transactions) after appropriate certification of substantial compliance with the Second Request. 15 U.S.C. 18a(e)(2). For convenience, this rulemaking refers to the standard 30-day initial waiting period that applies to most transactions even though the Agencies have even less time to review information provided in the HSR Filing for cash tender or certain bankruptcy transactions.

[24] Keith Brand et al., ''In the Shadow of Antitrust Enforcement: Price Effects of Hospital Mergers from 2009–2016,'' 66 J. L. Econ. 639 (2023).

[25] One commenter suggests that this study proves the opposite and provides evidence that the current HSR Form provides Agency staff with sufficient information to identify potentially anticompetitive mergers. *See* Comment of U.S. Chamber of Com., Doc. No. FTC–2023–0040–0684 at 14 n.32. The Commission disagrees with this assessment of the results. Indeed, in their study, the authors suggested that their results should encourage further study of the process of granting early termination to better illuminate why mergers that receive truncated review had higher price effects than those that received a preliminary review but not a Second Request. *See* Brand et al., *supra* note 24, at 663–64.

[26] Anonymous Comment, Doc. No. FTC–2023–0040–0134.

[27] Anonymous Comment, Doc. No. FTC–2023–0040–0203.

[28] Comment of Joan Friedman, Doc. No. FTC–2023–0040–0237.

[29] Comment of Cybersecurity Engineer, Doc. No. FTC–2023–0040–0238.

[30] Comment of Joseph Cook, Doc. No. FTC–2023–0040–0244.

the common good and promoting competition within and across industries.[31]

• Capitalism can only work with a robust system of competition, and we are lo[]sing that at an ever-increasing rate. I am in an agricultural business. There is virtually no competition for the dollars I spend, and an equal lack of competition for what I produce. This is stunningly true when looked at over the 40 years I have been in business.[32]

• Businesses certainly have a right to pursue mergers and acquisitions as a means of improving their market positions, but the public also has a right to know the ''five W's'' driving these decisions: Who is funding the HSR Action; What are the specifics of the proposed action; When are the HSR Actions taking place; Where are the affected communities/localities; and Why are the stakeholders pursuing the HSR Action (or, what is their business goal)? Another key piece of information that the public has a right to know, is WHO will be affected by the proposed merger or acquisition? The issues at stake here are National Security, fair market competition, supply chain disruptions, and negative impacts on labor markets. . . . I hope the FTC sticks to their plan and implements these common-sense and much needed reporting requirements.[33]

• I am a 25-year veteran in an industry (publishing) that has seen both jobs and innovation suffer due to unchecked consolidation by large players. It is very possible some of this consolidation might have been prevented, or at least steered in a direction that encouraged innovation and growth, if regulators had this kind of information available beforehand.[34]

• I am a private, sole-practitioner entrepreneur with a vested interest in a diversified economic ecology that supports and sustains vibrant, fair competition. . . . From my perspective, the requirements for getting approval for large mergers should include gathering enough information about the companies involved that the FTC can make a best and rational assessment of the effects of the maneuver on the industries, labor markets, consumer pricing, industry trends, trading markets, etc, that they (mergers) will potentially affect.[35]

On the other hand, several commenters stated that the Agencies have not provided any evidence that current information requirements are insufficient, or identified transactions they did not challenge due to shortcomings in the current premerger review process. One commenter suggested that if the Commission intends to expand the information requirements for the HSR Filing, it should lay a stronger legal and evidentiary foundation that would justify its need for the additional information. Another commenter urged the Commission to consider how best to balance the need to determine whether further investigation is warranted against the burden to filing parties.

In response to the comments and to explain further the need for this rulemaking, the Commission discusses below the gaps that exist in current HSR information requirements relating directly to potential violations of the antitrust laws, and identifies the new information requirements in the final rule that will provide a factual basis for the Agencies to determine whether to conduct a more searching review of a transaction based on these concerns. The gaps described below are intended to be illustrative and not exhaustive.

1. Disclosure of Entities and Individuals Within the Acquiring Person

In reviewing a transaction filed under the HSR Act, the Agencies must quickly understand the scope and nature of the buyer's business and business relationships to determine whether the acquisition may harm competition and thus violate the antitrust laws,[36] which include section 7 of the Clayton Act. The scope of section 7 is broad: it prohibits any acquisition whose effect may be substantially to lessen competition or to tend to create a monopoly, including those that result in a small ownership stake.[37] In many acquisitions, the buyer gains control of the acquired entities or assets and directs the decision-making at the combined firm post-merger. In addition, if the buyer has a complex corporate or governance structure, an acquisition can bring together individuals or investors within the buyer that control or influence decision-making at a competitively significant business, such as a competitor of the target[38] of the filed-for transaction.[39] Indeed, holdings of entities within the acquiring person that do not result in control under the HSR Rules nevertheless can result in the ability to influence competitively important decisions of the acquiring entity, and thus affect the analysis of whether the acquisition of the target may harm competition.[40]

The HSR Act states that, unless exempt, no person shall acquire, directly or indirectly, any voting securities or assets of any other person without first filing a notification with the Agencies and waiting for the statutory period to expire.[41] The HSR Rules require notification of the transaction from the entity that, pursuant to the Rules, controls the buyer (or seller), which the Commission has defined as the Ultimate Parent Entity or ''UPE.''[42] But to determine

[31] Comment of Sue Ravenscroft, Doc. No. FTC–2023–0040–0259.

[32] Comment of Jeffrey Bender, Doc. No. FTC–2023–0040–0267.

[33] Comment of Thomas Newman, Doc. No. FTC–2023–0040–0325.

[34] Anonymous Comment, Doc. No. FTC–2023–0040–0332.

[35] Comment of Marla McFadin, Doc. No. FTC–2023–0040–0377.

[36] 15 U.S.C. 12(a).

[37] 15 U.S.C. 18. *See United States* v. *E.I. du Pont de Nemours & Co.,* 353 U.S. 586, 592 (1957) (any acquisition is within the reach of section 7 whenever the reasonable likelihood appears that the acquisition will result in a restraint of commerce or the creation of a monopoly in any line of commerce).

[38] To aid the clarity of the Form and Instructions, the Commission defines ''target'' in the Instructions to include all entities and assets to be acquired by the acquiring person from the acquired person in the reported transaction. *See* section VI.A.1.h.

[39] *See, e.g., In re Red Ventures Holdco, LP,* No. C–4627 (F.T.C. Nov. 2, 2017) (complaint) (overlapping limited partnership holdings violated section 7); *In re TC Group, L.L.C.,* No. C–4183 (F.T.C. Mar. 16, 2006) (complaint) (acquisition involving minority stake giving two private equity investors seats on the boards of competitors); *In re Dan L. Duncan,* No. C–4173 (F.T.C. Aug. 18, 2006) (complaint) (acquisition combined general partners of competing energy storage companies under common control). Competition concerns about partial stakes can arise between horizontal competitors; *United States* v. *Dairy Farmers of Am.,* 426 F.3d 850, 860 (6th Cir. 2005), or a supply relationship, *du Pont,* 353 U.S. at 602–604 (23% interest in General Motors, a key supplier, and a shared board member). Section 7 does not apply to buyers making an acquisition solely for the purpose of investment when the buyer does not intend to use its position to bring about or attempt to bring about a substantial lessening of competition. *United States* v. *Tracinda Inv. Corp.,* 477 F. Supp. 1093, 1100 (C.D. Cal. 1979).

[40] *See du Pont,* 353 U.S. at 607 n.36 (finding the influence of du Pont's 23% stock interest to be greater, due to diffusion of remaining shares); *Denver & Rio Grande W. R.R. Co.* v. *United States,* 387 U.S. 485, 504 (1967) (identifying section 7 concerns with a 20% investment). *See also Dairy Farmers of Am., Inc.,* 426 F.3d at 862 (no voting interest but leverage via its position as financier to control or influence competitor's decisions).

[41] 15 U.S.C. 18a(a). Congress rejected a proposal to limit covered acquisitions to those made by corporations, using the term ''person'' instead because the anticompetitive nature of a merger is not dependent upon the legal form of the acquiring entity. 122 Cong. Rec. 30876 (1976).

[42] One of the many initial challenges that the Commission faced in implementing the HSR Act was how to define ''control'' for the purposes of determining reportability of transactions. The Commission immediately understood that no set percentage of ownership dictated whether an individual or entity had functional control of or significant influence over a company, which is

whether the transaction may violate the antitrust laws, the Agencies need to understand the nature of the buyer's holdings pre- and post-merger, as well as the identities of others who have holdings in the buyer and thus may have influence, including possible veto power, over the buyer's decision-making, since that ability affects the evaluation of the competitive effects of the acquisition of the target. Increasingly, this includes individuals and entities with significant management rights that give them a ''seat at the table'' when the buyer is making competitively important decisions.

Today, the mechanisms of influence are not limited to equity stakes; the ability to influence corporate decision-making arises from a variety of interests beyond voting rights.[43] It may arise from sharing key decision-makers, such as executives or members of their respective boards of directors, or from a combination of a significant minority stake and rights to appoint or nominate members of the board.[44] The power of key decision-makers of one competitor to place members on the board of another competitor or veto financial decisions can result in substantial influence over the buyer, and thus the target after the transaction is consummated, rendering an acquisition of a related target potentially illegal under section 7.[45] A merger might also violate the law if it gives individuals and entities of one competitor access to officers, directors, or employees of another competitor.[46] Similarly, the existence of subsidies, among other means, may subject the buyer to additional pressures from individuals or entities not directly a party to the reportable transaction.[47] Beyond voting rights, these interest holders can have similar influence as holders of minority and non-corporate interests.

a. Trends in Private Investment

Understanding the operations of the buyer has become more challenging due to vast changes in M&A activity since the promulgation of the HSR Rules in 1978. One notable recent trend in M&A activity is that the role of private investors, including private equity, has become more pronounced.[48] In the Agencies' experience, these private investors often utilize complicated structures of ownership and managerial control. They also frequently take either majority or minority stakes in many different operating companies (which may have competitively significant relationships) and can exercise significant influence over management and strategic decision-making. In particular, the percentage of equity interest is often not a good indicator of the extent to which investors can direct the strategic decisions of the business.[49] Investors can participate in the management of companies by serving on the company's board, selecting or monitoring the management team, having veto rights, acting as sounding boards for CEOs, or stepping into management roles themselves.[50]

When these private investors take active positions in a wide variety of companies, such holdings can create direct links between competitors or other competitively relevant firms, such as critical suppliers or distributors. Economic research has shown that transactions that lead to cross-ownership of horizontal competitors or other firms in a competitively significant business relationship can create similar incentives and cause similar anticompetitive effects as a full merger.[51] But when these relationships are not well known or easy to identify, the risk that anticompetitive harm from an unlawful acquisition will go

critical to the analysis of the competitive effects of a transaction. In 1976, the Commission originally proposed that ''control'' would include not only ownership of 50% or more of the voting securities of an entity, but also the power to influence through a minority stake. 41 FR 55488, 55490 (Dec. 20, 1976). Commenters objected to such a subjective test for control. *See* 42 FR 39040, 39043 (Aug. 1, 1977). So, the Commission proposed to include the contractual power to designate a majority of the directors or trustees of an entity. *Id.* This proposal was also criticized for being overly broad and subjective. In the end, in setting up the premerger notification program, the Commission adopted the simple 50% or more threshold for control to give prospective filers certainty as to their reporting obligations. But in doing so, the Commission did not dismiss the significance of understanding who has actual or working control of the filing parties. 43 FR 33450, 33457–58 (July 31, 1978). This definition limited the number of transactions subject to the filing requirements of the HSR Act, but the Commission did not minimize the importance of examining who may have significant influence over the acquiring person while assessing antitrust risk arising from the transaction.

[43] Gabriel V. Rauterberg, ''The Separation of Voting and Control: The Role of Contract in Corporate Governance,'' 38 Yale J. Reg. 1124, 1148–54 (2021) (documenting trend of public companies being subject to stockholder agreements that provide various species of control rights to favored investors); Jill E. Fisch, ''Stealth Governance: Shareholder Agreements and Private Ordering,'' 99 Wash. U. L. Rev. 913, 930–33, 946–53 (2021) (discussing similar trend in private companies).

[44] *E.g., United States* v. *U.S. West, Inc.,* No. 96–002529, 1997 WL 269482 (D.D.C. Feb. 28, 1997) (acquired firm had 20% stake plus board seats in a competitor of acquiring firm).

[45] *E.g., United States* v. *Univision Commc'ns., Inc.,* No. 1:03–cv–00758, 2003 WL 23192527 (D.D.C. Dec. 22, 2003) (buyer held substantial equity stake plus ability to influence certain strategic decisions through issuance of equity or debt or veto of future acquisitions). *See also Dairy Farmers of Am.,* 426 F.3d at 862 (buyer had influence due to role as financier, so that acquired firm is ''locked in'' to a relationship with the buyer, which could lead to anticompetitive effects).

[46] *E.g., In re Time Warner Inc.,* No. C–3709 (F.T.C. Sept. 12, 1996) (analysis to aid public comment) (walling off two individuals and one entity to prevent them from influencing officer, directors, and employees of competitor and its day-to-day operations).

[47] As discussed elsewhere, Congress has directed the Commission to require the reporting of subsidies received from foreign countries or foreign entities of concern due to concerns that these entanglements can distort the competitive process by enabling the subsidized firm to submit a bid higher than other firms in the market, or otherwise change the incentives of the firm in ways that undermine competition following an acquisition. Merger Filing Fee Modernization Act of 2022, 15 U.S.C. 18b. Congress also enacted the Foreign Investment Risk Review Modernization Act of 2018 (FIRRMA) to expand the jurisdiction of the Committee on Foreign Investment in the United States (CFIUS) over certain non-controlling investments and real estate transactions involving foreign persons that may be a threat to national security. Public Law 115–232, 132 Stat. 2173, Title XVII, Subtitle A (2018). For certain foreign investments in U.S. businesses operating critical technologies or infrastructure, or that collect sensitive personal data of U.S. citizens, FIRRMA regulations require notification of non-controlling investments, direct or indirect, that afford the foreign investor (1) access to material non-public technical information; (2) membership or observer rights on the board directors (or similar) or the right to nominate an individual to that board; or (3) any involvement, other than through voting of shares, in substantive decision-making of the U.S. business. 31 CFR 800.211. Such relationships are deemed a non-controlling interest in a U.S. business that afford a foreign investor access to information or involvement in substantive decision-making. *See* 85 FR 3112 (Jan. 17, 2020).

[48] Elisabeth de Fontenay, ''The Deregulation of Private Capital and the Decline of the Public Company,'' 68 Hastings L. J. 445, 447 (2017). Private equity has accounted for an increasing share of all merger activity over time, although private equity activity is highly cyclical. *See* Michael Mauboussin & Dan Callahan, ''Public to Private Equity in the United States: A Long-Term Look,'' Morgan Stanley Inv. Mgmt., Counterpoint Global Insights 1 (Aug. 2, 2020), *https://www.morganstanley.com/im/publication/insights/articles/articles_publictoprivateequityintheusalongtermlook_us.pdf.* Recent estimates suggest that private equity firms managed about 20% of U.S. corporate equity and that private equity deal-making has accounted for 40% or more of domestic M&A activity. Rogé Karma, ''The Secretive Industry Devouring the U.S. Economy,'' Atlantic (Oct. 30, 2023). *See also* Steven A. Cohen, et al., ''Private Equity in 2023—A Year (Not) to Remember,'' Harv. L. Sch. Forum on Corp. Governance (Jan. 13, 2024), *https://corpgov.law.harvard.edu/2024/01/13/private-equity-in-2023-a-year-not-to-remember/* (private equity deal volume declined in 2023 and increasingly focused on smaller deals and minority investments).

[49] *See generally* Bob Zider, ''How Venture Capital Works,'' Harv. Bus. Rev. (Nov.-Dec. 1998), *https://hbr.org/1998/11/how-venture-capital-works*; Thomas Hellman, ''The allocation of control rights in venture capital contracts,'' 29 RAND J. Econ. 57 (1998).

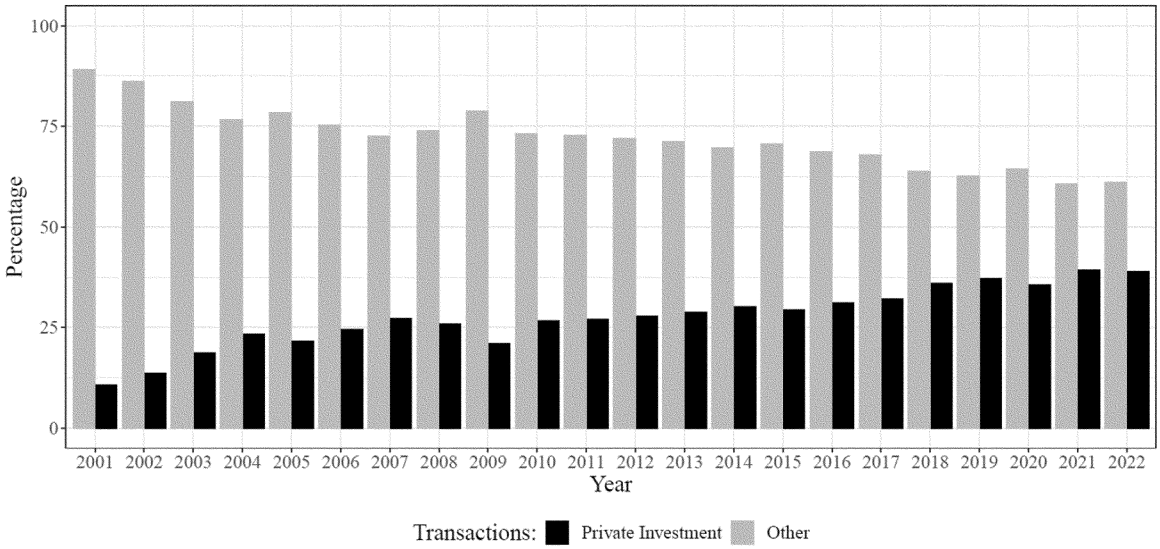
[50] *See, e.g.,* Sec. Exch. Comm'n, ''Private Equity Funds,'' *Investor.gov* (last visited Sept. 10, 2024), *https://www.investor.gov/introduction-investing/investing-basics/investment-products/private-investment-funds/private-equity.*

[51] Timothy Bresnahan & Steven C. Salop, ''Quantifying the competitive effects of production joint ventures,'' 4 Int'l J. Indus. Org. 155 (1986).

undetected is greatly increased.[52] This includes the risk of collusive[53] or coordinated behavior,[54] or the risk that cross-ownership of the combined firm will lead to foreclosure of rivals.[55]

The increasing role of private capital is reflected in the shifting mix of reportable transactions. Using data from the Agencies' Annual HSR Reports for the past 20 years, Figure 2 shows that the number of transactions for which the name of the Ultimate Parent Entity of the acquiring person included ''fund'' or some variation of ''L.P.'' has increased from approximately ten percent to nearly 40 percent of all reportable transactions.[56] The acquiring person for these transactions can be shell companies that have been created by an investment group in order to make a particular acquisition, or an entity that owns a variety of other operating entities (often referred to as ''portfolio companies''). In either scenario, the entity is part of the structure of a larger investment company or group.

Figure 2: Acquisitions Involving Funds and Limited Partnerships



Note: Private Investment refers to the percentage of HSR Reportable Transactions with "Fund" or variation of "L.P." in the name of the UPE of the acquiring person.

Since the beginning of the premerger program, the Commission has required filers to report certain entities that hold minority interests in the filing parties to alert the Agencies to situations in which the potential antitrust impact of the reported transaction does not result solely or directly from the acquisition, but may arise from direct or indirect shareholder relationships between the parties to the transaction.[57] As explained in the NPRM, reporting requirements regarding the identification of certain minority holders of the filing persons have been adjusted over time to reflect market realities, including changes in investment activity and the growing role of these intermediaries.[58] Nonetheless, changes in the investment landscape discussed above have created meaningful gaps in the reporting requirements for a growing number and type of minority holders that have the ability to influence competitive decision-making and to harm competition via acquisitions that violate the antitrust laws.

b. Corporate Structure Changes

Several commenters supported the need for additional information that would identify entities holding minority

[52] Daniel P. O'Brien & Steven C. Salop, ''Competitive Effects of Partial Ownership: Financial Interest and Corporate Control,'' 67 Antitrust L. J. 559, 570 (1999) (overview of the complex corporate financial and governance structures of modern corporations, including different types of shareholding and the relationships to the boards of directors).

[53] Robert J. Reynolds & Bruce R. Snapp, ''The competitive effects of partial equity interests and joint ventures,'' 4 Int'l J. Indus. Org. 141 (1986); David Flath, ''When is it rational for firms to acquire silent interests in rivals?,'' 9 Int'l J. Indus. Org. 573 (1991); David Reitman, ''Partial Ownership Arrangements and the Potential for Collusion,'' 42 J. Indus. Econ. 313 (1994); Sandro Shelegia & Yossi Spiegel, ''Bertrand competition when firms hold passive ownership stakes in one another,'' 114 Econ. Letters 136 (2012).

[54] Rune Stenbacka & Geert Van Moer, ''Cross ownership and divestment incentives,'' 201 Econ. Letters 109748 (2021).

[55] Nadav Levy et al., ''Partial Vertical Integration, Ownership Structure, and Foreclosure,'' 10 a.m. Econ. J.: Microeconomics 132 (2018).

[56] *See* Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Annual Report, Fiscal Year 2010 appendix A (FY 2010) (reporting Adjusted Transactions in which a Second Request could have been issued from years 2001–2010); Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Annual Report, Fiscal Year 2013 appendix A (FY 2013) (reporting Adjusted Transactions in which a Second Request could have been issued from years 2004–2013); Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Annual Report, Fiscal Year 2022 appendix A (FY 2022) (reporting Adjusted Transactions in which a Second Request could have been issued from years 2013–2022). *See also* Fed. Trade Comm'n Annual Reports to Congress Pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, *https://www.ftc.gov/policy/reports/annual-competition-reports* (collecting reports). The Total Number of Adjusted Transactions omits from the total number of transactions reported all transactions for which the agencies were not authorized to request additional information. These include (1) incomplete transactions (only one party filed a complete notification); (2) transactions reported pursuant to the exemption provisions of sections 7A(c)(6) and 7A(c)(8) of the Act; (3) transactions which were found to be non-reportable; and (4) transactions withdrawn before the waiting period began. In addition, where a party filed more than one notification in the same year to acquire voting securities of the same corporation, *e.g.,* filing for one threshold and later filing for a higher threshold, only a single consolidated transaction has been counted because as a practical matter the agencies do not issue more than one Second Request in such a case. These statistics also omit from the total number of transactions reported secondary acquisitions filed pursuant to § 801.4 of the Premerger Notification rules. Secondary acquisitions have been deducted in order to be consistent with the statistics presented in most of the prior annual reports.

[57] 43 FR 33450, 33531 (July 31, 1978).

[58] NPRM at 42188.

positions. One commenter stated that investors have shifted strategies since the 1980s, when portfolios consisted of unrelated companies and investors mainly focused on optimizing capital structures and improving corporate governance.[59] Another commenter stated that without a full picture of the entire corporate structure of the merging parties, it can be difficult or impossible to untangle or understand the potential anticompetitive impacts of a transaction. Several commenters supported the need to adjust information requirements to have a broader view that reflects how firms are organized today. One commenter supported the collection of more comprehensive information related to the merging entities, arguing that a more holistic and systems-level approach would examine the networks of firms involved in a market, which could expose companies that can operate as bottlenecks or supply key resources to other market participants. A group of State antitrust enforcers supported the collection of more information related to corporate control or the degree of financial interest so the Agencies can quickly assess how the resulting ownership structure may change the parties' incentives to compete, enhance the acquirer's ability to influence decision-making through changes in voting interests or governance rights, or facilitate the sharing of competitively sensitive information between rivals.

Another development that has caused the Commission to reassess its rules is that the particular corporate structure of an entity is now less indicative of its market behavior, and thus distinctions made on that basis may no longer be sound. The decision to form as a corporation, limited liability company, or limited partnership is often influenced more by risk, liability, and tax considerations than by the entity's business operations. Now more than ever, distinctions made based on corporate form have little impact on an assessment of whether and how firms compete. Moreover, corporate governance literature highlights the changing nature of decision-making within even standard organizational structures, such as corporations. Corporate law provides sufficient flexibility to alter traditional roles, including the rights of shareholders and the scope of director liability, by contract[60] or through modification of bylaws or certificates of incorporation.[61] The rise of shareholder agreements—private contracts by and among shareholders—has affected who has the ability to direct decisions of the company, separating voting and control, especially for those given veto rights via contract.[62] These forms of 'stealth governance' have implications for how decisions are made within the firm, making it difficult for investors to know who is exercising control within the company.[63]

After careful consideration of these points and others raised by commenters, the Commission has determined that the requirements of the current Form and Instructions have not kept pace with market realities and the accompanying changes in ownership structures. In light of these shifts in corporate formation and governance, the current requirements do not provide the Agencies with sufficient information that allow them to understand how decisions are made at the respective companies, let alone whether the acquiring person may have competitively relevant premerger entanglements with the target's industry and minority holders that may have significant rights to direct the acquiring entity's actions.

To keep pace with prior changes in corporate form, the Commission has adjusted the disclosure requirements for minority investors over time and in light of its experience reviewing thousands of filings each year, balancing the need to surface competitively relevant relationships without burdening filers to provide information that would not change the Agencies' premerger screening decisions. Under the current rules, it has become increasingly difficult to screen transactions because deal structures often have minority investors with significant rights that are not disclosed. See Figures 4 through 8 below, section VI.D.1.d.ii. This includes situations where an investor group is, for practical purposes, making the acquisition (or otherwise significantly involved), but the HSR Filing does not alert the Agencies to their role in the acquisition. These relationships are not currently disclosed if the minority investment is not in the UPE or acquiring entity, but rather in an entity (often a shell entity) that sits between these two in the structure of the acquiring person. Even if the minority investment is made in the UPE, if the UPE is an LP, only the name of the general partner is disclosed. For situations where the current information on the HSR Filing is unrelated to the public-facing name of the entity that controls the acquiring person, the HSR Filing does not alert the Agencies to the premerger relationships that exist solely due to that investor's relationship with and role in the buyer.[64]

To close this information gap, the Commission has determined that the Agencies need additional information about entities in between the UPE and the acquiring entity. If any of these entities or individuals has a minority stake or other rights that give them the ability to influence decision-making post-merger, then they are functionally ''in the deal'' and their existing business relationships are relevant to a thorough premerger antitrust assessment of the transaction. As explained in more detail in section VI.D.1.d.ii.a., this information was required of all corporate entities within the acquiring person prior to a rule change in 2011 that limited the requirement in order to exclude entities not related to the transaction. However, as transaction structures have become more complex, application of the 2011 change has eliminated the requirement to provide information about minority entities that are related to the acquiring entity. The final rule addresses this gap in information so that the Agencies can identify existing relationships among individuals and entities that have interests in (1) the acquiring entity (and any entities it controls or are controlled by it) and (2) other entities within the UPE that have competitive relationships

[59] *See also* Aslihan Asil et al., ''Misaligned Measures of Control: Private Equity's Antitrust Loophole,'' 18 Va. L. & Bus. Rev. 51 (2023). Asil et al. argue that the complicated structure of ownership in the typical private equity acquisition may make some anticompetitive deals technically non-reportable under the HSR act, because the investment structure under-represents the proportion of control actually conferred by the transaction. *Id.* at 53.

[60] *See* Jill E. Fisch, ''Governance by Contract: The Implications for Corporate Bylaws,'' 106 Cal. L. Rev. 373, 379 (2018).

[61] Megan Wischmeier Shaner, ''Interpreting Organizational 'Contracts' and the Private Ordering of Public Company Governance,'' 60 Wm. & Mary L. Rev. 985, 988 (2019) (the charter and bylaws of public corporations are being used as tools for restructuring key aspects of corporate governance).

[62] Rauterberg, *supra* note 43.

[63] Jill E. Fisch, ''Stealth Governance: Shareholder Agreements and Private Ordering,'' 99 Wash. U. L. Rev. 913, 947 (2021) (One investor's capacity to monitor may be limited by an agreement to support director candidates chosen by another investor, or an ownership structure that appears to involve shared power may be undermined by the contractual formation of a control group).

[64] For example, a fund that operates as Alpha Capital Partners could create an entity named 123ABC, LP to effectuate an acquisition. 123ABC, LP could be its own UPE because Alpha Fund I and Alpha Fund II each hold 49.9% of the 123ABC, LP, with the general partner, 123ABC GP, LP, holding 0.2%. Currently, the Form only requires 123ABC, LP to disclose that 123ABC GP, LP is its general partner. The issue is compounded if Alpha Capital Partners is co-investing with Beta Capital Partners and 123ABC, LP is held 49.9% by Alpha and 49.9% by Beta (or if Beta invests in an entity that is not the UPE or acquiring entity). Disclosure of these relationships are not currently required.

with the target. These minority holders are competitively relevant because they may have the ability to influence decision-making and operations of the target post-merger [65] but it is difficult for the Agencies to detect these relationships based on information available the current Form.

As discussed below in section VI.D.1.d. and VI.D.3.c., the final rule requires additional information for Minority Shareholders or Interest Holders as well as Officers and Directors from the acquiring person. Information about other individuals or entities holding a minority position or rights to serve or appoint members of the governing board will fill an existing gap that has created a blind spot for the Agencies that prevents a thorough premerger screening, especially for transactions involving complex corporate structures and investment vehicles. This information is most relevant from the entity that will be making decisions post-consummation, and so the final rule does not seek this information from the seller, other than the identification of minority interest holders that will ''roll over'' their investments post-consummation.[66] This information is necessary to identify additional areas of competitive concern created by minority stakeholders or other influential decision-makers (*i.e.,* officers and directors) that may have a relationship with entities related to the target of the acquisition.

However, in light of concerns raised by commenters about the burden and relevancy of providing this information with respect to limited partners, the Commission has modified these requirements to focus only on those limited partners that also have management rights, such as the right to appoint members to the board. Moreover, the final rule does not adopt certain proposed requirements to identify board observers, or creditors, holders of non-voting securities, or entities with management agreements. The Commission has determined not to require this information at this time but will continue to monitor market activity as it implements the final rule.

Similarly, new document requirements contained in the final rule are aimed at providing a more in-depth understanding of the motivation and purpose of the transaction, and how the combined company will be operated post-consummation. In particular, additional transaction-related documents will provide a more complete picture of the buyer's reason for pursuing the transaction, and for companies with complex investment structures, these documents may reveal whether there are other individuals or entities who will be participating in competitive decisions post-merger. The final rule also requires a small set of business plans and reports shared at the highest level of management that discuss market shares, competition, competitors, or markets of any product or service that is provided by both the acquiring person and acquired entity. Together, these documents may reveal whether there are significant investors in either party that also have investments in businesses that compete with the target or if there are any other planned investments in competitively relevant businesses, such as competitors or suppliers, that would impact the Agencies' assessment of whether the transaction may violate the antitrust laws.

2. Identifying Potential Labor Market Effects

The Clayton Act's prohibition on acquisitions that may substantially lessen competition or tend to create a monopoly applies to acquisitions that have these effects on competition to purchase inputs that firms use to produce goods and services just as it does to acquisitions that threaten competition in downstream markets for goods and services themselves,[67] and the antitrust laws protect competition in markets for labor services.[68] As evidence of decreasing competition for labor continues to mount,[69] the Agencies have increasingly recognized the importance of evaluating the effect of mergers and acquisitions on labor markets and have stepped up efforts to identify and investigate potential labor market effects arising from reportable transactions. The Agencies have challenged a few transactions that may result in labor market harms,[70] and consent agreements have included provisions that stop the use of certain non-compete clauses that limit the ability of potential market entrants to hire key employees.[71]

As stated in the NPRM, current notification requirements under the HSR Act do not require any specific information about employees. And yet virtually every firm competes for labor in at least one labor market and, more commonly, in multiple labor markets, and transactions that involve two firms

[65] *See United States* v. *Dairy Farmers of Am., Inc.,* 426 F.3d 850, 860 (6th Cir. 2005) (district court erred in focusing on control which ignored the possibility that there may be a mechanism that causes anticompetitive behavior other than control, such as leveraging position as financier).

[66] In many transactions, the acquired firm ceases to exist post-consummation. Even when some entity continues to generate revenues, possibly in competition with some aspects of the buyer's business, the Commission has determined to collect additional information about entities within the UPE only from the acquiring person at this time.

[67] *See United States* v. *Bertlesmann SE & Co.,* 646 F.Supp.3d 1 (D.D.C. 2022) (violation of section 7 where merger likely to substantially lessen competition in market for publishing rights to anticipated top-selling books due to harm to targeted sellers—authors of top-selling books); *Boardman* v. *Pac. Seafood Grp.,* 822 F.3d 1011, 1022 (9th Cir. 2016) (acquisition may violate section 7 by substantially lessening competition in multiple seafood input markets). *See also Mandeville Island Farms, Inc.,* v. *Am. Crystal Sugar Co.,* 334 U.S. 219, 235–36 (1948) (antitrust laws protects not just consumers, purchasers, competitors or sellers but all victims of illegal practices); *Weyerhaeuser Co.* v. *Ross-Simmons Hardwood Lumber Co.,* 549 U.S. 312, 321–22 (2007); *United States* v. *Syufy Enterprises,* 903 F.2d 659, 663 n.4 (9th Cir. 1990); *In re Grifols, S.A.,* No. C–4654 (F.T.C. Aug. 1, 2018) (order requiring divestitures to prevent monopsony in three local markets for the collection of plasma).

[68] *NCAA* v. *Alston,* 594 U.S. 69, 86–87 (2021) (plaintiff student-athletes need not show harm in seller-side market as well as buyer-side labor market); *Anderson* v. *Shipowners Ass'n of the Pac. Coast,* 272 U.S. 359, 365 (1926) (Sherman Act protects competition for labor).

[69] *See e.g.,* Anna Stansbury & Lawrence H. Summers, ''The Declining Worker Power Hypothesis: An Explanation for the Recent Evolution of the American Economy'' (Nat'l Bureau of Econ. Rsch., Working Paper No. 27193, 2020), *https://www.nber.org/papers/w27193*; Orley Ashenfelter et al., ''Labor Market Monopsony,'' 28 J. Lab. Econ. 203 (2010); V. Bhaskar et al., ''Oligopsony and Monopsonistic Competition in Labor Markets,'' 16 J. Econ. Perspectives 155 (2002); William M. Boal & Michael R. Ransom, ''Monopsony in the Labor Market,'' 35 J. Econ. Lit. 86 (1997); Alan B. Krueger, Luncheon Address at Kansas City Federal Reserve Bank, Reflections on Dwindling Worker Bargaining Power and Monetary Policy (Aug. 24, 2018), *https://www.kansascityfed.org/documents/6984/Lunch_JH2018.pdf*; Brianna L. Alderman et al., ''Monopsony, wage discrimination, and public policy,'' 61 Econ. Inquiry 572 (2022); David Berger et al., ''Labor Market Power,'' 112 a.m. Econ. Rev. 1147 (2022); Chen Yeh et al., ''Monopsony in the US Labor Market,'' 112 a.m. Econ. Rev. 2099 (2022); José Azar et al., ''Labor Market Concentration,'' 57 J. Hum. Resources S167 (2022).

[70] Press Release, Fed. Trade Comm'n, ''FTC Challenges Kroger's Acquisition of Albertsons'' (Feb. 26, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/02/ftc-challenges-krogers-acquisition-albertsons*; *United States* v. *Anthem* et al., 1:16–cv–01493 ¶ 71 (D.D.C. filed July 21, 2016) (complaint); *United States* v. *Aetna, et al.,* 3–99–CV 1398 ¶ 27 (N.D. Tex. filed June 21, 1999) (complaint). *See also* Concurring Statement of Commissioner Slaughter and Chair Khan Regarding FTC and State of Rhode Island v. Lifespan Corporation and Care New England 1–2 (Feb. 17, 2022), *https://www.ftc.gov/system/files/ftc_gov/pdf/public_statement_of_commr_slaughter_chair_khan_re_lifespan-cne_redacted.pdf* (recommending including a count in the complaint that the proposed merger would have violated section 7 of the Clayton Act in a relevant labor market).

[71] Press Release, Fed. Trade Comm'n, ''FTC Imposes Strict Limits on DaVita, Inc.'s Future Mergers Following Proposed Acquisition of Utah Dialysis Clinics'' (Oct. 25, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/10/ftc-imposes-strict-limits-davita-incs-future-mergers-following-proposed-acquisition-utah-dialysis.*

that purchase labor from the same labor market(s) may substantially lessen competition between employers for labor services. Merging parties may compete in the same labor market even when they do not compete in the same product market.

The Commission received hundreds of comments from individuals, many of whom are in the entertainment industry, who supported the need for the Agencies to conduct a robust search for potential labor market effects before the acquisition is consummated. Several dozen recounted the effects that prior mergers have had on them. Examples of comments supportive of reviewing transactions for labor market effects include the following:

• I'm a working TV writer at the beginning of my career. I'm afraid for the future—the consolidation of the media companies in this town and their vertical integration has made things so much harder and less competitive, even in the time that I've been in LA and worked within the system. Now that there are so few ''shops'' in town, salaries are depressed and it's become incredibly difficult to not only demand fair pay, but treatment as well. They know that they don't have to negotiate or budge on whatever terms they set because there are increasingly few alternatives to them.[72]

• My background includes Strategy consulting for major transnational Mergers. I think the new rules are very good as they demand greater clarity from the firms before the transaction starts. I have seen a lot of waste and backtracking as executives struggle between their ego and the analytics that do not tell them the story that they want about why the transaction will succeed. And the new labor and financing provisions offer much needed transparency—layoffs are a knee jerk habit and are not really helpful for the firm or the industry.[73]

• Please collect data on labor markets. I've been affected by the monopolies in the entertainment industry and likely will lose my livelihood as well as that of my staff due to unchecked mergers within the next month. After starting a successful business 23 years ago, it's heartbreaking to lose it and will be costly to our economy as more and more of us lose our businesses due to these unchecked mergers and the power they wield to save them money.[74]

• I work in a small accounting firm and I have seen the effects of mergers on consumer satisfaction and worker wellbeing personally. . . . [M]any of the job-searching or hiring firms we'd contract with to seek additional workers are worried about raising the ire of the large firm in the region, as it comprises so much of their client base now[.] . . . As a result, we're forced to go with larger, national firms for hiring, and become part of the problem of sectoral concentration.[75]

• As a lifelong union member I also believe the requirement for detailing merger effects on workers and unions to be a vital necessity. Those of us outside the C suites, boardrooms and stockholder meetings are stakeholders too, and our livelihoods and well being should be considerations.[76]

• I personally know many folks in entertainment (writers, crew, actors, etc.) who have had such a difficult time surviving in Hollywood that they've simply had to quit or move home. And, frankly, folks who specifically represent cultures that are least visible in society are often the first to go—because they don't necessarily have the resources or didn't face as many obstacles as other artists. It's a terrible cycle, magnified greatly by vertical mergers.[77]

Numerous commenters, including State antitrust enforcers and members of Congress, expressed general support for an increasing focus on labor market competition in merger analysis and requiring additional labor market information in the Form to screen for such issues. Some commenters highlighted potential efficiencies in the merger review process from providing the Agencies with labor market information in the earlier stages of review, including a more uniform process that could result in the termination of more merger reviews within the 30-day waiting period and a more efficient use of Agency resources where no labor market issues exist.

The Commission disagrees with a commenter who stated that the analysis under the Clayton Act requires consideration of competition issues, but not labor. Antitrust law, including the Clayton Act, has always been concerned with workers and labor markets.[78] As noted by the State antitrust enforcers, in the congressional debates on the Clayton Act in 1914, legislators expressed concerns regarding the monopsonist's power to dictate to its labor the wage it will pay for the only commodity labor has to sell.[79] As recently as 2021, a unanimous Supreme Court in *NCAA* v. *Alston* affirmed that the antitrust laws are designed to prevent harm to competition in labor markets.[80] As noted in the concurring opinion: ''Price-fixing labor is price-fixing labor. And price-fixing labor is ordinarily a textbook antitrust problem because it extinguishes the free market in which individuals can otherwise obtain fair compensation for their work.'' [81] And there is bipartisan agreement among current Federal enforcers and their predecessors that the Agencies are empowered to enforce the Clayton Act to prevent competitive harms in labor markets caused by mergers.[82] Moreover, recent empirical work demonstrates the impact that mergers have on competition in labor markets.[83]

One commenter stated that requiring merging parties to provide labor and employment information is at odds with the consumer welfare standard. This is not correct. Judge Easterbrook, writing for the Seventh Circuit, recently rejected an employer's argument that restrictions on the movement of employees could be justified because it expanded the output of consumer products: ''One problem with this approach is that it treats benefits to consumers (increased output) as justifying detriments to workers (monopsony pricing). That's not right; it

[72] Anonymous Comment, Doc. No. FTC–2023–0040–0511.

[73] Comment of Punya Upadhyaya, Doc. No. FTC–2023–0040–0283.

[74] Comment of Karen Wood, Doc. No. FTC–2023–0040–0271.

[75] Comment of John Kurpierz, Doc. No. FTC–2023–0040–0462.

[76] Comment of Chas McClelland, Doc. No. FTC–2023–0040–0273.

[77] Comment of Alice Stanley, Doc. No. FTC–2023–0040–0508.

[78] *Anderson* v. *Shipowners Ass'n of the Pac. Coast,* 272 U.S. 359, 365 (1926).

[79] Comment of State Atty's Gen., Doc. No. FTC–2023–0040–0695 at 21 n.123 (citing 51 Cong. Rec. 9184 (1914) (statement of Rep. Guy Helvering)). *See also* 21 Cong. Rec. 2457 (1890) (statement of Sen. Sherman asserting trusts command the price of labor).

[80] *NCAA* v. *Alston,* 594 U.S. 69 (2021). The Agencies' approach to evaluating the potential labor market effects of mergers is set forth in the Merger Guidelines. U.S. Dep't of Justice & Fed Trade Comm'n, Merger Guidelines 2.10 (2023).

[81] *Alston,* 594 U.S. at 109–110 (Kavanaugh, J., concurring).

[82] *See generally* FTC Chairman Joseph J. Simons, Prepared Keynote Address at American University Washington College of Law Conference on Themes of Professor Jonathan Baker's New Book, *The Antitrust Paradigm: Restoring a Competitive Economy* 9 (Mar. 8, 2019), *https://www.ftc.gov/system/files/documents/public_statements/1515179/simons_-_jon_baker_speech_3-8-19.pdf;* Assistant Attorney General Makan Delrahim, Remarks at the Public Workshop on Competition in Labor Markets 3 (Sept. 23, 2019), *https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-remarks-public-workshop-competition.*

[83] *See* Elena Prager & Matt Schmitt, ''Employer Consolidation and Wages: Evidence from Hospitals,'' 111 a.m. Econ. Rev. 397 (2021); David Arnold, ''Mergers and Acquisitions, Local Labor Market Concentration, and Worker Outcomes'' (Working Paper, Oct. 27, 2019), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3476369.*

is equivalent to saying that antitrust is unconcerned with competition in the markets for inputs, and *Alston* establishes otherwise.'' [84] There is a clear consensus that the consumer welfare standard is sufficiently flexible to encompass antitrust enforcement to prevent competitive harms to labor markets.[85] Because section 7 reaches these concerns, it is appropriate for the Agencies to collect information to determine if the transaction may violate the antitrust laws by substantially lessening competition in any market for labor. The fact that the Commission has not previously required this information to be reported in HSR filings does not mean that the information is not necessary and appropriate to enable the Agencies to determine whether an acquisition, if consummated, may violate the antitrust laws. While not every negative impact on workers reflects a harm to competition, growing evidence about the potential for mergers to cause harm in input markets for labor in violation of the antitrust laws shows that the Agencies have a sound basis to review transactions for potential competitive impacts on labor markets.

As discussed below in section VI.I.3., the final rule does not require filers to submit specific information about their employees as suggested in the proposed rule. Instead, the Agencies will rely on other information and documentary materials required in the final rule to conduct a preliminary assessment of whether the transaction may violate the antitrust laws with respect to any affected labor market. The Agencies have been gaining experience analyzing information about employees during ongoing merger reviews and other investigations of conduct that may harm competition for workers, and the Commission relies on this experience to determine which documents and information have been most useful in identifying those transactions that warrant an in-depth review of potential labor market effects through the issuance of Second Requests.

As discussed below in section VI.I.3., the Commission will rely on information contained in the new Overlap and Supply Relationships Descriptions, as well as additional documents required by the final rule to conduct a preliminary assessment of potential labor market effects. In the Agencies' experience, those transactions that are flagged for closer review due to concerns about effects in output markets may also require a closer look at potential impacts in input markets, including labor markets. Because the final rule will allow the Agencies to conduct a more robust screening for potential effects in output markets, it will also permit more robust screening for potential effects in input markets, including those related to labor services. In addition, the final rule requires the submission of certain plans and reports shared at the highest level of management that discuss market shares, competition, competitors, or markets of any product or service that is provided by both the acquiring person and acquired entity. These documents may also indicate whether the parties view themselves as employing similar categories of employees or competing for certain types of labor services. As a result, the final rule will enhance the Agencies' ability to conduct a premerger assessment to determine if the transaction may violate the antitrust laws with respect to competition for labor. Although the Commission has determined not to require specific information about workers or workplace safety information in the HSR Filing at this time, as the Agencies acquire more experience with conducting competition analyses of labor markets, the Commission may revisit the issue in future rulemakings.

3. Identifying Acquisitions That Create a Risk of Foreclosure

Mergers between firms that are not direct competitors can still violate the antitrust laws. As stated in the NPRM, an acquisition may violate the law if it creates opportunities for post-merger foreclosure of rivals arising from vertical or non-horizontal relationships.[86] The nature and scope of potential non-horizontal competitive concerns can often be complex and unique. To fully account for all the ways in which a proposed transaction may violate the antitrust laws, the Agencies need information to determine whether there are any existing or emerging business relationships between the merging parties that would allow the merged firm to limit access to products or services that its rivals use to compete, referred to as ''foreclosure.'' [87] Current information requirements in the Rules do not reveal these existing relationships, which are well known to the parties. Even more than in horizontal mergers, which require an assessment of whether the merger may eliminate existing competition between rivals whose products are viewed as substitutes, non-horizontal concerns arise from distinct facts and industry structure that are not readily available to the Agencies from other sources.

Various commenters, including members of Congress, supported new information requirements targeting non-horizontal competitive issues. A comment from State antitrust enforcers underscored the concern about foreclosure, noting that because mergers may change the firms' incentives or ability to disadvantage or eliminate rivals at one or more levels of their supply chains, one of the anticompetitive harms that may result from a merger—particularly non-horizontal mergers—is the risk of foreclosure. The comments from a farmer-led advocacy organization warned that dominant firms have expanded across product markets—primarily through product-extension and conglomerate mergers—to insulate against cross-industry competition or to develop product-tying and other capacities for entrenchment and exclusion.

Other commenters maintained that vertical merger challenges are uncommon and that antitrust precedent does not sufficiently support non-horizontal theories of competitive harm to warrant the new information requirements. For example, commenters stated that the Agencies challenge very few vertical transactions, and the courts generally have not been receptive to those challenges. One commenter stated that an assessment of potential future competitors goes well beyond what is typically relevant because non-horizontal theories of harm are rare under section 7. The same commenter reasoned that when challenging a vertical merger the antitrust agency must prove that one party has substantial market power and that information regarding the vendor-vendee relationship is not required to assess this threshold question. A tech industry trade association stated that

[84] *Deslandes* v. *McDonald's USA, LLC,* 81 F.4th 699, 703–04 (7th Cir. 2023).

[85] *See* Herbert Hovenkamp, ''Is Antitrust's Consumer Welfare Principle Imperiled?,'' 45 J. Corp. L. 65, 78 (2019) (injury that results from the exercise of monopsony power is technically similar to the injury caused by monopoly; in both cases the defendant reduces output); Delrahim, *supra* note 82, at 3–4 (consumer welfare standard is flexible enough to take into account harm to competition that is localized in an upstream labor market, not just a downstream product market); FTC Commissioner Christine S. Wilson, Keynote Address: Welfare Standards Underlying Antitrust Enforcement: What You Measure Is What You Get 7 (Feb. 15, 2019), *https://www.ftc.gov/system/files/documents/public_statements/1455663/welfare_standard_speech_-_cmr-wilson.pdf* (consumer welfare standard does address possible monopsony concerns, and the agencies apply the consumer welfare standard to labor markets).

[86] NPRM at 42179.

[87] *See Illumina, Inc.* v. *FTC,* 88 F.4th 1036, 1055 (5th Cir. 2023) (violation of section 7 where merger will result in the potential foreclosure of key input by the sole supplier). *See also Ford Motor Co.* v. *United States,* 405 U.S. 562 (1972).

most vertical mergers promote competition, so filers should not need to answer detailed questions about vertical relationships.

While in the past non-horizontal challenges were less common than those involving direct competitors, in recent years the Agencies have brought a significant number of non-horizontal merger enforcement actions that have resulted in merger abandonment and ordered divestitures,[88] and other mergers were abandoned or restructured prior to legal action.[89] The Commission also disagrees that potential harm from foreclosure is uncommon or does not warrant robust scrutiny. Empirical economic studies of vertical mergers find no basis to assume that they are either procompetitive or anticompetitive in general. Instead, each transaction must be examined on its facts and in the context of the markets served by the merging parties. A review of twenty-nine recent studies of vertical integration reports that fourteen studies found some evidence of competitive harm, while fourteen found some evidence of benefits.[90] The same review also evaluated two frequently cited surveys of vertical integration and found that the subjects and methods used limit any conclusions that can be drawn for antitrust policy purposes.[91]

The Agencies have an obligation to screen transactions for non-horizontal effects, including the risk of post-merger foreclosure, because the law clearly requires it. In 1950, Congress amended section 7 of the Clayton Act to expressly reach non-horizontal transactions to combat ''the rising tide of economic concentration . . . [providing] authority for arresting mergers at a time when the trend to a lessening of competition in a line of commerce was still in its incipiency.'' [92] The Supreme Court subsequently set forth frameworks for analyzing vertical [93] and other non-horizontal [94] mergers to address concerns about foreclosure.[95] Relying on these precedents, the Agencies bring enforcement actions against transactions that create a risk that the merger will create a firm that may limit access to products or services rivals use to compete.[96] Several of these enforcement actions resulted in the parties abandoning their merger plans in the face of litigation. Just recently, the U.S. Court of Appeals for the Fifth Circuit upheld the Commission's finding that Complaint Counsel carried their initial burden of showing that Illumina's acquisition of Grail was likely to substantially lessen competition in the U.S. market for research and development of multi-cancer early detection tests and that Illumina failed to establish cognizable efficiencies.[97] The decision is significant for its application of vertical theories of harm, as well as its inclusion of products in the relevant market based on precommercial activity.

In the Agencies' experience, it can be difficult to detect whether current or potential rivals of one merging party are dependent on the other merging party for a key product, service, or route to market necessary to compete. The Agencies currently do not receive sufficient information in the HSR Filing to identify candidate ''related products'' nor to assess the degree to which rivals may be dependent on the related product.[98] Accordingly, the Agencies are not well positioned to conduct a robust initial screen for this significant mechanism of competitive harm. Being able to quickly assess whether the transaction presents a risk of foreclosure would permit the Agencies to target their investigative resources most efficiently on those transactions that are most likely to raise this competitive concern.

As discussed in more detail below, the Commission has determined that information that reveals existing supply relationships between the merging parties or their rivals is necessary to fully account for the potential that the transaction may create a firm that could limit rivals' access to key products or services they need to compete in violation of the antitrust laws. The Commission previously required information about vendor-vendee relationships, but eliminated this requirement when the reported information did not provide a sufficient basis for that analysis such that the benefit to the Agencies did not outweigh the burden of providing it.[99] The Supply Relationships Description in the final rule requires information that is specifically targeted to identifying whether rivals may be dependent on the merged firm for key inputs post-merger. Thus, the information is more relevant to the Agencies' screening for such risks than prior vendor-vendee information.

Additionally, the final rule also contains new document requirements that are intended to reveal any existing or future non-horizontal business relationships that could give rise to risks from foreclosure of rivals. For example, the buyer must indicate whether it has existing contracts with the seller in broad categories that are relevant to an initial antitrust assessment, such as leases, licensing agreements, master service agreements, operating agreements or supply agreements, or

[88] *Illumina,* 88 F.4th at 1048, 1059; *FTC* v. *Tempur Sealy Int'l, Inc.,* 4:24–cv–02508 (S.D. Tex. filed July 2, 2024) (complaint); *In re Lockheed Martin Corp.,* No. 9405 (F.T.C. Jan. 25, 2022) (complaint alleging merger would enable missile systems manufacturer to use control over missile propulsion systems to harm rival defense prime contractors) (transaction abandoned); *In re Nvidia Corp.,* No. 9404 (F.T.C. Dec. 2, 2021) (complaint alleging merger would give chip manufacturer the ability and incentive to use control over microprocessor design technology to undermine competitors) (transaction abandoned). For a compilation of the Agencies' enforcement actions involving vertical mergers, see Steven C. Salop & Daniel P. Culley, ''Vertical Merger Enforcement Actions: 1994–April 2020'' (Geo. L. Faculty Pub. & Other Works No. 1529, 2020), *https://scholarship.law.georgetown.edu/facpub/1529/* (reporting 66 vertical matters over 26 years).

[89] *See, e.g.,* Press Release, U.S. Dep't of Justice, ''Antitrust AAG Kanter Statement After Adobe and Figma Abandon Merger'' (Dec. 18, 2023), *https://www.justice.gov/opa/pr/antitrust-aag-kanter-statement-after-adobe-and-figma-abandon-merger*; Cat Zakrzewski, ''Amazon ends $1.7B iRobot acquisition in rare victory for tech regulators,'' Wash. Post (Jan. 29, 2024), *https://www.washingtonpost.com/technology/2024/01/29/amazon-irobot-antitrust-europe/*.

[90] Marissa Beck & Fiona Scott Morton, ''Evaluating the Evidence on Vertical Mergers,'' 59 Rev. Indus. Org. 273, 274 (2021) (explaining many of the studies reviewed were not designed to assess the net effect of vertical integration on welfare).

[91] *Id.*

[92] *Brown Shoe Co.* v. *United States,* 370 U.S. 294, 317 (1962); Celler-Kefauver Antimerger Act of 1950, Pub. L. 81–899, 64 Stat. 1125 (1950).

[93] *Brown Shoe,* 370 U.S. 294 (vertical merger violated section 7); *see also Ford Motor Co.* v. *United States,* 405 U.S. 562 (1972) (same).

[94] *See FTC* v. *Procter & Gamble Co.,* 386 U.S. 568, 577–578 (1967) (product-extension merger violated section 7). *See also Fruehauf Corp.* v. *FTC,* 603 F.2d 345 (2d Cir. 1979); *U.S. Steel Corp.* v. *FTC,* 426 F.2d 592, 599 (6th Cir. 1970).

[95] The Agencies' analyses of how vertical and other non-horizontal transactions may harm competition are set forth in detail in the recently revised Merger Guidelines. U.S. Dep't of Justice & Fed Trade Comm'n, Merger Guidelines 5 (2023).

[96] *See, e.g., FTC* v. *Tempur Sealy Int'l, Inc.,* 4:24–cv–02508 (S.D. Tex. filed July 2, 2024) (complaint); *In re Amgen, Inc,* No. 9414 (F.T.C. Dec. 13, 2023) (consent order settling charges that the acquisition would enable Amgen to leverage its large portfolio of drugs to pressure insurance companies and PBMs into favoring Horizon's monopoly products or disadvantaging rivals); *In re Lockheed Martin Corp.,* No. 9405 (F.T.C. Jan. 25, 2022) (complaint alleging merger would enable missile systems manufacturer to use control over missile propulsion systems to harm rival defense prime contractors) (transaction abandoned); *In re Nvidia Corp.,* No. 9404 (F.T.C. Dec. 2, 2021) (complaint alleging merger would give chip manufacturer the ability and incentive to use control over microprocessor design technology to undermine competitors) (transaction abandoned); *In re Microsoft Corp.,* No. 9412 (F.T.C. Dec. 8, 2022) (complaint).

[97] *Illumina, Inc.* v. *FTC,* 88 F.4th 1036, 1048, 1059 (5th Cir. 2023) (remanding to Commission to consider whether supply agreement offered to rivals sufficiently mitigated merger's effect). *See also United States* v. *AT&T, Inc.,* 916 F.3d 1029, 1045 (D.C. Cir. 2019) (vertical mergers can create harms beyond higher prices for consumers, including decreased product quality and reduced innovation).

[98] *See* U.S. Dep't of Justice & Fed Trade Comm'n, Merger Guidelines 2.5 (2023).

[99] NPRM at 42196–97.

any noncompete or non-solicitation agreements that might be affecting current levels of competition. Filers with an existing business relationship also will submit one year's worth of plans and reports provided to a Chief Executive Officer or the Board of Directors that analyze markets and competition pertaining to any product or service both parties supply (including products or services in development). Based on the Agencies' experience, these types of high-level business documents can reveal whether and how the parties interact in the market today to understand how the merger may affect market conditions more broadly, including any risk of foreclosure that could harm other market participants as well as competition overall. Finally, the expanded set of transaction-related documents ensure that the Agencies receive key documents that have been collected for the purposes of the deal but have not yet been shared with the board of directors. In the Agencies' experience, when there is an existing non-horizontal business relationship between the parties, these documents often reference that relationship and how it might be affected by the transaction, including whether the parties believe that there are synergies or efficiencies that may be gained.

4. Identifying Potential Law Violations Involving Innovation Effects, Future Market Entry, or Nascent Competitive Threats

In markets where concentration is already great or trending in that direction, a merger may be illegal if it eliminates ongoing innovation efforts or the possibility that entry or expansion by one or both firms would have resulted in new or increased competition.[100] Relatedly, the acquisition of a firm that represents a nascent competitive threat—namely, a firm that could grow into a significant rival, facilitate other rivals' growth, or otherwise spur more robust competition in the future—may violate the antitrust laws.[101] Concerns that a transaction may violate the antitrust laws by reducing innovation efforts [102] or eliminating a future competitor [103] are core to section 7's purpose to arrest the anticompetitive effects of market power in their incipiency. Established incumbents may seek to acquire a potential entrant or a nascent competitive threat in order to eliminate beneficial future competition, especially at critical junctures when the acquired firm is poised to introduce a disruptive product.[104]

As noted in the NPRM, there has been tremendous growth in sectors of the economy that rely on technology, such as pharmaceutical, medical device, and digital markets. Given the dynamic nature of these markets and the importance of acquisition strategies to success as well as market growth and penetration, mergers and acquisitions in these markets present a unique challenge for the Agencies. In particular, the Agencies must closely examine mergers in these and other rapidly evolving markets to account for the possibility that the merger may violate the antitrust laws by eliminating a nascent competitor or potential entrant, including the acquisition's effects on ongoing innovation competition.[105]

Competition policy debates in Congress have increasingly focused on markets that lack sufficient competition, especially in critical technology sectors.[106] Concerns about the role of certain dominant companies have caused the Agencies to deploy additional resources to counter the economic power of these firms, including through costly and resource-intensive monopolization suits, some of which focus on the harmful effects of their prior acquisitions.[107] Both Agencies have hired technologists and other experts to build their in-house capacity to keep pace with developments in dynamic markets that are reliant on emerging technology.[108] The Agencies have also invested in better understanding how dominant firms can use strategic acquisitions as part of an interrelated course of monopolistic conduct. For example, the Agencies have brought challenges alleging that firms have engaged in ''buy-or-bury'' strategies against actual or potential rivals.[109] The Agencies have also alleged that firms have attempted to buy or exercise control of adjacent products or services that might be used to steer customers to their other products or exclude competing platforms.[110] These strategies can be very hard to detect because merger activity in these sectors increasingly involves firms in business lines that currently may not be related in a clearly horizontal or vertical way. Without information that identifies products in development and the firms' assessments of where potential competitive threats are likely to emerge in the future, the Agencies have no basis to identify whether a transaction may eliminate ongoing innovation competition, a potential entrant, or a nascent competitive threat.[111]

When transactions involve firms whose premerger relationship is not yet well established in the marketplace and is occurring outside the public eye through ongoing product development efforts, the Agencies cannot rely on the reporting of current overlapping revenues to spot transactions that may

[100] *United States* v. *Marine Bancorp, Inc.,* 418 U.S. 602, 630 (1974).

[101] *See FTC* v. *Procter & Gamble,* 386 U.S. 568, 577–78 (1967). *See also United States* v. *El Paso Nat. Gas Co.,* 376 U.S. 651 (1964); *Polypore Int'l* v. *FTC,* 686 F.3d 1208 (11th Cir. 2012) (acquisitions that eliminate competitive threats violate section 7). Like the Clayton Act, the Sherman Act bars a firm from gaining or maintaining a monopoly position through anticompetitive conduct, including acquisitions that exclude nascent or potential threats to its dominance. *See, e.g., United States* v. *Grinnell Corp.,* 384 U.S. 563 (1966) (acquisitions are among the types of conduct that may violate the Sherman Act). Acquisitions by monopolists of nascent competitive threats violate section 2 of the Sherman Act because they are reasonably capable of contributing significantly to the defendant's monopoly power. *United States* v. *Microsoft Corp.,* 253 F.3d 34, 79 (D.C. Cir. 2001) (en banc) (per curiam) (Sherman Act does not allow monopolists free reign to squash nascent, albeit unproven, competitors at will).

[102] For a discussion of how mergers may violate section 7 by eliminating on-going innovation competition, see Note by the United States to the OECD, The Role of Innovation in Enforcement Cases (Dec. 5, 2023) (DAF/COMP/WD(2023)84), *https://one.oecd.org/document/DAF/COMP/WD(2023)84/en/pdf.*

[103] *See United States* v. *Falstaff Brewing Corp.,* 410 U.S. 526, 561–62 (1973) (Marshall, J, concurring). *See also United States* v. *Continental Can Co.,* 378 U.S. 441, 465 (1964) (fact that merging parties were not direct competitors for all end uses at the time of the merger may actually enhance the long-run tendency of the merger to lessen competition).

[104] *See United States* v. *Visa Inc.,* No. 3:20–cv–07810 (N.D. Cal. Nov. 5, 2020) (complaint) (transaction abandoned and case dismissed) and Assoc. Attorney General Vanita Gupta, Remarks at Georgetown Law's 15th Annual Global Antitrust Enforcement Symposium (Sept. 14, 2021), *https://www.justice.gov/opa/speech/associate-attorney-general-vanita-gupta-delivers-remarks-georgetown-law-s-15th-annual. See also supra* note 15 (collecting studies).

[105] *FTC* v. *PPG Indus., Inc.,* 798 F.2d 1500, 1505–06 (D.C. Cir. 1986) (Bork, J.).

[106] Majority Staff of H.R. Subcomm. on Antitrust, Com. & Admin L. of the Comm. On the Judiciary, 116th Cong., Majority Staff Rep. & Recommendations, Investigation of Competition in Digital Mkts. 38 (2020), *https://democrats-judiciary.house.gov/uploadedfiles/competition_in_digital_markets.pdf* (hereinafter ''Investigation of Competition in Digital Markets'').

[107] *FTC* v. *Facebook, Inc.,* 581 F. Supp. 3d 34, 40–42 (D.D.C. 2022); *United States* v. *Google LLC,* No. 1:23–cv–00108 at 31–35, 65–68 (E.D. Va. filed Jan. 24, 2023) (complaint); *United States* v. *Live Nation Entertainment, Inc.,* No. 1:24–cv–03973 (S.D.N.Y. filed May 23, 2024); *see also Klein* v. *Meta Platforms, Inc.,* No. 3:20–cv–8570 (N.D. Cal. filed Dec. 3, 2020).

[108] *See* Note by the United States to the OECD, Theories of Harm for Digital Mergers (June 16, 2023) (DAF/COMP/WD(2023)50), *https://one.oecd.org/document/DAF/COMP/WD(2023)50/en/pdf.*

[109] *FTC* v. *Facebook, Inc.,* 581 F. Supp. 3d at 54.

[110] *United States* v. *Microsoft Corp.,* 253 F.3d 34, 73–74 (D.C. Cir. 2001).

[111] *See United States* v. *Google LLC,* No. 20–cv–3010, 2024 WL 3647498 (D.D.C. Aug. 5, 2024). (loss of nascent competitors is a clear anticompetitive effect).

eliminate areas of emerging or potential competition.[112] The Agencies need a reliable factual basis for identifying transactions that create this risk, which is not provided in the current Form. For instance, the Agencies need information about products in development that are not currently generating revenues, but that the filer expects will soon. Because legal precedent makes clear that a merger that substantially lessens competition for innovation or research and development violates the law,[113] the Agencies need information that will identify areas of pre-revenue investments and competition. The Agencies also need information that reveals the rationale for the transaction, including whether the acquired firm is considered a nascent competitive threat, and documents that reflect each firm's horizon-scanning for potential acquisition targets. This information is known only to the parties and is relevant to an initial assessment of whether the transaction may violate the antitrust laws by eliminating a potential entrant or nascent competitive threat.

Failure to account for the merger's potential impact on ongoing innovation competition can have meaningful implications. Consumers and businesses reap enormous benefits from the efficiency and convenience brought about by significant innovations. According to Nobel Prize winner Robert Solow: ''Technological progress, very broadly defined to include improvements in the human factor, was necessary to allow long-run growth in real wages and the standard of living.'' [114] Courts, academic literature and commenters confirm the importance of innovation to growth in the economy and as a source of dynamism that can shake loose entrenched incumbents.[115] Acquisitions of innovator firms may also deny the public the benefits of those investments in innovation, including any future competition those investments may have unleashed, if the acquirer does not make use of the discoveries [116] or is able to crowd out nascent competitors by foreclosing access to a key input.[117] The stakes are also high for innovators: startups may find fewer investors and lower acquisition prices in sectors where the expectation is that incumbents will ultimately identify and acquire any promising innovation.[118]

Comments from State antitrust enforcers supported proposals seeking materials and information regarding potential or nascent entrants. However, other commenters stated that the HSR Filing is not an appropriate vehicle for advancing novel legal theories such as nascent competition or research and development competition, and any related revisions should be postponed until those theories are better established in case law.

The Commission disagrees with commenters who suggested that concerns about innovation competition, potential entrants, and nascent threats are not well-grounded in existing law and economic learning. The importance of scrutinizing mergers for potential effects on innovation is well-documented.[119] Economic evidence supports current legal precedent. Research demonstrates a growing phenomenon of dominant firms—buoyed by acquisitions—taking over industries.[120] This is particularly true in the tech industry, where the markets in which digital platforms compete share several characteristics that tend toward a single dominant firm.[121] Sustained high economic profits suggest that dominant firms in these concentrated sectors possess substantial and durable market power.[122] In addition, insufficient competition and entry result in harms to investment and innovation.[123] For these reasons, economic research supports the current legal framework, and reflects the need to carefully scrutinize proposed transactions involving a dominant incumbent or monopolist seeking to acquire a nascent threat or adjacent complement that could someday challenge the incumbent's position.[124]

Going back many years, the Agencies have successfully challenged several mergers that would have eliminated a potential entrant or nascent competitive threat. These enforcement actions include the acquisition of a pipeline firm or product that, once launched, would compete directly with the incumbent merging party,[125] as well as the acquisition of a firm with products already on the market that, although small, was poised to add features or capabilities in the future that could render it a closer and more formidable competitor than it is today.[126] Other transactions challenged by the Agencies involved the acquisition of a firm whose current market share understated its future competitive significance because it did not account for new innovations, business strategies, or other factors.[127] Mergers that impact future competition between products or services that have not yet been developed can also violate the antitrust laws.[128]

[112] *See Illumina, Inc.* v. *FTC,* 88 F.4th 1036, 1049–51 (5th Cir. 2023) (antitrust markets not limited to products that exist but may include those that are anticipated or expected or encompass research, development and commercialization of products in development); *FTC* v. *PPG Indus., Inc.,* 798 F.2d, 1500, 1504 (D.C. Cir. 1986) (merging firms competed in evolving high technology market at the request-for-proposal stage of product development).

[113] *See United States* v. *Anthem, Inc.,* 855 F.3d 345, 361 (D.C. Cir. 2017) (threat to innovation alone is anticompetitive effect from acquisition); *Illumina, Inc.* v. *FTC,* 88 F.4th 1036, 1051 (5th Cir. 2023) (''Antitrust law does not countenance such a cramped view of competition, particularly in a research-and-development market.'').

[114] Robert Solow, ''Growth Theory and After,'' 78 Am. Econ. Rev. 307, 313 (1988).

[115] *See* Giulio Federico et al., ''Antitrust and Innovation: Welcoming and Protecting Disruption,'' 20 Innovation Pol'y & Econ. 125, 128–29 (2020); C. Scott Hemphill & Tim Wu, ''Nascent Competitors,'' 168 U. Pa. L. Rev. 1879, 1886 (2020).

[116] *See* Hemphill & Wu, *supra* note 115, at 1893. *See also* Mark Lemley & Andrew McCreary, ''Exit Strategy,'' 101 B.U. L. Rev. 1 (2020).

[117] *See Illumina* v. *FTC,* 88 F.4th at 1053.

[118] Sai Krishna Kamepalli et al., ''Kill Zone'' (Nat'l Bureau of Econ. Rsch., Working Paper No. 27146, May 2020 rev. June 2022), *https://www.nber.org/papers/w27146.*

[119] *See generally* Carl Shapiro, ''Competition and Innovation: Did Arrow Hit the Bull's Eye?,'' in The Rate and Direction of Econ. Activity Revisited 389–400 (Josh Lerner & Scott Stern eds., 2012).

[120] Carl Shapiro, ''Protecting Competition in the American Economy: Merger Control, Tech Titans, Labor Markets,'' 33 J. Econ. Perspectives 69 (2019).

[121] Stigler Comm. On Digital Platforms, Final Report 7–8 (2019), *https://www.chicagobooth.edu/-/media/research/stigler/pdfs/digital-platforms-committee-report-stigler-center.pdf* (explaining network effects, returns increasing with scale, low marginal costs, high returns on amassing user data, and low distribution costs underlie trend toward monopoly).

[122] Shapiro, *supra* note 120, at 70.

[123] Stigler Comm. On Digital Platforms, *supra* note 121, at 31.

[124] Cunningham et al., *supra* note 15 (presenting empirical evidence that pipeline drug program is less likely to be developed when acquired by firm with overlapping existing product with significant market power); Stigler Comm. On Digital Platforms, *supra* note 121, at 81, 88; Shapiro, *supra* note 120, at 75; Michael L. Katz, ''Big Tech mergers: Innovation, competition for the market, and the acquisition of emerging competitors,'' 54 Info. Econ. & Policy 100883 (2021).

[125] *See, e.g., In re Sanofi Corp.,* No. 9422 (F.T.C. Dec. 11, 2023) (complaint) (transaction abandoned); *United States* v. *Visa Inc.,* No. 3:20–cv–07810 (N.D. Cal. Nov. 5, 2020) (transaction abandoned); *FTC* v. *Mallinckrodt ARD Inc. (f/k/a Questcor Pharms., Inc.),* No. 1:17–cv–120 (D.D.C. Jan. 30, 2017) (consent decree ordered license and $100 million equitable monetary relief); *United States* v. *Westinghouse Air Brake Techs. Corp.,* No.1:16–cv–02147 (D.D.C. Oct. 26, 2016) (consent decree ordered divestiture); *In re Thoratec Corp.,* No. 9339 (F.T.C. July 28, 2009) (transaction abandoned); *In re Inverness Med. Innovations, Inc.,* No. C–4244 (F.T.C. Dec. 23, 2008) (Commission order requiring divestiture and other conditions).

[126] *FTC* v. *PPG Indus., Inc.,* 798 F.2d 1500, 1505–06 (D.C. Cir. 1986) (Bork, J.). *See also In re Illumina, Inc.,* No. 9387 (F.T.C. Dec. 17, 2019) (complaint) (transaction abandoned).

[127] *United States* v. *Novelis, Inc.,* No. 1:19–cv–02033 (N.D. Ohio Aug. 26, 2020) (arbitration-ordered divestiture); *In re The Procter & Gamble Co.,* No. 9400 (F.T.C. Dec. 8, 2020) (complaint) (transaction abandoned); *In re CDK Global, Inc.,* No. 9382 (F.T.C. Mar. 19, 2018) (complaint) (transaction abandoned).

[128] *See, e.g., PPG Indus., Inc.,* 798 F.2d at 1505–06. *See also United States* v. *Bayer AG,* No. 1:18–

Continued

A number of commenters opposed changes contained in the proposed rule over concerns that they would disproportionally impact small innovation companies and startups, which rely on venture capital and acquisitions to sustain their business model. One commenter stated that preventing such exit strategies would make it difficult for startups to obtain early-stage funding, reducing both the number and vitality of these innovative firms. Several cautioned the Commission to avoid increasing the burden and risk associated with the acquisition of startups, which they stated would damage the dynamic U.S. tech innovation system. Another stated that acquisitions that increase concentration can still be procompetitive and drive dynamic efficiency.

As the discussion above clearly demonstrates, acquisitions involving nascent or potential competitors as well as those that impact innovation competition may violate the antitrust laws. The Commission disagrees with commenters that contend that these types of acquisitions should be subjected to a more permissive standard or that the Agencies are singling them out for closer scrutiny. The Agencies routinely review acquisitions of and by innovative companies and apply the same legal standard to those mergers as any other acquisition. When the Agencies challenge these mergers, they are held to the same liability requirements necessary to establish a violation of section 7. However, as discussed above, there is a gap in the current information requirements that undermines the Agencies' ability to determine whether a transaction would eliminate nascent or future competition. To detect those types of acquisitions and to assess whether they violate the antitrust laws, the Agencies need information regarding these forms of ongoing or emerging competition, even if some commenters disagree with the law as applied by the courts in this area.

The Commission acknowledges that the sale of a business to an incumbent may represent a valuable exit strategy for startups. But when such exits are effectuated by a dominant firm to absorb a future or emerging competitor, the overall effect may be to reduce innovation and violate the law.[129] In fact, antitrust enforcement can drive innovation and growth by ensuring that market outcomes are determined through competition rather than left to the decisions of a dominant incumbent who can on its own determine the fate of innovative companies and the future of competition. The history of U.S. antitrust enforcement contains many examples of how government action was required to unleash the forces of competition and innovation, creating new opportunities for investments and startups.[130] Recent research suggests that existing firms may be acquiring innovative capacity not for the purpose of advancing those discoveries but rather to shelve those discoveries, leading to a reduction in innovative output and eliminating an independent source of future competition.[131] Two individual commenters shared their experiences with acquisitions that have had that effect:

- I work in the software industry and despite the constant talk of ''innovation,'' I have seen many mergers that eliminate new product development. Mergers/acquisitions often consist of a company acquiring a product and immediately discontinuing either the acquired product or their own competing product. Most engineers I know want to develop new products and many mergers stop this from happening.[132]
- I work in the tech industry for a large technology firm. It's disgusting that our philosophy is now to buy other companies and never grow organic products because it is too hard. There's no innovation anymore it is simply make enough money to buy out the actual innovators in an industry. Any new startup is now faced with a massive hill to climb as getting VC money is paramount, but then the moment you do well your VC's will just sell to the highest bidder. This is stagnating tech, and you won't see the effects for some years down the road when 5 tech companies are left in this country. We need tighter oversight on mergers . . . .[133]

In light of all these considerations, the Commission believes this rulemaking strikes the right balance that permits the Agencies to evaluate transactions for their potential effects on innovation while not standing in the way of acquisitions and other investments that do not present antitrust risks that need to be addressed prior to consummation. The critical task for the Agencies is to identify which transactions may substantially lessen competition or tend to create a monopoly, prior to consummation and before the possibility of future competition is snuffed out.[134] The Commission is not subjecting acquisitions of startups or innovative firms to heightened scrutiny, as some commenters suggest. Rather, the Agencies are modernizing premerger requirements in light of the changes in M&A activity for all transactions that must be reported under the HSR Act, including those involving innovative firms.[135] However, the final rule has been adjusted to lessen the burden on the targets of acquisitions generally. Moreover, many of the new requirements focus on increasing visibility into complex entities and therefore would not be applicable to the relatively straightforward structures of many startup companies.

The Commission notes that many acquisitions of startups and small innovator firms are not reportable and thus are not subject to antitrust scrutiny prior to consummation. In September 2021, the Commission released its findings from an inquiry into past acquisitions by the largest technology platforms that did not require reporting under the HSR Act.[136] Launched in

cv–01241 (D.D.C. Feb. 8, 2019) (consent decree ordered divestiture); Press Release, U.S. Dep't of Justice, ''Applied Materials Inc. and Tokyo Electron Ltd. Abandon Merger Plans After Justice Department Rejected Their Proposed Remedy'' (Apr. 27, 2015), *https://www.justice.gov/opa/pr/applied-materials-inc-and-tokyo-electron-ltd-abandon-merger-plans-after-justice-department*; *In re Nielsen Holdings N.V.,* No. C–4439 (F.T.C. Feb. 28, 2014) (Commission order requiring divestiture).

[129] *See* Lemley & McCreary, *supra* note 116 (exit by acquisition leads to concentration in the tech industry and short-circuits the development of truly disruptive new technologies that have historically displaced incumbents in innovative industries).

[130] *See* Giovanna Massarotto, ''Driving Innovation with Antitrust,'' Promarket (Apr. 10, 2024) *https://www.promarket.org/2024/04/10/driving-innovation-with-antitrust/*.

[131] *See* Cunningham et al., *supra* note 15. *See also* Florian Szücs, ''M&A and R&D: Asymmetric Effects on acquirers and targets?'' 43 Rsch. Pol'y 1264 (2014); Carmine Ornaghi, ''Mergers and innovation in big pharma,'' 27 Int'l J. Indus. Org. 70 (2009); Justus Haucap et al., ''How mergers affect innovation: Theory and evidence,'' 63 Int'l J. Indus. Org. 283 (2019) (showing a reduction in innovation competition post-merger).

[132] Comment of Darryl Pretto, Doc. No. FTC–2023–0040–0434.

[133] Anonymous Comment, Doc. No. FTC–2023–0040–0600.

[134] *See* Cristina Caffarra et al., '''How Tech Rolls:' Potential Competition and 'Reverse' Killer Acquisitions,'' 2 CPI Antitrust Chron. 13, 15 (May 2020).

[135] According to a recent study, investment in U.S. startups continues to grow each year, reaching a combined deal value of $165.8 billion for 12,235 such deals in 2020. *See* Gary Dushnitsky & D. Daniel Sokol, ''Mergers, Antitrust, and the Interplay of Entrepreneurial Activity and the Investments That Fund It,'' 24 Vand. J. Ent. & Tech. L. 255, 271 Table 1 (2022). The authors note that a case-by-case analysis of particular deals allows for a more nuanced approach to address particular potentially problematic deals in such settings. *Id.* at 277–78. *See also* D. Daniel Sokol, ''Merger Law for Biotech and Killer Acquisitions,'' 72 Fla. L. Rev. Forum 1, 8 (2020) (explaining that innovation effect is fact-dependent).

[136] *See* Press Release, Fed. Trade Comm'n, ''FTC Staff Presents Report on Nearly a Decade of Unreported Acquisitions by the Biggest Technology Companies'' (Sept. 15, 2021), *https://www.ftc.gov/*

February 2020, this inquiry analyzed the terms, scope, structure, and purpose of exempted transactions by five large technology companies: Alphabet, Inc., Amazon.com, Inc., Apple Inc., Facebook, Inc., and Microsoft Corp. The study covered ten years of acquisitions (from January 1, 2010 to December 31, 2019) and found that the companies collectively made 819 acquisitions that were not reported under the HSR Act.[137] None of these acquisitions was filed under HSR, although many of them were concentrated in just a few categories of technology, such as mobility, application software, and internet content and commerce.[138]

This study provided other insights into these companies' practices and acquisition strategies, including how they structured acquisitions and how these acquisitions fit into the companies' overall business strategies.[139] For instance, not only were many of the acquisitions ''small'' in deal value (*i.e.,* under the various HSR reporting thresholds), they were also ''young,'' with nearly 40 percent of the acquisitions involving target firms that were less than five years old.[140] Most of the acquisitions involved the buyer taking control of the acquired assets or entity, although there were also a significant number of investments that resulted in the large company holding a minority interest in the target firm.[141] Moreover, over three-quarters of the transactions included non-compete clauses for founders and key employees of the acquired entities, with relatively small variation in the percentage of transactions with non-compete clauses across the five respondents. [142] Together, these findings indicate that during the study period, these five companies acquired many small, nascent firms operating in related business lines and their founders and other key employees agreed to refrain from continuing their own efforts to innovate outside the company for some period of time. While the study focused on transactions that were not reportable under the HSR Act, the information collected from these tech companies provided the Commission with insight into information that is available to parties in all types of acquisitions but that is not required by the current Form and Instructions.

In light of the benefits to the public from preventing mergers that violate the antitrust laws by reducing innovation competition or eliminating a potential entrant or nascent threat, the Commission has determined that the Agencies need certain additional information with the HSR Filing to conduct an initial antitrust assessment prior to consummation. In the Agencies' experience, it is necessary to obtain this type of information directly from the filing parties because typically their plans regarding future products or business lines are not public.

Several new information requirements in the final rule are aimed at providing the Agencies with sufficient information to determine if the transaction is likely to raise concerns about potential, emerging, or nascent competition. For instance, the new Overlap Description and Supply Relationships Description directly address the scope of existing and emerging competition between the parties. In particular, the Overlap Description requires filers to identify their own products and services, including those that are pre-revenue, that compete with the products and services of the other party that are known to the filer.[143] This information will provide a basis for the Agencies to know that there are areas of emerging and direct competition beyond existing products or services, including important ongoing innovation competition. The Overlap Description also requires filers to produce measurement information for products or services not yet generating revenue, or those whose performance is not measured by revenue, such as projected revenue, estimated volume, or any other applicable performance metric. This change recognizes the importance of capturing the competitive significance of nascent or emerging products and services.

The final rule also requires the buyer to indicate whether there are any existing contracts between the parties, including non-compete, non-solicitation, or licensing agreements, which would alert the Agencies to any limits on future competition that are created by these agreements, especially when the buyer is not acquiring all of the acquired entity. The existence of non-compete or non-solicitation agreements can be especially useful in revealing that the parties consider themselves to be 'in competition' with one another, now or in the future, such that there is value in contracting away the ability to compete for or solicit business or workers. In addition, the Supply Relationships Description requires information for products, services, or assets (including data) that the other party or any other business uses or could use to compete. This forward-looking assessment, based on each filer's business experience, would reveal whether there are future uses of either party's products that could give rise to concerns about non-horizontal effects from the transaction. The inclusion of data as a potentially key asset is purposeful, given the competitive significance of data access for effective competition in so many modern markets.[144]

Similarly, new document requirements contained in the final rule are aimed at revealing each firm's assessment of market conditions and horizon-scanning for competitive threats. For instance, the final rule requires a broader search for documents that evaluate or analyze the transaction to include not only those provided to board members but also to the person who has primary responsibility for supervising the deal. These documents, along with certain ordinary course plans and reports shared at the highest level of management described above and in section VI.G.2., will reveal additional information about how each filer views the competitive landscape more broadly, including in ways that may impact current or future competition. Together, these documents may signal whether either party has identified emerging threats to competition—from the other party or from firms not involved in the transaction—that would impact the Agencies' assessment of whether the transaction may violate the antitrust laws.

As discussed above in section II.B.1., new information contained in the

news-events/news/press-releases/2021/09/ftc-staff-presents-report-nearly-decade-unreported-acquisitions-biggest-technology-companies.

[137] *See* Fed. Trade Comm'n, Non-HSR Reported Acquisitions by Select Technology Platforms, 2010–2019: An FTC Study 10–11 Fig. 1 (2021), *https://www.ftc.gov/system/files/documents/reports/non-hsr-reported-acquisitions-select-technology-platforms-2010-2019-ftc-study/p201201technology platformstudy2021.pdf* (hereinafter ''Non-HSR Reported Acquisitions''). Data supplied by commenter Engine confirms that the vast majority of startup acquisitions are valued below $50 million, meaning that they are rarely reported to the Agencies in advance. *See* Comment of Engine, Doc. No. FTC–2023–0040–0681, appendix B at 16.

[138] Non-HSR Reported Acquisitions, *supra* note 137, at 27–35.

[139] Other competition enforcement agencies around the world conducted similar studies involving acquisitions of digital platform companies. *Id.* at 2 n.6.

[140] *Id.* at 23–26.

[141] *Id.* at 15.

[142] *Id.* at 21–22.

[143] As explained in section VI.I., the parties should not exchange information for the purpose of responding to the Competition Descriptions.

[144] *See FTC* v. *IQVIA Holdings Inc.,* No. 1:23 Civ. 06188 (S.D.N.Y. Dec. 29, 2023) (order granting preliminary injunction on horizontal theories of harm without addressing FTC allegations that the acquisition would allow IQVIA to foreclose other industry participants from accessing its data as a key input for healthcare professional programmatic advertising).

Minority Shareholders or Interest Holders and Officers and Directors sections will provide a basis for the Agencies to identify any existing or potential management relationships between the acquiring person and target, including through entities or individuals who can influence decision-making of the acquiring person post-merger. These relationships can be especially concerning if used to gain access to non-public information about future plans or investments in products-in-development when those same individuals also have interests in competitively relevant businesses.

Finally, the final rule collects additional information about the acquisition rationale of the buyer to assist the Agencies in understanding the purpose of the transaction. For example, the final rule requires the buyer to describe any rationale for the transaction and to indicate any document submitted with the HSR Filing that confirms or discusses that rationale. These answers will provide context for the Agencies' initial antitrust assessment through a deeper understanding of what purpose the buyer has for engaging in a transaction that is large enough to require premerger review. In addition, the final rule for the first time requires the seller to report prior acquisitions in the same or related lines of business, which would provide a basis for the Agencies to better assess whether the transaction implicates emerging, nascent, or potential competition, especially through the combined effects of roll-up or serial acquisition strategies or ''killer'' acquisitions in which assets were purchased but not used as a means of eliminating a competitor.

5. Disclosing Roll-Up or Serial Acquisition Strategies

Another trend in M&A activity has been the rise of serial acquirers, firms that engage in strategic acquisitions in the same industry, often ''rolling up'' many small competitors in the same or adjacent markets to establish a large, sometimes dominant, position.[145] Serial acquisition strategies have been subject to antitrust scrutiny for over 100 years.[146] In the seminal merger case, *United States* v. *Philadelphia National Bank,* 374 U.S. 321 (1963), the Supreme Court noted that both the buyer and the seller had previously acquired many other independent banks,[147] driving a trend toward concentration that rendered their merger suspect.[148] Given the popularity and prevalence of these serial acquisition strategies in recent years, especially in healthcare and technology markets, this trend has attracted the attention of academics and policymakers alike.[149] A pattern or strategy of buying up smaller competitors or firms in the same or related lines of business can lead to harm of the same magnitude and type as mergers of larger or established firms, but serial acquisitions are less likely to attract the attention of enforcers until the strategy is identified. A series of small acquisitions can lead to consolidation within an industry, often without ever triggering the obligation to report these acquisitions under the HSR Act. This strategy has been particularly prevalent in healthcare markets involving private equity buyers.[150]

Often the Agencies are not able to detect these strategies until it is too late, after the serial acquirer has established a dominant position and is able to exercise market power to the detriment of market participants. For instance, in September 2023, the FTC charged U.S. Anesthesia Partners, a for-profit corporation, with a multi-year anticompetitive scheme to consolidate anesthesia practices in Texas.[151] This lawsuit, which is pending in Federal court in Texas, alleges that the company acquired over a dozen anesthesiology practices in Texas to eliminate competition and create a single dominant provider with the power to demand higher prices.

The Commission is aware of the impact of serial acquisitions based on its experience with the dialysis industry, which is an area in which economic research has documented adverse effects from serial acquisitions. Throughout the 2000s, the Commission reviewed a series of large acquisitions by DaVita, the largest U.S. provider of life-sustaining treatments for end stage renal disease patients. In 2006, in conjunction with DaVita's $3.1 billion acquisition of rival Gambro Healthcare, Inc., the Commission required DaVita to divest 69 dialysis clinics in 35 markets across the United States to resolve charges that the acquisition violated section 7. In 2011, DaVita sought to acquire rival DSI for $689 million, and the Commission required divestitures to preserve competition for dialysis services in 22 local markets. Then in 2017, the Commission ordered DaVita to divest seven clinics in New Jersey and Dallas to proceed with its $358 million acquisition of Renal Ventures. During roughly the same period, the Commission also reviewed a series of acquisitions by Fresenius, the other leading U.S. provider of dialysis services, and required significant divestitures to maintain competition.[152]

Notwithstanding these enforcement actions, the dialysis industry has experienced growing concentration, mostly as a result of acquisitions that were not reportable under the HSR Act. According to one 2020 study, there were more than 1,200 acquisitions of independent dialysis facilities over a 12-year period, resulting in DaVita and Fresenius operating more than 60 percent of all clinics nationwide.[153] The study concluded that these changes in

[145] NPRM at 42202 n.62 (citing Gerry Hansell et al., ''Lessons from Successful Serial Acquirers: Unlocking Acquisitive Growth,'' Boston Consulting Grp. (Oct. 1, 2014), *https://www.bcg.com/publications/2014/mergers-acquisitions-unlocking-acquisitive-growth*); ''Stealth Consolidation,'' *supra* note 18.

[146] *See, e.g., United States* v. *Grinnell Corp.,* 384 U.S. 563, 576, 578, 580 (1966); *Standard Oil Co.* v. *United States,* 221 U.S. 1, 31–42 (1911); *United States* v. *Am. Tobacco Co.,* 221 U.S. 106, 157–60 (1911). *See also* Note by the United States to the OECD, Serial Acquisitions and Industry Roll-ups (Dec. 6, 2023) (DAF/COMP/WD(2023)99), *https://one.oecd.org/document/DAF/COMP/WD(2023)99/en/pdf* (discussing the history and roots of antitrust enforcement against anticompetitive serial acquisitions). Serial acquisition strategies may also violate section 2 of the Sherman Act when a firm with monopoly power relies on acquisitions, among other conduct, to acquire or maintain its monopoly. *See Credit Bureau Reps., Inc.* v. *Retail Credit Co.,* 358 F. Supp. 780 (S.D. Tex. 1971), *aff'd,* 476 F.2d 989 (5th Cir. 1973); *United States* v. *Jerrold Elecs. Corp.,* 187 F. Supp. 545 (E.D. Pa. 1960).

[147] *See United States* v. *Phila. Nat'l Bank,* 374 U.S. 321, 331 (1963) (PNB previously acquired nine independent banks while Girard acquired six).

[148] *Id.* at 367 (evidence of several remaining competitors insufficient to rebut inherently anticompetitive tendencies of high post-merger market shares, in light of strong trend toward mergers, including those of the defendants).

[149] *See* Investigation of Competition in Digital Markets, *supra* note 106, at 24–25.

[150] Richard M. Scheffler et al., Am. Antitrust Inst., ''Soaring Private Equity Investment in the Healthcare Sector: Consolidation Accelerated, Competition Undermined, and Patients at Risk'' 8–16 (May 18, 2021), *https://publichealth.berkeley.edu/wp-content/uploads/2021/05/Private-Equity-I-Healthcare-Report-FINAL.pdf.* The Commission recently hosted a public workshop to discuss the growing body of economic research examining the role of private equity investment in health care markets. Fed. Trade Comm'n, Private Capital, Public Impact: An FTC Workshop on Private Equity in Health Care (Mar. 5, 2024), *https://www.ftc.gov/news-events/events/2024/03/private-capital-public-impact-ftc-workshop-private-equity-health-care.*

[151] *FTC* v. *U.S. Anesthesia Partners, Inc.,* No. 4:23cv3560 (S.D. Tex. Sept. 21, 2023) (complaint).

[152] *See In re Fresenius AG,* No. C–4159 (F.T.C. July 5, 2006) (decision and order requiring divestiture of ninety-one clinics and financial interests in twelve more); *In re Am. Renal Assocs. Inc.,* No. C–4202 (F.T.C. Oct. 23, 2007) (consent order terminating purchase agreement for five clinics and closure of three additional clinics); *In re Fresenius Med. Care AG,* No. C–4348 (F.T.C. May 25, 2012) (decision and order requiring divestiture of sixty dialysis clinics).

[153] Paul J. Eliason et al., ''How Acquisitions Affect Firm Behavior and Performance: Evidence from the Dialysis Industry,'' 135 Q. J. Econ. 221, 222 (2020) (from 1990 to 2020, the share of independent dialysis facilities fell from 86% to 21%).

ownership resulted in higher prices, lower levels of service, and worse outcomes for patients.[154] One commenter stated that, based on his research, merger enforcement against reportable acquisitions prevented illegal consolidation 95 percent of the time, while the many non-reportable acquisitions of dialysis clinics were blocked only 5 percent of the time. He contended that these 'stealth' acquisitions accounted for much of the increase in within-market concentration.[155]

In light of the failure of prior interventions to stem the adverse consequences of roll-up acquisitions in this industry, when DaVita in 2022 sought to buy 18 clinics in a non-HSR-reportable transaction, the Commission unanimously voted to require DaVita not only to divest three clinics but also to obtain prior Commission approval before buying any new ownership interest in dialysis clinics in Utah.[156] The Commission determined that imposing a prior approval obligation was appropriate in light of the company's history of attempting anticompetitive transactions that do not trigger a notification under the HSR Act.[157]

The Commission has also imposed prior notice or prior approval provisions on another serial acquirer, JAB Consumer Partners, a private equity firm that has made several significant acquisitions in the emergency and specialty veterinary services markets across the United States. JAB is the parent company of two large veterinary clinic chains, Compassion-First Pet Hospitals and National Veterinary Associates Inc., that have been built through a series of acquisitions. In 2020, Compassion-First bought NVA for $5 billion, and the Commission required JAB to divest clinics in three local markets.[158] In June 2022, Compassion-First/NVA acquired Sage Veterinary Partners for $1.1 billion, and the Commission required divestitures in three additional local markets.[159] The Commission also determined that, in light of JAB's ongoing acquisition strategy, it would require prior approval and prior notice requirements on JAB's future acquisitions of specialty and emergency veterinary clinics.[160] Later in 2022, when JAB also sought to acquire another veterinary chain with significant competitive overlap in four geographic markets, the Commission again required divestitures and prior approval requirements in the affected local markets for emergency and specialty veterinary services markets.[161]

But resorting to imposing prior approval obligations after an industry has already experienced significant concentration due to roll-up strategies is suboptimal. A central purpose of the HSR Act is to allow the Agencies to arrest trends toward concentration through effective premerger review. For any reportable transaction under the HSR Act, the Agencies have an obligation to determine whether the transaction is one of a series of acquisitions that could lead to harm in the affected markets. Information about each party's prior acquisitions will provide a basis for the Agencies to assess this risk to competition during their initial antitrust assessment for any reportable transaction.

Several commenters supported the need for more information related to prior acquisitions, including a group of State antitrust enforcers. One commenter noted that the private equity industry pioneered and perfected the serial 'roll-up' acquisitions that were too small to attract antitrust agency attention but nonetheless amassed considerable market power over time. The same commenter pointed out that private equity firms use these add-on buyout deals to purchase multiple competitors of an existing portfolio company or expand their geographic reach to create a much bigger player in an industry—and that this strategy can in aggregate substantially lessen competition or tend to create a monopoly. Another commenter raised similar concerns that the business strategy of making a series of small acquisitions—whether an intentional tactic to avoid regulatory scrutiny or not—has become concerningly common in recent decades and led to many consolidated industries. An individual commenter shared their experience with the broader impact of rollup acquisitions on local communities:

• As the wife of a small business owner and member of a community, I'm dismayed at seeing how many small local and regional businesses have disappeared after becoming the target of mergers and rollups. Those businesses—funeral homes, hospice care, newspapers, hardware stores, coffee shops, veterinarians—were [] an important part of the community. Now it is nearly impossible to start local businesses in those sectors and turn any sort of profit while competing with PE backed rollups.[162]

Other commenters stated that the proposed changes are unnecessary because they lack sufficient justification, are out of step with their view of case law and market realities, and do not seem to have a strong factual basis. One commenter stated that the proposal to expand the lookback period for prior acquisitions would invite the Agencies to scrutinize long-consummated deals, including those that the HSR Act were never intended to capture. Some raised concerns that the proposed changes will substantially increase the burden of reporting on prior acquisitions beyond what is currently required for the HSR Form. Another stated that the costs of the proposed changes regarding prior acquisitions far outweigh the potential benefit that information about immaterial prior transactions could provide to the evaluation of the transaction. One commenter stated that requiring disclosure of non-reported transactions will reduce investments in startups.

The Commission has determined that, to detect whether serial or roll-up acquisition strategies have changed the market dynamics such that the transaction under review could have widespread harmful effects that will be hard to undo, the Agencies need additional information about prior acquisitions, including from the acquired firm. Knowing each party's record of prior acquisitions in the same business lines will allow the Agencies to understand the long-term competitive strategy for the transaction at issue, including whether it is one in a series of prior or planned acquisitions in the same industry and whether the

[154] *Id.* at 223.

[155] *See* Comment of Thomas Wollmann, Doc. No. FTC–2023–0040–0680 at 1 n.2 (citing to Thomas G. Wollmann, ''Stealth Consolidation: Evidence from an Amendment to the Hart-Scott-Rodino Act,'' 1 a.m. Econ. Rev.: Insights 77–94 (2019) and Thomas G. Wollman, ''How to Get Away with Merger: Stealth Consolidation and Its Effects on US Healthcare'' (Nat'l Bureau of Econ. Rsch., Working Paper No. 27274, May 2020 rev. Mar. 2024), *https://www.nber.org/papers/w27274*).

[156] *In re DaVita Inc.,* No. C–4677 (F.T.C. Oct. 25, 2021) (decision).

[157] *See* Fed. Trade Comm'n, Statement of the Commission on Use of Prior Approval Provisions in Merger Orders (Oct. 25, 2021), *https://www.ftc.gov/system/files/documents/public_statements/1597894/p859900priorapproval_statement.pdf.*

[158] *In re Agnaten SE,* No. C–4707 (F.T.C. Apr. 9, 2020) (decision and order).

[159] *In re JAB Consumer Partners SCA SICAR,* No. C–4766 (F.T.C. Aug. 2, 2022) (decision and order).

[160] The Commission's order requires JAB to obtain prior Commission approval before acquiring a specialty or emergency veterinary clinic within twenty-five miles of any JAB clinic in California or Texas, and prior notice to the Commission thirty days prior to a similar acquisition anywhere in the United States that is not required to be reported under the HSR Act. *Id.* (decision and order).

[161] *In re JAB Consumer Partners SCA SICAR,* No. C–4770 (F.T.C. Oct. 10, 2022) (decision and final order).

[162] Comment of Nora Johnson, Doc. No. FTC–2023–0040–0618.

transaction is a merger of ''consolidators.'' The additional information would also permit the Agencies to better identify transactions whose effects should not be viewed in isolation but rather as a pattern of consolidation.[163]

The Commission has always required information about prior acquisitions in the HSR Filing to help identify strategies aimed at gaining market share through acquisitions rather than internal expansion or more vigorous competition, and the Commission disagrees that it is outside its rulemaking authority under the HSR Act to require filers (including the target) to report prior acquisitions in the same or related business lines even if they were not previously reported to the Agencies for premerger review. The final rule contains modest expansions of this long-standing requirement, to better account for the increased number of firms engaged in roll-up strategies. Nonetheless, the final rule does not contain certain expansions suggested in the proposed rule, such as eliminating the $10 million exception or expanding the lookback period from 5 to 10 years in response to comments that providing this level of information about prior acquisitions would be costly and burdensome. The modest expansion of this information requirement should provide the Agencies with a more complete record of consolidation in the relevant business lines that has been driven by the merging parties in order to identify when a reported transaction is the latest in a series of acquisitions, and thus one that may violate the antitrust laws.

As noted elsewhere, the Agencies remain committed to identifying consummated mergers that have resulted in harm and to take steps to unwind them as resources permit. But regardless of the legality or reportability of any particular prior acquisition, the fact that it occurred and involved the same business lines under review is directly relevant to whether the reported transaction may violate the antitrust laws, including through a series of mergers that ''convert an industry from one of intense competition among many enterprises to one in which three or four large concerns produce the entire supply.'' [164] For these reasons, the Commission has determined there is a need to collect information about prior acquisitions from the seller as well as the buyer. The cost of complying with this requirement should be minimal except in instances where the seller has made many acquisitions in the same or related business lines, in which case the information may prove highly relevant to Agency review.

Other new requirements in the final rule will also help the Agencies identify these roll-up strategies. In particular, the Overlap Description will provide an alternative basis for identifying product or service market overlaps for which prior acquisitions should be reported. Information about the buyer's acquisition rationale will reveal the purpose of the transaction, including whether is it part of a strategy of pursuing transactions in similar business lines. The new requirement to submit a small set of business plans and reports shared with the highest levels of management that discuss market shares, competition, competitors, or markets of any product or service that is provided by both the acquiring person and acquired entity may reveal whether there are other acquisition targets identified by either the acquiring or acquired person.

III. Statutory Authority and Economic Analysis

The HSR Act directs the Commission, with the concurrence of the Assistant Attorney General and consistent with the purposes of the Act, to issue rules requiring the submission of documentary material and information relevant to a proposed acquisition as is ''necessary and appropriate to enable [the Agencies] to determine whether such acquisition may, if consummated, violate the antitrust laws.'' [165] The HSR Act was enacted to assist the Agencies in enforcing other provisions of the Clayton Act, and to give the FTC and the Department of Justice a tool—premerger notification—to identify problematic mergers and acquisitions before they are consummated and a short period of time to complete their analysis.[166] The statute grants the Commission explicit authority to require the submission of documents and information the Agencies determine are necessary and appropriate to identify proposed acquisitions that may result in an antitrust violation.[167]

In the administrative law context, the Supreme Court has held that Congress' use of terms such as ''appropriate'' or ''reasonable'' in a statute authorizing agency rulemaking gives the agency ''flexibility'' to regulate.[168] As the Supreme Court has explained, ''[o]ne does not need to open up a dictionary in order to realize the capaciousness of this phrase. In particular, 'appropriate' is the classic broad and all-encompassing term that naturally and traditionally includes consideration of all the relevant factors.'' [169] The phrase ''leaves agencies with flexibility,'' although ''an agency may not entirely fail to consider an important aspect of the problem.'' [170] In at least some contexts, courts have held that ''necessary and appropriate'' requires consideration of a rule's costs and benefits.[171]

The Commission is not convinced that Congress intended the words ''necessary and appropriate'' to require a cost-benefit analysis in this context. Had Congress intended to require the Commission to consider costs and benefits, it could easily have done so.[172] Instead, it gave the Commission broad authority to establish requirements it deems necessary and appropriate for determining whether a proposed acquisition may violate the antitrust laws during premerger review, and even gave the Commission express authority to define statutory terms. Nonetheless, in the particular circumstances of this rule, the Commission has considered the reasonableness of requiring additional information in the HSR Filing in light of the statutory scheme established by Congress to more effectively prevent undue consolidation that violates the antitrust laws, including the costs and the benefits of the final rule. The Commission has evaluated, on the one hand, the benefits to the Agencies, the parties, third parties and the public in making premerger review more efficient and effective by obtaining information necessary to properly assess the competitive effects of proposed acquisitions; and on the other hand, the need to reduce unnecessary burden, costs, and delay on filers and the transactions they hope to pursue in a manner consistent with the

[163] *See Brown Shoe Co.* v. *United States,* 370 U.S. 294, 334 (1962).

[164] *Id.* (quoting S. Rep. 81–1775, at 5 (1950) and citing H.R. No. Rep. 81–1191, at 8 (1949)).

[165] 15 U.S.C. 18a(d)(1).

[166] *PhRMA,* 790 F.3d at 199, 206.

[167] *Id.* at 199, 201, 205.

[168] *Loper Bright Enterprises* v. *Raimondo,* 144 S.Ct. 2244 (2024).

[169] *Michigan* v. *EPA,* 576 U.S. 743, 752 (2015) (citation and internal quotation marks omitted).

[170] *Id.* (citation and internal quotation marks omitted).

[171] *See id.; Mex. Gulf Fishing Co.* v. *U.S. Dep't of Commerce,* 60 F.4th 956, 965 (5th Cir. 2023) (finding that the necessary and appropriate standard at a minimum requires that a rule's benefits reasonably outweigh its costs).

[172] *See Chamber of Com* v. *Sec. Exch. Comm'n.,* 412 F.3d 133, 142 (D.C. Cir. 2005) (statute requires SEC to consider whether rule will promote efficiency, competition, and capital formation which requires a consideration of the costs of the conditions imposed by the rule).

mandatory premerger notification regime of the HSR Act.

In determining what information is necessary and appropriate to determine whether a reported transaction merits the issuance of Second Requests, the Commission also draws on the Agencies' decades of experience reviewing filings and responding to informal requests for guidance.[173] This operational experience informs the Commission's assessment of the existing rules' shortcomings and supports its decision that it is necessary and appropriate—and consistent with the text and purpose of the HSR Act—for the Agencies to require the merging parties to provide sufficient information to enable the Agencies to conduct a preliminary assessment of the risk that the filed-for transaction may violate the antitrust laws, particularly where some information is available only from the parties.

After careful consideration of the public comments as well as the costs and benefits of the proposed changes, the Commission has determined to adopt a modified version of the information requirements proposed in the NPRM. As modified, the final rule will facilitate the provision of relevant documentary materials and information that allow the Agencies to assess whether a proposed acquisition may violate the law within the statutory period available for their initial review while minimizing the cost and burden of producing such materials as much as practicable.

The following analysis considers the potential economic effects that may result from the final rule consistent with the Commission's statutory power to obtain information necessary and appropriate to conduct an effective premerger review, including the benefits and costs to market participants. In conducting this assessment, the Commission has identified existing costs to filers, the Agencies, and third parties that could be avoided by adjusting the information requirements for HSR Filings. Avoiding such costs would generate benefits for filers, the Agencies, and third parties in addition to broader public benefits of effective premerger screening to identify potentially unlawful mergers prior to consummation.

The Commission believes that the final rule will improve the efficiency of the premerger review process and help the Agencies identify transactions that may violate the antitrust laws along all parameters of potential harm, but not all of these benefits can be quantified. Wherever possible, the Commission quantifies the likely economic effects of its final rule. However, some economic effects are inherently less conducive to sound quantification either due to the lack of reliable data or the lack of a well-established economic methodology that would provide estimates or ranges of costs. For example, producing quantitative estimates of certain costs and benefits would require numerous assumptions to generate a behavioral forecast of how parties contemplating an acquisition and other affected third parties would respond to the rule, and how those behavioral responses would in turn affect the overall cost of compliance and the merger review process. In addition, some factors determining certain economic effects of the rule are transaction-, firm- and industry-specific and thus inherently difficult to quantify. Even if it were possible to calculate a range of potential quantitative estimates for these effects, the range would be so wide as to not be informative about the magnitude of the associated benefits or costs. Where sound economic methodology is not available to measure particular benefits or costs, the Commission addresses those qualitatively.[174] In sum, to show the connection between the facts found and the agency's decision, the Commission provides, where feasible and appropriate, a quantified estimate of the economic effects of the final rule, and a qualitative description of the benefits and costs.

A. Statutory Authority and Congressional Intent

The HSR Act provides that the Commission ''shall require'' that premerger notifications be in such form and contain such documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable the Agencies to determine whether such acquisition may, if consummated, violate the antitrust laws.[175] Thus, the HSR Act explicitly requires the Commission, with the concurrence of the Assistant Attorney General, to determine what types of documents and information are required to conduct an initial assessment of antitrust risk. Mandatory premerger review strengthens merger enforcement by giving the Agencies a fair and reasonable opportunity to detect and investigate large mergers before consummation.[176] The ability to spot ''problem areas'' during the initial screen is the key feature of the HSR Act that converts merger enforcement from ineffective ex-post litigation to expeditious and effective premerger proceedings.[177]

To that end, Congress passed the HSR Act to provide the Agencies with advance notice of planned acquisitions and an opportunity to challenge such acquisitions as unlawful prior to consummation. The overall intent was to avoid lengthy, costly post-consummation enforcement that is ineffective at preventing undue concentration and permits an illegal acquisition to cause harm until unwound:

> The problem this bill cures is startlingly simple, but it goes to the very foundations of our merger law. Under present law, companies need not give advance notification of a planned merger to the Federal Trade Commission and the Department of Justice. But if the merger is later judged to be anticompetitive, and divestiture is ordered, that remedy is usually a costly exercise in futility—untangling the merged assets and management of the two firms is like trying to unscramble an omelet.[178]

[173] *See PhRMA,* 790 F.3d at 210 (the Commission may provide the factual predicate for a finding through its cumulative experience and resulting expertise).

[174] *See Chamber of Com* v. *Sec. Exch. Comm'n.,* 85 F.4th 760, 768 (5th Cir. 2023) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc.* v. *State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 43 (1983)). *See also id.* at 773–74 (explaining that securities law provisions providing rulemaking authority do not require the agency to conduct a quantitative inquiry to ascertain the economic effects of a rule, that the agency could instead rely on a qualitative assessment of the rule's economic implications, and that the agency can determine the analysis that most effectively reflects the economic consequences of its rule) (citation omitted); *All. For Fair Bd. Recruitment* v. *Sec. Exch. Comm'n.,* 85 F.4th 226, 263 (5th Cir. 2023) (agency's analysis of unquantifiable benefits sufficiently supports a rule as long as it provides an adequate explanation for its determination, and agency need not support its analysis with hard data where it reasonably relied on intangible benefits that were difficult to quantify) (citations omitted); *Mex. Gulf Fishing.,* 60 F.4th at 965–66 (a necessary-and-appropriate condition does not require applying a strict cost-benefit analysis but simply a showing that expected benefits are reasonably related to anticipated costs) (citations omitted).

[175] 15 U.S.C. 18a(d)(1).

[176] H.R. Rep. No. 94–1373, at 5 (1976).

[177] *Id.* at 10–11 (chief virtue of the Act is to help eliminate endless post-merger proceedings and replace them with far more expeditious and effective premerger review generating considerable savings; if the initial notification form reveals 'problem areas,' the government can request additional data during the initial 30-day period).

[178] 122 Cong. Rec. 25051 (1976) (remarks of Rep. Rodino). Premerger review was not the only tool given the Agencies to rectify the inadequacy of post-consummation merger enforcement. In 1973, Congress amended the FTC Act to authorize the Commission to seek injunctions in Federal court in recognition of the inadequacy of post-consummation divestitures. *See FTC* v. *H.J. Heinz Co.,* 246 F.3d 708, 726 (D.C. Cir. 2001) (Section 13(b) of the FTC Act reflects congressional recognition that divestiture is an inadequate and unsatisfactory remedy in a merger case, citing 119 Cong. Rec. 36612 (1973)). The inability of the

Continued

As noted by the Antitrust Modernization Commission (AMC)—a special body commissioned by Congress in 2002 to conduct a comprehensive review and make recommendations for revisions to U.S. antitrust laws—the HSR Act addressed the defects of post-consummation merger enforcement, which ''could neither fully compensate society for the interim loss of competition, nor fully restore a competitive market structure, particularly if the companies had already integrated their productive assets, or 'scrambled the eggs.' '' [179] Congress also intended to avoid deterring or impeding the consummation of the vast majority of acquisitions and therefore fashioned a regime that reflected ''a careful balancing of the need to detect and prevent illegal mergers and acquisitions prior to consummation without unduly burdening business with unnecessary paperwork or delays.'' [180]

The Agencies have administered the premerger notification program required by the HSR Act for more than 45 years, and the Commission has engaged in numerous rulemakings to change the information requirements for premerger notification in response to changes in market realities. Although many commenters object in whole or in part to the proposals contained in the NPRM, several conceded that some updates to the Rules are reasonable or justified by increasingly complex markets. Others commended the Commission for undertaking a periodic review of its rules. Even so, some argue that the Commission lacks the authority to make any changes to its current process that would increase the burden or delay HSR-reportable transactions, asserting that Congress intended to reduce costs and delay and to focus the Agencies' scrutiny on only the largest corporate transactions. The Commission disagrees with certain commenters that the Commission lacks the authority to adjust information requirements over time to make premerger review efficient and effective for the purpose of detecting potentially illegal mergers in light of changing market conditions.

Given the number of comments that assert that the proposed rule violated the intent of the HSR Act, the Commission responds first to these broad objections. The Commission also responds to assertions that it has failed to properly weigh the benefits and costs of changing the notification requirements in light of the statutory premerger scheme.

As an initial matter, the Commission disagrees that avoiding potential cost or delay to those involved in dealmaking is the primary focus of the HSR Act. The legislative history and plain text of the HSR Act make clear that the goal of establishing a premerger review regime was not to minimize the number of transactions that are reviewed by the Agencies or to reduce the delay for reported transactions below the statutory obligations.[181] In fact, it is clear that Congress explicitly contemplated that a mandatory premerger notification regime would impose burdens on merging parties. Prior to the passage of the HSR Act, parties were free to merge without providing any notification and without any delay, which led to concerns that the Agencies were practically unable to block or unwind illegal transactions.[182] Congress determined that new and meaningful requirements were necessary to achieve the overarching Congressional goal of promoting vigorous and effective enforcement of the antitrust laws:

> Amended Section 7 has failed to achieve its objectives—not because of its substantive standards, but because of the lack of an effective mechanism to detect and prevent illegal mergers prior to consummation. . . . The Committee believes that [premerger notification] represents a careful balancing of the need to detect and prevent illegal mergers and acquisitions prior to consummation without unduly burdening business with unnecessary paperwork or delays . . . Complex mergers or acquisitions of the kind encompassed within this subsection generally require a great deal of prior planning, and this provision will provide the Government appropriate opportunity to evaluate the legality of significant business behavior at the most propitious moment for all parties, with the least possible disaccommodation.[183]

When setting up the premerger notification program, the Commission rejected assertions that the term ''notification'' implies only a minimal burden for the initial HSR Filing. Some commenters at the time maintained that the initial notification should do little more than inform the Agencies of the participants to the transaction, the projected date of consummation, and other noncontroversial and generally uninformative data, leaving a fuller information demand to the Second Request. The Commission disagreed that the HSR Act should be read this way, stating that this position is contrary to the statutory text and fundamentally misconceives the amount of information necessary to make even a tentative determination whether a transaction may violate the antitrust laws.[184] The Commission explained that the HSR Filing should contain information necessary and appropriate for an effective premerger notification program.[185] The Commission reasoned that requiring perfunctory information in the HSR Filing would not fulfill the statutory provision and would result in more Second Requests that would extend the average waiting period under the HSR Act.[186] Then and now, to fulfill the purpose of premerger review, there must be sufficient information provided in an HSR Filing to determine whether to issue Second Requests and what information those requests would seek. Consistent with Congress' expectations that HSR Filings would consist of data and documents reasonably available to filing companies, such as the information and documents they relied

Commission to obtain injunctive relief sooner to prevent widespread harm from mergers was a widely acknowledged shortcoming of its agency design. *See, e.g., FTC* v. *Dean Foods Co.,* 384 U.S. 597, 606 n.5 (1966) (experience shows that the Commission's inability to unscramble merged assets frequently prevents entry of an effective order of divestiture).

[179] Antitrust Modernization Comm'n, Rep. & Recommendations 155 & n.21 (2007), *https://govinfo.library.unt.edu/amc/report_recommendation/toc.htm* (citing H.R. Rep. No. 94–1373 at 7–11) (hereinafter ''AMC Report''). The Antitrust Modernization Commission was created pursuant to the Antitrust Modernization Commission Act of 2002, Pub. L. 107–273, 116 Stat. 1856, Div. C., Title I, Subtitle D (2002). The AMC was charged with examining whether there was a need to modernize the antitrust laws and to identify and study related issues; to solicit views; and to evaluate proposals for change. The AMC provided its Report and Recommendations to Congress and the President on April 2, 2007, and was terminated on May 31, 2007, having completed its statutory duties.

[180] S. Rep. No. 94–803, at 65 (1976).

[181] Efforts to require premerger notification date back to 1908. Leading up to the passage of the HSR Act, the Commission regularly urged Congress to pass legislation that would require advance notice for acquisitions. For a short time, the Commission relied on its authority under section 6 of the FTC Act to require merging parties to file special reports 60 days prior to consummation in certain industries, such as food distribution and cement. None of these programs required the parties to stay their merger plans. After passage of the HSR Act, the Commission discontinued reliance on special reports for prior notice of pending mergers. *See* Kelly Signs, ''Milestones in FTC History: HSR Act launches effective premerger review,'' Fed. Trade Comm'n Competition Matters blog (Mar. 16, 2015), *https://www.ftc.gov/enforcement/competition-matters/2015/03/milestones-ftc-history-hsr-act-launches-effective-premerger-review.*

[182] *See* S. Rep. No. 94–803, at 64 (1976).

[183] *Id.* at 63–66. *See also id.* at 9–10.

[184] 43 FR 33450, 33519–20 (July 31, 1978).

[185] *Id.* The Commission also rejected suggestions that it make certain burdensome requests optional for the parties, finding that such an approach would undermine the usefulness of the second request mechanism, hinder the Agencies in their efforts to carry out their congressionally mandated review, and be administratively unworkable. *Id.* at 33520.

[186] *Id.* at 33520. *See also* 42 FR 39040, 39043 (Aug. 1, 1977).

on when contemplating the deal,[187] the final rule seeks information that is readily available to the parties to fill information gaps that the Agencies have identified in the current HSR Form.

As discussed above, information reported in the current HSR Form is not sufficient due to differences in corporate structure and investment activity as well as profound changes in economic activity. In this rulemaking, the Commission is responding to these changes and how they have affected the Agencies' ability to conduct premerger screening in light of today's market realities. The Agencies need information to be able to spot all types of potential harm and the Commission has determined that the information requirements contained in the final rule are necessary and appropriate to conduct effective and efficient premerger screening and avoid even greater costs associated with collecting additional information through issuing more Second Requests. Without sufficient information available in the HSR Filing on the first day of the statutory review period, the Agencies cannot fulfill their mandate to identify and prevent illegal mergers or avoid potentially costly and protracted investigations.

Several commenters suggested that because Congress recently authorized the collection of additional information relating to foreign subsidies, that is the only information the Commission has the authority to collect.[188] The Commission disagrees that in passing this new requirement, Congress intended to repeal or in any way limit the Commission's statutory authority under 15 U.S.C. 18a(d) to impose other reporting requirements that are necessary and appropriate to determine whether the transaction may violate the antitrust laws. Indeed, the Commission is relying on its section 18a(d) authority to require the submission of information related to foreign subsidies in the final rule. The other changes contained in the final rule are a reasonable exercise of the Commission's rulemaking authority to require information that is necessary and appropriate for detecting problematic mergers during the initial waiting period of the HSR Act. The final rule updates the premerger notification regime based on the Agencies' experience in reviewing thousands of HSR Filings each year and in light of observable changes in market dynamics, contemporary investor behavior, investment arrangements, and acquisition strategies, as discussed in section II.B. above.

Some commenters suggested that the Commission lacks authority to make changes to the notification requirements because doing so increases the likelihood that the Agencies will subject more transactions to close scrutiny or seek to block them as illegal, and that this increased scrutiny will disincentivize dealmaking. This line of argument is contrary to the purpose of the HSR Act and the final rule.

Congress passed the HSR Act to create an effective mechanism to detect, deter, and prevent large transactions that violate the antitrust laws. The inadequacy of current notification requirements may encourage parties to enter into unlawful transactions due to the low risk of premerger detection.[189] One commenter supporting the need for change noted that the gaps created by the existing HSR Form and Instructions make it possible for anticompetitive mergers to go through unnoticed. Parties considering a merger are aware of this, so under the current system, parties are likely more willing to consider or attempt a merger that would be more obviously unlawful under a more rigorous disclosure regime. To the extent that one effect of the final rule would deter unlawful dealmaking, that effect is clearly consistent with Congress' intent that mandatory premerger review more effectively prevent illegal mergers.[190] Filing parties cannot claim an interest in inadequate detection or in avoiding an in-depth antitrust investigation that may lead to a court injunction blocking the merger because these concerns directly contravene U.S. law. Based on statutory text and clear Congressional intent, the Commission must ensure that HSR notification requirements enable the Agencies to detect the potential for harm before the harm occurs; that is the purpose of premerger review. When the Agencies' ability to detect the violation is compromised by inadequate disclosures in the HSR Filing, the Commission must use the authority expressly conferred by Congress to adjust the Agencies' detection tools to fulfill the purpose of premerger review.

Other commentors suggested that the Agencies' infrequent challenges to consummated mergers, including those reported but not challenged prior to consummation, are proof that the Agencies are not ''missing deals'' that cause harm. But given the significant effort required to unwind completed mergers, the frequent lack of information about the effects of consummated mergers, and the limited resources the Agencies have available to devote to all types of merger enforcement, in addition to their other statutory responsibilities,[191] the relatively low number of challenges to consummated mergers does not indicate that the current information requirements for premerger screening are sufficient to detect illegal deals. The Agencies must make difficult decisions about how to use their resources to address consummated mergers that may be causing real and ongoing harm while also working to fulfill their obligations to conduct a robust premerger screening of reported transactions. The critical task of screening reported transactions for antitrust risks can be especially challenging during times of peak M&A activity. See Figure 1.

According to one commenter whose members have been directly affected by consolidation in the retail food sector, third parties sometimes alert the Agencies to competitive issues, but that may not occur until after the waiting period has expired or the deal has been consummated. This commenter noted that these untimely scenarios are exactly the opposite of the HSR Act's legislative intent and force the Agencies and courts into a precarious position to preserve competition or obtain effective remedies. Congress certainly did not provide immunity for reported mergers that are not challenged prior to consummation (as most jurisdictions do)[192] so it is not a binary choice for the

[187] 122 Cong. Rec. 30877 (1976) (remarks of Rep. Rodino).

[188] *See* Consolidated Appropriations Act, 2023, Public Law 117–328, 136 Stat. 4459 (2022).

[189] *See* ''Stealth Consolidation,'' *supra* note 18.

[190] *See* S. Rep. No. 94–803, at 65 n.28 (the purposes underlying enactment of section 7 of the Clayton Act could have been accomplished if premerger notification had been enacted when originally proposed, and that if it had the economy would be less concentrated.).

[191] In addition to merger enforcement, both Agencies investigate and challenge anticompetitive conduct that may violate the antitrust laws. The Antitrust Division has sole responsibility to prosecute criminal violations of the antitrust laws, while the Commission has authority under section 5 of the FTC Act (15 U.S.C. 45) to challenge unfair methods of competition beyond the scope of the Sherman or Clayton Acts. In addition, the Commission's budget supports its consumer protection work, which is devoted to stopping unfair or deceptive acts or practices that violate the FTC Act as well as enforcement of more than 80 other statutes. *See generally* Fed. Trade Comm'n, ''Legal Library: Statutes,'' *https://www.ftc.gov/legal-library/browse/statutes*.

[192] *See* The Merger Control Review Preface, x (Ilene Knable Gotts, ed., 14th ed., 2023) (in most jurisdictions, a transaction that is not notified is not subject to review or challenge by the competition authority), *https://www.wlrk.com/webdocs/wlrknew/AttorneyPubs/WLRK.28469.24.pdf*. Canada recently extended its lookback period from one year to three years for non-notified transactions but left unchanged the one-year limitation to challenge notified transactions. *See* Competition Bureau Canada, ''Guide to the June 2024 amendments to

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Agencies to ''act or stand down'' on a reported merger. But once a merger is consummated (whether reported in advance or not), the Agencies face decisions about the significant costs of mounting a merger challenge to unwind the deal as well as the opportunity costs of doing so. Given the limited resources the Agencies have to devote to merger enforcement, the Agencies will often focus on enforcement of reported mergers due to these opportunity costs.[193]

The legislative record leading to the HSR Act is replete with references to the costs, delays, and ineffectiveness of relying on post-consummation enforcement to interdict mergers that may cause harm in their incipiency.[194] In the Agencies' experience, unwinding illegal consummated mergers continues to be a costly exercise, and there remain significant delays in obtaining effective relief through unwinding. A merged firm has strong incentives to delay the outcome, and Commission orders requiring divestiture of acquired assets are often appealed, further deferring relief.[195] Moreover, smaller or seemingly inconsequential acquisitions can later be revealed as potentially illegal exclusionary conduct when they are used by firms with dominant market positions to maintain or extend a monopoly in violation of section 2.[196] There are enormous costs and delays associated with prosecuting section 2 cases involving the largest companies in the world to unwind harmful acquisitions.[197]

In mandating government review of acquisitions prior to consummation, Congress intended for the Agencies to avoid these types of protracted antitrust cases when possible. Instead, Congress envisioned that merger enforcement would occur mostly through a system of premerger review, even at the cost of requiring premerger review for many mergers that may not ultimately warrant an in-depth investigation let alone a challenge in court.[198] The Commission has determined that imposing some limited additional upfront costs on filers so that they submit sufficient information to allow the Agencies to conduct the mandatory initial antitrust review fulfills the Agencies' statutory responsibilities and should be weighed against the benefit of avoiding large expensive antitrust actions required to unwind illegal acquisitions that were not detected at the screening phase. Importantly, the final rule imposes fewer information requirements on transactions that are reportable but have low antitrust risk while seeking the most information from those transactions most likely to require in-depth review at the screening phase. Otherwise, the consequences of poor detection are improperly shifted to those harmed by illegal consummated mergers—which is plainly at odds with the purpose of the HSR Act.

The benefits of stopping an illegal merger before it happens can be significant, especially for those who would bear the consequences of harm induced by the merger. The chart below collects estimates of avoided harm due to likely price changes for affected products or services in cases litigated by the Agencies and accepted by Federal courts as a basis for enjoining illegal mergers in recent years.

the Competition Act'' (June 25, 2024), *https://competition-bureau.canada.ca/how-we-foster-competition/education-and-outreach/guide-june-2024-amendments-competition-act*.

[193] *See* Zarek Brot-Goldberg, et al., ''Is There Too Little Antitrust Enforcement in the US Hospital Sector?'' (U. Chi., Becker Friedman Inst. for Econ. Working Paper No. 2024–59, May 2024) (forthcoming, Am. Econ. Rev.: Insights), *https://bfi.uchicago.edu/working-paper/is-there-too-little-antitrust-enforcement-in-the-us-hospital-sector/* (FTC is intervening in the most anticompetitive transactions but not preventing a significant number of hospital mergers that nonetheless cause harm).

[194] *See* H.R. Rep. No. 94–1373, at 7–10 (1976).

[195] *See, e.g., Illumina, Inc.* v. *FTC,* 88 F.4th 1036 (5th Cir. 2023); *ProMedica Health Sys., Inc.* v. *FTC,* 749 F.3d 559 (6th Cir. 2014), *cert. denied,* 575 U.S. 996 (2015); *Polypore Int'l, Inc.* v. *FTC,* 686 F.3d 1208 (11th Cir. 2012).

[196] *See supra* note 107 (collecting cases).

[197] The Commission filed its monopolization complaint against Facebook (now Meta) on December 9, 2020, and was joined by a coalition of forty-six States, the District of Columbia and Guam. *See* Press Release, Fed. Trade Comm'n, ''FTC Sues Facebook for Illegal Monopolization'' (Dec. 9, 2020), *https://www.ftc.gov/news-events/news/press-releases/2020/12/ftc-sues-facebook-illegal-monopolization*. The FTC is seeking a permanent injunction that would, among other things, require the divestiture of previously acquired assets. As of September 27, 2024, the parties have concluded pretrial discovery; a trial date has not been set.

[198] The Agencies can and do challenge reportable mergers after the expiration of the waiting period. *See, e.g., Chi. Bridge & Iron Co. N.V.* v. *FTC,* 534 F.3d 410 (5th Cir. 2008); *United States.* v. *Parker Hannifin Corp.,* No. 17–cv–01354 (D. Del. Sept. 26, 2017) (complaint). *See also* Note by the United States to the OECD, Investigations of Consummated and Non-Notifiable Mergers (Feb. 25, 2014) (DAF/COMP/WP3/WD(2014)23), *https://one.oecd.org/document/DAF/COMP/WP3/WD(2014)23/En/pdf* (discussing Agencies' challenges of consummated mergers); Menesh S. Patel, ''Merger Breakups,'' 2020 Wisc. L. Rev. 975, 990 (2020) (observing that, since 2001, the Agencies have challenged at least four mergers that previously underwent HSR review). Because of the confidentiality protections afforded HSR filings, market participants are often not aware of the merger or the timing of the expiration of the statutory waiting periods. *See* Comment of Strategic Org. Ctr., Doc. No. FTC–2023–0040–0708 at 3 (urging public notice of the date of HSR filings and the identity of the filers so that interested and affected parties can contact the Agencies during the initial review period). Many investigations of consummated mergers, including reported but not challenged transactions, are initiated after market participants reach out to the Agencies about the observed effects of the merger.

Table 2: Estimates of Harm in Blocked Mergers

Case	Estimate of Harm
U.S. v. JetBlue/Spirit Airlines	$1 billion per year[a]
FTC v. IQVIA/PMI	Post-merger price increase of 7.4%[b]
U.S. v. Bertelsmann SE & Co.	Post-merger decreases in advances range from 4% to 11.5%[c]
FTC v. Hackensack	$31 million per year[d]
FTC v. Peabody Energy	$1 billion over 10 years[e]
FTC v. Wilhelmsen	$14.4 million to $23 million per year[f]
FTC v. Sanford	$16 million to $27 million per year[g]

[a] United States v. JetBlue Airways Corp., No. 1:23-cv-10511 (Dec. 16, 2024) (Findings of Fact and Conclusions of Law) and Plaintiff's Post-Trial Brief at 18-19 (Dec. 13, 2023) (Proposed Acquisition Is Conservatively Projected to Cause Nearly $1 Billion of Harm Each Year to American Consumers in the Relevant Markets).
[b] FTC v. IQVIA Holdings Inc., No. 1:23-cv-06188 at 81-82 (S.D.N.Y. Jan. 8, 2024) (Op. & Order).
[c] United States v. Bertelsmann SE & Co., No. 1:21-cv-2886 at 54 (D.D.C. Nov. 7, 2022) (Mem. Op.).
[d] FTC v. Hackensack Meridian Health, Inc., No. 2:20-cv-18140 at 48-49 & n.26 (D.N.J. Aug. 4, 2021), aff'd, 30 F.4th 160, 174 (3d Cir. 2022).
[e] FTC v. Peabody Energy Corp. 492 F. Supp.3d 865, 906 (E.D. Mo. 2020).
[f] FTC v. Wilh. Wilhemsen Holding ASA, 341 F. Supp.3d 27, 65 (D.D.C. 2018).
[g] FTC v. Sanford Health, No. 1:17-cv-00133 at 28, 2017 WL 10810016 at *13 (D. N.D. Dec. 15, 2017) (Mem. Decision), aff'd, 926 F.3d 959, (8th Cir. 2019).

In addition to merger-induced price effects, which can vary widely due to differences in the economic size of the relevant markets affected by the merger, there can also be harm to customers from the loss of non-price competition. For example, the court found that JetBlue's anticipated reconfiguration of Spirit's aircraft would result in a decrease in the number of seats available on JetBlue flights of more than 6,100,000 per year.[199] These types of effects reduce output and result in a welfare loss due to the exercise of market power. In a vertical merger context, the Fifth Circuit affirmed the Commission's findings that Illumina's acquisition of Grail lessened competition via a different mechanism: the potential foreclosure of a key input by the sole supplier would lead to chilled investment by firms reliant on those inputs for their own competitive success.[200]

Moreover, merger retrospectives document merger-induced effects such as increased prices and decreased product quality or availability across a range of industries.[201] Given the significant economic costs imposed on market participants harmed by an illegal consummated merger, the Agencies will continue to challenge consummated mergers when practical and as resources permit. But relying on post-consummation merger enforcement to correct for information deficiencies in the HSR Form is contrary to Congressional intent that premerger review be used to stop illegal mergers before they occur.

1. Congress Determined Which Acquisitions Must Bear the Costs Associated With Premerger Review

Congress determined that the burden of premerger review should apply, regardless of antitrust risk, to a small subset of mergers where that burden would not be so great in comparison to the size of the deal and the size of the parties involved. Because the final rule does not require reporting for any additional transactions, it maintains the balance struck by Congress that only some mergers be subject to mandatory premerger review.

Congress incorporated several features in the HSR Act to lessen the burden on dealmaking, especially for small business and small transactions.[202] For instance, the HSR Act as first passed in 1976 contained three specific requirements that determined reportability for a planned transaction: the acquiring person is engaged in interstate commerce (the commerce test); one of the parties was worth at least $10 million and the other worth at

[199] *United States* v. *JetBlue Airways Corp.,* No. 1:23–cv–10511 at 43 (D. Mass., Jan. 16, 2024) (Findings of Fact and Conclusions of Law).

[200] *Illumina, Inc.* v. *FTC,* 88 F.4th 1036, 1055 (5th Cir. 2023).

[201] *See generally* Vivek Bhattacharya et al., ''Merger Effects and Antitrust Enforcement: Evidence from US Consumer Packaged Goods'' (Nat'l Bureau of Econ. Rsch., Working Paper No. 31123, Apr. 2023, rev. June 2024), *https://www.nber.org/papers/w31123* (studying fifty mergers in the consumer-packaged goods industry and finding that, on average, these mergers raised prices by 1.5 percent and decreased quantities sold by 2.3 percent); Daniel Hosken et al., ''Do Retail Mergers Affect Competition? Evidence from Grocery Retailing,'' 27 J. Econ. & Mgmt. Strategy 3 (2018) (finding that the majority of grocery mergers in highly concentrated markets resulted in price increases of more than 2 percent); John E. Kwoka, Jr., Mergers, Merger Control, and Remedies: A Retrospective Analysis of U.S. Policy 110–11 (2014) (providing a meta-analysis of retrospective literature, finding that more than 80 percent of mergers resulted in price increases and the mean price increase was 5.88 percent across all studied transactions); Orley C. Ashenfelter et al., ''Did Robert Bork Understate the Competitive Impact of Mergers? Evidence from Consummated Mergers,'' 57 J. L. & Econ. S67 (2014) (reviewing prior retrospectives and concluding that mergers in oligopolistic markets can result in economically meaningful price increases, as 36 of 49 studies surveyed found evidence of merger-induced price increases); Leemore Dafny et al., ''Paying a Premium on Your Premium? Consolidation in the US Health Insurance Industry,'' 102 a.m. Econ. Rev. 1161 (2012) (examining healthcare mergers and finding the mean increase in local market HHI during the studied period raised premiums by roughly 7 percent); Orley Ashenfelter & Daniel Hosken, ''The Effect of Mergers on Consumer Prices: Evidence from Five Mergers on the Enforcement Margin,'' 53 J. L. & Econ. 417 (2010) (examining a set of mergers that were unchallenged by the government and finding that the majority resulted in a significant increase in consumer prices in the short run); Thomas Koch & Shawn W. Ulrick, ''Price Effects of a Merger: Evidence from a Physicians' Market,'' 59 Econ. Inquiry 790 (2021) (concluding that a merger of orthopedic physicians' practices increased prices to some payors by ten to twenty percent while prices in nearby areas not affected by the merger remained unchanged); Zack Cooper et al., ''The Price Ain't Right? Hospital Prices and Health Spending on the Privately Insured,'' 134 Q. J. Econ. 51 (2019) (examining 366 hospital mergers and finding that prices increased by over six percent when merging hospitals were geographically close); Prager & Schmitt, *supra* note 83 (examining hospital mergers and finding reduced wage growth when merger significantly increases concentration).

[202] The Senate version of the premerger notification bill would have given the Commission authority to require reporting from additional ''small'' mergers, but the House bill and the final law did not include this provision. 122 Cong. Rec. 30877 (1976).

least $100 million (the size-of-person test); and as a result of the transaction, the acquiring person would hold at least 15 percent or $15 million of the acquired entity (the size-of-transaction test). These thresholds were adopted in response to concerns that requiring reporting for all mergers would unduly affect capital markets.[203] The size-of-person test was seen as especially important to limit the impact of premerger reporting on small businesses:

> Approximately the largest 700 U.S. companies meet the $100 million jurisdictional requirement. Although $100 million companies account for roughly 40 percent of mergers and acquisitions, Title V's *dual* requirement of (i) a $100 million acquiring company, and (ii) a $10 million acquired company would have required such 30-day notification, over the past 5 years, in less than 100 acquisitions per annum. With this limitation, the Committee sought to include within the ambit of the premerger notification provision primarily those mergers or acquisitions that were most likely to have a substantial effect on competition. That is not to say that smaller mergers may not run afoul of the Clayton Act. To include the bulk of the approximately 3,000 mergers that would have occurred annually in the course of the past several years would, however, in the Committee's judgement, impose an undue and unnecessary burden on business.[204]

Together, these criteria were designed to focus mandatory premerger review on the largest transactions and limit the number of transactions that would have to be reported to the Agencies. See Table 1 (on average 16.5% of mergers reported during FY 2018 to FY 2022).

During the 1990s, several years of intense M&A activity drove merger filings ever higher, so that by FY 2000, the Agencies reviewed over 4,900 reported transactions.[205] This dramatic increase in HSR filings led to calls for Congress to amend the HSR Act to reduce its broad sweep, and to especially address its impact on small businesses. In response, Congress made several changes in 2000 to reduce the number of transactions subject to reporting: (1) increased the size-of-transaction threshold from $15 million to $50 million and required the Commission, starting in 2005, to adjust the thresholds in the HSR Act annually based on changes in the gross national product; (2) eliminated the 15 percent size-of-transaction threshold, making $50 million (as adjusted) an absolute floor; and (3) eliminated the size-of-person test for larger transactions, making transactions valued in excess of $200 million (as adjusted) reportable without regard to the size of the parties.[206] Today, as a result of these adjustments and with annual indexing, HSR filings are required for only a small fraction of overall merger activity in the United States. See Table 1.

Many commenters pointed out that the Congress that enacted the HSR Act envisioned the Agencies reviewing only 150 of the largest mergers.[207] In 1976 when the HSR Act was passed, 150 mergers represented approximately 12.8 percent of M&A deal volume, given that there were 1,171 completed acquisitions in 1976.[208] Overall, the burden imposed on M&A activity by the HSR Act is not that different today than in 1976. See Table 1 (HSR reportable mergers on average 16.5 percent of M&A from FY 2018 to 2022). At the same time, the size of the U.S. economy has grown exponentially: in 1976, the seasonally adjusted U.S. Gross Domestic Product was $1.934 trillion; today it is over $28 trillion.[209] From these figures, it appears that M&A activity, and the economy in general, has not been affected by the obligations imposed on those pursuing certain large acquisitions to submit to mandatory premerger review.

Moreover, Congress enacted several explicit statutory exemptions to reduce the burden of reporting,[210] and also authorized the Commission to issue rules exempting persons and acquisitions that it deemed at the time as posing little to no antitrust risk, which eliminated the burden of reporting for many additional transactions.[211] The Commission has also faithfully implemented Congress' mandate to annually index the HSR thresholds, which keeps premerger review limited to those acquisitions Congress wants the Agencies to review prior to consummation.[212]

Some commenters noted that the current process is inefficient because of the over-inclusiveness of HSR reporting standards. They pointed out that of all reported transactions, the Agencies issue Second Requests in only 2 to 3 percent per year, suggesting that this is a reason for the Commission to keep the status quo and not adopt any adjustments to current information requirements.

The Commission believes that the low percentage of transactions that have received Second Requests is not a reliable indicator that the Agencies have achieved the goals of mandatory premerger review or that the current

[203] *See* S. Rep. No. 94–803, at 65–66 (1976).

[204] *Id.* at 66.

[205] Fed. Trade Comm'n & U.S. Dep't of Justice, Annual Report to Congress Pursuant to Subsection (j) of Section 7A of the Clayton Act, Hart-Scott-Rodino Antitrust Improvements Act of 1976 1 (Twenty-Third Report) (FY 2000).

[206] Public Law 106–553, 114 Stat. 2762 (2000) (codified at 15 U.S.C. 18a(a)). *See also* 146 Cong. Rec. S11872 (daily ed. Dec. 15, 2000) (statement of Sen. Kohl) (exempting small transactions from premerger review will significantly lessen regulatory burdens and expenses imposed on small businesses). This legislation also provided the Agencies more time to review materials submitted in response to a Second Request, extending the second waiting period under the HSR Act from 20 to 30 days after substantial compliance. *See* 15 U.S.C. 18a(e)(1)(A). *See* Fed. Trade Comm'n & U.S. Dep't of Justice, Annual Report to Congress Pursuant to Subsection (j) of Section 7A of the Clayton Act, Hart-Scott-Rodino Antitrust Improvements Act of 1976 (Twenty-Fifth Report) appendix A (FY 2002) (from FY 2000 to 2002, reported transactions dropped from 4,926 to 1,187).

[207] The prediction of 150 mergers turned out to be unrealistic from the start. In just the first three months of the premerger program, the Agencies received notifications for 292 transactions, nearly double the expected amount. *See* Fed. Trade Comm'n, Second Annual Report to Congress pursuant to Section 201 of Hart-Scott-Rodino Antitrust Improvements Act of 1976 3 (FY 1978). In the first full year of the HSR program, the Agencies received filings for 814 transactions. Fed. Trade Comm'n, Third Annual Report to Congress pursuant to Section 201 of Hart-Scott-Rodino Antitrust Improvements Act of 1976 3 n.4 (FY 1979). The Commission moved quickly to amend the HSR Rules to exempt additional types of transactions to further reduce the burden of the premerger reporting program. 44 FR 66781 (Nov. 21, 1979). *See also* David A. Balto, ''Antitrust Enforcement in the Clinton Administration,'' 9 Cornell J. L. & Pub. Pol'y 61, 119–20 (1999) (discussing two early HSR exemptions which resulted in approximately 20% and 10% reductions in filings).

[208] *See* Fed. Trade Comm'n, Statistical Report on Mergers and Acquisitions 25 Table 10 (1978), *https://www.ftc.gov/system/files/documents/reports/statistical-report-mergers-acquisitions-1978/statistical_report_on_mergers_aug1980.pdf*. This number does not include partial acquisitions which did not confer control on the buyer.

[209] U.S. Bureau Econ. Analysis, Gross Domestic Product (updated Aug. 29, 2024) (retrieved from FRED, Fed. Reserve Bank of St. Louis), *https://fred.stlouisfed.org/series/GDP*.

[210] *See* 15 U.S.C. 18a(c) and 16 CFR part 802.

[211] *See* 15 U.S.C. 18a(d)(2)(B) and 16 CFR part 802. Several commenters urge the Commission to engage in rulemaking to exempt additional transactions from HSR filing obligations. These suggestions are outside the scope of this rulemaking. Due to deficiencies in the information currently collected in the Form, as explained elsewhere in this document, the Commission is not able to identify any additional types of transactions that could be exempted at this time. Until the Commission has sufficient information to provide a reasonable basis to exempt additional categories of transactions from HSR reporting requirements, the Commission is not in a position to reduce the total number of reported transactions. As discussed in section VI.A.1.f., the Commission is excusing certain types of transactions (select 801.30 transactions) from many requirements of the final rule and has modified the proposed rule in many places to apply only where certain conditions have been met.

[212] To the extent that commenters suggest that the NPRM expands reporting requirements for additional transactions, they are wrong. Nor would changing the information requirements of the HSR Filing affect the obligations of public companies to comply with disclosure requirements of the Securities and Exchange Commission (''SEC''). *See* Comment of Am. Sec. Ass'n, Doc. No. FTC–2023–0040–0682 at 2.

process is efficient in identifying problematic transactions and effective in deterring illegal mergers. As discussed above in section II.B., the Commission has identified significant deficiencies in the information provided in the HSR Filing that prevent the Agencies from assessing the potential harm presented by reportable transactions. In light of these deficiencies, the number of mergers investigated through the issuance of Second Requests is not instructive on whether the Agencies are fulfilling their duty to the American public to screen large mergers in advance of consummation. The Agencies must continue to review reportable transactions to determine which ones warrant the issuance of Second Requests regardless of, and despite, fluctuations in the overall number of filings.

2. Delays Associated With Premerger Review Depend on Antitrust Risk

Congress also determined how much delay would be associated with those transactions subject to mandatory premerger review, and this rulemaking attempts to adjust the information required for premerger screening in light of legislative intent to avoid delays for any deal other than those with the highest antitrust risk. The main statutory feature of the HSR Act is the suspensory waiting period, which requires that the parties not consummate the proposed acquisition until the prescribed waiting period has expired. For all transactions, the statute limits that delay by keeping the waiting period short: 30 days for most transactions and 15 days for those most at risk of not happening at all due to delay, such as cash tenders and acquisitions of assets out of bankruptcy. Congress determined to hold up cash tender offers and the purchase of assets in bankruptcy only briefly due to heightened concerns over timing. For cash tender offers, which do not require consent of the target and can sometimes be actively opposed by the target, Congress shortened the suspensory waiting period to 15 days to balance premerger notice with the intent of the securities laws, specifically the Williams Act, so as not to ''tip the balance'' in favor of the incumbent management of the target firm.[213] Similarly, for acquisitions of assets subject to bankruptcy proceedings, Congress understood that time is of the essence to prevent liquidation of productive assets and applied the shortened 15-day initial waiting period to these transactions as well. Congress thus recognized that a particular subset of transactions require especially speedy review.

At the same time, Congress provided that the Agencies can extend the waiting period for any type of reportable acquisition by requiring the submission of additional information or documentary material in response to a Second Request. The decision to issue Second Requests has significant consequences for the transaction because if that happens, the parties cannot consummate the transaction until 30 days after each party has substantially complied with the Second Requests.[214]

The Commission disagrees that the final rule entails any delay beyond that which was expressly contemplated in the HSR Act. First, the final rule does not extend the statutory waiting periods, which are established by Congress.[215] Second, Congress made clear that the initial waiting period will commence once the Agencies have received a completed Form, or a partially completed Form with a specific statement of the reasons for partial non-compliance.[216] Third, Congress directed the Commission to devise and maintain a mandatory notification program that would give the Agencies the information that is necessary and appropriate to conduct an initial antitrust assessment during the initial 15- or 30-day waiting period.

That said, the Commission does not question the need, when appropriate, to minimize delay for notified transactions, especially for non-problematic deals. In fact, the Commission believes that the final rule may shorten the overall waiting period for a significant number of transactions and perhaps even reduce the overall number of delayed transactions. As discussed above, Congress determined that 30 days was the appropriate delay for the majority of reportable transactions (other than cash tenders and acquisitions in bankruptcy), regardless of their size or economic impact. It is a feature of the HSR Act that an open market stock purchase by an individual can be subject to the same 30-day initial waiting period as a multi-billion-dollar merger of competitors operating in multiple local markets throughout the country. Yet these two transactions present very different antitrust risks.

In order to quickly dispense with those transactions that present low risk of a law violation so as to focus on those with moderate to high risk, the Agencies need more information in the HSR Filing. Any time and effort the Agencies must spend collecting necessary information that is not contained in the HSR Filing is time and effort taken away from quickly determining which deals do not warrant an in-depth investigation. Especially as it relates to cash tender acquisitions—which are among some of the largest deals reviewed by the Agencies over the years and yet are subject to a 15-day initial waiting period—the short time given for the initial antitrust assessment severely strains the Agencies' limited resources, especially during periods of intense M&A activity. See Figure 1. But the statutory time limit is absolute and if the Agencies do not issue Second Requests before the end of the initial waiting period, the parties are free to consummate the transaction.[217] This is as Congress intended, but Congress also gave the Commission the authority to determine the necessary and appropriate information that must be included in HSR Filings to make the

[213] 122 Cong. Rec. 30877 (1976) (listing a number of defensive actions the target could take to undermine the offer if it had enough time, effectively denying shareholders of the target firm the choice to accept the offer).

[214] The Agency that issued the Second Requests can grant early termination of the waiting period, permitting the parties to consummate their proposed acquisition, or a Federal court may extend the waiting period if the Agency applies for preliminary relief and the court finds that the party has not substantially complied with the information requirements of the HSR Act. 15 U.S.C. 18a(g)(2).

[215] As discussed in section V.D. below, if the parties have not executed a definitive agreement, the final rule requires that they submit a document with the HSR Filing that contains sufficient details of the transaction they intend to consummate. This may be the executed preliminary agreement, or the agreement may be supplemented by one additional dated document, such as a term sheet or the latest draft agreement. While this new requirement may cause some filers to delay notification compared to the current rules, the Commission believes this change is necessary and the delay is appropriate to avoid wasting the Agencies' time and attention on deals that may never occur or are too hypothetical or lacking material details to assess.

[216] 122 Cong. Rec. 30876 (1976). The Commission does not dispute that the HSR Act allows for substantial compliance with its requirements. In response to such arguments, the sponsors dropped the ''automatic stay'' provisions and adopted a requirement that filers ''substantially comply'' with the Second Request so that arguments that the parties had not fully complied could not hold up the deal. Under 15 U.S.C. 18a(g)(2), a district court may extend the statutory waiting periods of the HSR Act if filers fail to substantially comply with the requirements of the HSR Act.

[217] As part of the 2000 amendments to the HSR Act, Congress made plain that if the end of the waiting period falls on a Saturday, Sunday, or legal public holiday, then the waiting period is extended to the next day that is not one of those days. 15 U.S.C. 18a(k). This change was necessary to eliminate gamesmanship by parties who timed their compliance so that the waiting period ended on a weekend or holiday, effectively shortening the waiting period to the previous business day. 146 Cong. Rec. S11872 (daily ed. Dec. 15, 2000) (statement of Sen. Kohl).

statutory scheme work—not for the purpose of minimizing delay but for the purpose of enforcing the antitrust laws for the benefit of the public. That is the problem this rulemaking addresses: by adjusting the amount of information available to the Agencies on the first day of the waiting period, the final rule makes possible quick but thorough premerger review for all reportable transactions.

For many years, and mainly due to the lack of sufficient information contained in HSR Filings, many filers and practitioners have become accustomed to artificially lengthened waiting periods. In 2013, the Commission issued a rule that formalized a previously informal process that offers filers the option to withdraw and refile their filings without paying an additional filing fee. The option to withdraw-and-refile was intended to benefit both the parties and the Agencies by providing an additional 15- or 30-day waiting period for the Agencies to review the transaction without issuing Second Requests while seeking additional relevant information on a voluntary basis from the merging parties or from third parties.[218]

As shown in Table 3 below, the option to withdraw-and-refile has been used with some frequency by filers to give the Agencies more time to conduct an initial premerger assessment. Based on the Agencies' review of their HSR-related investigations during the five-year period of FY 2018 to 2022, parties withdrew their HSR filing and refiled in a total of 546 transactions. In the majority of these extended investigations, the Agencies determined not to issue a Second Request: nearly two-thirds of the time, opting to withdraw and refile resulted in the transaction closing at the end of the initial waiting period, thereby avoiding the cost and burden of a Second Request investigation. That is, once the filing parties submitted information beyond what was submitted with the HSR Form, the investigating Agency was able to determine that the transaction did not warrant Second Requests.

Table 3: Withdrawn & Refiled Transactions Fiscal Years 2018 – 2022

	5 Year Total
Transactions	546
Transactions Not Issued Second Request	365
Percentage Not Issued Second Request	67%

While the parties can rely on the option to withdraw and refile as an ad hoc tactic to avoid the issuance of Second Requests, the Agencies' experience illustrates in a very tangible way the inefficiencies associated with the current HSR Form. Over the five years sampled, an average of 73 transactions each year (546 in total) were delayed by an additional 30 days and filers were burdened by having to submit additional materials on a voluntary basis even though the investigation did not lead to the issuance of Second Requests. These delays impose costs on the parties and the Agencies, as well as third parties contacted during the extended initial review period.

Moreover, getting more time to review the transaction does not address the information deficiencies outlined above and addressed by the final rule. While serving as an existing work-around to give the Agencies more time to collect additional information not contained in the HSR Filing, the option to withdraw-and-refile is a poor substitute for having the necessary information submitted with the HSR Filing for several reasons. First, the current information requirements leave important gaps, as detailed above in section II.B., leading staff to flag filings for no-action when in fact they may warrant a closer review.[219] In practical terms, the HSR Filing must contain sufficient information from the filers to allow the Agencies to spot transactions that may warrant follow up. Merely adding time on the clock does not fill the information gaps identified above.

Second, withdraw-and-refile is optional for filers and thus is not a tool the Agencies can rely on to collect more information when needed. While parties may decide to delay their transaction to lower the chances of receiving a Second Request, in many instances the parties do not withdraw and refile precisely because they fully expect to receive Second Requests. When the parties do withdraw and refile, the Agencies spend considerable time waiting for answers to key questions; in any event, having more time is not the same as having the information needed to conduct an initial antitrust assessment. The Agencies' experience is that these voluntary submissions are often late or incomplete. When the information arrives near the end of the extended waiting period, there is often not enough time to review and verify the information. As a result, investigations that are extended through a withdrawal and refile are costly in time and effort for both Agency staff and the parties: extra time does not always translate to collecting the right information to make the initial determination whether the transaction should be fully investigated through the issuance of Second Requests.

Finally and most importantly, a filer's submission of any additional information beyond what is required for an HSR Filing is voluntary. Given that the Agencies have no ability to demand compliance with voluntary requests, there is an overwhelming incentive for filers to prioritize the collection and submission of information suggesting that there is no competitive problem, rather than supplying the necessary information in an objective and neutral manner. Thus, while the agency may receive additional relevant information on a voluntary basis, it remains extremely challenging for the Agencies to both review and verify this information in whatever short period of time is available to decide whether to issue Second Requests.

Expending so many resources on withdraw-and-refile investigations is

[218] 78 FR 10574, 10576 (Feb. 14, 2013).

[219] *See supra* note 24 (citing research finding that consummated hospital mergers that received early termination resulted in the largest average percentage price increase).

inefficient both for the parties and the Agencies and is a source of undue delays for many deals every year, because having more time is not a substitute for having sufficient and reliable information provided on a mandatory basis on the first day of the waiting period. The Commission believes that requiring more information in the HSR Filing through a final rule that is focused on surfacing competition problem areas will reduce the need for extended withdraw-and-refile investigations for a significant number of transactions that do not require Second Requests.

Expanding the information that filers are required to provide upfront has certain benefits for filers and gives full effect to the purpose of a very short initial waiting period: because the information will be available to the Agencies on the first day of the initial waiting period, this will reduce delays for deals that do not receive Second Requests but nonetheless are delayed because staff must collect information from third parties or public sources, including when the parties withdraw and refile their HSR Filing. In addition, having this information upfront may allow Agency staff to narrow the areas of focus to only those business lines that require further investigation.[220] Based on the Commission's experience, the additional information will allow the Agencies to significantly reduce burdens on filing parties in many circumstances.

Moreover, the additional information required by the final rule addresses the fundamental information asymmetry that currently exists between what the parties know about their business and what information they are required to reveal to the Agencies in the HSR Filing. Shifting the burden of information collection from the Agencies to the filing parties minimizes the burden on Agency staff to collect basic business information about the filers from other sources, such as their customers or other market participants, or from public sources, which may not surface key confidential business information known only to the parties. It also minimizes the burden on those third parties. This basic business information is relevant to the Agencies' antitrust assessment and often comes in late in the initial waiting period close to when the Agencies need to determine whether to issue Second Requests.

Moreover, certain information is most readily and reliably available from the parties to the transaction. Although Agency staff collect relevant information from other sources including third parties during the initial waiting period, the benefit of getting this information from the filing parties is that it is likely more accurate and up-to-date and therefore more reliable for the purpose of quickly conducting a premerger assessment of antitrust risk. Obtaining basic business information about the operations of the filing parties secondhand from third parties and public sources is no substitute for getting that information directly from the parties themselves. The parties will have the most reliable and relevant information necessary to conduct a preliminary assessment of the transaction during the initial waiting period.

Having reliable and accurate information directly from the entity most likely to have it reduces overall information-collection costs and delays. That is just good government, according to some members of Congress: ''Requiring transacting parties to provide regulators with the information necessary to examine a proposed merger is a commonsense way to save taxpayer dollars and enable antitrust enforcers to fulfill their congressional mandate and protect consumers, the economy, and national security.'' [221]

To further reduce delays for transactions that pose little or no antitrust risk based on information contained in the HSR Filing, the statute also provides the Agencies with the discretion to grant an early termination of the initial waiting period, reducing the statutory 15- or 30-day delay to something less.[222] For many years, the Agencies routinely granted early termination to those filers that requested it.[223] Contrary to the assertions of some commenters, the Commission reviews the information provided in *every* filing (typically two filings per transaction) [224] to ensure compliance with the requirements of the HSR Act and to conduct a preliminary assessment of antitrust risk. The decision to grant discretionary termination of the waiting period prior to the statutory deadline is the result of staff review of the information contained in the HSR Filing, a determination that takes time, knowledge of the HSR Rules, and often additional research from public sources to ensure that there is little to no risk that the transaction requires additional investigation prior to consummation. There is also the additional time spent coordinating both Agencies' conclusions as well as processing the granting of early termination through publication in the **Federal Register**.[225]

Prioritizing staff resources to reduce delays through early termination over the identification of problematic deals became impractical during the latest surge in HSR-reportable transactions, beginning in the fall of 2020 when the Agencies were faced with an unprecedented increase in merger filings.[226] As reflected in Figure 1 above, the number of HSR-reportable transactions spiked in FY 2021, resulting in more than twice the number of filings as compared to the prior year. Given the time and effort required to collect additional information during the initial waiting period—information that is not contained in the current Form but that bears directly on whether the Agencies should conduct a more in-depth investigation or grant early termination—the Agencies temporarily suspended the granting of early termination, first briefly in order to adjust to the challenges of processing premerger filings during the COVID–19 pandemic, and then again due to a surge in merger filings.[227]

As an additional measure, the Commission determined that it would

[220] As discussed elsewhere, the Commission did not consider any ''burden'' associated with better detection of illegal mergers. Identifying additional transactions for investigation and possible challenge is a benefit of effective and efficient premerger review.

[221] Comment of Sen. Elizabeth Warren et al., Doc. No. FTC–2023–0040–0711 at 5.

[222] 15 U.S.C. 18a(b)(2).

[223] Not all parties request early termination; whether to request early termination is solely at the discretion of the filing parties. Because the Agencies are required to make public grants of early termination through publication in the **Federal Register**, some filers may prefer not to have their acquisitions made public in this way.

[224] As reflected in appendix A of the Annual HSR Reports, the Agencies typically receive two filings for each transaction, one from the acquiring person and one from the acquired person. In FY 2022, the Agencies reviewed 6,288 filings for 3,152 reported transactions. Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Report, Fiscal Year 2022 appendix A (FY 2022).

[225] Commission staff take seriously the statutory obligation not to disclose information about an HSR Filing. Because the granting of early termination requires public notice in the **Federal Register** and is often the first indication that a proposed acquisition is in the works, staff must take great care to avoid mistakes when processing these requests.

[226] Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Annual Report, Fiscal Year 2021 appendix B (FY 2021) (reporting monthly HSR filings for FY 2012 to FY 2021). *See* Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter Regarding the FY 2020, Hart-Scott-Rodino Annual Report for Transmittal to Congress (Nov. 8, 2021) (''FY 2020 HSR Statement''), *https://www.ftc.gov/system/files/documents/public_statements/1598131/statement_of_chair_lina_m_khan_joined_by_rks_regarding_fy_2020_hsr_rep_p110014_-_20211101_final_0.pdf.*

[227] *See* Press Release, Fed. Trade Comm'n, ''FTC, DOJ Temporarily Suspend Discretionary Practice of Early Termination'' (Feb. 4, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/02/ftc-doj-temporarily-suspend-discretionary-practice-early-termination.*

provide notice to filers whose deals could not be adequately screened during the initial waiting period, warning them that although the waiting period had expired, the transaction remains subject to antitrust challenge under section 7.[228] In the Commission's view, these pre-consummation warning letters are consistent with the legislative intent that lack of agency action prior to the expiration of the initial 15- or 30-day waiting period does not bar the Agencies (or other enforcers of the Clayton Act such as States or private parties) from later challenging the notified transaction. That is, premerger review provides the Agencies with the opportunity to investigate and challenge suspect transactions as violative of section 7; it does not require nor allow the Agencies to determine that the merger does not or would never violate section 7.

These recent adjustments to the Agencies' premerger review process reflect the burdens on Agency staff to triage filings during the very limited statutory period allowed for the initial review, which underscores the need for additional information at the outset of the initial waiting period. Even for those transactions in which the parties give the Agencies additional time by withdrawing and refiling their notification, relying on voluntary submissions has not been sufficient to overcome the lack of relevant information needed to conduct a robust screening for a significant number of deals.

As several commentators noted, it is appropriate that the Agencies, who have the responsibility to identify which transactions should be challenged, address the significant information asymmetry between the parties and the Agencies by collecting more information from the parties upfront. The Commission agrees. The Commission has determined that the information deficiencies of the current reporting requirements are imposing undue delay on those transactions that the Agencies determine do not require intervention prior to consummation. The final rule addresses these inefficiencies by shifting more of the costs of information acquisition to the merging parties, both because they are the most reliable and ready sources for that information and to reduce the costs and delays associated with information acquisition from other sources, including third parties. The Commission believes that the final rule represents a reasonable adjustment to the information requirements for premerger notification that will reduce the number of transactions that are delayed beyond the initial review period.

3. The Purpose of the HSR Form Versus Second Requests

Several commenters asserted that if the Agencies need more information, they should issue more Second Requests as an alternative to issuing this final rule, because that is the mechanism Congress gave the agencies to collect more information. Commenters also compared the requirements of the proposed rule to those contained in a Second Request, asserting that this rulemaking would inappropriately convert the HSR Filing into the equivalent of a Second Request in terms of scope and burden. As discussed below, the Commission disagrees with these commenters. Congress gave the Agencies a mandate to collect information that is necessary and appropriate in the HSR Filing to determine whether the reported transaction may violate the antitrust laws, which would justify the burden (on both the parties and the Agency) associated with issuing Second Requests. The purpose of requiring an HSR Filing is to give the Agencies time and information to conduct mandatory premerger screening. The purpose of issuing Second Requests is to conduct an in-depth review of other information and documentary materials that would allow the Agency to determine whether to challenge the transaction prior to consummation. The Commission has concluded that the final rule more appropriately reflects the purpose of the statutory scheme, which requires the information from all filers that is necessary for premerger screening but requires extensive information in response to a Second Request (which today, often represents millions of documents and terabytes of data) only from those filers whose transactions warrant an in-depth antitrust investigation. Thus the final rule is a reasonable exercise of the Commission's rulemaking authority to address the information deficiencies identified in section II.B. rather than rely on the extraordinarily costly alternative of using Second Requests to address those deficiencies.

Commenters point to research that indicates there is a high probability that a transaction will be challenged if the Agencies issue Second Requests and suggest that this means that Second Requests are the most reliable tool for the Agencies to identify potentially harmful deals. But a close read of the study cited by commenters reveals that there are reasons to question the conclusions commenters have drawn from the low number or high through-rates of Second Requests. Billman and Salop examined the Agencies' enforcement record and calculated that for those transactions that receive a Second Request, 28 percent are cleared as proposed.[229] Billman and Salop also report that the percentage of Second Request investigations has fallen over time, from about 3.49 percent in 2001 to 2.92 percent in 2020. These figures are consistent with information reported by the Agencies in annual HSR Reports.[230] In their report, Billman and Salop contend that the reason behind the falling number of Second Requests is limited agency resources, not diminishing antitrust risk due to mergers:

> The agencies issue so few second requests because they have been budget constrained during this entire period. Under these circumstances, the agencies must engage in a type of triage process. Being limited in the number of second requests they can issue and cases that they can afford to litigate in court, the agencies target only the limited number of most problematical looking mergers for second requests. Not surprisingly, they generally discover evidence of potential anticompetitive effects. And not surprisingly, the firms generally consider the validity of the concerns, and most are then willing to accept a consent decree or abandon the transaction. Indeed about 26% (*i.e.,* 254/969) of the firms that receive second requests choose to abandon the transaction even *before* a complaint is issued.[231]

The Commission is well aware of the challenges of fulfilling its mission to prevent harmful mergers with existing resources. Fully resourcing the Commission's competition mission—especially merger review—has been an ongoing challenge. For instance, the Commission's headcount remains well below what is needed in light of the volume and complexity of proposed deals. Over the past ten years, the absolute number of HSR filings has nearly doubled, while the number of FTC employees assigned to competition work has remained nearly flat. As a result, the Commission has been forced to make difficult triage decisions and forgo potentially worthy investigations.[232] Moreover, funding

[228] *See* FY 2020 HSR Statement, *supra* note 226.

[229] Logan Billman & Steven C. Salop, ''Merger Enforcement Statistics: 2001–2020,'' 85 Antitrust L. J. 1, 6 (2023).

[230] *See* appendix A of HSR Annual Reports, available at Fed. Trade Comm'n, Annual Reports to Congress Pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, *supra* note 56.

[231] Billman & Salop, *supra* note 229, at 7.

[232] *See* Statement of Chair Lina M. Khan, joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya Regarding the FY 2022 HSR Annual Report to Congress (Dec. 21,

levels for the antitrust agencies has not kept pace with the impressive growth of the U.S. economy: according to one report, from 2010 to 2019, U.S. GDP increased 37 percent but appropriations for the Antitrust Division and the FTC increased only 3 percent.[233]

Commenters who supported expanded information requirements suggested that limited resources justify this rulemaking, while those opposed claimed that resource limitations are the real source of underenforcement of the antitrust laws, a problem that will not be solved by adding burdensome new information requirements. Whatever the funding levels, the Agencies must deploy their resources to be good stewards of public funds and make resource allocation decisions to pursue their mutual mission to enforce the antitrust laws for the benefit of the public. The Commission has concluded that regardless of resource levels, it is critical to the task of detecting illegal mergers that the HSR Filing contain sufficient information for an effective premerger antitrust assessment of the transaction rather than relying on issuing more Second Requests to compensate for information deficiencies in the HSR Filing.

The Commission has determined there are several reasons why issuing more Second Requests is not a reasonable alternative to address the information gaps discussed in section II.B. above. First, without the additional information required by the final rule, the Agencies would continue to struggle to uncover key facts necessary to determine whether to issue Second Requests for reported transactions that warrant in-depth review. The Agencies are currently making these assessments and relying on Second Requests when necessary, but they are doing so knowing that there are deficiencies in the information currently collected on the HSR Form, resulting in significant extra effort to generate sufficient information to make that determination prior to the expiration of the initial waiting period. In light of the deficiencies in the information currently collected that are discussed in section II.B., the Commission has determined that the status quo does not permit the Agencies to fulfill their statutory mandate to identify those transactions that warrant the issuance of Second Requests.

Second, issuing more Second Requests is an extremely costly alternative to the final rule. The costs, burdens, and delay associated with Second Requests—for both the parties and the Agencies—are well documented. In 2000, Congress amended the HSR Act to provide for an optional internal review process for Second Request recipients to object to the breadth and cost of complying with those requests [234] and requiring the Agencies to conduct ''an internal review and implement reforms of the merger review process in order to eliminate unnecessary burden, remove costly duplication, and eliminate undue delay, in order to achieve a more effective and more efficient merger review process.'' [235] Yet despite Agency reforms to reduce burdens and costs, [236] the AMC noted the widespread belief that complying with a Second Request imposed significant costs. The AMC cited a survey conducted by the Antitrust Section of the American Bar Association which reported that, on average, investigations during the second waiting period took seven months and resulted in median compliance costs of $3.3 million.[237] A more recent survey conducted in 2014 by the Mergers & Acquisitions Committee of the ABA reported that average cost of compliance with a Second Request was $4.3 million among respondents.[238] Another study shows that Second Requests impose significant delays and risks, even for deals that are ultimately not challenged by the Agencies, increasing the time required for premerger review from an average of 98 days (3.3 months) for acquisitions that do not receive a Second Requests to 237 days (7.9 months) from announcement to closing.[239]

The Commission has determined that the final rule is a better regulatory alternative than issuing more Second Requests because the final rule provides the Agencies with the information necessary for an efficient and effective premerger assessment and to determine which reportable transactions warrant the issuance of Second Requests. The Commission considers the costs that would be associated with issuing more Second Requests as an alternative to the final rule to be unnecessary and unjustified. By relying on only the information contained in current HSR requirements and issuing more Second Requests, the Agencies would be imposing these significant costs on deals that are even more ''on the margin'' than the ones that are currently identified for a Second Request investigation. Issuing more Second Requests without adjusting the information in the HSR Filing would most likely result in significant costs for additional transactions and undue delay for even more deals that are not ultimately challenged in court.

More importantly, without addressing the information deficiencies outlined in section II.B., the Agencies would miss certain transactions that warrant further review. For these transactions, which are currently not subject to Second Requests, the costs of complying with the additional information requests for the HSR Filing are justified by the enhanced ability of the Agencies to detect the potential for the transaction to violate the antitrust laws. In other words, the final rule makes it more likely that the transactions that present the most significant risk violating the antitrust laws, and therefore most clearly warrant the costs and delays associated with an in-depth investigation, are those that will receive Second Requests.

As an added benefit, the additional information contained in the HSR Filing will allow the Agencies to focus their investigation on those aspects of the transaction that create antitrust risk, and

2023). *https://www.ftc.gov/system/files/ftc_gov/pdf/StatementofChairKhanJoinedbyComm%27rSlaughterandComm%27rBedoyareFY2022HSRAnnualReport.pdf.*

[233] Michael Kades, ''The state of U.S. federal antitrust enforcement,'' Wash. Ctr. Equitable Growth 22–23 & Fig. 12 (Sept. 17, 2019), *https://equitablegrowth.org/research-paper/the-state-of-u-s-federal-antitrust-enforcement/?longform=true.*

[234] 15 U.S.C. 18a(e)(1)(B).

[235] *Id.* sec. 18a(e)(1)(B)(iii).

[236] *See* Prepared Statement of the Fed. Trade Comm'n Before the Comm. on the Judiciary, Subcomm. on Antitrust, Competition, and Small Bus. and Consumer Rights, United States Senate Concerning An Overview of Fed. Trade Comm'n Antitrust Activities 3 (Sept. 19, 2002), *https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-overview-enforcement-antitrust-laws/020919overviewtestimony.pdf.* In 2002, the Commission's Bureau of Competition issued Guidelines on Merger Investigations, which eliminated some of the more onerous requirements of compliance. *See* Debbie Feinstein, ''A fine balance: toward efficient merger review,'' Fed. Trade Comm'n Competition Matters blog (Aug. 4, 2015), *https://www.ftc.gov/enforcement/competition-matters/2015/08/fine-balance-toward-efficient-merger-review.*

[237] AMC Report, *supra* note 179, at 163. The AMC noted that the survey's value was limited due to reliance on a non-scientific, self-selected sample of only twenty-three responses, and that the median values for most measures of cost were much lower than the means, suggesting the average values were influenced by a few very high observations. *Id.*

[238] Peter Boberg & Andrew Dick, ''Findings from the Second Request Compliance Burden Survey,'' Vol. XIV No. 3 Threshold: Newsletter of the Mergers & Acquisitions Comm. 26, 37 (Summer 2014) (A.B.A. Antitrust L. Sec.). In about one-third of these investigations, parties had withdrawn and refiled their notification, indicating that the strategy was not always effective in avoiding a Second Request. This is consistent with the Commission's assessment of withdraw and refile data, reflected in Table 3 *supra.*

[239] Jana Fidrmuc et al., ''Antitrust merger review costs and acquirer lobbying,'' 51 J. Corp. Fin. 72, 73 (2018).

minimize ''overly broad'' Second Requests, which can also impose unnecessary costs and delays. Specifically, the final rule provides the Agencies with the information that is necessary to make the critical decision whether and how to burden the filers and the Agencies with the costs and delays associated with an in-depth investigation of the reported transaction.

Indeed, one goal of this rulemaking is to reduce the number of Second Request investigations that do not lead to an enforcement action. Imposing substantial costs in addition to undue delay on transactions that are unlikely to face a court challenge is the wrong response to the information deficiencies outlined in section II.B. The Commission has determined that imposing minimal additional costs on all filers to properly conduct premerger screening will likely reduce the number of transactions that receive a Second Request but do not face a court challenge, a very significant benefit to filers. The Commission expects that, on balance, the final rule will reduce the number of unnecessary or overly broad Second Requests and that this outcome is consistent with the statutory scheme created by Congress.

Much of the increased cost of a Second Request investigation (for both the parties and the Agencies) is due to the increasing complexity of merger litigation, and including the costs associated with post-complaint discovery. Federal judges overseeing merger trials routinely remark on the scope and effort of proving and refuting the facts needed to assess whether a proposed transaction violates the antitrust laws.[240] The Agencies' costs in litigating these cases have also increased significantly in recent years, especially the cost of hiring outside experts to support the litigation.[241] To a large extent, the scope and burden of a Second Request is driven by the growing need for data and other evidence required to make an informed decision whether to devote scarce resources to a particular case in light of the likelihood that the agency can establish liability under section 7 of the Clayton Act.

Of the commenters objecting to the proposed rule, some argued that the final rule would collapse the distinction between the notification form and a Second Request. The Second Request is the Congressionally mandated tool for the collection of additional information to determine whether to challenge the transaction prior to consummation. The Commission states that it is not its intention in any way to require in the initial notification all the information that may be necessary to determine whether to file a complaint alleging an antitrust violation. Instead, the final rule ensures that the Agencies have the information necessary to identify those transactions that require the issuance of Second Requests, a decision that must be made prior to the expiration of the statutory waiting period. The Commission disagrees that the final rule requires anything near the amount of data and documents sought in Second Requests, which are tailored for each recipient. For example, the Commission's Model Second Request requires the submission of all documents related to pricing for any relevant product for the last three years[242] and the Department of Justice's Model Second Request requires the submission of each database or data set containing a range of information about the relevant product.[243] That level of detail and analysis is not required by the final rule and is not warranted in an HSR Filing. In the final rule, the Commission has identified the information that the Agencies need to conduct a preliminary screen for antitrust risks. A Second Request represents a whole different level of detail and analysis, one much more aligned with determining whether there are facts sufficient to establish to a court that the merger may substantially lessen competition or tend to create a monopoly.

As discussed in section III.A., the Commission believes that it is consistent with the statutory premerger regime to collect certain critical information directly from those involved in the transaction and to have that information available on the first day of the initial waiting period. The Commission believes that it is well within its statutory authority to require minimally sufficient information in the HSR Filing that is necessary and appropriate to screen each reported transaction for antitrust risk without resorting to issuing more Second Requests to require information that is not currently submitted with the HSR Form.

Moreover, the Commission believes that Second Requests should continue to be reserved for those transactions more likely to violate the antitrust laws and to result in measurable harm if not blocked prior to consummation. Issuing more Second Requests as a remedy for deficient HSR Filings imposes opportunity costs on the Agencies, diverting resources that could be used to address other potential violations of the antitrust laws. Moreover, as discussed above, one potential benefit of the final rule is that it may reduce the number of Second Requests or limit their scope. Issuing more Second Requests runs counter to that goal and would also impose significant additional costs on the Agencies, the filing parties, and third parties. In the words of one commenter: ''These proposed changes exemplify good government. They would save regulators valuable time and resources in evaluating merger proposals, making the agency's processes more efficient.''[244]

In sum, in adopting this final rule, the Commission believes that it has identified the specific additional information that, in the Agencies' experience, is most relevant to determining whether to issue Second Requests or narrow their scope. Moreover, as detailed below in sections IV. through VI., the Commission has made significant modifications in the final rule to better balance the need for additional relevant information while avoiding undue delay and cost where the likely benefit to the Agencies is low, especially for those deals that they can quickly determine are not likely to violate the antitrust laws. The Commission believes that the final rule, as modified, would better address the information deficiencies outlined above as compared to other available regulatory options such as relying on more Second Requests.

The Commission has also considered whether to rely on the expanded use of voluntary supplemental submissions from the parties, including as part of a pull-and-refile investigation, as an alternative to the final rule. See section III.A.2. But this alternative does not address the information deficiencies that this rulemaking has identified with

[240] *See, e.g., FTC* v. *Peabody Energy Corp.,* 492 F. Supp. 3d 865, 874 (E.D. Mo. 2020); *FTC* v. *Staples, Inc.,* 190 F. Supp. 3d 100, 110 (D.D.C. 2016); *FTC* v. *Sysco Corp.,* 113 F. Supp. 3d 1, 15 (D.D.C. 2015); *United States* v. *JetBlue Airways Corp.,* cv–23–10511 (D. Mass. Jan. 16, 2024).

[241] *See* Letter from Lina M. Khan, Chair, Fed. Trade Comm'n to Rep. Thomas P. Tiffany 5–6 (Nov. 3, 2023) *https://www.ftc.gov/system/files/ftc_gov/pdf/2023.11.3_chair_khan_letter_to_rep._tiffany_re_merger_challenges.pdf* (citing expert witness costs related to merger enforcement in Federal court).

[242] *See* Fed. Trade Comm'n, Bureau of Competition, Model Second Request Specifications 8 (rev. Jan. 2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/Final-Rev-Model-Second-Request-01-26-2024.pdf.*

[243] U.S. Dep't of Justice, Model Second Request, Specification 2, *https://www.justice.gov/atr/file/706636/dl.*

[244] Comment of SEIU, Doc. No. FTC–2023–0040–0699 at 2.

the current information requirements. Without the collection of information related to the antitrust risks identified in section II.B., the Agencies lack a basis to identify the need for additional voluntary submissions from the parties. The Agencies are already relying on supplemental submissions from a large number of filers, often resulting in the parties withdrawing and refiling their notification. See Table 3. Routinely requiring voluntary submissions from even more filers as an alternative to obtaining needed information in the HSR Filing would impose unnecessary burden and delay on filings that are not currently flagged for follow up.

Based on the Agencies' experience of conducting premerger review for over four decades, the Commission identified the additional data and documents that, if submitted with the HSR Filing, would reduce delays and burdens associated with information-gathering during the initial waiting period and satisfy the Agencies' mandate to conduct a premerger assessment of each reported transaction. To that end, the final rule targets information that is likely already available to filers, such as documents related to the transaction, as well as historical data and documents about their business, including ordinary course business plans and reports. The final rule marries descriptive responses with documents submitted with the HSR Filing, providing the Agencies with a holistic view of the operations of each party, including any existing business relationships that would be affected by the transaction. Overall, the final rule aligns the information requirements of the HSR Filing with the Agencies' task of identifying transactions that may violate the antitrust laws. For many of the new requirements, parties only have to respond if they identify an existing business relationship (*e.g.,* one party is the other party's competitor or supplier). Based on the Agencies' experience, parties in most cases do their own assessment of the antitrust risk associated with the planned transaction before submitting an HSR Filing and will therefore already have relevant information about any existing business relationship. In short, the Commission has calibrated the HSR Filing's reporting requirements so that the filing contains sufficient information for the Agencies to determine whether the transaction is one that is likely to raise antitrust concerns. The Commission believes that the final rule is well within the authority given to it by Congress to implement a notification scheme that minimizes costs and delays associated with mandatory premerger review and yet generates the benefits of preventing illegal mergers prior to consummation.

B. Major Questions Doctrine

Two commenters suggested that the proposed rule implicates the major questions doctrine.[245] The Commission disagrees. According to the Supreme Court, the major questions doctrine is implicated in ''extraordinary cases . . . in which the history and the breadth of the authority that the agency has asserted, and the economic and political significance of that assertion, provide a reason to hesitate before concluding that Congress meant to confer such authority.'' [246]

This rulemaking does not involve a major question as the Supreme Court has used that term. The final rule merely updates the disclosure requirements for acquisitions that already are required to submit to mandatory premerger notification. As reflected in Table 1, transactions reported under the HSR Act constitute only a fraction of the total number of mergers and acquisitions that occur each year in the United States. Congress has determined that most acquisitions should not be subject to premerger review, and this rule does not impact them.

Considerations of history and breadth also demonstrate that the final rule does not involve a major question. The breadth of the Commission's authority here ''fits neatly within the language of the statute. . . .'' and is well established.[247] The Commission has clear congressional authorization to issue rules and a long history of exercising its authority to promulgate HSR Rules under section 18a(d). The Commission has made both substantive and ministerial amendments to the rules dozens of times to improve the program's effectiveness and to adjust the reporting requirements to keep pace with market realities.[248] Requiring

[245] One commenter also argues that the Commission's rule runs afoul of the non-delegation doctrine. The Commission disagrees. First, the Commission's rule has no bearing on the authority Congress delegated to the Commission when it passed the HSR Act. Second, Congress' delegation of rulemaking authority to the Commission does not run afoul of the non-delegation doctrine. The non-delegation doctrine is based on the Supreme Court's interpretation of Article I, Section 1 of the Constitution, which vests all legislative powers in Congress. The Court has interpreted this clause to mean that Congress cannot delegate its legislative power to another branch of government without supplying an intelligible principle. *See J.W. Hampton, Jr., & Co.* v. *United States,* 276 U.S. 394, 409 (1928); *Gundy* v. *United States,* 139 S. Ct. 2116, 2129 (2019). Congress provided several intelligible principles in the HSR Act to guide the Commission's exercise of authority. For instance, it directed the Commission to require notification in such form and contain such documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable the Agencies to determine whether the acquisition may, if consummated, violate the antitrust laws. Congress also stated that the Commission may define terms and exempt classes of persons, acquisitions, transfers, or transactions not likely to violate the antitrust laws from the reporting requirements.

[246] *West Virginia* v. *EPA,* 597 U.S. 697, 721 (2022) (cleaned up); *see also Biden* v. *Nebraska,* 143 S. Ct. 2355, 2372 (2023).

[247] *Biden* v. *Missouri,* 595 U.S. 87, 93 (2022).

[248] *See* 43 FR 33450 (July 31, 1978) (publishing final rules for premerger notification); 44 FR 66781 (Nov. 21, 1979) (increasing minimum dollar value exemption contained in 16 CFR 802.20); 45 FR 14205 (Mar. 5, 1980) (replacing requirement that certain revenue data for the year 1972 be provided in the Notification and Report Form with a requirement that comparable data be provided for the year 1977); 48 FR 34427 (July 29, 1983) (amending premerger notification rules to clarify and improve the effectiveness of the rules and of the Form and reduce the burden of filing notification); 50 FR 46633 (Nov. 12, 1985) (revising Form at 16 CFR part 803 appendix); 51 FR 10368 (Mar. 26, 1986) (same); 52 FR 7066 (Mar. 6, 1987) (amending rules to reduce cost of complying with the rules and to improve the program's effectiveness); 52 FR 20058 (May 29, 1987) (amending definition of the term ''control'' as it applies to partnerships and other entities that do not have outstanding voting securities); 54 FR 21425 (May 18, 1989) (interim rule codifying practices that make public administrative grants of early termination of the waiting period through means other than publication in the **Federal Register**); 55 FR 31371 (Aug. 2, 1990) (revising revenue reporting); 60 FR 40704 (Aug. 9, 1995) (same); 61 FR 13666 (Mar. 28, 1996) (defining or creating exemptions to filing); 63 FR 34592 (June 25, 1998) (exempting divestitures pursuant to consent agreements); 66 FR 8680 (Feb. 1, 2001) (interim rule implementing changes to the HSR Act); 66 FR 23561 (May 9, 2001) (interim rule revising revenue reporting); 66 FR 35541 (July 6, 2001) (implementing May 9, 2001 interim rule with slight changes); 67 FR 11898 (Mar. 18, 2002) (amending certain exemptions); 67 FR 11904 (Mar. 18, 2002) (clarifying); 68 FR 2425 (Jan. 17, 2003) (same); 70 FR 4988 (Jan. 31, 2005) (amending the premerger notification rules to reflect adjustment and publication of reporting thresholds required by the 2000 amendments to section 7A of the Clayton Act, 15 U.S.C. 18a); 70 FR 11502 (Mar. 8, 2005) (amending rules to address treatment of corporations, partnerships, limited liability companies and other types of non-corporate entities and the application of certain exemptions); 70 FR 73369 (Dec. 12, 2005) (amending Form and Instructions to relieve some of the burden of complying with Items 4(a) and (b) and specifying that notifications in certain types of transactions expire after eighteen months if a second request remains outstanding); 70 FR 77312 (Dec. 30, 2005) (requiring that 2002 revenue data, identified by the 2002 NAICS, be provided in response to certain items on the Form); 71 FR 35995 (June 23, 2006) (allowing submission of notification and report forms electronically via the internet); 76 FR 42471 (July 19, 2011) (implementing changes to streamline the Form, adding Items 4(d), 6(c)(ii) and 7(d) to capture additional information that would significantly assist the Agencies in their initial review, addressing omissions from 2005 rulemaking involving unincorporated entities); 78 FR 41293 (July 10, 2013) (setting forth the procedure for voluntarily withdrawing an HSR filing, establishing when an HSR filing will be automatically withdrawn if a filing publicly announcing the termination of a transaction is made with the SEC, and setting forth the procedure for resubmitting a filing after a withdrawal without incurring an

Continued

information necessary and appropriate to determine whether a transaction, if consummated, may violate the antitrust laws is certainly a ''tool'' in the Commission's ''toolbox,'' given the Commission's history of taking action against anticompetitive mergers.[249] Since 1977, the Commission and the Antitrust Division of the Department of Justice have published an annual report outlining their efforts to protect competition by identifying and investigating mergers and acquisitions that may violate the antitrust laws.[250] These reports demonstrate that premerger notification and merger enforcement is an area that falls squarely within the Commission's ''wheelhouse.''[251]

Even if the final rule could be characterized as implicating a major question, the HSR Act provides ''clear congressional authorization'' for the rule.[252] Congress spoke clearly when it granted the Commission authority to determine the form and content of premerger notifications as necessary and appropriate to enable the Agencies to determine whether a proposed acquisition may, if consummated, violate the antitrust laws,[253] and the final rule falls squarely within that delegation of authority. The Commission is asking filers to provide information necessary to evaluate whether a transaction may violate the antitrust laws. This information is missing from the current filings, and it is appropriate that filers, who are in the best position to report basic information about their own businesses, provide that information. The rule updates are necessary and appropriate for the Commission to accomplish the goals Congress set out for it: effective premerger review as a tool to prevent illegal mergers prior to consummation and fully enforce the antitrust laws' proscription against undue concentration. And just recently, Congress increased the requirements of the premerger notification program by requiring the Commission to collect information about foreign subsidies in order to use this data as part of the Agencies' premerger review.[254] Congress has left it to the Commission to ''fill up the details'' based on the many clear principles articulated in the HSR Act[255] and in furtherance of sound and effective enforcement of the U.S. antitrust laws. Accordingly, even if the major questions doctrine applies, the Commission's authority to issue the final rule is clear.

C. Benefits and Costs of the Final Rule

The final rule is intended to address existing information deficiencies in the current HSR Rules so the Agencies can identify transactions that may violate the antitrust laws during the short period of mandatory premerger review provided in the HSR Act. The Commission has determined that the status quo is insufficient because it leaves information gaps that prevent the Agencies from efficient and effective premerger screening to identify which transactions require in-depth review. The final rule also addresses significant information asymmetries between the parties and the Agencies by shifting more of the costs of information acquisition to the parties, who are most familiar with their business operations and structure and who are pursuing the transaction under review. The Commission has considered alternatives to the final rule that would rely on other regulatory options, including the Short Form Alternative discussed in section III.E., and has determined that those alternatives offer different tradeoffs between benefits and costs. The Commission believes that the final rule has the best balance of benefits and costs within the statutory scheme of the HSR Act because it imposes less delay and is less costly than issuing more Second Requests, and it imposes less delay and provides more certainty regarding the completeness of the information than relying on more extensive voluntary submissions of information. Moreover, the final rule is superior to the short form alternative, an option suggested by commenters and discussed below in section III.E., because the Commission lacks a basis at this time to identify a set of transactions that should be eligible for short form treatment using the current information requirements. Most importantly, none of the other alternatives close the information gaps identified in section II.B. to permit the Agencies to effectively and appropriately identify a subset of filings for which Second Requests are warranted and to make critical resource decisions, preventing the Agencies from fulfilling their mandate to conduct a premerger antitrust assessment of reported transactions.

Given that the final rule is the best of the available alternatives, the Commission now addresses comments on whether it is a reasonable exercise of the Commission's statutory authority to adopt the final rule to enable the Agencies to determine whether an acquisition may, if consummated, violate the antitrust laws in fulfillment of their premerger review obligations under the HSR Act.

1. Benefits

The Commission has determined that, due to evolving commercial realities, the current information requirements for the HSR Form and Instructions are not delivering the benefits of mandatory premerger review as contemplated by Congress. As discussed in section II.B., changes in M&A activity, corporate structures, and investment strategies have exposed significant information gaps that undermine the Agencies' ability to efficiently and effectively identify transactions that may violate the antitrust laws during the initial 30-day waiting period based on information contained in the current HSR Form. As a result, the Agencies lack sufficient information about the parties and transaction to conduct an initial antitrust assessment for all types of potential harm that could occur due to the merger. Moreover, these changes have amplified information asymmetries between what the parties know about their business activities and how the Agencies collect the information necessary to decide whether to issue Second Requests. The Commission has determined that to realize the benefit of detecting illegal mergers prior to

additional filing fee); 78 FR 68705 (Nov. 15, 2013) (defining and applying the concepts of ''all commercially significant rights,'' ''limited manufacturing rights,'' and ''co-rights'' in determining whether the rights transferred with regard to a patent or a part of a patent in the pharmaceutical industry constitute a potentially reportable asset acquisition under the Act); 81 FR 60257 (Sept. 1, 2016) (allowing DVD submissions and clarifying the Instructions to the Form); 82 FR 3212 (July 12, 2017) (amending the Form); 83 FR 32768 (July 16, 2018) (amending rules for clarity, allowing use of email, and updating Instructions); 84 FR 30595 (June 27, 2019) (requiring use of 10-digit codes based upon the North American Product Classification System in place of the 10-digit codes based upon the North American Industry Classification System); 88 FR 5748 (Jan. 30, 2023) (amending the Rules to conform to the new filing fee tiers enacted by the Merger Filing Fee Modernization Act of 2022, 15 U.S.C. 18b); 89 FR 7609 (Feb. 5, 2024) (amending Parts 801 and 803 of the Rules to make ministerial changes required to reflect the annual adjustment of the filing fee thresholds and amounts required by 2022 Amendments).

[249] *West Virginia* v. *EPA,* 597 U.S. at 730.

[250] *See* Fed. Trade Comm'n Annual Reports to Congress Pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, *supra* note 56 (collecting reports).

[251] *Biden* v. *Nebraska,* 143 S. Ct. 2355, 2382 (2023) (Barrett, J., concurring).

[252] *West Virginia* v. *EPA,* 597 U.S. at 723–24.

[253] 15 U.S.C. 18a(d)(1).

[254] *See* Merger Filing Fee Modernization Act of 2022, 15 U.S.C. 18b (requiring the Commission to promulgate a rule requiring HSR filings to include information on subsidies received from certain foreign governments or entities that are identified as foreign entities of concern).

[255] *Gundy* v. *United States,* 139 S. Ct. 2116, 2136 (2019) (Gorsuch, J., dissenting) (quoting *Wayman* v. *Southard,* 23 U.S. 1, 31, 43 (1825)).

consummation through mandatory premerger review, the Agencies need more information relevant to the antitrust risk of reportable acquisitions in the HSR Filing.

The Commission has considered the extent to which the final rule furthers the Congressional goal of preventing illegal mergers prior to consummation through mandatory premerger review. The benefit of having sufficient information in the HSR Filing to screen for all types of antitrust risks derives from several sources:

(1) the non-consummation of harmful mergers that otherwise would not have been caught during premerger screening, whose harm continues unless and until the merger is unwound and competition in the affected market is restored, if it can be restored at all;

(2) the reallocation of staff hours from attempting to collect additional necessary information from the parties on a voluntary basis and reduced uncertainty that delay and insufficiency create for resource allocation decisions;

(3) the reallocation of staff hours from collecting additional necessary information from third parties regarding the parties' business operations;

(4) the reduction in burden required for third parties to respond to the Agencies' outreach to provide information known to the filing parties, but not currently required by the Form;

(5) improvements in premerger screening through

(i) more accurate identification of transactions requiring in-depth review;

(ii) the reduction in the number of HSR Filings withdrawn and refiled for the purpose of allowing Agency staff to collect and review more information from the parties;

(iii) reduction in delays associated with HSR Filings, including those that are withdrawn and refiled but do not receive Second Requests;

(iv) the narrowing of issues required to properly focus any in-depth review, including through the issuance of more targeted and less burdensome Second Requests;

(v) the reduction in the number of Second Request investigations that do not ultimately result in enforcement or voluntary restructuring; and

(6) a more efficient allocation of resources devoted to merger enforcement, including by avoiding expensive and time-consuming litigation to unwind consummated mergers that cause harm but were not identified under the current rules.

Consistent with Congressional intent, all of these benefits accrue to the American public in the form of reductions in the harmful effects of illegal consummated mergers, including price increases or reductions in output, reductions in quality and innovative activity, lower wages, and other effects, and more effective use of public resources devoted to antitrust enforcement. Other market participants that would otherwise be harmed by an illegal merger also benefit from improved detection that leads to enforcement that prevents or neutralizes the harm from that merger.

Many of these benefits cannot be quantified, or quantification cannot be done with a high degree of reliability. Where the Commission is unable to estimate a benefit quantitively, it provides a qualitative description of the benefit using the best available methods,[256] and in light of the purpose of mandatory premerger review. Based on its experience gathered over decades of premerger review of transactions reported under the HSR Act, the Commission considered the following benefits that would derive from the final rule as compared to the status quo.

a. Detecting Additional Harmful Mergers

Section 7 of the Clayton Act prohibits an acquisition where the effect of such acquisition may be to substantially lessen competition or to tend to create a monopoly. Acquisitions that have these effects deprive the public of the benefits of competition, which include lower prices, improved wages and working conditions, higher quality and resiliency in the supply chain, and more innovation and choice, among other benefits. section 7 of the Clayton Act was designed to arrest anticompetitive tendencies in their incipiency,[257] and mandatory premerger review gives the Agencies time and information to assess whether a reported transaction may violate the antitrust laws and seek to block it in Federal court prior to consummation. While it is difficult to calculate with precision the likely ill effects of an acquisition before it happens, Table 2 above contains estimates of potential harm from mergers in cases that were litigated by the Agencies in recent years, representing a range of outcomes from mergers that were not consummated as a result of premerger review and a subsequent Agency enforcement action. For any particular illegal merger, the potential for harm may be small or large and depends on many factors, including the size of the companies involved, the geographic scope of their operations, the number of customers they serve, and the value of their products. Many of the benefits of competition that may be lost due to a merger are more difficult to quantify, such as the loss of innovation competition or degradation in the quality of products or services offered. Thus, the magnitude of the anticompetitive effect of any particular merger that would have occurred but for the Agencies' intervention is imprecise at best and does not capture the full impact of the loss of dynamic and beneficial competition now and in the future.

In connection with their enforcement and reporting mandates, the Agencies also provide public estimates of the average consumer savings resulting from antitrust enforcement, including mergers that the Agencies challenge in an enforcement action (which include negotiated settlements requiring divestitures or transactions that are restructured prior to consummation). These estimates are contained in each agency's budget justification submitted to Congress.[258] Table 4 below summarizes the Agencies' estimates of harms to consumers and other market participants that would have occurred in the affected markets but for the agency's antitrust enforcement action. These savings reflect all civil antitrust enforcement activities, which include merger enforcement.

[256] *See generally* Anthony E. Boardman et al., Cost-Benefit Analysis: Concepts and Practice 44 (5th ed. 2018); Office of Management and Budget, Circular A–4 at 5 (Nov. 9, 2023), *https://www.whitehouse.gov/wp-content/uploads/2023/11/CircularA-4.pdf.*

[257] *See, e.g., Brown Shoe Co.* v. *United States,* 370 U.S. 294, 318 nn.32–33 (1962); *see also United States* v. *AT&T, Inc.,* 916 F.3d 1029, 1032 (D.C. Cir. 2019); *Saint Alphonsus Med. Ctr.-Nampa* v. *St. Luke's,* 778 F.3d 775, 783 (9th Cir 2015); *Polypore Int'l., Inc.* v. *FTC,* 686 F.3d 1208, 1213–14 (11th Cir. 2012); *FTC* v. *IQVIA Holdings Inc.,* No. 1:23 Civ. 06188 (S.D.N.Y. Dec. 29, 2023).

[258] The Agencies provide annual budget justifications to Congress which contain these estimates. *See* Fed. Trade Comm'n, ''Budget, Performance, and Financial Reporting,'' *https://www.ftc.gov/about-ftc/budget-strategy/budget-performance-financial-reporting* (collecting reports) and U.S. Dep't of Justice, ''Budget and Performance,'' *https://www.justice.gov/doj/budget-and-performance* (collecting reports).

Table 4: Annual Estimated Consumer Savings from Antitrust Enforcement (Millions of Dollars)

Fiscal Year	FTC	DOJ	Total
2014	1,419	3,378	4,797
2015	3,400	3,387	6,787
2016	3,610	2,271	5,881
2017	3,710	1,408	5,118
2018	3,760	928	4,688
2019	4,860	3,939	8,799
2020	2,681	712	3,279
2021	2,840	1,567	4,407
2022	3,190	529	3,719
2023	3,290	1,822	5,112
		Average Annual Savings	**5,259**

The Agencies' estimates of consumer savings in Table 4 are calculated based on the relevant product and geographic markets that were alleged (or would have been alleged) in either a litigation or settlement complaint. However, sometimes litigation or settlements do not address the full scope of the Agencies' competitive concerns. Due to various reasons (resource constraints, investigative efficiency, litigation strategy, etc.), a complaint may, for example, exclude certain markets of concern or theories of harm. When such a merger is blocked or abandoned in its entirety, any expected harm is avoided in all implicated markets and for all theories of harm. In those cases, limiting the calculations to just those markets and theories that would have appeared in a filed complaint further understates the full scope of consumer benefit.[259] These calculations also do not include less quantifiable harms that are avoided through antitrust enforcement, such as reduced innovation or quality.

The Commission believes that the enhanced ability of the Agencies to detect illegal mergers under the final rule will result in similar benefits to additional consumers and other market participants that would have been affected by an illegal merger but for the enhanced detection made possible by the final rule. In addition to these benefits, the final rule permits the Agencies to fulfill their statutory mandate to conduct premerger review for the purpose of preventing illegal mergers prior to consummation, which is a key competition policy directive that undergirds our nation's reliance on open and competitive markets to drive innovation and economic growth.

b. Avoidable Costs and Delays Arising From Insufficient Information on the HSR Form

To understand the inefficiencies created by inadequate information in the current HSR Filing, the Agencies conducted a review of the effort required to collect additional information beyond what is contained in the HSR Filing for investigations that did not result in an enforcement action.[260] The Agencies examined all HSR Filings in FY 2021, when they received 7,002 HSR Filings for an associated 3,520 transactions.[261] The Agencies identified those transactions for which either Agency opened an investigation that did not result in (1) an action brought in Federal court to block the transaction, (2) a negotiated settlement with divestitures, or (3) the transaction being abandoned or restructured as a result of one agency's antitrust investigation.[262] On the basis of this review, the Agencies determined that they conducted 100 investigations in FY 2021 for which they collected information from non-public sources but that did not result in an enforcement action, referred to here as ''no-action investigations.'' [263] Investigational costs associated with these no-action investigations are one product of inefficiencies created by insufficient information in the HSR Filing because they create unnecessary burdens for the parties, the Agencies, and third parties that could be avoided if the HSR Filing contained sufficient information to determine that the transaction is not one that requires challenge via litigation prior to consummation. In addition to the benefits of improved detection outlined above, these benefits represent opportunity costs for Agency staff (who would spend their time on other tasks if not collecting necessary information for transactions that do not warrant enforcement action prior to

[259] Most calculations seek to use quantification tools that align theories of harm being pursued, but not all theories are associated with readily available tools. Thus, for some merger wins, the Agencies' estimates of consumer savings will not reflect the full scope of theories due to the challenges of quantification. This is most relevant for coordinated effects; when a merger raises both unilateral and coordinated effects concerns, the calculations put forward will often reflect only the unilateral concerns (due to the greater availability of unilateral merger simulation tools) but not a robust estimation of additional harm arising from the threat of increased coordination.

[260] The Agencies selected FY 2021 for this effort because of the large number of reportable transactions that year, 3,520, which provided for a robust data set. The Agencies have no basis to believe that the mergers that occurred in that year were different in any material way from the mergers that occurred in other years and so consider them to be representative of HSR-reportable merger activity in general.

[261] Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Annual Report, Fiscal Year 2021 appendix A (FY 2021). As appendix A n.1 notes, there are typically two filings for each transaction, one from the acquiring person and one from the acquired person.

[262] These criteria are the ones used by the Agencies to report publicly on their merger enforcement activities.

[263] In FY 2021, the Agencies took action against 32 transactions. *See* Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Annual Report, Fiscal Year 2021 appendix A (FY 2021) at 2. The Agencies provide data on HSR reportable mergers on a fiscal year basis, but enforcement decisions may occur in a fiscal year after the transaction was first reported. As a result, the number of enforcement actions reported in the annual HSR reports are not necessarily related to the transactions that are reported for that fiscal year. For this exercise, the Agencies tracked the outcomes of transactions that were reported to the Agencies in FY 2021 but decisions about those transactions may have occurred in the following fiscal year.

consummation), as well as burdens and costs for the parties and third parties who respond to staff inquiries designed to collect the information necessary to conduct a premerger assessment of a reported transaction.

In the 100 no-action investigations, staff contacted at least one third party, with an average number of 18 third-party interviews per investigation. Each of these interviews required significant time from these third parties to identify the knowledgeable personnel in the related business operations, and prepare for questions in advance of talking to Agency staff. While some third parties rely on in-house counsel to help prepare for these interviews, some retain outside legal counsel who have experience with antitrust investigations. The Commission lacks a reliable methodology to calculate or estimate the costs borne by third parties to provide necessary information relevant to the Agencies' initial antitrust assessment. The Commission believes that it is appropriate to shift some of this information-gathering burden to the merging parties and away from other market participants—including customers who may suffer harm if the merger is consummated—who currently absorb this burden due to deficiencies in the existing HSR Form. The final rule realigns the burden of providing necessary information toward the parties themselves and away from other third-party companies, including smaller entities who are saddled with unexpected compliance and legal costs solely because they operate in the same or adjacent business lines as the merging parties. As a result, the Commission anticipates a reduction in third parties' costs from adopting the final rule.

Moreover, given the effort that is required to obtain this information from third parties, there is often a delay in collecting critical business facts until late in the initial waiting period, near the time when a decision must be made about issuing Second Requests. As discussed above, additional information from the parties and third parties that is submitted on a voluntary basis often arrives late in the review period. These delays contribute to additional avoidable costs through the issuance of Second Requests that might have been avoided or that were not tailored to areas of competitive concern due to insufficient information in the HSR Filing.[264]

One source of delay is the parties' voluntary decision to withdraw and refile their HSR Filing. In 53 of the 100 no-action investigations, the parties voluntarily withdrew and refiled their HSR Filings, which restarted the initial waiting period and gave Agency staff additional time to conduct the review. As discussed above, the Commission believes that most of the investigations in which the parties withdraw and refile their HSR Filings are the result of the parties' concern that the Agency may issue Second Requests when they are not warranted or that the Agency will issue a Second Request that is too broad. As Table 3 shows, when the parties withdrew and refiled, they avoided Second Requests nearly 70 percent of the time in the period FY 2018 through FY 2022. For the remaining 30 percent, the additional time allowed the parties to engage in additional advocacy to avoid or potentially narrow any Second Requests. For withdraw and refile transactions that avoid Second Requests altogether, there is unnecessary delay and uncertainty that could be avoided if the information required to make a no-action decision was provided sooner, including with the HSR Filing.

But for transactions that receive Second Requests, the delay can be substantial; seventeen of the 100 no-action investigations referenced above involved a Second Request. The decision to issue Second Requests, which requires approval from Agency leaders,[265] has significant consequences. As discussed in section III.A.3., the costs and delays associated with Second Requests are substantial, and for any no-action Second Request investigation, those burdens may be avoided if sufficient information were available at an earlier time in the investigation, including in the HSR Filing. For the Agencies, there are significant consequences as well. A Second Request investigation requires a team of lawyers, economists, and support staff. The broader the scope of the investigation (*e.g.,* covering many different products or many different geographic areas), the more staff must be assigned. As a result, avoiding unnecessary or unfocused Second Requests would provide a benefit to the parties, the Agencies, and any third parties contacted during the investigation.

Based on this experience, the Commission believes that the final rule will provide a substantial benefit to the Agencies, the parties, and third parties by reducing the number of Second Requests issued or narrowing the scope of any Second Request. A more efficient process that better identifies transactions that do not require additional investigation benefits parties as well.

Many commenters asserted that the Commission failed to take into account the increased burden on staff of reviewing additional information in HSR Filings. Several stated that given the purportedly huge volume of materials generated by the new requirements, especially the expanded document demands, Agency staff would be overwhelmed, thereby undermining effective screening even for deals they could evaluate with current information requirements. One commenter estimates that the proposed rule would result in over 177,000 additional staff hours (100 full-time attorneys) needed to review the information contained in the revised HSR Filing. On the other hand, other commenters asserted that the proposed changes would modernize the premerger process to better account for the evolving complexities of today's mergers and address potential shortcomings of past merger review that have become clearer in retrospect.

Based on its own experience and in light of the significant reductions contained in the final rule as compared to the proposed rule, the Commission believes that the additional information required by the final rule would result in an overall reduction in the number of staff hours spent collecting additional information from all sources, including the parties, as well as a reduction in associated burdens of reviewing and processing that information. For example, while Agency staff may need to review the transaction documents and additional information submitted with an HSR Filing, they would spend less time on more costly and time-consuming tasks such as conducting independent research or outreach to third parties, preparing voluntary information requests, reviewing additional information submitted by the parties, drafting Second Requests, reviewing voluminous submissions from the parties in response to those requests, and preparing internal reports and memoranda for review by managers. The Commission also acknowledges that it may incur minimal additional administrative and support system costs associated with the revised HSR Form,

[264] For any investigation that results in Second Requests, staff spends a significant amount of time during the initial 30-day waiting period trying to identify the areas of a potential antitrust violation. Both Agencies make public their Model Second Requests. *See supra* notes 242–43. Starting from these models, staff customize each request by identifying areas of existing competition and modifying the terms to fit the particular industry dynamics, products and services, or geographic reach.

[265] For the Commission, the Chair issues the Second Requests; for the Antitrust Division, that determination is made by the Assistant Attorney General. 15 U.S.C. 18a(c)(1)(A).

such as technology costs to process and host additional documents and filings. Overall, however, the work of Agency staff will be more efficient and effective as they will be able to more readily and accurately identify those transactions that pose a risk that they may violate the antitrust laws.

In sum, under the existing HSR reporting requirements, inadequate information in the HSR Filing leads to significant time and effort for Agency staff, third parties, and merging parties even for transactions that do not warrant a legal challenge. These costs (and associated delays) represent an opportunity for the Agencies to realize benefits from the enhanced information requirements contained in the final rule by (1) streamlining the Agencies' internal processes and resources devoted to merger review; (2) reducing costly delays for certain parties whose deals are eventually consummated; and (3) reducing the burden on third parties to collect information for premerger screening. By requiring more of the information to be collected upfront from the parties as part of the HSR Filing, the final rule will reduce some of the costs and effort currently associated with premerger review for transactions that the Agencies ultimately determine do not require enforcement action.

The Commission acknowledges that for some filings, Agency staff will still engage in some of these activities to verify the information in the HSR Filing and reach out to stakeholders who may be affected by the transaction. However, the Agencies will not need to spend as much time and resources to acquire the basic business information about the parties and the transaction that is needed to evaluate the antitrust risk, because more of that basic information will now be contained in the HSR Filing. The reduction in those information-acquisition costs will allow resources to be redeployed to other critical tasks of the Agencies, such as investigating other mergers (including consummated mergers) or other antitrust violations. In addition, any reduction in the costs and burdens imposed on third parties during no-action investigations is a direct benefit of the final rule.

2. Costs

The Commission anticipates that the incremental costs attributable to the final rule will primarily fall on individuals and companies who must make HSR Filings because they are a party to a reportable transaction. The final rule may have effects on other individuals or companies who are considering a reportable transaction but do not eventually pursue one, although these costs will be indirect and hard to quantify. This indirect effect does not include those potential deal partners who decide not to pursue an unlawful transaction because the final rule decreases the likelihood that it will go undetected. That is, any improvement in the Agencies' ability to detect potentially illegal mergers is a benefit of the final rule and cannot reasonably be viewed as imposing unnecessary or unreasonable costs on parties contemplating a reportable transaction. The final rule may also impose additional costs on the Agencies to ensure compliance and review additional information contained in the HSR Filing, although these costs will be more than offset by other reductions in costs, as discussed above.

For those individuals and companies that must submit an HSR filing, the burden of complying with the final rule will primarily consist of the additional cost of completing and submitting an HSR Filing to the Agencies. This includes internal costs (for employees tasked with collecting and reviewing relevant information as well as in-house compliance attorneys and other non-legal support staff) and external costs (including outside experts hired to assist in preparing the HSR Filing such as counsel expert in HSR rules or other tasks that filers chose to outsource to a third-party service provider). The majority of filers hire experienced attorneys who are familiar with current HSR Rules. The Commission expects that filers will continue to do so and that those professionals (and other legal and technical support staff) will require some additional time to prepare filings.[266] Current requirements also require knowledgeable personnel from the filing entity to collect and prepare data and documents for the Filing, and the Commission expects that these individuals will expend some additional time and effort to comply with the final rule.

The Commission anticipates that the final rule will result in incrementally higher direct costs for all filers.[267] As discussed above, some of these information acquisition costs are currently borne by third parties and the Agencies and will now be borne directly by the filers themselves. Incremental direct costs associated with the final rule will be borne primarily by those UPEs (and the entities they control) that must submit an HSR Filing, though some portion of the costs may be borne by officers or directors of entities within the acquiring person that will have to provide information to the acquiring person related to other entities for which they serve as officers and directors to complete the HSR Filing.[268] Direct costs vary depending on a number of factors that are different for each reportable transaction: the type of interest being acquired; the complexity of the transaction; the complexity of the UPE and its related entities and investors; the scope and number of existing business relationships between the merging parties; whether the filer is the acquiring or the acquired person; and the size and scope of each filer's business operations. Generally, costs are lower for simple transactions (such as for open market purchases of stock or conversion of stock options), for acquisitions of non-controlling stakes, and for acquisitions of control where the merging parties do not have an existing business relationship. Costs are highest for strategic acquisitions of a competitor or of a key supplier or customer where the Agencies must engage in a thorough review and are more likely to engage in an in-depth investigation including through the issuance of Second Requests. The key variable that is likely to determine the monetary impact of the final rule on any particular filer is the level of the antitrust risk associated with the reported transaction. The Commission believes that this outcome is consistent with the legislative intent in imposing mandatory premerger review as a means of preventing illegal mergers prior to consummation.

The Commission expects that the incremental increase in costs associated with the final rule will be most significant for the first HSR Filing prepared by a given filer because there will be costs associated with becoming familiar with the new reporting Form and Instructions and to gather the required information about the filer's operations. In addition, the Commission believes that some filers (or their counsel) will find it efficient to

[266] The Agencies receive a small number of filings from companies or individuals who do not hire attorneys to prepare their HSR Form.

[267] As compared to the current rules, the proposed rule contained modifications that eliminated certain information requirements that the Commission has determined no longer provide a benefit for premerger screening. These reductions in burden are incorporated in the final rule and are reflected in the analysis of incremental costs associated with the final rule.

[268] Sometimes, the parties will allocate the costs associated with premerger review between them by contract. These provisions are typical for strategic acquisitions where the parties expect some level of antitrust scrutiny and often require the acquiring party to compensate the acquired party for costs related to the HSR Filing as part of the purchase price. In conducting its cost assessment, the Commission has assumed that each filer is responsible for its own costs.

automate some portion of the reporting process, which will increase the burden of the first filing. For any subsequent HSR filing related to another acquisition, these repeat filers will incur lower costs because some of this prior work will not be necessary to the extent that they made investments to put processes in place to maintain or automate the collection of relevant business information. In other words, any estimated incremental costs are expected to decline over time.

Nothing in this rulemaking affects the filing fees for making an HSR Filing, which are mandated by Congress and adjusted by the Commission annually.[269] While the final rule does not alter these HSR-related costs, recent congressional changes in these fees use an approach that takes into account the size of the reportable transaction and the size of the parties involved. Last year, Congress revised the schedule of HSR filing fees, creating a new fee structure with five tiers, which increased fees for some transactions while reducing them for others.[270] Specifically, the new fee structure lowered fees for some mergers valued under $500 million and increased fees for transactions valued at $1 billion and more. Prior to this law, HSR filing fees had a three-tier structure, with thresholds adjusted every year. The purpose of creating a new five-tier fee structure was two-fold: to provide the Agencies with additional resources to review mergers and enforce the antitrust laws, and to better reflect that reviews of larger mergers generally consume more Agency resources.[271] Effective February 28, 2023, the Commission implemented the new fee levels, and on March 6, 2024, the Commission published the adjusted fees for 2024.[272]

Table 5: HSR Filing Fees

HSR Fees Effective February 23, 2022		HSR Fees Effective March 6, 2024	
Size of Transaction	Fee	Size of Transaction	Fee
$101 million to $202 million	$45,000	$119.5 million to $173.3 million	$30,000
		$173.3 million to $536.5 million	$105,000
$202 million to $1.0098 billion	$125,000	$536.5 million to $1.073 billion	$260,000
		$1.073 billion to $2.146 billion	$415,000
$1.0098 billion or greater	$280,000	$2.146 billion to $5.365 billion	$830,000
		$5.365 billion or greater	$2,335,000

The Commission has identified significant deficiencies in existing information requirements, and those gaps are hindering the Agencies' ability to obtain key facts needed for an initial assessment of whether the transaction may violate the antitrust laws and to determine whether to issue a Second Request. See section II.B. Congress authorized the Commission to issue rules to collect information that is necessary and appropriate for the Agencies to conduct premerger review within the statutory time frame. The final rule requires filers to gather information relevant for screening the transaction and results in relatively higher costs for those reported transactions that are more likely to pose competition issues, including transactions with complex party or deal structures, or transactions involving two entities with many overlapping business operations or existing business relationships in the supply chain, or transactions in which the parties have a history of acquisitions in the same business lines. This is consistent with the HSR Act's focus on the largest transactions, which are often the most complex, and the overall intent to reduce cost and delay for reportable transactions other than those that may violate the antitrust laws.

As discussed in more detail in section V.D., the Commission believes that most filers will not experience delays because the final rule requires collection of business information that should be readily available or collected as part of each filer's due diligence efforts related to the transaction. Filers who would prefer to submit a letter of intent or other preliminary agreement that is no longer compliant with the final rule may need to come to an agreement on more details of the planned-for transaction. But the Commission has determined that this represents less than 10 percent of current filers, meaning that most parties are already coming to agreement on the key terms that are required by the final rule even if their transaction documents are referred to as a letter of intent.

a. Calculation of Direct Costs

To estimate the potential increase in direct costs for filers attributable to the changes in the final rule, the Commission calculated the average compliance burden by conducting a survey of experienced HSR attorneys who now work for the Agencies. See section VIII. That survey revealed a range of estimated costs for each new information requirement in the final rule. These estimates include the amount of additional time required from a variety of knowledgeable individuals, including, for example, HSR specialists at law firms hired to prepare the Filing as well as individuals associated with the UPE who collect and verify the business information and responsive documents, as well as costs associated with any outside vendors hired to complete the HSR Filing, such as data vendors.

As explained in section VIII., the Commission estimates that the amendments contained in the final rule would increase the time required for a filer to prepare an HSR Filing, on average, 68 hours, resulting in

[269] Each year, the thresholds that determine reportability under the HSR Act are adjusted based on changes in the gross national product, 15 U.S.C. 18a note, while filing fees are adjusted in line with the Consumer Price Index, Public Law 117–328, 136 Stat. 5967–68, Div. GG, Title I, sec. 101.

[270] Public Law 117–328, 136 Stat. 5967, Div. GG, Title I.

[271] H.R. Rep. No. 117–493 pt. 1, at 3–5 (2022).

[272] *See* Fed. Trade Comm'n, ''New HSR thresholds and filing fees for 2024,'' Fed. Trade Comm'n Competition Matters blog (Feb. 5, 2024), *https://www.ftc.gov/enforcement/competition-matters/2024/02/new-hsr-thresholds-filing-fees-2024.*

additional costs of approximately $39,644 per filing on average.[273] The Commission believes that this level of direct costs is small in relation to other merger costs. Indeed, these total costs are small in relation to the value of the deals that must be reported under the Act. The current minimum size for a reportable transaction is $119.5 million; as outlined in section VIII, for FY 2023, the Commission estimates that the total direct costs associated with the final rule would have been only slightly more than the value of a single reportable transaction. Moreover, the Commission believes that these direct costs may be overstated and should decline over time as parties and their lawyers become more familiar with the requirements of the final rule. Finally, these direct costs do not take account of the substantial benefits to the Agencies, the parties, and third parties generated from a more efficient premerger review process that shifts some of the burden of information collection and reporting away from third parties to merging parties and allows the Agencies to obtain critical business facts earlier in the initial waiting period, which in turn helps mitigate avoidable costs associated with Second Requests that might have been avoided or that were not tailored to areas of competitive concern due to insufficient information in the HSR Filing.

In addition, the costs associated with completing an HSR Filing are often minimal compared to other fees associated with mergers and acquisitions. Based on publicly available data, the 20 largest M&A transactions during 2021 and 2022 ranged in size from $1.44 billion to over $70 billion, with average deal size of $10.6 billion.[274] Using the current Congressionally mandated HSR filing fees associated with deals of this size, the average HSR filing fee for these transactions would be $1,198,500, ranging from $415,000 to $2,335,000. For 18 of these deals, the fees paid by the target to financial advisors are available from public sources. These fees varied considerably, ranging from $800,000 to $96 million. In 14 out of these 18 cases, the fees paid by the targets to just their financial advisors were more than ten times the estimate by one commenter of the average total cost per filing for completing the HSR Form ($437,314) [275] and in five cases, fees to financial advisors were more than 100 times of that estimate. In any of these cases, financial adviser fees are several multiples of the estimated average new costs associated with the final rule of $79,288 per transaction ($39,644 + $39,644) based on the Commission's estimates. See section VIII. These advisor fees are instructive in demonstrating that HSR filing fees and HSR-related transaction costs for most transactions do not comprise a significant share of total transaction costs and therefore would have minimal impact on costs of dealmaking across the economy.[276]

Another survey of middle-market investment bankers, brokers and other advisors reports that merger advisory fees for deals valued up to $150 million come in the form of retainers, monthly or hourly charges, or success fees, which are paid if the deal closes.[277] For deals in the $100 to $150 million range, namely those most likely to be reportable under the HSR Act, success fees paid to financial advisors represented 1 to 2 percent of deal value, or $1,500,000 to $3,000,000 for a $150 million deal. As with higher valued transactions, the other merger-related costs for transactions on the lower end of HSR reportability dwarf the costs associated with the final rule.

One commenter commissioned a report (''the Kothari Report'') that projected that the direct cost of the proposed changes may be nearly seven times greater than the Commission estimated for the proposed rule, after accounting for both direct monetary costs and further costs to the economy.[278] The Kothari Report critiqued the Commission's methodology of calculating direct costs in the NPRM's PRA analysis in several respects. The Commission considered these comments and those of other commenters and, as discussed in section VIII, made adjustments to its cost estimate methodology for the final rule.

As a result, the Commission disagrees that the final rule will impose the level of costs presented in the Kothari Report for several reasons. First, the Commission made significant modifications to all aspects of the proposed rule in response to concerns raised in this report and in other comments. As a result, the estimates contained in the Kothari Report reflect costs for a very different rule, one that the Commission has determined not to adopt. The Kothari Report relied on a survey of experienced practitioners and so did the Commission. The survey of practitioners relied on in the Kothari Report estimated that the proposed rule would require an additional 242 hours of time from outside counsel and internal personnel. While the Commission's estimate was much lower, that comparison is no longer relevant because the Commission is not adopting the rule it proposed. Instead, the Commission is adopting a rule that is substantially more modest in scope, one that aligns compliance costs as much as practicable with the risk that reported transaction is one that requires a closer look.

Moreover, even if the Commission's estimate of the economic impact of the proposed rule was flawed, the Commission made improvements to the methodology it used to estimate the additional effort that will be required of filers to comply with the final rule. As discussed in section VIII, the Commission has accounted for the same costs in its own estimates, such as the time required from outside counsel, in-house counsel, and business personnel as well as costs associated with other services such as data vendors. The Commission believes that its estimates of the economic impact of the final rule are reliable and sufficient for it to determine that the final rule is a reasonable exercise of its rulemaking authority even if it imposes modest costs on overall dealmaking and in light of the benefits of the final rule for efficient and effective detection of illegal mergers via mandatory premerger review.

Much of the difference between the Commission's estimate and the one contained in the Kothari Report is attributable to the higher hourly rate applied to the required hours, which the Kothari Report suggests is more likely

[273] As further described in section VIII, the Commission estimates the range at 10 to 121 additional hours, or approximately an additional $5,830 to $70,500 per filing, with the highest costs borne by the acquiring person in a transaction with overlapping products or supply relationships in the target's industry.

[274] *See* ''Deal Analytics,'' Bloomberg L. (last viewed Apr. 3, 2024) (Prologis Inc.'s June 13, 2022 acquisition of Duke Realty Corp. (advisor fees over $135M); Thermo Fisher's Apr. 15, 2021 purchase of PPD Inc. (advisor fees over $70M); sale of Twitter Apr. 25, 2022 (advisor fees over $50M)). *See also* Comment of U.S. Chamber of Com., Doc. No. FTC–2023–0040–0684 at 20–21 & Fig. 3.

[275] Comment of U.S. Chamber of Com., Doc. No. FTC–2023–0040–0684.

[276] In conjunction with the passage of the Merger Modernization Act, the Congressional Budget Office estimated the budgetary impact of changing merger filing fees for transactions reported under the HSR Act. CBO estimated that the bill H.R. 3843 (which reflected fee levels that were eventually enacted) would increase HSR filing fees by $1.4 billion over the 2023–2027 period. Cong. Budget Office, Cost Estimate, H.R. 3843, Merger Filing Fee Modernization Act of 2021 3 (Sept. 27, 2022), *https://www.cbo.gov/publication/58527*. CBO estimated that the aggregate cost of the private-sector mandate would be about $325 million in each of the first five years. *Id.*

[277] Firmex, M&A Fee Guide 22/23 (N. Am. ed., 2022–23).

[278] Comment of U.S. Chamber of Com., Doc. No. FTC–2023–0040–0684 at 21. Professor Kothari's report is attached as an annex to this comment. *See id.* at 54–85 (hereinafter ''Kothari Report'').

$936 per hour, and a category of ''other'' costs that is nearly one-third of the total projected costs. The Commission believes that its estimates of incremental costs associated with the final rule are more consistent with the range of filings and filers based on its experience receiving thousands of filings every year and the merger investigations conducted by the Agencies. See section VIII. The Commission has no basis to inflate the overall costs associated with the final rule beyond what was estimated by those with experience filling out HSR Forms for a variety of filers and transactions. As with prior rulemakings, if the Commission determines that certain requirements in the final rule are not generating a benefit to the Agencies' preliminary antitrust assessment in light of the associated costs, the Commission can consider adjusting those requirements in future rulemakings.

The Commission acknowledges that the incremental costs associated with this rulemaking are more material than its prior rulemakings, which frequently reduced the burdens associated with submitting an HSR Form. In fact, the current Form is very similar to the original 1978 version in its scope and content. But the cumulative effect of the economy-wide changes described in section I. have seriously undermined the Agencies' ability to engage in extensive fact-gathering to compensate for deficiencies in the HSR Form. The effort required by the Agencies to conduct premerger review in today's economy threatens to render the process ineffective for its specific purpose—detecting and preventing illegal mergers before they cause harm that cannot be undone. The status quo does not allow the Agencies to quickly identify which transactions may violate the antitrust laws, causing them to spend too much time on ones that likely do not while at the same time lacking sufficient information to identify ones that do. With this rulemaking, the Commission is updating the Agencies' tools for detecting illegal mergers during premerger review to match the size and complexity of reportable transactions, restoring rigor and efficiency to the task of premerger review.

The Commission disagrees with other assertions made in the Kothari Report or finds them unpersuasive and not entitled to significant weight. The report focuses on the small number of transactions that receive a Second Request and ignores the benefits to filers from the Agencies reviewing and dispensing with non-problematic transactions with greater efficiency and assurance than before. The Kothari Report also ignores the benefits to the public from the Agencies' ability to more effectively identify and investigate potentially problematic transactions based on the availability of better initial information about potential competitive harms. The Commission discusses these and other benefits of the final rule in section III.C.1.

b. Other Costs Not Attributable to the Final Rule

Commenters raised concerns that the proposed rule would lead to other costs for those seeking to engage in M&A activity. The Kothari Report predicted that the proposed rule would so increase the costs of M&A that it would reduce the number of mergers, including ones that would be beneficial for consumers, innovation, investors, and the economy. Other commenters similarly argued that the Commission's objective is to stop all mergers by making them too costly to pursue. The Commission disavows any intention to stop all mergers by imposing unreasonable costs on those that are subject to premerger review and disagrees that the final rule will have this effect. Moreover, the commenters provided only speculation that the proposed rule would deter or delay some deals merely by increasing the costs associated with making an HSR Filing as compared to other factors that more directly affect M&A activity, such as interest rates. In the absence of actual data from commenters, the Commission must make a predictive judgment based on the evidence available to it.[279] As noted in section III.C.1., the evidence available to the Commission indicates that the Agencies' antitrust enforcement saves consumers and other market participants billions of dollars a year, and in light of known information deficiencies outlined in section II.B., there are strong indications that closing known information gaps will allow the Agencies to better identify additional transactions that may also violate the antitrust laws if consummated. The final rule does not impose new incremental costs that could plausibly deter beneficial or competitively benign acquisitions, particularly after the additional revisions narrowing the requirements in the final rule are taken into account.

Relatedly, other commenters raised arguments about additional macro impacts of expanding information requirements for HSR Filings, such as concerns about the impact on institutional investors, including retail investors, by indirectly impacting the performance of investment portfolios. Some said they were concerned generally about the chilling effect on M&A. Others raised concerns that changing the status quo would create market uncertainty, citing increased market, labor, and operational volatility. Several of these commenters raised specific concerns that acquisitions in their particular sector were typically not challenged or even reviewed closely by the Agencies. Concerns about disproportionate impact for certain sectors or types of filers are addressed in section III.D. below.

The Kothari Report states that delays caused by the additional time that will be required to prepare a HSR filing could kill deals and lead parties to abandon transactions. It also stated that delay breeds uncertainty in product, labor, and capital markets, enabling competitors to raid customers and staff, and that delay would lead to lost economic efficiencies that are realized through mergers. For these propositions, the Kothari Report cites an advisory committee report by the U.S. Department of Justice issued in 2000. While that committee report explains how delays can influence pending mergers, the cited portion is discussing international jurisdictions that do not impose strict timelines or which have prolonged agency investigations into mergers[280]—this rule does not contemplate either. In addition, as discussed above, the final rule will allow the Agencies to reduce the number of Second Requests or narrow their scope, significantly reducing delays in many instances.

Moreover, the Commission disagrees that any delays and incremental costs associated with an HSR Filing could have a significant impact on overall M&A activity. Deal volumes fluctuate, often substantially, from year to year, and these fluctuations are reflected in the number of HSR Filings received by the Agencies. But these fluctuations are attributable to many economic factors,

[279] *See, e.g., Huawei Techs. U.S., Inc.* v. *FCC,* 2 F.4th 421, 454 (5th Cir. 2021) (''Huawei does not object to specific cost calculations such as these but to the agency's failure to consider additional, difficult-to-measure costs about which the FCC lacked hard data, such as 'the broader economic costs of depriving Americans of access to Huawei's market-leading technology.' The agency's decision to base its analysis instead on the replacement cost estimates before it does not render its analysis unreasonable.''); *FCC* v. *Prometheus Radio Project,* 592 U.S. 414, 427 (2021) (''The APA imposes no general obligation on agencies to conduct or commission their own empirical or statistical studies. . . . In the absence of additional data from commenters, the FCC made a reasonable predictive judgment based on the evidence it had.'').

[280] Int'l Competition Pol'y Advisory Comm., Final Report to the Attorney General and Assistant Attorney General for Antitrust Ch. 3 (2000), *https://www.justice.gov/atr/final-report.*

including the cost of capital. Research relied on by one commenter provides evidence that a major driver of uncertainty in M&A activity generally is stock market volatility.[281] This is consistent with the Agencies' experience. Figure 1 reflects the volatility of HSR-reportable transactions, and the Commission believes that much of this volatility is attributable to changes in interest rates and other macro factors that drive M&A activity generally, unrelated to premerger review or the specific information collected in an HSR Filing.

The Kothari Report also asserted that M&A activity is beneficial to the economy, and that any potential delay or chilling of acquisitions due to the final rule would lead to significant loss of value creation. But the evidence cited to support these concerns is inapposite. For instance, a paper cited for support that acquired plants become more productive points to credit spreads and aggregate market valuation as being major drivers for merger activity.[282] Similarly, another source relied on a stylized, theoretical model of mergers that does not provide any empirical evidence about the benefits of M&A, applying the theoretical model to a situation where there is no M&A at all to calculate the benefits of M&A.[283] There is no reason to believe that the final rule will significantly chill M&A activity. Furthermore, in the model, the author finds that preventing a small fraction of deals over $1 billion has little effect on aggregate efficiency, and that due to the inefficiencies in the M&A market, a policy of blocking a fixed number of deals regardless of antitrust concerns can improve aggregate outcomes. Thus, the paper actually demonstrates that preventing some deals can improve economic performance. The paper does not provide a basis for the Commission to conclude that changes of the magnitude contained in the final rule threaten economic efficiencies gained through M&A activity generally.

Another paper cited in the Kothari Report, which purports to support the proposition that any discouragement of pending mergers results in significant value loss, is not on point.[284] First, this final rule is not intended to and should not discourage mergers—the final rule merely requires companies who are already submitting HSR Filings to submit more information with their filings. In the paper's survey of past empirical assessments of mergers, it highlights evidence that mergers that create market power yield no better performance, and sometimes worse. That assessment is wholly consistent with the Commission's efforts in this final rule: to collect information that better allows Agency staff to identify potentially anticompetitive mergers. The Kothari Report mischaracterizes this study as supporting the value of all mergers. In fact, the author concludes that mergers are not universally accretive in value, stating: ''[T]he buyer in M&A transactions must prepare to be disappointed. It is also true that most transactions are associated with results that are hardly consistent with optimistic expectations. Synergies, efficiencies, and value-creating growth seem hard to obtain. It is in this sense that deal doers' reach exceeds their grasp.'' [285] Last, it should be noted the study is dated 2002, and the latest mergers it analyzes are from 1999, whereas the Commission crafted this final rule to address changes it has observed in more recent transactions that reflect current dealmaking dynamics discussed in section II.B.

Indeed, one goal of this rulemaking is to ensure that any benefits from M&A are realized as quickly as possible and that the costs of anticompetitive mergers do not materialize. The Commission acknowledges that there are benefits generated from M&A activity generally, and that those benefits flow broadly throughout the economy. But the Agencies are not tasked with determining whether an acquisition is ''beneficial'' in any sense. The challenge given to the Agencies by Congress is to distinguish which acquisitions, among the many thousands they review each year, may violate U.S. antitrust law. For this task, they need certain facts that would reveal potential antitrust risks. For instance, event studies may indicate that M&A can result in significant value creation, but these outcomes may be the result of genuine synergies or they can also occur due to the anticompetitive creation of market power.[286] This highlights the very purpose of mandatory premerger review: to subject a certain number of larger acquisitions to a quick and thorough antitrust review prior to consummation solely for the purpose of identifying the few that need in-depth investigations. Throughout the history of the HSR Act, the Agencies have investigated just a small fraction of deals through the issuance of Second Requests. The Commission believes that the final rule will render premerger review more effective and efficient in identifying those mergers that may lead to anticompetitive harm, and that the small incremental costs and delays associated with the final rule are necessary and appropriate and consistent with the scheme established by Congress.

Moreover, to the extent these concerns arise from a belief that disclosure of additional relevant information to the Agencies will mean that a reported transaction is more likely to be challenged or investigated, that outcome fulfills the purpose of premerger review. As discussed above, to the extent that the HSR Act itself requires reporting for a large number of transactions that may never violate the antitrust laws, that has always been a feature of HSR premerger notification. Congress recently reaffirmed that particular tradeoff by imposing new disclosure requirements for foreign subsidies on all filers while not adjusting existing filing obligations.

In light of these considerations, the Commission does not believe that the final rule will have an undue effect on dealmaking, including by discouraging transactions that have little or no antitrust risk. The expected costs of this final rule are very small relative to the overall value of reportable transactions, the level of M&A activity in the United States, and the size of the overall economy. The benefits of the final rule are expected to be proportional to reductions in the errors in detection of illegal mergers that this final rule addresses.

Each year, the Agencies review reported transactions with an aggregate dollar value of nearly $2 trillion, on average.[287] Yet this is just a fraction of the level of M&A activity in the United States: as reflected in Table 1, over 80 percent of mergers completed in the United States are not reported to the Agencies. The costs associated with the

[281] Comment of U.S. Chamber of Com., Doc. No. FTC–2023–0040–0684 (Kothari Report ¶ 57 n.46, citing Vineet Bhagwat et al., ''The Real Effects of Uncertainty on Merger Activity,'' 29 Rev. Fin. Studies 3000–34 (2016)).

[282] Comment of U.S. Chamber of Com., Doc. No. FTC–2023–0040–0684 (Kothari Report at 24 n.47, citing Vojislav Maksimovic et al., ''Private and Public Merger Waves,'' 68 J. Fin. 2177–2217 (2013).

[283] *Id.* (Kothari Report at 25 n.49, citing Joel M. David, ''The Aggregate Implications of Mergers and Acquisition,'' 88 Rev. Econ. Studies 1796–18 (2021)).

[284] *Id.* (Kothari Report at 26 n.52, citing Robert F. Bruner, ''Does M&A Pay? A Survey of Evidence for the Decision-Maker,'' J. Applied Fin. 48–68 (Spring/Summer 2002)).

[285] *See* Bruner, *supra* note 284, at 65.

[286] W. Kip Viscusi et al., Economics of Regulation and Antitrust 217–18 (5th ed. 2018) (horizonal mergers raise the possibility of creating market power and the possibility of achieving socially beneficial cost savings).

[287] *See* HSR Annual Reports for FY 2014 through 2023, available at Fed. Trade Comm'n, Annual Reports to Congress Pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, *supra* note 56.

final rule are very small in comparison to the U.S. economy, which was valued at nearly $28 trillion in 4Q 2023.[288] Any improvement in the Agencies' ability to detect illegal mergers prior to consummation will lead to benefits that will help reduce antitrust harm from illegal mergers and improve the efficiency and effectiveness of premerger review. The greater the improvement in detection and in avoiding the costs and burdens of acquiring information from sources other than the parties, the greater the benefits. The Commission expects that the costs from the final rule will be so small in relation to the total value of reported transactions, to the level of U.S. M&A activity in general, or to the U.S. economy that there will be negligible indirect effects, if any, on dealmaking, innovation, investments, and growth.

Nonetheless, the Commission has narrowed its proposals so that the final rule limits the incremental costs for filers as much as practicable while still generating additional information that is critical for the initial antitrust assessment in light of changes in market realities and information gaps outlined in section II.B. The need to modernize premerger review to adjust to market changes is compelling, and the Commission is acting within its statutory mandate to determine what information is required to conduct premerger screening that is appropriate in the modern economy.

The Kothari Report also commented that there is additional uncertainty for potential filers arising from the Agencies turning away from the decades of practice under the current rules. Any change brings with it some level of uncertainty and will require adjustment by all those involved. As with other adjustments to the HSR rules in the past, the Commission's PNO staff will be providing guidance and assistance to filers who have questions about the final rule. But the Commission believes that the uncertainty related to the new rule is a short-term issue that will be resolved after the final rule goes into effect. The commenters are overstating the effect of uncertainty on the economy. Not only are these concerns temporary; they ignore the greater benefits of a more efficient premerger review process that may result in a *faster* resolution of some deals, including by reducing the number of Second Requests and narrowing others. The goal of this rulemaking is to provide sufficient information so that the Agencies can quickly and confidently distinguish those transactions that present little or no risk that they may violate the antitrust laws, and identify those transactions that require a more searching investigation. As discussed above, the Commission believes that the final rule will reduce the delays that are attributable to information deficiencies.

Moreover, the Commission disagrees that the final rule will lead to greater uncertainty about the outcome of the Agencies' premerger review. This rulemaking does not (and cannot) affect the ultimate determination of whether a transaction violates the antitrust laws. A Federal court will make that determination for any transaction that the Agencies or others seek to block prior to consummation under prevailing legal standards.[289] Any ''uncertainty'' about the eventual outcome of premerger review is directly related to whether the merger violates the antitrust laws and whether the Agencies are able to detect that risk when conducting a premerger assessment. Premerger review is simply the tool Congress gave to the Agencies to detect those mergers that may violate the law so that the Agencies can take steps to prevent their consummation. On the margin, the Commission believes that the final rule will reduce uncertainty about the outcome by providing more transparency to the parties (and the public) about the information the Agencies rely on to make their assessment that a transaction may violate the antitrust laws. To the extent that the commenters are concerned that disclosing more information reveals a risk to competition that the current rules do not, that additional ''uncertainty'' is a benefit of the final rule as a result of improved detection and possibly greater deterrence achieved through more effective premerger review.

It is not feasible to design premerger review requirements to only apply to those mergers that will be found to violate the antitrust laws, because there are too many variables that weigh in that outcome. Establishing that a merger may substantially lessen competition or tend to create a monopoly is highly fact-dependent exercise. The final rule represents a reasonable reflection of the Congressional policy to screen those mergers in advance to discover the few that may cause lasting harm throughout the economy and that should be blocked prior to consummation. The Commission has determined that the current HSR reporting requirements are not sufficient for the critical task of premerger review in light of changes in the economy and in M&A activity.[290]

Some commenters argued that the proposed rule's expansion of reporting requirements would negatively impact investments in biotech innovation, or deny startups or other innovative companies an exit strategy. Others asserted that the acquisition of a small company by a larger one can create efficiencies by bringing together two entities that specialize in activities in which they have a comparative advantage or provide assistance necessary to bring discoveries to market. One study cited by a commenter estimates that it costs approximately $2.6 billion to develop and bring a new drug to market.[291] Another commenter noted that startups operate on tight budgets and that exits, most often facilitated by an acquisition, provide liquidity, enable capital flows through the startup ecosystem, and give startups incentives to innovate. The Commission recognizes these possible benefits and does not seek to deny them to small companies or others, nor does it believe that the HSR reporting requirements in this final rule will have any of these negative effects on the opportunities for small or startup companies to exit via lawful acquisitions. As noted in section II.B.4., many acquisitions of startups and small innovator firms are not reportable. For those acquisitions that Congress has determined are large enough to be reportable, the long-term benefits, both monetary and non-monetary, well outweigh the incremental costs associated with the final rule. Not surprisingly, acquisitions of this type (and others) declined in 2023 due to higher interest rates. Nonetheless, the Commission does not believe that small companies are so short-sighted that they will forgo benefits of a negotiated exit acquisition where the expected benefits dwarf HSR filing costs.

Moreover, the Commission cannot ignore that certain acquisitions may also reduce innovation and harm

[288] U.S. Bureau Econ. Analysis, Gross Domestic Product (updated Aug. 29, 2024) (Q2 2024 $28,652,337,000,000) (retrieved from FRED, Fed. Reserve Bank of St. Louis), *https://fred.stlouisfed.org/series/GDP.*

[289] In the Agencies' experience, when faced with an imminent or pending legal challenge to the legality of the transaction, many parties chose to abandon their merger plans rather than incur the additional legal costs associated with defending an injunction action in Federal court. This decision is solely in the discretion of the parties and reflects their assessment of litigation risks.

[290] As discussed in section III.E., other countries have adopted other procedures to review proposed and consummated mergers.

[291] Comment of Biotech. Innovation Org., Doc. No. FTC–2023–0040–0706 at 7 n.16 (citing Joanna Shepherd, ''Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem,'' 21 J. Health Care L. & Pol'y 1, 16 (2018)).

competition in violation of the antitrust laws, particularly when dominant firms use acquisitions to acquire nascent threats. One commenter acknowledged that an environment where a few large companies dominate is undesirable, and another noted that smaller companies have flexibility, the ability to pivot in response to new evidence, and a willingness to accept risk that is rare in larger firms. While acquisitions of small firms by large firms can be beneficial, when they substantially lessen competition or tend to create a monopoly, they can be detrimental to innovation and growth. For these reasons, and as discussed in section II.A., Congress tasked the Agencies with carrying out premerger review. The Agencies would be remiss if they did not fulfill that task by ensuring that the HSR reporting requirements are attuned to the risk that large firms are buying up smaller firms in order to eliminate nascent and potential threats. For any negotiated exit acquisition that must be reported under the HSR Act, the incremental costs imposed by the final rule are justified by the benefit to the Agencies and the public of assessing the risk that the acquisition may violate the antitrust laws.

To be clear, not all exit partners are denied to small firms due to antitrust scrutiny; it is only those whose acquisition would violate the antitrust laws. For instance, when a large incumbent seeks to acquire a smaller company that constitutes a nascent threat or an actual or potential competitor, the Agencies may challenge that merger. But in the Agencies' experience, a startup firm deemed valuable by a dominant incumbent also enjoys other exit options. For example, the Commission recently challenged the proposed acquisition of a license to an innovative, early-phase candidate drug treatment for Pompe disease by the company with the only FDA-approved treatments for the disease.[292] The parties abandoned the transaction after the Commission authorized a lawsuit to block the deal; within five months the innovator company had found an alternative partner, negotiated a new agreement, completed antitrust review, and closed the deal. Moreover, the terms of the new deal appear largely equivalent to what the innovator had negotiated with the incumbent.[293] In other words, if the acquisition of a startup by a dominant incumbent carries a risk that the Agencies may determine that the transaction is one that may violate the antitrust laws, it is likely that there are other buyers that do not create those risks and any of those buyers present a viable exit strategy via acquisition.

The Commission disagrees with the suggestion that incremental changes in the information requirements for HSR Filings could have a chilling effect in sectors that are especially acquisitive. One commenter stated that in 2022 alone, 16,464 U.S.-based VC-backed companies received $240.9 billion in funding, yet when these transactions were reportable they were rarely investigated. Unless the new information requirements in the final rule reveal that a reported transaction may violate the antitrust laws, the Commission expects M&A activity in these sectors to continue to be subject to other economic forces that will determine their viability or profitability.[294] Similarly, claims that an industry or sector is ''unconcentrated'' are unavailing. The Agencies must conduct a fact-specific, case-by-case assessment of market dynamics to determine whether any particular relevant market affected by the merger is concentrated, and that assessment is typically left to an in-depth investigation after the issuance of Second Requests. Although the Agencies routinely decline to investigate transactions where there are many remaining competitors post-merger, this is a decision made after assessing relevant facts about the transaction including those contained in the HSR Filing, and is not based on an advance determination that certain sectors are ''unconcentrated.''

The Commission has taken into account the additional costs imposed on small and innovative companies, as well as those that operate in sectors where the Agencies have historically not engaged in merger enforcement. As discussed in section II.B.5., the emergence of strategic buyers engaged in serial acquisition strategies raises the possibility that some sectors that were not concentrated in the past are becoming more concentrated, especially through transactions that are not subject to premerger review. Thus, the Agencies should not rely on assumptions about historical levels of concentration when conducting premerger review of a reportable transaction in those sectors. By requiring information about prior acquisitions of both the buyer and target, the Agencies are given better information about the current competitive landscape so that they can make more accurate assessments about the potential effect of the filed-for transaction.

To the extent possible, the Commission has imposed as few additional requirements as is practicable in light of the benefits derived from more effective premerger review. If, based on experience of collecting new information, the Commission finds that some requirements generate less-than-expected benefits to the Agencies, it can eliminate those requirements in future rulemakings. In many prior rulemakings, the Commission adjusted its rules to reduce the burden on filers after experience revealed that the information did not provide the hoped-for benefit to the Agencies sufficient to justify the costs to filers of providing the information.[295]

3. Adjustments Made to the Final Rule To Align Costs With Antitrust Risk

Since establishing a premerger notification program pursuant to the HSR Act, the Agencies have relied on information contained in HSR Filings to conduct their initial premerger review. However, in light of the information gaps identified in section II.B., the Commission has determined that the current requirements are not sufficient for that task and determined to reset the baseline requirements for all filers to fill these information gaps. As a result, the final rule eliminates some requirements that are contained in the current Form, and requires each filers to submit some

[292] *In re Sanofi Corp.,* No. 9422 (F.T.C. Dec. 11, 2023) (complaint alleging Sanofi's proposed acquisition of an exclusive license to Maze Therapeutics' pipeline Pompe therapy would have eliminated nascent threat to Sanofi's monopoly) (transaction abandoned).

[293] *Compare* Press Release, Maze Therapeutics, ''Maze Therapeutics Announces Exclusive Worldwide License Agreement with Sanofi for MZE001, an Oral Substrate Reduction Therapy for the Treatment of Pompe Disease'' 1–2 (May 1, 2023), *https://mazetx.com/wp-content/uploads/2023/04/Maze-Therapeutics-Press-release-MZE001-license-Final-.pdf* (proposed license included $150 million upfront cash and equity investment, the possibility of another $600 million in development, regulatory, and commercial milestone payments, plus further royalties), *with* Press Release, Shionogi & Co., ''Shionogi & Co., Ltd. and Maze Therapeutics, Inc. Announce Exclusive Worldwide License Agreement for MZE001, a Novel Therapeutic Candidate for the Treatment of Pompe Disease'' 1 (May 10, 2024), *https://mazetx.com/wp-content/uploads/2024/05/CONFIDENTIAL_Project-Magenta-Press-Release_Final-FINAL.pdf* ($150 million upfront fee, plus development, regulatory, and commercial milestones, plus further royalties).

[294] *See, e.g.,* Press Release, Nat'l Venture Cap. Ass'n, ''NVCA 2024 Yearbook: Charting the New Path Forward for Venture Capital'' (Apr. 9, 2024) (noting that the U.S. venture capital investment ecosystem is still the envy of the world.), *https://nvca.org/press_releases/nvca-2024-yearbook-charting-the-new-path-forward-for-venture-capital/.*

[295] *See, e.g.,* 76 FR 42741 (July 19, 2011) (elimination of requirement to provide Base Year in Item 5); 81 FR 60257 (Sept. 1, 2016) (elimination of requirement to explain valuation of the transaction).

information that is not currently required or certify that the request does not apply to its operations.

After careful consideration of the comments that identified aspects of the proposed rule that would be a source of significant costs for filers if adopted, the Commission made significant modifications to the final rule as compared to the proposed rule. In several instances, the Commission determined that the costs of a particular proposed requirement outweighed the benefits and chose not to adopt those provisions as part of the final rule. For other proposals and where possible, the Commission has tailored each information request contained in the final rule to reduce the cost of compliance for filers yet generate the information that is necessary and appropriate for the Agencies to conduct a premerger assessment of the transaction. See sections IV to VI. Overall, the final rule balances the cost of collecting additional information in the HSR Filing in light of the benefits of obtaining additional information that is relevant to the Agencies' premerger antitrust risk assessment, and aligns those costs in proportion to the antitrust risk associated with the transaction under review. As a result, the final rule is a reasonable exercise of the Commission's authority to require information that is necessary and appropriate to determine whether an acquisition may, if consummated, violate the antitrust laws. The additional information required by the final rule will close information gaps described in section II.B. and address information asymmetries by shifting the burden of collecting necessary information about the transaction and the business of the filers from the Agencies and third parties to filers.

To make these modifications to align costs and benefits, the Commission relied on the following tools and approaches it has used when exercising its HSR rulemaking authority over the last forty-six years and consistent with the statutory scheme. In addition to the features of the HSR Act described in section III.A. above that treat different filers differently (*e.g.,* requiring notification from acquirers but not the acquired person for cash tender offers in order to start the waiting period and exempting certain types of acquisitions entirely), the Commission has administered HSR reporting requirements over the years in a flexible way to minimize the burden on each filer and each type of transaction as much as practicable. Thus, contrary to the assertions of several commenters, the reporting requirements of the HSR Act have never been a ''one-size-fits-all'' reporting scheme because different filers face different burdens for complying with applicable reporting requirements. Rather, the HSR Form and Instructions have relied and will continue to rely on an IF/THEN format that excuses certain filers from information requirements based on answers provided to other requirements. For instance, several current information requirements need only be answered if the filer reports that it generates revenues in the same NAICS [296] code as the other party to the transaction. The final rule expands the existing IF/THEN format as the primary means of mitigating the costs of reporting certain new information in a way that, as much as practicable, aligns the information with the antitrust risk associated with the transaction, resulting in higher costs for those transactions most likely to require close scrutiny by the Agencies to determine if they may violate the antitrust laws.

As summarized above in section I. and explained in further detail in section VI., the Commission has also eliminated several information and document requirements and reduced the scope of many others as compared to the proposed rule to align the cost of reporting to the antitrust risk associated with each transaction. First, the Commission has eliminated in toto the proposals that would have imposed significant costs as compared to the benefits, such as those requiring filers to provide employee information, geolocation information, the identity of other interest holders or board observers, or draft versions of submitted documents. Second, the Commission created a new category of filings, select 801.30 transactions, for which the costs of complying with the final rule will be minimal as compared to current requirements. Next, the final rule imposes relatively fewer new reporting requirements on acquired persons, reducing their costs as compared to the acquiring person, which is the party pursuing the transaction that requires HSR reporting, and will operate the acquired interests post-consummation. The Commission has also reduced the burden on filers by limiting the lookback periods for several categories of information and created de minimis exclusions where appropriate. Finally, the Commission will continue to allow filers to rely on good faith estimates or answer in the negative to confirm that certain information does not exist. For instance, for a transaction in which there are no existing overlaps or supply relationships responsive to the final rule, filers can indicate that there are no such overlaps or relationships, although there may be costs for the filer associated with verifying that response.

The Commission also relies on definitions and clarifications to reduce or eliminate filing obligations or to reduce uncertainty regarding compliance. For instance, the Act applies to a wide variety of acquisitions; as a result, the Commission has provided definitions and guidance over the years to maximize compliance. Sometimes this results in certain transactions not being reported or reducing reporting requirements for certain types of transactions. The final rule contains several new definitions that are intended to reduce uncertainty and costs, and improve compliance.

Select 801.30 Transactions

As part of the Commission's effort to reduce the cost of the final rule, the Commission has created a new category of transactions, defined as ''select 801.30 transactions,'' that will have minimal reporting requirements, including a few of the new information requirements required by the final rule. Where the Commission has not excused requirements, it believes that the burden of compliance will be low because parties to select 801.30 transactions generally have less complex internal structures, do not hold significant stakes in similar companies, and have not generated the types of documentation the Form and Instructions generally require. As a result, the Commission expects that responses to the remaining requirements for these types of transactions will generally be short, and may just confirm that the parties do not have responsive material. However, for those transactions in which select 801.30 filers incur additional costs from complying with the final rule, there will be a benefit to the Agencies in learning about potential competitive issues that are not revealed by the current information requirements, especially the new information related to other entities between the UPE and acquiring or acquired person.

For select 801.30 transactions, filers are excused from the following information requirements:

i. Transaction Rationale
ii. Transaction Diagram
iii. Plans and Reports
iv. Transaction Agreements
v. Overlap Description

[296] The North American Industry Classification System is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the U.S. business economy. *See* U.S. Census Bureau, North American Industry Classification System (rev. Sept. 10, 2024), *https://www.census.gov/naics/.*

vi. Supply Relationships Description
vii. Defense and Intelligence Contracts

Additionally, even where select 801.30 transactions are not expressly excused from responding, there are many items for which the Commission believes the response will be ''none'' because of the nature of the transaction or of the parties.

Less Information From the Acquired Person

The final rule also seeks to reduce costs by tailoring information requests to each party's role in the transaction. Because the buyer (the acquiring person) will have a larger stake in or control of the target (the acquired entity or assets), and often will be operating the assets or business acquired post-consummation, more information is needed from acquiring persons than acquired persons. The acquiring person is more likely to have certain types of information relevant to the Agencies' enforcement analysis, such as the transaction's structure, information about other minority holders who might have managerial control or influence, and overlapping officers and directors who could affect competitive decision-making after consummation. This approach reflects the more limited time the seller has had to consider the implications of the planned transaction, and to a lesser extent, the seller's less-honed strategic assessments of competitive opportunities. In addition, for certain information, such as a transaction diagram, the Agencies only need one response, and it is appropriate to place the cost of providing this information on the acquiring person and not require the acquired person to provide duplicative information.

Consistent with these considerations, the final rule excuses the acquired person from certain additional information requirements that apply to acquiring persons. In the final rule, acquired persons are excused from the following requirements:

i. Minority Shareholders, other than those that will roll over to the acquiring person
ii. Ownership Structure Description and Chart
iii. Reporting of Officers and Directors
iv. Identification of International Antitrust Notification
v. Transaction Diagram
vi. Identification of Other Agreements Between the Parties

Balanced against these reductions in burden, the final rule does require the acquired person to report prior acquisitions for the first time, for the reasons explained in sections II.B.5. and VI.J.4.

IF/THEN Format

Certain information requirements of the final rule are only applicable to filers who provide a positive response to other information requirements. That is, the final rule reflects an IF/THEN format by requiring some information only if filers have provided other information first. For example, many information requirements do not require a response if the filer indicates that there is no reported overlap or supply relationship between the merging parties. This is a main feature of the current HSR Form, and the Commission expands that approach in the final rule to closely align the information requirements with the risk of a law violation the transaction presents, resulting in an IF/THEN format that adjusts the cost of complying based on the existing competitive relationship of the parties to the transaction.

Importantly, information that is critical to identifying competitive overlaps or areas of premerger competition justifies a higher cost of collection and reporting.[297] Examples include reporting revenues for identified overlaps by geographic location so that the Agencies have some basis to screen overlapping products for local market impacts.[298] Even if there is some additional cost associated with collecting this information, a notification form that does not contain such information would be unreliable for detecting the risk that the transaction would cause harm to competition at the State or local level. Limiting the requirement to provide certain information only if both parties generate revenues in the same or similar business lines (as reflected in overlapping NAICS code reporting or the descriptive responses) or only if the parties operate in the same areas of the country is a powerful limitation aimed at generating information that bears directly on the question whether the transaction involves direct competitors. For any transaction that does not have these overlaps, there is no burden associated with answering questions that depend on the reporting of such overlaps other than certifying that such overlaps do not exist. In the final rule, the following information requirements are dependent on the identification of an existing overlap or a supply relationship:

i. Overlap Description
ii. Supply Relationships Description
iii. Officers and Directors (acquiring person only)
iv. Plans and Reports
v. Prior Acquisitions
vi. State and Street-Level Reporting of Geographic Market Information
vii. Author information for submitted documents
viii. Defense and Intelligence Contracts

Limited Lookback Periods

The Commission also relies on limited lookback periods to collect the most recent and reliable information and data related to the risk of a law violation. For example, filers are only required to submit the most recent annual reports and annual audit reports. This type of limitation is intended to focus on more recent economic activity and reduce the cost associated with collecting potentially less probative or out-of-date historical data. As discussed below in section VI., the Commission has reduced the lookback periods for some information requirements as compared to the proposed rule to reduce compliance costs and focus the information requirements on the most recent and probative data needed for premerger screening. In other places, the Commission has identified a fixed reporting period to limit the information filers must gather to prepare the HSR Filing and provide certainty for filers about what is required. For example, as compared to the proposed rule, the final rule contains shortened lookback periods for the following information:

i. Overlap Description
ii. Supply Relationships Description
iii. Officers and Directors
iv. Transaction Rationale
v. Minority Shareholders
vi. Prior Acquisitions

[297] In the initial rulemaking implementing the HSR premerger program, the Commission proposed to require the reporting of revenues by Standard Industry Classifications (SIC) codes. Many commenters complained about the costs associated with providing this information. But the Agencies needed to establish some system for reporting overlaps. This provides an early example of the Commission determining that, where the information is essential to enforcement of the antitrust laws, the costs associated with collecting and reporting that information is justified by the benefits in light of other available options.

[298] The Agencies rely on analytical tools to identify an area of effective competition, often by defining a relevant antitrust market. A relevant antitrust market comprises both product (or service) and geographic elements. *See* U.S. Dep't of Justice & Fed. Trade Comm'n, Merger Guidelines 4.3 (2023) (describing the information and analysis used by the Agencies to define markets for the purpose of antitrust analysis). For screening purposes, the Agencies may conclude that the parties to the transaction do not serve the same set(s) of local customers if there is reliable information in the HSR Filing that indicates that they generate revenues in different locales even if they supply the same product or service.

De Minimis Exclusions

The Commission also relies on de minimis exclusions to excuse the reporting of otherwise relevant information that might be costly to collect. De minimis exclusions can sometimes require extra effort by filers, because filers must evaluate whether the information is above or below the de minimis threshold. In the Commission's experience, it can sometimes take less time for filers to collect and report all responsive information than to report less information after conducting the assessment required to eliminate de minimis amounts. In deciding whether to add de minimis exclusions, the Commission carefully weighed the additional costs for filers to determine what information falls below the de minimis thresholds and can therefore be excluded, as compared to the costs of collecting all responsive information. The final rule contains new de minimis exclusions for certain information in the following requirements:

i. Supply Relationships Description
ii. Prior Acquisitions
iii. Defense and Intelligence Contracts

Voluntary Information

Finally, one new information request is not strictly required by the final rule, but filers may provide it on a voluntary basis. As part of the HSR Form, filers may agree to waive the confidentiality protections of the HSR Act to permit the Agencies to share HSR materials with other enforcers in order to facilitate cooperation during any investigation of the transaction. Such a waiver would be beneficial for the Agencies, and the filer may want to provide it as a way to limit the need to produce multiple or duplicative data sets and documents to other enforcers that are investigating the transaction, thereby reducing its overall regulatory compliance costs. Filers may view this as a benefit and therefore may grant a waiver even though their HSR Filing would be compliant with the final rule without it.

Non-Compliance Statement

In addition to these limits, the Act allows for incomplete answers with a statement of the reasons for non-compliance, and the Commission has the discretion to permit filers to rely on good faith estimates or no answer at all. If the filer is unable to answer any question fully, it must provide the information that is available and provide a statement of reasons for non-compliance as required by § 803.3, which is intended to reduce disagreements between filers and PNO staff.[299] Where exact answers cannot be given, filers are allowed to enter best estimates, while indicating the source or basis of the estimate, and marking the information with the notation ''est'' to any item where data are estimated. Finally, filers already routinely indicate under the current rules that certain required information is not applicable given the type of transaction being reported, and filers will continue to be able to do so under the final rule.

Summary of Requirements Based on Transaction Type

In the final rule, the Commission has employed all of these techniques to align the cost of complying with the final rule in light of the benefit to the Agencies, filers, and the public of the Agencies having the information on the first day of the statutory review period to conduct their preliminary antitrust assessment. The chart below summarizes the different information requirements of the final rule for the acquiring person and the acquired person for three distinct types of transactions: (1) select 801.30 transactions, (2) those transactions that will have no NAICS or described overlaps or supply relationships; and (3) transactions that report a NAICS or a described overlap, or a supply relationship, which includes transactions with significant pre-merger competitive interaction between the filers (for example a company acquiring one of its principal competitors or suppliers).[300] The chart indicates which type of filer will not provide this information because it is not required by the final rule. As depicted in this chart, the final rule creates different information requirements for different types of filers and different types of transactions, resulting in a range of costs associated with filing that are directly proportional to the complexity of the deal, corporate structure, and most importantly the risk of law violation.

[299] The submission of the statement of reasons for noncompliance is not intended to be a substitute for compliance with the notification obligation but it serves two salutary purposes: (1) reducing disagreement between the Agencies and the filer, and (2) providing a basis for any civil penalty proceeding that may be brought under 15 U.S.C. 18a(g)(1). *See* 122 Cong. Rec. 29342 (1976); *see also* 43 FR, 33450, 33508–09 (July 31, 1978).

[300] These three scenarios were used to calculate costs for the Paperwork Reduction Analysis, discussed below in section VIII.

Figure 3: Applicability of Significant Updated and New Information Requirements By Filer and Transaction Type

	Select 801.30		No Overlap / No Supply Relationship Transaction		Overlap / Supply Relationship Transaction	
	A-Side	B-Side	A-Side	B-Side	A-Side	B-Side
Translations						
Changes to Identification of Additional Minority Interest Holders						
Organization of Controlled Entities	■	■				
Description of Ownership Structure		■		■		■
Organizational Chart (if exists)		■		■		■
Identification of Certain Officers and Directors		■		■		■
Description of Business of the Acquiring Person		■		■		■
Transactions Subject to International Antitrust Notification		■		■		■
Transaction Rationale	■	■				
Transaction Diagram (if one exists)	■	■		■		■
Competition Documents from Supervisory Deal Team Lead		■				
Plans and Reports	■	■	■	■		
Transaction Agreements	■	■				
Other Agreements Between the Parties		■		■		■
Overlap Description	■	■				
Supply Relationships Description	■	■	■	■		
Geographic Market Information (new organization, street-level reporting, and reporting of francisees)			■	■		
Limiting Minority-Held Entity Identification to Overlaps			■	■		
Prior Acquisitions			■	■		
Subsidies from Foreign Entities or Governments of Concern						
Defense or Intelligence Contracts	■	■	■	■		

D. Disproportionate Impact on Certain Sectors

Here the Commission addresses arguments that the final rule would have a disproportionate impact on certain sectors as part of its consideration of how the benefits and costs associated with the final rule are distributed among various groups.[301]

Small Businesses

Several commenters are concerned about the additional costs associated with the final rule for small businesses who are parties to a reportable transaction, stating that the proposed rule would disproportionally affect small businesses because they would be less equipped than larger businesses to cover the additional costs. Commenters said that these additional costs would not only deprive small businesses of funds that are needed for operations or innovation, they might also slow or deter dealmaking involving small businesses altogether. On the other hand, an individual commenter explained that the proposed rule would help small businesses who have been affected by mergers.

The Commission addresses concerns about undue costs throughout this final rule, making many adjustments to limit the costs of complying for those filers who do not have complex corporate structures or extensive business lines, including small businesses. In section IX., the Commission certifies that the final rule will not have a significant economic impact on a substantial number of small entities as that term is defined by the Small Business Administration (''SBA''). HSR reporting requirements apply to very few small businesses. Congress adjusted the statute in 2000 to require annual indexing of reporting thresholds so as to minimize the effect of inflation that would otherwise require more reporting for small businesses and small transactions, and nothing in the final rule changes which acquisitions are subject to premerger review. See section III.A.1.

In fact, the Commission believes that many small entities will benefit from the final rule. As noted by one commenter, the goal of antitrust enforcement is to strike the right balance: too little enforcement could allow some companies to gain an unfair advantage, while too much enforcement risks driving up compliance costs and undermining legitimate efforts to compete. The Supreme Court has explained that Congress designed section 7 of the Clayton Act to ''prevent economic concentration in the American economy by keeping a large number of small competitors in business,''[302] and to retain '' 'local control' over industry and the protection of small businesses.''[303] As a result, a merger of two small companies that allows the combined entity to compete more effectively with larger rivals may be unlikely to violate the antitrust laws. In contrast, the legislative history of the Clayton Act reveals Congress was very much concerned with, and sought to prevent, acquisitions involving large companies buying smaller or up-and-coming rivals that would otherwise cease to be independent businesses.[304] By making possible more effective and efficient premerger review of HSR-reportable transactions, the final rule will facilitate effective enforcement of the antitrust laws, which in turn will preserve opportunities for small businesses to thrive in markets that are not dominated by much larger competitors.

In passing the HSR Act, Congress made plain that it was not interested in burdening mergers between two small companies with premerger review, since small businesses generally do not present the same risks of anticompetitive effects as do larger businesses. To that end, the HSR Act specifically exempts certain smaller companies from its reach. But it is not possible to say that all transactions involving small businesses carry little or no antitrust risk, whether they are

[301] *See generally* Boardman et al, *supra* note 256, at 506; Executive Order 12866 directs agencies when designing regulation to ''consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.'' E.O. 12866 Sec. 1(b)(5) (1993).

[302] *United States* v. *Von's Grocery Co.,* 384 U.S. 270, 275–76 (1966) (also noting that undue concentration drives small businesses out of the market).

[303] *Brown Shoe Co.* v. *United States,* 370 U.S. 294, 316 (1962).

[304] *United States* v. *Aluminum Co. of America,* 377 U.S. 271, 281 (1964).

reported or not. When they are required to be reported, the Agencies are obligated to conduct a premerger assessment. Therefore, it is appropriate for the Agencies to receive information from even small businesses that are a party to a reportable transaction to determine whether those transactions may violate the antitrust laws.

Based on the Commission's experience, deals of any size can present significant antitrust risk. The American Antitrust Institute analyzed historical data about HSR filings from 1985 to 2020 and prepared a chart that reflects the percentage of Second Request investigations to transactions by deal value.[305] This data shows that while transactions valued at under $100 million rarely receive Second Requests, a not insignificant number of transactions in the $100 to $150 million range do. This confirms the Agencies' experience that although many deals that are subject to an in-depth investigation involve large companies, especially on the buyer side, it is not possible to ignore that some transactions that involve small businesses also violate the antitrust laws.[306] And of course, the Agencies are also attentive to small-value acquisitions that cause harm even if they were not subject to premerger review and seek to unwind them as resources and precedents allow.[307]

As modified, however, the final rule imposes lower costs on transactions involving independent small businesses, as they typically involve fewer business lines and less complex corporate structures. Typically, the larger the company, the more extensive and complex its business lines. Many of the changes in the final rule are designed to allow the Agencies to quickly understand complicated entities and the businesses that they have connections to. These changes generally will not impact small business. Further, where possible, the final rule imposes less burden on sellers (the acquired person), which tend to be smaller in size than buyers.[308] In effect, the final rule imposes costs on filers that are commensurate with the antitrust risk presented by the transaction: those with low risks (*e.g.,* simple corporate structures, few lines of business or no preexisting commercial relationship with the other party) have the lowest costs. Wherever practicable, the Commission took into account the burden across smaller businesses who may engage in competitively benign transactions and has adjusted the final rule in several significant ways to mitigate this burden. For example, the Commission has excluded select 801.30 transactions from certain requirements, eliminated other proposed requirements, and modified other proposed requirements as described throughout this final rule. The Commission believes that this approach, which is focused on antitrust risk and not necessarily business size, nonetheless minimizes the costs for small businesses involved in transactions subject to mandatory premerger review consistent with the statutory scheme.

Startups

A number of commenters expressed the view that the requirements of the proposed rule would deter innovation by denying startup firms an exit path; they observed that many startups plan for eventual acquisition, and this strategy drives investment that allows the firm to grow. Commenters stated that any change to the status quo will upset this balance. Others observed that acquisitions by large, established firms play a crucial role as an exit strategy for startups securing venture capital, which is an important source of funding in many sectors, including tech. Some of the same commenters, however, acknowledged the valuable role startups play by challenging established incumbents. Various commenters made nonspecific objections to increased burdens imposed upon startups by the proposals in the proposed rule.

Startup companies are not unique to particular industries but represent an important business model throughout the U.S. economy. For any transaction that does not present facts indicating it may violate the antitrust laws—including those involving startups—the minimal additional burden of disclosing more information is justified by the Agencies' need to conduct a thorough review in light of the information gaps discussed in section II.B. Where those facts are absent, there should be no additional delay or additional risk of detection for those transactions. Given the small incremental costs associated with the final rule relative to other M&A costs and the potential magnitude of returns from an exit sale of a successful startup, HSR compliance costs would not plausibly factor into the *ex ante* investment decision. To the extent that the final rule requires additional disclosures regarding the business lines of startups, that burden is not different from those imposed on established businesses in the same sector. Moreover, the Commission has no basis to excuse startup companies from complying with the final rule; it is not the case that they always or mostly present no antitrust risk. See sections II.B.4. and III.C.2.

Private Equity and Other Types of Investments

The Commission received several comments from groups representing investors raising concerns about the burden of gathering the information for the proposed rule as well as the burden of having to disclose the new information. One commenter asserted that certain proposed requirements would be particularly onerous for transactions involving private equity and venture capital, such as the expanded lookback period, information regarding limited partnerships, more information about prior acquisitions, the identities of past and present members of boards of directors, and disclosure of the buyer's prior acquisitions. Another commenter said that the burden of the information requirements would affect the efficiency of transactions and introduce more uncertainty and risk into the deal process, which would adversely impact returns for investors. Another noted that the burden of the proposed information requirements would, among other effects, make capital markets less efficient, resulting in a significant impact on its members and the thousands of pensioned workers, retirees, universities, and other investors who rely upon them. The Commission discusses these concerns elsewhere and has concluded that the incremental costs associated with the

[305] *See* Diana L. Moss, Am. Antitrust Inst., ''What Does the Billion-Dollar Deal Mean for Stronger Merger Enforcement?'' 3 Fig. 2 (Sept. 20, 2022), *https://www.antitrustinstitute.org/wp-content/uploads/2022/09/AAI_Billion-Dollar-Mergers_9.20.22.pdf.*

[306] *See, e.g., United States* v. *Neenah Enterprises, Inc.,* No. 1:21–cv–02701 (D.D.C. Oct. 14, 2021) (complaint) ($110 million asset purchase); *In re Global Partners LP,* No. C–4755 (F.T.C. Mar. 2, 2022) (decision and final order) ($151 million acquisition); *In re ANI Pharmaceuticals, Inc.,* No. C–4754 (F.T.C. Jan. 12, 2022) (decision and final order) ($210 million acquisition); *United States* v. *Grupo Verzatec S.A. de C.V.,* No. 1:22–cv–01401 (N.D. Ill. Mar. 17, 2022) (complaint) ($360 million acquisition). Note that the value of the transaction is considered by some filers to be confidential information and is not always disclosed in public filings. *See FTC* v. *IQVIA Holdings Inc.,* No. 1:23-civ-06188 (S.D.N.Y. Dec. 29, 2023); *In re Lifespan Corp.,* No. C–9406 (F.T.C. Feb. 17, 2022) (complaint).

1 *See, e.g., In re The Golub Corp.,* No. C–4753 (F.T.C. Jan. 20, 2022) (decision and final order) (divestiture of 12 supermarkets); *United States* v. *B.S.A. S.A.,* No. 1:21–cv–02976 (D.D.C. Mar. 15, 2022) (divesture of two business lines).

[307] *See, e.g., Polypore Int'l, Inc.* v. *FTC,* 686 F.3d 1208 (11th Cir. 2012); *In re Otto Bock HealthCare N. Am., Inc.,* No. 9378 (F.T.C. Dec. 1, 2020).

[308] *See* Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Annual Report, Fiscal Year 2022, Tables VI through IX (FY 2022).

final rule are small relative to the value of the transaction and the costs of other merger-related fees. As noted throughout this final rule, the Commission has taken many steps to reduce the burden on all types of filers as compared to the proposed rule, including investors.

The same commenter who mentioned the effect on capital markets also noted that the HSR-reportable transactions in which its members engage often do not pose competitive risk. These are transactions in which the acquiring persons are investment groups, trusts, or other financial vehicles or are providing securities, commodities contracts, and other financial investments or related advice. According to this commenter, its members rarely, if ever, have horizontal or even vertical relationships with the issuers whose securities they acquire. Rather, the kinds of HSR-reportable transactions in which its members engage are not mergers or acquisitions but the acquisition of minority positions, for instance, when concentrated funds make large purchases due to sizeable investor inflows, when benchmark-relative funds make large purchases due to index rebalancing, or when managers shift portfolios into highly liquid names in anticipation of redemptions or in connection with wind-downs.

This and other comments generally reflect three different types of concerns: potential burdens for investors that must make HSR filings, potential burdens for minority investors in entities that have to make HSR filings (but have no HSR filing obligation themselves), and potential burdens related not to filing out the Form, but to potential enforcement actions to block the transaction that may arise from the Agencies having more complete information. The Commission addresses each below.

As a starting point, the Commission emphasizes that the final rule does not change who must file [309] and the HSR Act and Rules exempt passive investments of 10% or less,[310] or 15% or less for institutional investors.[311] The final rule does not alter the analysis regarding passive investments and therefore the final rule has no impact on investors who hold passive investments [312] unless these investors acquire more of a company than these significant ''investment only'' exemptions permit and are, as a result, required to report their investments for premerger review. As a result, many of the types of investors discussed in the comments will not have HSR filing obligations for their transactions, and thus would not be required to fill out the Form that is the subject of the final rule.

Some investors will have filing obligations either because they will hold a stake that provides them with the ability to direct or influence the management of the company in which they are investing (*i.e.,* above the 10% and 15% exemptions), or because they do not intend to be merely passive investors. In these instances, the Act treats them as any other acquiring person and the Agencies use the Form to screen for potential competitive effects. Until now, though, the Agencies have received less information about transactions where private equity and other types of investors are involved because the current Form does not require sufficient information to explain the often complex structures and relationships between different entities that are within the acquiring or acquired person. The final rule intends to close these information gaps and focuses on information that should be within the records of the acquiring or acquired person.

Further, the Commission acknowledges that investors can have different motivations in making acquisitions. Some do not seek to control or influence the companies in which they invest, but rather only seek a desired rate of return. In contrast, others seek positions with significant management rights or stakes that result in control of or influence in the target business. The Commission has sought to tailor the requirements of the final rule to illuminate those factors that could give rise to competitive concerns while minimizing additional costs for those investors that do not seek to participate in or influence decision-making of entities related to the acquiring entity or other entities within the buyer that are in the same industry as the target. As a result, the Commission has made significant changes as compared to the proposed rule, declining to adopt many of the proposed changes and significantly tailoring others. The Commission has also introduced the concept of select 801.30 transactions, which it anticipates will capture the transactions of many investors that do not seek to influence, direct, or manage the companies in which they invest. *See* section VI.A.1.f. The Commission has relieved such transactions from many of the new requirements, which it anticipates will mitigate the potential burden of providing information for many investors who do have to file.

As to investors that do not have HSR filing obligations but hold minority interests in entities that do, the final rule does require additional information about some minority investors if those investments are in entities controlled by the acquiring person that are either related to the transaction or operate in the same industry as the target. However, as described in section VI.D.2.a., the burden of providing this information rests on the acquiring person, not on those minority investors. Their presence as an investor should be known to the filer because the filer controls the entity, and when revealed in the HSR Filing, will provide information that will assist the Agencies in determining whether those investors also hold interests or have relationships with entities related to the target.

Additionally, the Commission modified the proposed rule to scale back requirements that would have broadly required disclosure of the limited partners of certain entities. As discussed below, the Commission has limited the final rule to require identification of only those limited partners that have certain rights related to the board of directors or a similar body. When required, this information is limited to providing the legal and business name of the minority investor, its address, and the percentage the investor holds in the entity controlled by the acquiring person. In most instances, the Commission believes this information should be available in the records of the acquiring person. When it is not, the Commission has explained that the acquiring person can note that the information is not available and why. The final rule does not create an obligation for the acquiring person to request this information from its minority investors. Therefore, the final rule imposes no burden on such minority investors in filling out the revised Form. Investors that do not have HSR Act filing obligations, but hold minority interests in entities that do, will not have any new obligations to either make filings or provide information for the filings of entities in which they have minority holdings.

Several commenters raised concerns that the additional information requirements for funds, especially those managed by activist investors, would

[309] One commenter suggests that the proposed rule would result in an increase in filings among investors. Comment of TIAA, Doc. No. FTC–2023–0040–0691 at 3. The Commission disagrees.

[310] 15 U.S.C. 18a(c)(9); 16 CFR 802.9.

[311] 15 U.S.C. 18a(c)(11); 16 CFR 802.64.

[312] Some commenters discussed shareholder engagement encouraged by the SEC. *See, e.g.,* Comment of Managed Funds Ass'n, Doc. No. FTC–2023–0040–0651 at 8. The Commission notes that the SEC is a different agency with a different law enforcement mission.

have a detrimental impact on these investors as a result of the disclosure of the information itself. They pointed to the disclosure of the interests and rights of limited partners as creating disincentives for shareholder engagement or as undue interference in the market for corporate control. Another commenter stated that disclosure requirements may deter investments in private equity firms, potentially reducing the flow of capital to small- and medium-sized businesses.

The final rule does not target information specific to any type of investor. But if an investor holds a small but significant stake (five percent or more) or plays a role in the acquiring person's decision-making, the Commission believes that disclosure of these interests is justified by the Agencies' need to know about such investments to conduct premerger screening. As discussed in section II.B.1. and section VI.D.1.d.ii, there have been significant changes in the number and breadth of investment companies managing portfolios that include investments in companies with competitively significant relationships. Due to these changes and others, the Commission has determined that the Agencies need more information about minority holders between the UPE and the acquiring person, as well as information about those who serve as officers and directors and who will be involved in decision-making after the transaction is consummated. Many commenters specifically objected to providing any information about limited partners, noting that the existence of significant management rights such as board seats or board approval rights, is ''atypical.'' The final rule has been modified to require disclosure only of these types of limited partner situations, which should mitigate these concerns.

Another commenter said that having to disclose the required information would deter investment in in certain types of investment vehicles because of the exposure of proprietary contractual information and Personally Identifiable Information (PII) about every facet of the M&A process. This commenter noted, for instance, that the requirement to provide a term sheet or draft agreement reflecting sufficient detail about the proposed transaction when filing on the basis of a Preliminary Agreement would expose details about transactions that could undermine competition in the industry and harm returns to LPs. In addition, this commenter stated that the requirement for PE firms to submit a narrative describing the justification for certain transactions would impinge on the proprietary information that PE firms exchange with target companies and their consultants.

As noted above and elsewhere, the Commission has made significant changes as compared to the proposed rule, and the changes in this final rule should address many of this commenter's concerns. That said, the Commission believes the commenter has overread the Commission's intent. The purpose of the final rule is to provide the Agencies with more information on those factors that could give rise to competitive concerns, not to expose every facet of the M&A process or investor strategy. The required information does not require social security numbers, addresses or other sensitive PII. Moreover, the final rule requires the disclosure of additional information to the Agencies, not to the public or third parties, and the confidentiality of the information provided to the Agencies as part of the HSR filings process is protected by statute, specifically 15 U.S.C. 18a(h).

Finally, as described in section VI, the final rule will provide the Agencies with more transparency into what the acquiring person holds and whether any person or entity that has influence over the acquiring person is also involved in the business of the target. Specifically, the Commission has not limited the information required about the acquiring person even in the case of select 801.30 transactions. As stated in the NPRM and throughout this final rule, the Commission believes this information is critical to the Agencies' initial review and the benefit for robust premerger screening justifies the burden of disclosing the information because it may identify an existing business relationship between the acquiring person and target (via common investors or shared managers) that are otherwise not revealed in the HSR Filing.

The Commission disagrees with comments that identify increased transparency about the filed-for transaction itself (and not the specific burden of collecting and providing the information) as a cognizable burden associated with the final rule. The purpose of the final rule is to require information that allows the Agencies to accomplish the task assigned to them by Congress: to determine whether the acquisition subject to the Act, if consummated, may violate the antitrust laws. Suggestions that increased transparency would endanger certain filed-for transactions implicitly indicate that the current Rules have led to under-enforcement of the antitrust laws. Any burden related to deal uncertainty that might arise from increased transparency is not a burden related to compliance with the HSR Act and the final rule, but rather is tied to whether the transaction itself may violate the antitrust laws.

Biopharmaceuticals

Two commenters from the biopharmaceutical sector suggested that several requirements of the proposed rule would disproportionately burden biopharmaceutical firms and transactions. They pointed to the burden of identifying information related to products in early stages of clinical development, and stated that, because the Commission's 2013 rule specific to pharmaceutical license agreements increased the universe of reportable transactions, any expansion of the Form disproportionately burdens the pharmaceutical sector. One additionally objected to providing information about employees, and the other asserted disproportionate impact from providing information regarding additional prior acquisitions because of the number of acquisitions in this sector, and from disclosing officers and directors due to biotech firms' dependence ''on a small cadre of qualified directors and officers.'' Both commenters claimed the changes to the HSR Form and Instructions will prolong the time required for HSR filing preparation and agency review, resulting in delayed transactions.

The final rule does not target any information that is unique to biopharmaceutical companies, and the Commission disagrees that the additional information that would be sought from these companies is not relevant. Where the final rule requires additional information from biopharmaceutical companies, the cost of supplying that information is justified by the benefit to the Agencies in having a more complete understanding of the companies' existing business operations and their business strategy, including prior acquisitions involving the same business lines. For instance, many biotech and pharmaceutical companies invest in extensive R&D pipelines, and the Agencies need information about products in development to determine if the companies are current competitors for innovation in a particular space to meet a particular need, or if one or both merging parties are potential competitors for any existing products.[313] As the commenters

[313] *See In re Sanofi Corp.,* No. 9422 (F.T.C. Dec. 11, 2023) (complaint alleging Sanofi's proposed acquisition of an exclusive license to Maze Therapeutics' pipeline Pompe therapy would have eliminated nascent threat to Sanofi's monopoly) (transaction abandoned); *FTC* v. *Mallinckrodt ARD Inc. (f/k/a Questcor Pharms., Inc.),* No. 1:17–cv–120

Continued

acknowledged, mergers, acquisitions, and exclusive licenses are particularly prevalent in the pharmaceutical sector, where the business model for new drug development centers around such transactions. Similarly, the comparatively higher number of transactions occurring in this sector can be expected to trigger a higher number of HSR Filings and could require filers to disclose a greater number of prior acquisitions. Even if biopharmaceutical companies have to report more prior acquisitions, this disclosure is also justified because it is relevant to determining whether there is a pattern of serial acquisitions. The fact that sharing of officers and directors is more common among companies in this sector means there is a greater need for the Agencies to screen for related competitive problems.[314]

On the other hand, other information requirements have been modified to reduce the costs for all types of filers, including those in the biopharmaceutical sectors. For instance, the Commission declined to adopt new information requirements related to employees, which commenters asserted could impose significant costs on those in the biopharmaceutical as well as other sectors. Overall, the impact of the final rule is proportional to the number and characteristics of transactions that occur in any given sector of the economy (including biopharmaceuticals). To the extent that the revised Rules will result in delayed transaction closings, the potential impact of incremental delay is outweighed by the Agencies' statutory mandate to examine each transaction for the potential for that it may violate the antitrust laws. In other instances, the additional information may actually reduce delay by permitting the Agencies to avoid issuing a Second Request or issuing Second Requests that are more tailored to the potential for competitive harm than would have been issued under the existing reporting requirements.

In sum, the Commission has determined that the burden imposed on this sector by the final rule is proportionate to the market realities and complexities of these companies and the likelihood that any transaction may require more in-depth antitrust review.

Hospitals

A national organization representing hospitals and several State hospital associations stated that the proposed rule would have a negative and wholly unnecessary impact on hospitals and health systems. They asserted that the additional information required by the proposed rule would not generate actionable information with respect to hospital mergers. They objected to specific requirements, stating that reporting prior acquisitions has no relevance in the context of hospital mergers, or that it is inconceivable that a hospital-related merger could plausibly harm competition in any labor market without also presenting at least some competitive risk in a downstream market.

The Commission responds that the final rule does not target any information that is unique to hospitals and health systems, and disagrees that the additional information, when sought from hospitals, is not relevant. For example, the commenters' suggestion that the Agencies not screen for hospital labor competition issues is inconsistent with growing empirical evidence of competitive harm to labor markets from consolidation generally and from hospital mergers in particular.[315] Moreover, as discussed above, an empirical assessment of the price effects of consummated hospital mergers reveals that there are meaningful information gaps in the current requirements that led the Commission to grant early termination of the waiting period for hospital mergers that caused significant price increases.[316]

As discussed, the final rule will exclude non-profit entities organized for religious or political purposes from the specific requirement to produce information disclosing officers, directors, and members. This carve-out will likely encompass some healthcare organizations, including certain religious-affiliated hospitals or other provider groups. While these entities will not be required to provide such information as a matter of course in the HSR Filing, it can nonetheless be relevant in any in-depth investigation of the transaction and may be sought from the parties at a later date.

Given the Commission's significant expertise and interest in preventing hospital mergers that may violate the antitrust laws, the final rule is appropriately focused on transactions that are most likely to present antitrust risk. The Agencies have determined the information sought by the final rule will close the information gaps that now exist with regard to hospital and other healthcare acquisitions. Moreover, because many hospital mergers are not reportable under the HSR Act, several States have enacted premerger notification laws for certain healthcare acquisitions, including those involving hospitals, to prevent consolidation that may affect their citizens directly. In light of all this evidence of a need for robust screening in this critical sector, there is no basis to excuse hospitals or health systems from any of the new requirements of the final rule beyond the modifications that reduce costs on filers overall, including on hospitals.

E. Regulatory Alternatives Considered

In addition to considering the costs and benefits of the final rule as compared to the status quo, the Commission considered other alternatives suggested by commenters.[317] The first alternative is to not finalize any modification to the current HSR Form and Instructions and to issue more Second Requests when the HSR Filing is insufficient to determine whether the proposed acquisition may violate the antitrust laws. Relatedly, commenters suggested that the Commission maintain current reporting requirements and make more extensive use of voluntary submissions from the parties post-filing. These alternatives are discussed above in section III.A.3. Another alternative suggested by commenters is for the Commission to create two separate sets of information requirements, one for acquisitions that present a low risk of a law violation and therefore require less reporting (a ''short form'') that would continue to report the information required by current HSR rules and a second form for acquisitions that cannot be considered low risk and that would contain all of the new information requirements in the final

(D.D.C. Jan. 25, 2017) (complaint alleging Questcor's acquisition of rights to pipeline competing drug eliminated nascent threat and protected its monopoly ACTH drug H.P. Acthar Gel) (consent decree ordered license and $100 million equitable monetary relief); *In re Thoratec Corp.,* No. 9339 (F.T.C. July 28, 2009) (complaint alleging Thoratec's proposed acquisition of HeartWare eliminated pipeline threat to Thoratec's left ventricular assist device monopoly) (transaction abandoned).

[314] Mark A. Lemley et al., ''Analysis of Over 2,200 Life Science Companies Reveals a Network of Potentially Illegal Interlocked Boards'' (Stan. L. & Econ. Olin Working Paper No. 578, 2022), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4253144.*

[315] Concurring Statement of Commissioner Rebecca Kelly Slaughter and Chair Lina M. Khan, *supra* note 70, at 2 n.1; *In re Lifespan Corp.,* No. 9406 (F.T.C. Feb. 17, 2022) (complaint).

[316] *See supra* note 24 and related text.

[317] Executive Order 12866 requires an assessment of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulations and an explanation of why the planned regulatory action is preferable to the potential alternatives. E.O. 12866 sec. 6(a)(3)(C) (1993). As an independent agency, the Commission is not subject to the requirements of this executive order but nonetheless used the principles outlined there to explain why the Agencies' chosen regulatory action is preferable to potential alternatives.

rule. Here the Commission discusses the relative merits of adopting this alternative over the final rule.

Several commenters suggested that the Commission consider creating two separate sets of information requirements for notification, stating that this approach is used by other jurisdictions to alleviate some costs and delays associated with merger notification under their laws. They asserted that it would be suitable for effective and efficient premerger review under U.S. law.

As discussed above, the HSR Form is not ''one size fits all'' and the costs of making an HSR Filing are unique for each transaction. In this rulemaking, the Commission is publishing, for the first time, separate Forms for the acquiring person and the acquired person. The final rule has materially different requirements for each filing person, and providing separate Forms allows for clearer instructions (avoiding terminology in the proposed rule such as ''the acquired person or acquired entity (as applicable)''). The Commission expects that having two separate forms for each side of the transaction will improve compliance and reduce errors for filers.

Moreover, while not styled as a ''short'' or ''long'' form, the final rule reflects the Commission's consideration of each requirement and makes clear where there is a need for the information for each type of transaction. In particular, the IF/THEN structure of the information requirements results in some filers responding to only a few information requirements. As a result, in practice, there are ''shorter'' and ''longer'' versions of the forms depending on the type of filer and the type of transaction under review. The Commission determined that this approach better reflected the varying information requirements the Agencies need in order to effectively and efficiently analyze the broad spectrum of filers and transactions.

Most importantly, in its review of past filings, the Commission found no set of objective criteria that would appropriately sort transactions into one or more discrete categories for the development of a single short form. Rather, the final rule adopts new information requirements but imposes them differently to reflect each filer's role in the transaction (acquirer versus acquired) and the relative antitrust risk associated with the proposed transaction. Filers with the highest information and document requirements are acquirers pursuing the acquisition of a firm with whom they have extensive existing business relationships or offer products or services in the same industries that must be assessed prior to consummation.

For one category of transactions, select 801.30 transactions (described in section VI.A.1.f.), the Commission has determined that the Agencies need minimal additional information such that the final rule should impose fewer new requirements. The Commission believes that the few new information requirements for select 801.30 transaction are justified in order to ensure that the Agencies conduct a premerger assessment to determine that even these transactions do not present risk of a law violation. Similarly, the Commission determined that other characteristics justify a different and lighter burden, such as whether the filing person is the buyer or the seller in the transaction. Finally, many requirements are tied to the acquiring and acquired person operating in the same industry or having a business relationship. These questions would be inapplicable to many filers, particularly activist, institutional, and retail investors, which typically do not have controlling stakes in operating companies or do not focus on a particular industry. As a result, the costs of complying with the final rule are tailored to the risk of a law violation associated with each transaction in a way that is similar to, but more flexible than, the ''short form'' alternative. The size and complexity of each party to the transaction, as well as the size and scope of their respective business, vary widely across filings. As discussed in section II.B., there are specific risks to competition that the current information requirements do not disclose, making the final rule a better alternative to achieve robust premerger screening even for select 801.30 transactions as compared to a short form alternative.

In addition, the short form alternative is likely to create uncertainty for filers that do not qualify for short form treatment but whose deals would suddenly be viewed as ''not low risk.'' Having a bifurcated system that targets some transactions as ''low risk'' is not consistent with the statutory premerger scheme Congress created when it determined that reporting would be required based on deal value regardless of the risk of a law violation, with additional authority for the Commission to exempt transactions that it has determined to present little to no antitrust risk. At this time, the Commission does not have a basis to conclude that the existing requirements continue to be sufficient for any category of transactions.

The Commission believes that broadening the use of the HSR Form's existing IF/THEN format so that the final rule aligns the cost of complying with the associated antitrust risks of the transaction is the most appropriate way to implement the premerger notification scheme established by Congress. Congress has determined which transactions are subject to premerger review, relying on deal value to determine reportability. This criterion provides administrative clarity and predictability for businesses. Some jurisdictions use market share or revenue (''turnover'') thresholds to determine reporting or eligibility for short form treatment. But in doing so, these regimes also typically depend on the competition authorities to provide extensive guidance to business, often prior to formal notification, regarding the proper definition of markets. This may require an in-depth analysis of the potential markets at issue and can delay formal notification.[318] Congress has chosen to rely on an objective and administrable system of reportability based on deal value and revenues for filers. Adopting a different standard for determining eligibility for short form treatment would require the Commission to engage in a separate and challenging rulemaking to seek public comment on what types of thresholds should be adopted that would be consistent with the premerger scheme Congress adopted in the HSR Act. At this time, the Commission has determined that one category of filings, select 801.30 transactions, will have minimal additional information requirements as compared to the current HSR Form and has made other modifications in the final rule to reduce the costs for other types of filers and transactions as well.

Although the short form alternative would save some filers additional direct costs associated with making an HSR, the Commission chose to adopt the final rule with modifications designed to reduce the cost of filing as much as possible for all types of filings, including those transactions that might be eligible for short form treatment. The Commission believes that this approach reflects, to the extent practicable, the antitrust risks associated with a variety

[318] Relying on market share thresholds presents many challenges, and several jurisdictions have replaced them with thresholds that are easier to administer. In the early 2000s, approximately half of the jurisdictions with merger control had subjective notification thresholds such as market share but by 2010 more than forty percent of these jurisdictions had replaced their subjective thresholds with objective, sales- or assets-based thresholds.

of filings, not just ones that could be eligible for short form treatment. A final rule that reasonably balances the benefits to Agencies' premerger review with the costs imposed on filers and others is a reasonable exercise of the Commission's rulemaking authority under the HSR Act and is consistent with the overall mandatory premerger review scheme established by Congress. The Commission believes that the final rule, with its tailored modifications based on the Agencies' experience in reviewing thousands of transactions, will result in minimal additional costs for certain filers and is preferable to adopting and maintaining a short form.

Final Instructions and Changes From the Proposed Rule

IV. Part 801

A. Sections 801.1(d)(2): Ministerial Changes To Reflect Reorganization of Form and Instructions

While the Commission will continue to use the same mechanism for electronic filing, it has re-organized the Form and Instructions, as discussed below in section VI. As a result, several ministerial changes must be made to § 801.1(d)(2). This section, which defines ''Associate'' and provides examples, currently refers to item numbers used in the current Form and Instructions. The Commission adopts revisions that align with the Form and Instructions as adopted in this final rule.

Specifically, the definition of ''Associate'' and the related examples refer to Items 6(c)(i), 6(c)(2), and 7. This information is now required by the Minority-Held Entity Overlaps and Controlled Entity Geographic Overlaps sections, which replace the previous item numbers. The Commission, accordingly, modifies the Rule to reflect these changes.

B. Section 801.1(r): Definitions of ''Foreign Entity or Government of Concern'' and ''Subsidy''

On December 29, 2022, the President signed into law the Consolidated Appropriations Act, 2023, which included amendments to the HSR Act in the Merger Modernization Act. 15 U.S.C. 18b. The Merger Modernization Act required the Commission, with concurrence of the Assistant Attorney General, and in consultation with Chairperson of the Committee on Foreign Investment in the United States, the Secretary of Commerce, the Chair of the United States International Trade Commission, the United States Trade Representative, and heads of other appropriate agencies (''Relevant Agencies''), to promulgate a rule to require persons making an HSR Filing to disclose subsidies received from countries or entities that are strategic or economic threats to the United States.

After conducting its own internal diligence to draft a rule and in consultation with the Relevant Agencies on this topic, the Commission proposed amending § 801.1 to add proposed paragraphs (r)(1) and (2), which define ''foreign entity or government of concern'' and ''subsidy,'' respectively.

The Commission received no objections to the proposed definitions and received input that they appear to be a reasonable implementation of the Merger Modernization Act. As such, the Commission adopts these definitions as proposed.

V. Part 803

A. Sections 803.2, 803.5, and 803.10: Adoption of Electronic Filing

The Commission proposed amending §§ 803.2(e) and (f); 803.5(a)(1) [319] and (3) and (b); and 803.10(c)(1)(i) and (ii) to eliminate references to paper and DVD filings and delivery to physical offices. The Commission has been successfully accepting filings electronically since March 17, 2020, as a result of the COVID–19 pandemic and resulting closures of Federal office buildings during the COVID emergency. The Commission received only one comment on this proposed change: One commenter noted that electronic filing is generally preferable and less burdensome to filing by paper or DVD. The Commission received no negative comments on the elimination of paper and DVD filings. The Commission adopts this change as proposed, though, as explained below, § 803.2(e) and (f) have been redesignated as (d) and (e), respectively.

Separately, the Commission noted in the NPRM that the Agencies were developing a new e-filing platform that would eventually replace the current mechanism for electronic filing. The same commenter stated that before seeking to impose an e-filing requirement on all parties, the FTC should provide further details regarding the proposed user interface; the ability for users to collaborate on a single filing; the ability of users to save, review, and edit; and how filing persons will receive complete copies of filings as submitted. At this time, no change has been made to the method for accepting filings. While the Form and Instructions have been updated, filers will continue to use the platform that has been in use since March 2020. The Commission continues to develop a new interface for electronic filing and will, at the appropriate time, issue a rulemaking that provides instructions and access to the new e-filing platform in advance of its effective date.

B. Sections 803.2(b), (c), and (e); 803.9(c); and 803.12(c): Ministerial Changes To Reflect Reorganization of Form and Instructions and Clarification of Time Zone

As discussed above in section IV.B., several ministerial changes must be made to the Rules to reflect the new organization of the Form and Instructions. Existing §§ 803.2(b), (c), and (e), and 803.9(c) all currently refer to item numbers used in the current Form and Instructions. The Commission adopts revisions that align the references in the Rules with the headings in the Form and Instructions as adopted in this final rule.

Additionally, existing § 803.2(b) of the Rules currently explains what information needs to be provided by the acquiring and acquired person for Items 5–8 of the current Form. As described below, the Commission adopts separate instructions for the acquiring and acquired person, making existing § 803.2(b) unnecessary. For this reason, existing § 803.2(b) is being removed, and existing § 803.2(c)–(f) are being redesignated as § 803.2(b)–(e), respectively. Further, existing § 803.2(c) and (e) have references to the current Form numbering and are being updated.[320] Similar ministerial changes are being made to §§ 803.9(c) and 803.12(c). Finally the references to time in, redesignated § 803.2(d) have been updated to specify Eastern Time, consistent with other provisions of the Rules and with longstanding practice.

C. Section 803.2: Requiring Separate Forms for Acquiring and Acquired Persons

The Commission proposed amending § 803.2(a) and deleting § 803.2(b)(1)(v) so that filing persons that are both the acquiring and acquired person are

[319] In making this change, the Commission also takes the opportunity to correct the capitalization of ''act'' to lower case to be consistent with the definitions and other usage of the term in the Rules.

[320] For purposes of consistency and clarity, the Commission is also making a ministerial change to § 803.2 to explain that documents must be provided by 5 p.m. Eastern Time. Because electronic filing permits parties to submit documents from different time zones, they will need clarity as to which time zone the Commission is referencing in the rules. The Commission notes that § 803.10 already specifies that Eastern Time should be used when determining the expiration of the waiting period as well as the date of receipt of filings and it has long been the practice of the Commission to use Eastern Time in applying this rule.

required to submit separate Forms in each capacity. The Commission proposed this change because, in its experience, filers that opt to combine the information on a single Form often do not include everything that is required and would be reported if they filed on separate Forms. Such combined filings are also very confusing for the Agencies to review. In contrast, when filers choose to submit two separate Forms for such transactions, the filings provide all the required information and in a much clearer format that allows the Agencies to quickly understand how the transaction might change the operation of the acquiring person post-acquisition.

The Commission received only one comment on this proposal, which expressed support and noted that it will enhance the understanding of the entire transaction. The Commission adopts the change as proposed but replaces the word ''should'' with ''shall.''

D. Section 803.5(b): Requiring Detailed Letters of Intent, Draft Agreements, or Term Sheets

The Commission proposed amending § 803.5(b) to require filers who have not executed a definitive transaction agreement to submit a draft agreement or term sheet describing the transaction that is the subject of the HSR Filing with sufficient detail to permit accurate analysis.[321] The Commission received numerous comments on this proposal focused on the increased burden and delay for filing parties. The Commission has adopted the proposal in the final rule with modifications that respond to these concerns.

Although filers can currently file on the basis of preliminary agreements, such as an indication of interest, letter of intent, or agreement in principle (''Preliminary Agreements''), in the Commission's experience, a small but significant minority (approximately 10%) of filings made on the basis of Preliminary Agreements do not contain enough information to permit the Agencies to conduct an accurate determination of whether the contemplated acquisition may violate the antitrust laws if consummated.[322] In addition, such filings may be made prior to significant negotiations or due diligence and can be so lacking in specifics that they could force the Agencies to expend resources on transactions too uncertain to merit review.

As discussed below, the Commission has determined that it is necessary to assure that filings are not made prematurely—before the scope of the transaction has been sufficiently determined and before the parties have engaged in enough diligence such that consummation is not merely hypothetical—and in contravention to the purpose of requiring an affidavit stating that there is a good faith intent to consummate the transaction. However, the final rule will not specifically require term sheets or draft agreements for all transactions where a definitive agreement has not been executed. Rather, the Commission will continue to require filers to submit an executed agreement but, if that agreement does not describe with specificity the scope of the transaction that the parties intend to consummate, filers must also submit an additional dated document, such as a term sheet or draft definitive agreement, that does contain sufficient details about the transaction that the parties intend to consummate. This dated document can also take other forms; the title of the document is not determinative.

One commenter sought clarity on what level of information would constitute sufficient detail as required by the proposed rule, including what types of terms that may still be subject to negotiations would render a term sheet as an insufficient basis to submit an HSR filing. The Commission agrees that the additional clarity suggested by the commenter would be helpful in reducing uncertainty. The Commission revises the Instructions accordingly, as noted in section VI.H.1., to describe what would be sufficient. The Instructions state that the transaction agreement or supplemental document should contain some combination of the following terms: the identity of the parties; the structure of the transaction; the scope of what is being acquired; calculation of the purchase price; an estimated closing timeline; employee retention policies, including with respect to key personnel; post-closing governance; and transaction expenses or other material terms. The Commission notes that these examples are meant to be illustrative and not exhaustive. In contrast, indications of interest or other agreements that merely indicate that the parties will commence negotiations or begin diligence will not be sufficient.[323]

Using the criteria adopted in the final rule, the Commission analyzed all filings that contained Preliminary Agreements submitted in FY 2021 to determine how many transactions would be impacted by the final rule.[324] Of the transactions that were submitted on the basis of a letter of intent, term sheet, or similar document that was not a definitive agreement, less than 10% did not provide the Commission with a sufficient level of detail to assess the transaction. From this data, the Commission believes that filing parties typically reach agreement on key terms prior to filing, and there would be no additional cost to them to comply with the final rule. Of those that do not reach such agreement prior to filing, the Commission believes that antitrust review is not warranted until such time as the parties have resolved key aspects of the transaction, such as those described above, because the transaction may never be consummated, or key terms may change in ways that would affect the Agencies' initial review.

The Commission believes the transaction agreement requirements of the final rule represents a middle ground between a merely conceptual deal and a ''ready to close'' deal. The Agencies need to know the key terms of the transaction to determine whether it may violate the antitrust laws if consummated. Given the short period of time given to the Agencies to make that determination, it is necessary for the transaction to be one that is likely to close. The Commission acknowledges that even with this modification, the final rule may not permit some parties to make an HSR Filing as early in their deal process as is currently permitted. However, parties will be able to file after they have agreed to material terms of the transaction even if a final agreement has

[321] NPRM at 42182.

[322] Some commenters assert that documents such as letters of intent and preliminary agreements give the agencies enough information to identify those transactions that require further scrutiny. Based on its experience over forty-five years of reviewing merger filings that include these Preliminary Agreements, the Commission disagrees that they always provide sufficient information, especially when filings are made prematurely, prior to any significant due diligence.

[323] Here is an example of the type of terms contained in agreements that have been filed with an HSR Form and conformed to existing requirements, but will no longer be accepted without filing an additional document that provides the key terms of the agreement once the final rule is effective: This letter agreement confirms the good faith intention of Alpha (''Purchaser''), to consummate the acquisition of Target, a corporation, from Beta (''Seller''), for in excess of $119.5 million and less than $235 million, subject to the terms of a definitive agreement to be negotiated and executed by them with respect to such acquisition and the satisfaction of conditions to be set forth therein. This letter agreement is non-binding and subject to satisfactory completion of due diligence, mutually acceptable definitive documentation to be negotiated between Purchaser and Seller. Purchaser will pay all filing fees in connection with all filings under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and the rules and regulations thereunder.

[324] The Commission reviewed transactions filed during FY 2021 due to the large number of filings received by the Agencies during that fiscal year, which made for a robust data sample. *See supra* note 260.

not been executed. The Commission notes that for many filings that do not contain an executed agreement today, the parties continue to negotiate final terms. The Commission expects that after the final rule, parties that have come to an agreement on key terms but have not yet signed a definitive agreement will continue to work to an executed agreement while the Agencies are conducting their antitrust review.

The transaction agreement requirements of the final rule are necessary to address a real shortcoming of allowing notification on Preliminary Agreements. As noted above, currently, some parties submit a ''letter of intent'' that substantively only states that the two parties have the good faith intent to consummate a transaction. Some documents are labeled an ''expression of interest'' in a future transaction that is similarly not specific. In the Agencies' experience, such filings are often made prior to any significant due diligence has begun and do not demonstrate that the parties have considered or agreed to key terms that would be required for consummation. Such filings require staff to dedicate time to collect facts and make an initial determination of potential illegality for a transaction that may never occur or without a sufficient basis to know the full scope of what the parties may agree to in the future. As noted in the original Statement of Basis and Purpose from 1978, because of the time and resource constraints upon the agency staff, the Agencies should not expend resources to review transactions so lacking in specifics that they could be considered merely hypothetical.[325]

The Commission has considered the additional effort required to review transactions that are filed with Preliminary Agreements and has determined that permitting filings on barebones agreements lacking sufficient details about key terms is contrary to the overall intent of the HSR Act. When a filing is made, triggering the initial waiting period, staff must start their review of the transaction and decide whether to issue Second Requests within the applicable statutory waiting period (15 or 30 days). If key terms of the transaction have not yet been established, staff may not have sufficient information to determine the potential antitrust risks. Further, if the parties have not yet begun robust negotiations or due diligence, the filing will not contain documents that provide business assessments of the transaction because such assessments have not been made. If the parties have not yet analyzed the impact of the transaction, it is not appropriate for the Agencies to begin such an assessment. This is particularly true if such assessments or negotiations lead the parties to abandon the transaction. In those cases, the Agencies will have needlessly spent scarce resources and may have burdened third parties investigating the transaction. Even if the parties do not abandon their transaction and the reviewing agency issues Second Requests, these investigations are often unnecessarily slowed down by the uncertainty surrounding the deal terms. The Commission understands that filers are anxious to get their HSR review completed so that it does not delay consummation of the transaction. But putting the burden on the Agencies to conduct antitrust assessments prematurely based on Preliminary Agreements that lack specificity undermines the purposes of the HSR Act. In addition, allowing notifications on mere expressions of interest in a future transaction creates opportunities to file as early as possible knowing that early filings put the Agencies at a disadvantage in conducting a thorough review.

Commenters raised concerns that the delay associated with negotiating additional deal terms would cause filers not to pursue beneficial transactions. One commenter claimed that as time is often of the essence in mergers, the result would be a significant chill on mergers. Another commenter contended that the proposal would deter investment in private equity and would increase costs that would likely be passed down to limited partners. Another commenter claimed that the Agencies failed to consider additional costs resulting from the additional delays in the transaction timeline.

The Commission disagrees that requiring more detail about transactions filed on Preliminary Agreements will chill M&A activity generally or for any particular type of investment. First, based on the Commission's review of filings detailed above, most reported transactions already meet the requirements adopted in the final rule. For those that do not, the Commission has identified a specific need for more detail to ensure that the reported transaction is likely to occur so that it is ripe for antitrust review. In addition, Congress identified those transactions where time is of the essence—namely, those that will be accomplished through a cash tender offer—and provided for a very short 15-day initial waiting period. For these transactions, the acquiring person does not need to file any agreement; it merely attests that its intention to make the tender offer has been publicly announced.[326] For other transactions, the Agencies need some basis to know that the reported transaction is one that is likely to occur so that they do not begin an antitrust assessment before fully understanding how the transaction will likely change the premerger market dynamics. In the Commission's experience, when parties cannot reach agreement on a few key terms within their desired timeline to consummate the transaction, that is an indication that the deal is one that is not likely to close or is likely to close on terms that are very different from the ones in the Preliminary Agreements. Finally, while the parties have an interest in starting the 30-day review period as soon as possible so that it does not unnecessarily delay their deal, the Commission has an obligation to review the transaction to determine whether it may violate the antitrust laws, and cannot effectively do so prematurely. The Commission believes that any delay associated with filers complying with the transaction agreement requirements of the final rule is necessary and justified by the benefits to the Agencies and the public in avoiding premature review of reported transactions.

Separate from the concerns about delay, one commenter expressed concerns that, as drafted in the NPRM, the Instruction arguably requires the production of the most recent draft agreement, even if a term sheet was also provided. The final rule requires filers to analyze the executed agreement to determine whether it provides sufficient detail about the transaction. If that document does not, then filers must provide one additional dated document that does sufficiently describe the transaction. The same commenter also questioned the value to the Agencies of receiving the most recent draft agreement, which they state is often slanted to reflect the views of the most recent party to circulate a draft and thus is not necessarily representative of what the definitive agreement will ultimately become. If the most recent draft agreement does not reflect the key terms of the transaction, then some other document, such as a term sheet, should be submitted. Otherwise, as described above, the filing may be premature. Further, the Commission acknowledges that certain provisions of a draft agreement that are not strictly necessary to understanding the antitrust implications of a transaction may change, sometimes substantially, and that the final definitive agreement is the most probative. However, the Commission believes that not permitting

[325] 43 FR 33450, 33511 (July 31, 1978).

[326] 16 CFR 803.5(a)(2).

filing until a definitive agreement has been reached is not necessary and could impose too great a cost due to the associated delays. The Agencies have extensive experience with reviewing draft agreements and find that even they can be probative. So long as the draft agreement and the associated executed agreement comply with the transaction agreement requirements of the final rule, the Commission will accept a supplemental document that is in draft form.

The same commenter suggested revising proposed § 803.5 to change ''will be consummated'' to ''the parties intend to consummate.'' The Commission agrees that this change in wording better captures the requirement for the parties to attest to their good faith intention to proceed with the transaction based on the submitted document and will add the phrase ''the parties intend to consummate'' to § 803.5. The Commission notes, however, that in order to satisfy the Act, parties must file and observe the waiting period for the transaction that will be consummated. Therefore, if there are material changes to the transaction after filing, the parties must continue to notify the Agencies so that they can determine whether an amended or new filing may be required. The Commission thus adopts the proposed requirement to submit a draft agreement or term sheet with the clarifications noted above.

In sum, the Commission has determined that changes to § 803.5 contained in the final rule are necessary and appropriate to prevent the Agencies from reviewing transactions for which the merging parties have not yet reached agreement on key terms. For premerger review to be timely and effective, the Agencies need some assurance that the transaction is likely to occur and that the scope of the transaction is revealed in the transaction documents submitted with the HSR Filing. The Commission has modified the final rule as compared to the proposal for this requirement to reduce the cost and delay for filers as much as practicable.

E. Section 803.8: Translation of Documents

The Commission proposed amending § 803.8 to require submission of English-language translations for all foreign-language documents submitted with the notification. Under § 803.8(a), filers currently do not need to translate these materials for the initial filing, and English-language outlines, summaries, extracts, or verbatim translations need only be provided if they already exist. Section 803.8(b), in contrast, requires that all foreign-language documents responsive to a Second Request be provided with English translations. The Commission proposed combining § 803.8(a) and (b) so that proposed § 803.8 would therefore be one paragraph requiring that verbatim English translations be provided with all foreign-language materials submitted as part of an HSR Filing or in response to a Second Request. The Commission adopts this proposed change with a revision to reduce potential confusion.

As explained in the proposed rule, when the Agencies receive key documents, such as the transaction agreements, relevant financial analyses or transaction-related assessments required by Item 4(c) with no translation at all or with unhelpful English-language outlines, summaries, or extracts, the Agencies are at a significant disadvantage during the very short period provided for initial review. The Commission received several comments on this proposal, principally regarding the burden and overall need for the proposed translation requirement. One commenter supported the proposed change, noting that with the help of modern software the cost of producing English translations should not be burdensome. The Commission agrees. As stated in the proposed rule, the Commission believes that translation tools available to the parties have become more abundant and these tools provide many options for translation that should significantly reduce the cost of providing translations. Moreover, it is important that the parties themselves provide translations because they created the documents at issue. The parties should ensure that translations are faithful to the original documents, a task that the Agencies are unable to complete, as they do not have the context or background to the transaction or companies that would be necessary to identify material errors. The Commission wants to avoid disputes over translations of these complex business documents that the parties have not reviewed.

The Commission notes that not requiring English-language translations from all entities, including foreign entities, under the current rule puts the Agencies at a disadvantage when reviewing HSR Filings with only foreign-language documents. This also creates an advantage for non-U.S. firms (whose materials are most likely to be in a foreign language). If key documents are not translated, the Agencies cannot give the transaction the same level of rigorous review and scrutiny as they do for transactions where all of the documents can be reviewed starting on the first day of the waiting period. Translation requires time that should not be taken from the short period available to the Agencies for the initial review. Time spent translating documents reduces the time available for more critical tasks, such as assessing the antitrust risk of filed transactions.

To understand the potential costs associated with requiring submitted documents to be translated, the Commission examined all HSR filings submitted in FY 2021.[327] Of the 7,002 HSR Filings that year, only 40 contained documents submitted in a language other than English and did not provide a translation. This represents fewer than 0.6 percent of filings that year. While the cost of providing translations may increase the cost of making an HSR Filing for these particular filers, the overall impact of this requirement is limited.

Beyond the issue of increased cost, some comments questioned the need to include translations with HSR Filings, especially for transactions that do not raise competitive concerns. The Commission disagrees that translations of submitted documents are not necessary for the Agencies to complete their analysis or that they are useless to the Agencies. The foreign-language versions of the documents are required by the Rules because they are responsive to specific information requests. As stated in the NPRM, the Agencies receive HSR Filings that contain only foreign-language versions of key materials, such as the transaction agreements submitted in response to current Item 3(b) of the Form, the relevant financials submitted in response to current Item 4(b), and the documents submitted in response to current Items 4(c) and 4(d) of the Form. These are the very documents that allow the Agencies to conduct a preliminary review of HSR Filings for compliance with filing requirements and to determine whether the transaction may violate the antitrust laws. Other filers submit these same types of documents in a form that staff can quickly review. Not being able to review these key materials on the first day of the waiting period puts the Agencies at a material disadvantage during their initial review.

After carefully considering the objections in the comments, the Commission continues to believe requiring translations of foreign-

[327] As noted above in footnote 260, the Agencies selected FY 2021 for this effort because of the large number of reportable transactions that year, 3,520, which provided for a robust data set. For these transactions, there were 7,002 filings, roughly two per transaction. *See* Fed. Trade Comm'n & U.S. Dep't of Justice, Hart-Scott-Rodino Annual Report, Fiscal Year 2021 appendix B (FY 2021).

language documents with HSR Filings is necessary and appropriate for the Agencies' premerger assessment, and notes that such translations may be especially important for those transactions that report foreign subsidies.[328] Despite the cost to filing parties, translations permit staff to review transactions and determine whether they require further investigation on the basis of the materials contained in the HSR Filing. With this cost in mind, the Commission invited commenters to suggest other alternatives that might achieve the Commission's goal of being able to understand and assess foreign-language documents while lessening the cost for filing parties and received a range of potential modifications to the proposal. One commented suggested that the requirement to provide verbatim translations should be limited to only final documents, not draft versions. As noted in section VI.G.1.b., the Commission has not adopted the proposal to require drafts, so no translations will be required for such documents in connection with the submission of the Form.

Commenters also proposed requiring only general summaries in English in lieu of verbatim translations, or permitting a filing party to produce a better-quality translation within a reasonable time period if the Agencies request them. The Commission acknowledges these suggestions but does not believe either presents a viable alternative to the version of § 803.8 contained in the final rule. General summaries do not provide the Agencies with a complete, detailed picture of the transaction. The Agencies' preliminary analysis of transactions often relies upon a nuanced and thorough reading of documentary attachments, and general summaries may not include facts or descriptions that the Agencies find relevant. The ability to require a better-quality translation within a reasonable time period after the submission of the HSR Filing will mean the Agencies must depend on filing parties to respond; this would likely delay Agency review within the already time-constrained initial waiting period. The time saved by the parties in preparing a summary in lieu of a translation is outweighed by the benefit to the Agencies of having a version of the underlying document available at the beginning of the waiting period.

Given the importance of having translations of key documents, the Commission adopts the proposed changes to § 803.8 but deletes the reference to ''understandable.'' The Commission believes this word is superfluous when used in conjunction with ''accurate and complete'' and may introduce confusion. Section 803.8 does not require any particular method of translation but specifies that, whatever translation method the parties choose, all verbatim translations must be readily understood, materially accurate, and complete. One commenter suggested revising the instructions to state explicitly that the submission of machine translations is acceptable. The Commission declines to state this explicitly and notes that in complying with the requirement to provide translations, parties must certify that translations are materially accurate even if they do not identify how they were created.

In sum, the Commission has determined that the translation requirement contained in the final rule is necessary and appropriate to enable the Agencies to quickly review submitted documents with English translations that have been certified as accurate.

F. Section 803.10: Commencement of Waiting Periods

The Commission proposed amending § 803.10(c)(1)(i) to clarify that filings made electronically are to be credited as received by the Agencies on the date filed if: (i) the electronic submission is complete by 5 p.m. Eastern Time; and (ii) such date is not a Saturday, Sunday, legal public holiday (as defined in 5 U.S.C. 6103(a)), or the observed date of such legal public holiday. This change codifies the current policy, and no comments were received. The Commission adopts this change as proposed.

G. Section 803.12: Information To Be Updated With Refiling

The Commission proposed amending § 803.12(c) to specify what updates would be required to the acquiring person's filing if the acquiring person chose to withdraw its HSR Filing and refile it. This procedure for voluntary withdrawal and refiling permits the acquiring person to restart the initial waiting period, providing the Agencies an additional 15 or 30 days (depending on the transaction type) to review the transaction without issuing a Second Request, as long as certain conditions are met. Currently, the rules require updates to Items 4(a), 4(b), 4(c), and 4(d). The NPRM proposed changes to § 803.12(c) including: eliminating the requirement to provide updated financials, currently required by Items 4(a) and (b); requiring updated Transaction-Related Documents with the updated HSR Filing; requiring updated transaction agreements; and requiring updated information about subsidies from Foreign Entities of Concern. The Commission adopts the proposed change with modifications to reflect ministerial changes to the names of sections of the Form.

The Commission received one comment on this proposal that noted that the proposal would impose a significant additional burden on the merging parties by requiring them to conduct a new search for Transaction-Related Documents with an expanded set of custodians. According to this commenter, it would also discourage the parties' use of pulling and refiling, and divert agency resources away from the review of other reported transactions.

Parties who withdraw and refile under § 803.12(c) must already search for new documents responsive to current Items 4(c) and 4(d). The basic requirement to search for new Transaction-Related Documents remains largely the same with the addition of only a single new custodian (the supervisory deal team lead, as defined) and a clarification that versions sent to any member of the board of directors (or similar body for non-corporate entities) are responsive and should not be treated as draft documents. The search required is a limited one, reaching back at most to the 15 or 30 days since the original filing was made. The Commission notes that these newly created documents and updated agreements are material to the Agencies' evaluation of the transaction and the determination of whether to issue a Second Request. Additionally, a change in information about subsidies may also be material and, until the Agencies have more experience with receiving this information, as required by Congress, parties must also provide updates to this item. The Commission therefore adopts the proposal with changes made to the names of the sections in the Form and Instructions.

VI. Part 803 Appendix A and Appendix B

Below, the Commission describes the changes to the appendices to Part 803, the Form and the Instructions. As discussed in section V.A., the Commission will continue to use the same electronic filing mechanism that has been in place since March 2020. Therefore, the Commission now provides a Form which will be available on the FTC's website in Microsoft Word format to collect the information required by the Instructions. Additionally, as discussed in section V.B., separate forms will be required for

[328] NPRM at 42182–83.

parties that are filing both as acquiring and acquired persons for related transactions. As a result, and to aid parties in understanding which provisions are applicable to acquiring persons and which are applicable to acquired persons, the Commission has now provided separate Instructions and Forms for acquiring and acquired persons. This change has also allowed the Commission to simplify the language of some of the instructions, such as by defining ''target'' to include all acquired entities or assets and eliminating use of phrases such as ''acquiring person or acquired entity as appropriate'' that were included in the draft instructions. Other ministerial changes to aid readability of the Instructions are also noted below.

For ease of reference, the Commission includes the following materials regarding the adopted Instructions and Form:

- An outline of the organization of the Form and Instructions,
- A chart that identifies proposed new locations of the current Items of the Form and Instructions, including whether substantive changes are adopted, and
- A chart of the new categories of required information.

These materials appear immediately below.

Instructions Outline

- General Instructions and Information
- Fee Information
- General Information
- Ultimate Parent Entity Information
  - UPE Details
  - Acquiring Person or Acquired Entity Structure
  - Additional Acquiring Person Information (Acquiring Person Only)
- Transaction Information
  - Parties
  - Transaction Details
  - Transaction Description
  - Additional Transaction Information
  - Joint Ventures (Acquiring Person Only)
  - Business Documents
  - Agreements (Acquiring Person Only)
- Competition Descriptions
  - Overlap Description
  - Supply Relationships Description
- Revenues and Overlaps
  - NAICS Codes
  - Controlled Entity Geographic Overlaps
  - Minority-Held Entity Overlaps
  - Prior Acquisitions
- Additional Information
  - Subsidies from Foreign Entities or Governments of Concern
  - Defense or Intelligence Contracts
  - Voluntary Waivers
- Certification
- Affidavits

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Cross Reference Between Current Form and Final Rule:

Current Form Item	New Location	Substantive Changes?
Fee Information	Fee Information	No
Corrective Filing	General Information	No
Cash Tender Offer	General Information	No
Bankruptcy	General Information	No
Early Termination	General Information	No
Foreign Jurisdictions	Transaction Information/Transactions Subject to International Antitrust Notification	Yes
Item 1(a)	Ultimate Parent Entity Information/UPE Details	No
Item 1(b)	Separate Forms will Identify Acquiring and Acquired Person, No Combined Form	No
Item 1(c)	Ultimate Parent Entity Information/UPE Details	No
Item 1(d)	Ultimate Parent Entity Information/UPE Details	No
Item 1(e)	Ultimate Parent Entity Information/UPE Details	No
Item 1(f)	Transaction Information/Parties	No
Item 1(g)	Ultimate Parent Entity Information/UPE Details	No
Item 1(h)	Ultimate Parent Entity Information/UPE Details	Yes
Item 2(a)	Transaction Information/Parties, Transaction Description	No
Item 2(b)	Transaction Information/Transaction Details	No
Item 2(c)	Transaction Information/Transaction Details (Acquiring Person Only)	No
Item 2(d)	Transaction Information/Transaction Details	No
Item 3(a) (Entities)	Transaction Information/Parties	No
Item 3(a) (Description)	Transaction Information/Transaction Description	Yes
Item 3(b)	Transaction Information/Agreements	Yes
Item 4(a)	Ultimate Parent Entity Information/UPE Details, Acquiring Person or Acquired Entity Structure	Yes (Natural Persons)
Item 4(b)	Ultimate Parent Entity Information/UPE Details, Acquiring Person or Acquired Entity Structure	Yes (Natural Persons)
Item 4(c)	Transaction Information/Business Documents	Yes
Item 4(d)	Transaction Information/Business Documents	No
Item 5(a)	Revenue and Overlaps/NAICS Codes	Yes
Item 5(b)	Transaction Information/Joint Ventures (Acquiring Person Only)	Yes
Item 6(a)	Ultimate Parent Entity Information/Acquiring Person or Acquired Entity Structure	Yes
Item 6(b)	Ultimate Parent Entity Information/UPE Details	Yes
Item 6(c)(i)	Revenue and Overlaps/Minority-Held Entity Overlaps	Yes
Item 6(c)(ii)	Revenue and Overlaps/Minority-Held Entity Overlaps (Acquiring Person Only)	Yes
Item 7(a)-(d)	Revenue and Overlaps/Controlled Entity Geographic Overlaps	Yes
Item 8(a)	Revenue and Overlaps/Prior Acquisitions	Yes

New Requirements and Categories of Information:

New Sections	Location
New Definitions	General Instructions and Information
Translations	General Instructions and Information
Identification of Additional Minority Interest Holders	Ultimate Parent Entity Information/UPE Details
Organization of Controlled Entities	Ultimate Parent Entity Information/Acquiring Person or Acquired Entity Structure
Identification of d/b/a	Passim
Description of Ownership Structure of the Acquiring Entities	Ultimate Parent Entity Information/Additional Acquiring Person Information (Acquiring Person Only)
Organizational Chart for Funds and Master Limited Partnerships (If One Exists)	Ultimate Parent Entity Information/Additional Acquiring Person Information (Acquiring Person Only)
Identification of Certain Officers and Directors	Ultimate Parent Entity Information/Additional Acquiring Person Information (Acquiring Person Only)
Description of the Business of the Acquiring Person	Transaction Information/Transaction Description (Acquiring Person Only)
Identification of Related Transactions	Transaction Information/Transaction Description
Mandatory Disclosure of International Antitrust Notification	Transaction Information/Transaction Description (Acquiring Person Only)
Transaction Rationale	Transaction Information/Additional Transaction Information
Diagram of the Transaction (If One Exists)	Transaction Information/Additional Transaction Information (Acquiring Person Only)
Production of Certain Documents of the Supervisory Deal Team Lead	Transaction Information/Business Documents
Production of Certain Plans and Reports	Transaction Information/Business Documents
Expansion of Transaction Agreements to be Produced	Transaction Information/Agreements
Identification of Other Agreements Between the Parties	Transaction Information/Agreements (Acquiring Person Only)
Description of Overlaps	Competition Descriptions/Overlap Description
Description of Supply Relationships	Competition Descriptions/Supply Relationship Description
Identification of Franchisees with Revenue Overlaps	Revenue and Overlaps/Controlled Entity Geographic Overlaps
Identification of Additional Prior Acquisitions	Revenue and Overlaps/Prior Acquisitions
Disclosure of Subsidies from Foreign Entities or Governments of Concern	Additional Information
Identification of Certain Defense or Intelligence Contracts	Additional Information
Voluntary Waivers for International Competition Authorities	Additional Information
Voluntary Waivers for State Attorneys General	Additional Information
Statement of Penalties for False Statements	Certification

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A. General Instructions and Information

The Commission proposed creating a General Instructions and Information section within the proposed Instructions that largely parallels the General section of the current Instructions but is significantly reorganized and includes a ministerial change to clarify what information is found on the PNO website. Within the proposed General Instructions and Information section, the Commission proposed substantive changes to the following sections: Definitions, Identification of the Filing Person, Responses, and Translations. As discussed below, the Commission adopts some of the changes as proposed, adopts others with modification, and does not adopt others. In addition, in order to effectuate separate, tailored Forms and Instructions for the acquiring and acquired person, and to enhance clarity, the Commission adopts certain ministerial changes discussed below.

1. Definitions and Explanation of Terms

a. Economic Research Service's Commuting Zones

The Commission proposed adding a definition for Economic Research Service's Commuting Zones to facilitate responses to proposed requirements related to labor markets. The Commission received several comments on the Economic Research Service's Commuting Zones, and all cited the burden of this proposal. Many noted that the U.S. Department of Agriculture

has not updated these metrics since 2012, which makes them unreliable as a basis for determining the geographic scope of labor markets. As the Commission is not adopting the information requirements for employees in the final rule (see section VI.I.3.), the Commission does not adopt this definition.

b. Fee Information

The Commission adopts a ministerial change related to this item. As a result of the new fee structure mandated by Congress in the Merger Modernization Act, the fee information description now refers to the adjusted fees and fee tiers.

c. North American Product Classification System Data

The Commission proposed eliminating the reporting of 10-digit North American Product Classification System (''NAPCS'') based codes, and, as a result, proposed deleting the NAPCS definition from the proposed Instructions. The Commission received one comment on the elimination of the NAPCS definition; the comment supported the proposed streamlining of manufacturing revenue reporting. The Commission adopts this change as proposed. See section VI.J.1. for further discussion on the elimination of NAPCS-based codes.

d. Notification Thresholds

The Commission adopts a ministerial change related to this item. Currently, the section entitled ''Thresholds'' discusses filing fee and notification thresholds as a single item. With the fee changes that were enacted in the Merger Modernization Act, these are now separate thresholds. As discussed in section VI.A.1.b., ''Fee Information'' discusses the fee tiers. The definition of ''Notification Thresholds'' now discusses only the notification thresholds that are defined in § 801.1(h).

e. Standard Occupational Classification

The Commission proposed adding a definition for Standard Occupational Classification (''SOC'') codes to facilitate responses to proposed requirements related to labor markets. As the Commission is not adopting information requirements for employees in the final rule that would require reporting on this basis (see section VI.I.3.), the Instructions do not contain a definition for SOC codes.

f. Select 801.30 Transactions

As discussed in section III.C., the Commission received many comments that objected to the burden of the new requirements as proposed. Among the objections were claims that the proposed requirements reached transactions that typically were not investigated by the Agencies, that the burden of the new requirements could slow the pace of some transactions and deter others, and that the burden would fall not just on acquiring persons but on target companies that did not initiate or consent to the transaction. One commenter urged the Commission to exempt from HSR reporting requirements certain transactions that the Agencies rarely challenge, including acquisitions of voting securities that do not transfer control of the target company. The Commission acknowledges these comments, and while it disagrees that there is any category of transaction for which all of the adopted proposals should not apply, it does agree that exempting certain transactions from some of the new requirements will not inhibit the Agencies' ability to understand the transaction and determine that it warrants further investigation. To that end, the Commission limits the amount of information required for the notification of certain transactions subject to § 801.30 that also meet specific conditions.

Section 801.30(a), first promulgated by the Commission in the original rules, defines certain types of transactions in which the consent of the acquired person may not be required.[329] These transactions include acquisitions made on the open market, via tender offers, through the exercise of warrants or options, or through the conversion of non-voting securities. The involvement of the acquired person varies across these transactions. In some instances, such as an investor acquiring voting securities on the open market, the acquired person does not have to agree to the transaction and may not even have knowledge of it. In others, the acquiring and acquired person both assent to the deal. For example, some transactions are effectuated by a tender offer or the acquisition of purchases on the open market or from third parties—making § 801.30 applicable—but are also subject to an agreement between the acquiring and acquired person.

When the agreement of the acquired person is not required in a transaction, the Commission believes that certain requirements of the final rule are unlikely to provide information necessary to determine whether that transaction may violate the antitrust laws. Several commenters agreed that in such transactions the target in particular would not be able to provide the new information required in the final rule in the short time they have to make their filing. Further, in such transactions, the acquired person may not know that it has a filing obligation until the acquiring person has filed and will have limited time to prepare its filing. For this select set of transactions, the Commission has determined that it is not necessary to collect certain information, particularly in light of the costs that would be imposed on these types of filings which often carry low antitrust risk. Therefore, the Commission, adapting suggestions from the comments, introduces and defines the term ''select 801.30 transactions.'' Select 801.30 transactions are those transactions that do not result in the acquisition of control to which § 801.30 applies and where there is no agreement or contemplated agreement between any entity within the acquiring and acquired person. An example of a select 801.30 transaction includes an acquisition of voting securities on the open market via a national exchange by an investor that has no other ties to the issuer and which acquisition does not result in the acquisition of control. Additionally, select 801.30 transactions include acquisitions resulting from a traditional executive compensation arrangement where the executive exercises contractual benefits pursuant to a compensation package to acquire voting securities and nothing more.

In addition to excluding transactions in which there is an agreement between the acquiring and acquired person, the definition of ''select 801.30 transactions'' excludes transactions that would result in the acquiring person obtaining control, as defined by the Rules, of the acquired entity or where the acquiring person has obtained or will obtain certain rights related to the board of directors, general partner, or management company of an entity within the acquired person. These excluded transactions are likely to require a more thorough review for potential antitrust risk, and therefore it is necessary and appropriate for the Agencies to receive some additional information related to them as contemplated in this rulemaking. The Commission uses the term ''select 801.30 transaction'' throughout the discussion below, and transactions that meet the definition will not be required to respond to certain items as part of the Commission's efforts to limit costs to filing parties in response to the comments. See Figure 3.

[329] 16 CFR 801.30(a); *see also* 43 FR 33450, 33483 (July 31, 1978).

g. Supervisory Deal Team Lead

As discussed in section VI.G.1, the Commission proposed that, in addition to requiring documents prepared by or for officers and directors in response to current Item 4(c), filing persons must also submit transaction-related documents prepared by or for supervisory deal team lead(s). This proposal targeted documents authored by or for the person who functionally led the deal team even if not an officer or director. In the Agencies' experience with Second Request responses, these documents often include information that would have been highly relevant to the Agencies' analysis of the transaction during the initial waiting period to determine whether Second Requests should issue and what additional information they should seek. The Commission adopts this definition to limit the proposal to a single individual and provide clarity regarding identification of the appropriate individual.

The proposed rule noted that the identification of any supervisory deal team lead would not be based upon title alone and that this addition would require the filing person to determine the individual or individuals who functionally lead or coordinate the day-to-day process for the transaction at issue. A supervisory deal team lead need not have ultimate decision-making authority but would have responsibility for preparing or supervising the assessment of the transaction and be involved in communicating with the individuals, such as officers or directors, who have the authority to authorize the transaction. In the proposal, any such individual(s) might be the leader(s) of an investment committee, tasked with heading the analysis of mergers and acquisitions, or otherwise given supervisory capacity over the flow of information and documents related to transaction.

The Commission received many comments on its proposal to require current 4(c) documents from the supervisory deal team lead(s). Several comments noted that the proposed Instructions do not offer a definition of supervisory deal team lead(s) and that the proposed rule's description of the term was vague, ambiguous, and subjective, leaving filers uncertain which individuals must be searched in addition to officers and directors. One comment stated that the term was neither defined nor self-explanatory, and the proposal's descriptions of what constitutes a supervisory deal team lead(s) offers two separate standards. Yet another comment noted that the description could potentially describe a company's entire corporate development team.

Concerns about the meaning of the term ''supervisory deal team lead'' led a number of commenters to propose a definition. One commenter suggested limiting supervisory deal team lead to the senior most member of the corporate development deal team responsible for driving the strategic vision and assessment of the deal, who would not otherwise qualify as an officer or director. Another commenter suggested it should be the most senior member of a filing party's deal team responsible for the company's strategic vision and who otherwise would not qualify as a director or officer. Also, another commenter offered that supervisory deal team lead(s) should be expressly defined to mean the individual with primary responsibility for supervising the assessment of the transaction, and that it should only be one person.

The Commission acknowledges that a definition of supervisory deal team lead in the Instructions would help filers accurately identify the appropriate individual to be searched for responsive materials. The Commission notes that many of the comments' proposed definitions provided useful contours to help define the term. As discussed above, certain commenters suggested a definition that the relevant individual have responsibility for business strategy associated with the transaction under review. The Commission agrees that centering the definition on the ''primary responsibility'' for the strategic assessment of the deal will help identify the correct individual.

The Commission also agrees that the definition should focus on one supervisory deal team lead to mitigate any confusion or uncertainty raised in the comments about having two or three supervisory deal team leads. As discussed in section VI.G.1., several commenters also raised concerns with the burden associated with collecting documents from additional custodians, particularly if multiple individuals fulfilled that role.

The Commission therefore adopts a new definition for ''supervisory deal team lead'' as the individual who has primary responsibility for supervising the strategic assessment of the deal, and who would not otherwise qualify as a director or officer. This definition focuses on the one person who oversees the strategic assessment of the transaction and it should mitigate the concerns of some commenters that the term is so vague that it might introduce uncertainty as to when the initial HSR waiting period begins. These commenters explained their concern that Agency staff may become aware of another employee who would better constitute a supervisory deal team lead than the individual selected by the filer and reject the filing. In response to comments that requiring filers to select a supervisory deal team lead will allow the Commission to reject filings, the Agencies will continue to rely on filers to certify to their good faith belief in completing and certifying to the accuracy of the filing, and the Agencies will continue to rely on that good faith. In the situation where the only individuals supervising the strategic assessment of the deal are already either an officer or director, filers can state that this is the case and identify an officer or director as the supervisory deal team lead.

h. Target

For additional clarity in the instructions, the Commission introduces and defines the term ''Target'' as a ministerial change. The target includes all entities and assets to be acquired by the acquiring person from the acquired person and eliminates the need to use the inadvertently confusing phrase ''the acquired entity(s) or assets'' throughout the Instructions. The Commission notes, however, that the Instructions do continue to use ''acquired entity(s)'' in certain instances where a question may not be relevant to the acquisition of assets.

i. Year

As part of the Commission's effort to add more clarity to the Instructions, the Commission makes a ministerial change to the definition of ''most recent year'' found in the definition of ''year'' to make clear that the ''most recent year'' is the most recently completed calendar or fiscal year. This is the current intent of the definition and consistent with the guidance that has been given informally and with how filing persons complete the form and provide information.

2. Filing as an Acquiring and Acquired Person

As discussed in section V.C., the Commission adopts the proposed changes to § 803.2 such that filing persons will be required to submit separate forms when filing as an acquiring and acquired person. Additionally, the Commission has created separate, tailored Forms and Instructions for the Acquiring and Acquired Person. Since filers will choose the appropriate Form for the filing, the Commission adopts the ministerial change to eliminate the question, currently Item 1(c), asking the

filing person to identify whether the filing is being made as an acquiring or acquired person.

3. Responses

In the new Responses section, the Commission proposed setting out the specifics of how filers would provide the information responsive to the proposed new questions. The revisions included eliminating instructions regarding filings made on paper or DVD, see above at section IV.A; the Commission adopts these changes as proposed. The proposed responses section also described the information that filing persons would need to provide in a log of responsive documents and descriptive responses to be submitted with an HSR Filing. This information would have generally been the same as the information currently required for documents submitted in response to Items 4(c) and 4(d) of the current Form, with two proposed expansions. The first would have required the filing person to identify the request(s) to which the document would be responsive. The second would have required the identification of the individual within the acquiring or acquired person who supervised the preparation of documents prepared by third parties, or for whom the document was prepared. The Commission adopts the proposal with modifications to reflect the layout of the Form and to reduce the burden for transactions that do not have either a NAICS overlap, see section VI.J., or overlap or supply relationship identified in the Competition Descriptions, see section VI. I.

The Commission received two comments regarding the new Responses section, both of which focused on the proposed requirement for filing persons to provide the name, title, and company of the individuals within the filing person who supervised the preparation of third-party documents or for whom the documents were prepared. One commenter expressed concern that the proposal could put certain fund employees at risk of violating their nondisclosure agreements with target companies. Another commenter noted that there is minimal if any value to the Agencies having this information for every single reportable transaction, but collecting and filing a comprehensive list of all the people who may have supervised the creation of these documents will require many hours of work.

The Commission acknowledges the cost but disagrees that this information is not valuable or informative. In the Agencies' experience, knowing the authors of documents assists in the evaluation of the documents as well as any subsequent investigation by providing context regarding who was involved in the preparation of the document. Currently, the Agencies do not receive this context for documents prepared by third parties. Therefore, for documents prepared by third parties, such as consultants or bankers, the Commission adopts the proposal for the filing person to identify the individual or individuals who supervised the production of such documents, or for whom the document was prepared. This information will not be required for documents that were provided to the parties without solicitation, or for documents provided to the acquiring or acquired person by the other party.

As part of the Commission's overall effort to reduce the burden on filing parties, the Commission has revised the proposal to only require authors (or the individuals that supervise the creation of documents) for filings in which there are NAICS overlaps, or overlaps or supply relationships identified in the Competition Descriptions. For those transactions where such an overlap or supply relationship has been identified, filers will be required to provide the same author information as is currently required for documents responsive to Items 4(c) and 4(d), as well as the individuals within the filing person who supervised the preparation of third-party documents or for whom the documents were prepared. The Commission notes that these third-party documents are already required. The additional information is related to the identification of the individuals within the acquiring or acquired person, so no new non-disclosure risks should result from the requirement. Finally, because the Form requires identification of the file name for each document submitted, the ''Responses'' section does not require a document log. A privilege log will still be required.

4. Translations

As noted in section V.E., the Commission amends § 803.8 to require the filing person to submit English translations of all foreign-language documents. The Instructions also reflect this change.

5. Non-Compliance

While the Commission does not make any changes to the explanation of ''non-compliance,'' it does emphasize that if the filer is unable to answer any question fully, it is required to provide the information that is available and provide a statement of reasons for non-compliance consistent with § 803.3 and as permitted by the HSR Act.[330] Further, where exact answers cannot be given, filers are allowed to enter best estimates, while indicating the source or basis of the estimate and marking the information with the notation ''est'' for any item where data are estimated. The Commission routinely accepts filings and commences waiting periods for filings that avail themselves of this procedure. For example, publicly traded filers are often unable to identify with certainty their minority shareholders, and instead provide information that has been filed with the SEC. The Commission did not propose any changes to this Instruction and does not change it now.

B. Fee Information

Although the Commission proposed moving the filing fee information to the Transaction Information section of the proposed Instructions, in the final Form and Instructions, filing fee information will instead be collected in its own section. The Form also includes new areas for filing persons to indicate whether the fee is being paid by more than one entity, and if so, how much each entity will pay. Additionally, the Commission adopts a ministerial change to eliminate the need to provide Taxpayer Identification or Social Security Numbers and the name of the institution, such as the bank, from which the fee will be paid. The Commission has determined that it no longer needs this information to identify filing fees, and parties therefore no longer need to provide it.

C. General Information

The General Information section of the Form and Instructions requires filing persons to indicate whether the transaction is a post-consummation filing, cash tender offer, or bankruptcy, and whether early termination of the transaction is requested—information that is currently collected on the first page of the Form. The Commission did not propose and does not adopt any material changes to these items.

D. Ultimate Parent Entity Information

1. UPE Details

The UPE Details section of the Form and Instructions requires information about the UPE of the acquiring or acquired person, including contact information, financial documents, and information about certain minority shareholders or interest holders. Much of this information is currently required by Items 1, 4(a) and (b), and 6(b). The Commission proposed (1) requiring

[330] 15 U.S.C. 18a(b)(1)(A)(ii).

contact information for the individual to whom Second Requests should be sent; (2) clarifying the instructions related to the provision of financial documents for natural person UPEs; (3) requiring filers to stipulate that the appropriate size of person threshold is met, if applicable; (4) identifying additional minority holders of entities within the acquiring person; and (5) reducing the types of minority holders of the acquired entity that must be reported. As discussed below, the Commission adopts some of these proposals without change and some with modification.

a. Contact Information

The Commission proposed that all filers, not just foreign filers, must identify the individual to whom Second Requests should be addressed. The Commission received no comments on this change and adopts it as proposed.

b. Annual Report and Audit Reports of the UPEs

This section requires information currently required by Items 4(a) and 4(b) as it pertains to the UPE of the acquiring or acquired person. Annual and audit reports of other entities within the acquiring and acquired person are required by the Acquiring and Acquired Person Structure section, as discussed in section VI.D.2.b. The Commission proposed clarifying the current instructions regarding which annual reports and audit reports are required from natural person UPEs. The Commission makes no change to the instruction that natural person UPEs should not produce any personal balance sheets or tax returns. Since natural persons should not provide personal financial information, no information should be provided in the UPE section. The Commission did not propose and does not make any change to the annual or audit reports required of the UPE of the acquiring or acquired person.

The Commission did propose clarifications regarding what other annual and audit reports entities within the same person as natural person UPEs must provide. This proposed clarification is discussed in section VI.D.2.b.

c. Size of Person Stipulation

The Commission proposed adding an item on the Form that would allow filers to stipulate that the size of person test is met (at the appropriate dollar amount) or indicate that the size of person test is not applicable. The Commission received no comments on this change and adopts it as proposed.

d. Minority Shareholders or Interest Holders

The Commission proposed a Minority Shareholders or Interest Holders section to require identification of minority interest holders of certain entities within the acquiring person and the acquired entities. Currently, Item 6(b) requires acquiring persons to identify minority holders of 5% or more but less than 50% of the acquiring entity and the UPE of the acquiring person (or, for natural person UPEs, the highest-level entities they control). Acquired persons are required to report such minority holders of the acquired entity. For UPEs of the acquiring person, acquiring entities, and acquired entities that are limited partnerships, only disclosure of the general partner is currently required.

The Commission proposed several changes to require additional information about the identity of minority holders, as well as identification of additional minority interest holders by the acquiring person, but potentially fewer by the acquired person. First, the Commission proposed requiring disclosure of the ''doing business as'' or ''street name'' of minority investors that are related to a master limited partnership, fund, investment group, or similar entity. Second, the Commission proposed to expand the entities for which the acquiring person must identify certain minority interest holders to include entities related to the acquiring entity. Third, the Commission proposed requiring the identification of certain minority holders of limited partnerships, rather than just the general partner. Finally, the Commission proposed limiting the minority interest holders that acquired persons would need to identify. The Commission adopts the first two proposals without change but modifies the limited partners that need to be identified, as discussed below.

(i) Provision of ''Doing Business As'' or ''Street Names''

First, the Commission proposed that the acquiring person provide the doing business as or ''street name'' of minority investors that are related to master limited partnerships, funds, or investment groups. The Commission did not receive comments on this specific proposal but did receive comments to similar proposed requirements in other areas of the Instructions. Objections in these other sections generally focused on the lookback period and the burden of searching for all names that were potentially used by a business. In this section, the Commission did not propose a lookback period, but instead proposed requiring only the current name of the related master limited partnership, fund, investment group, or similar entity.

The Commission continues to believe that this information should not be costly for filers. In many cases, communication between the acquiring person and the investor will include this information. For example, though the minority investor may be RANDOMNAME, LLC, the acquiring person regularly communicates with INVESTMENT GROUP and sends information related to the investment in care of that business. However, if this information is not known to the acquiring person, it can so note in a statement of non-compliance.

The task of screening transactions for potential competitive effects is stymied when filers provide only legal names, which are often unrelated to the name by which the public knows the business. Knowing the d/b/a or street name of the entities involved in the transaction allows staff to use public resources to gather additional information, for example through internet searches or look-ups using commercial services relied on by the Agencies to provide industry data. Because of the value to the screening process, the Commission adopts this requirement as proposed.

(ii) Identification of Additional Minority Investors in the Acquiring Person

The Commission next proposed two changes that could increase the number of minority investors the acquiring person would need to identify: First, it proposed that the acquiring person be required to report holders of 5% or more but less than 50% of (1) the acquiring entity, (2) any entity directly or indirectly controlled by the acquiring entity, (3) any entity that directly or indirectly controls the acquiring entity, and (4) any entity within the acquiring person that has been or will be created in contemplation of, or for the purposes of, effectuating the transaction. Second, it proposed that filing persons report holders of 5% or more but less than 50% of limited partnerships, in addition to the general partner.[331]

Comments on these two proposed changes were similar and often intertwined. One commenter urged the Agencies to collect the proposed new information and stated that the ownership structure resulting from the

[331] This change also relieved natural person UPEs from the obligation to identify minority shareholders of all top-level entities, instead only requiring identification for entities related to the transaction.

transaction may change the parties' incentives to compete, enhance the acquirer's ability to influence decision making through changes in voting interests or governance rights, or facilitate the sharing of competitively sensitive information between rivals. Two others also supported the proposal, with each noting the various potential anticompetitive impacts of minority interests. Specifically, one commenter stated that these new requirements would address complex corporate structures, which may obscure potentially significant relationships. The other commenter also supported providing more information about shareholders, particularly since the current Form and Instructions can treat portfolio companies of private equity funds as independent from each other and their management companies.

Broadly, critics of these proposed changes expressed concerns about the burden of collecting the requested information. Additional criticisms included objections to the five percent threshold for identification, with commenters stating that the interests of such minority investors may be wholly unrelated to the notified transaction, or less likely to result in a substantial lessening of competition. Concerns were also raised about confidentiality and disclosure, noting the Commission's prior consideration of the fact that the identity and investment level of limited partners is often highly confidential when it decided in 2011 not to require disclosure of limited partners. Commenters further speculated that requirements to disclose the identity of additional minority investors could create a chilling effect on fundraising and deals. Finally, commenters stated that such a decrease in fundraising and deal volume could affect smaller businesses, pension plans, endowments, charitable foundations, and activist investors, among others. Each of these objections is discussed below.

(a) Identification of Minority Holders of Additional Entities

Regarding the first proposal to expand the entities for which minority holders must be identified, the Commission notes that until 2011 acquiring persons were required to report minority holders of 5% or more for all corporate entities within the acquiring person that had assets of $10 million or greater. As part of the 2011 rulemaking, the Commission determined that this broad requirement, which could reach entities within the acquiring person that had no nexus to the reported transaction, was not essential to an initial review of the transaction.[332] Through this change, the Commission expanded the requirement to include identification of minority holders of non-corporate entities, but it limited the obligation for the acquiring person to the identification of minority holders of only the acquiring UPE and the acquiring entity. As a result, the Agencies receive information about what entities have a ''seat at the table'' in the case of very simple corporate structures where the acquiring person UPE directly controls the acquiring entity without any intermediary entities, or where intermediary entities are wholly owned by the acquiring person, without the acquiring person providing information about entities unrelated to the transaction.

Since 2011, however, the Commission has learned through experience that many acquiring persons have more complex structures that include many entities between the UPE and acquiring entity that are not wholly owned but that are related to the acquiring entity. For example, ''A'' plans to acquire a target and will bring in ''B'' as a co-investor. The UPE of ''A'' creates (or already has) a number of intermediary entities within its person to effectuate the transaction. ''B'' does not invest in either the UPE of ''A'' or the entity that will make the acquisition, but rather in one of these intermediary entities. Currently, as illustrated in Figures 4 and 5a, when ''A'' makes its filing, it is not required to disclose the co-investment of ''B'' so long as the investment is below 50%. The current focus on just the UPE and the acquiring entity deprives the Agencies of key information about individuals and entities that may have influence, or even management or operational oversight, over entities related to the transaction and could make or influence competitively important decisions post-acquisition.

[332] 75 FR 57110, 57118 (Sept. 17, 2010); 76 FR 42471, 42472 (July 19, 2011).

Figure 4: Current Rules Only Requires Disclosure of Minority Holders (or General Partner) of A

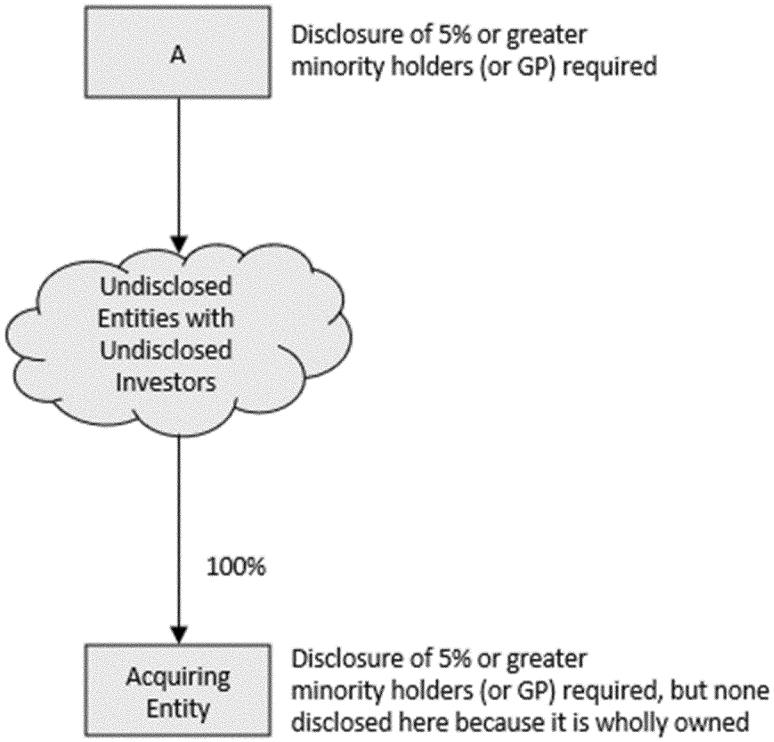
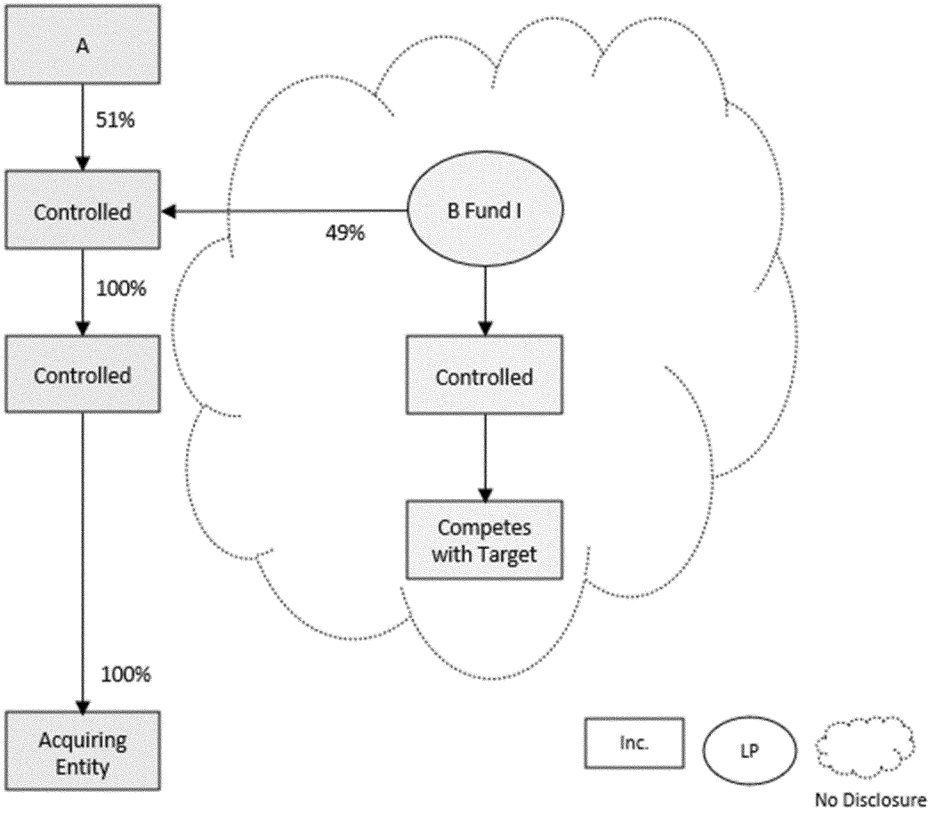
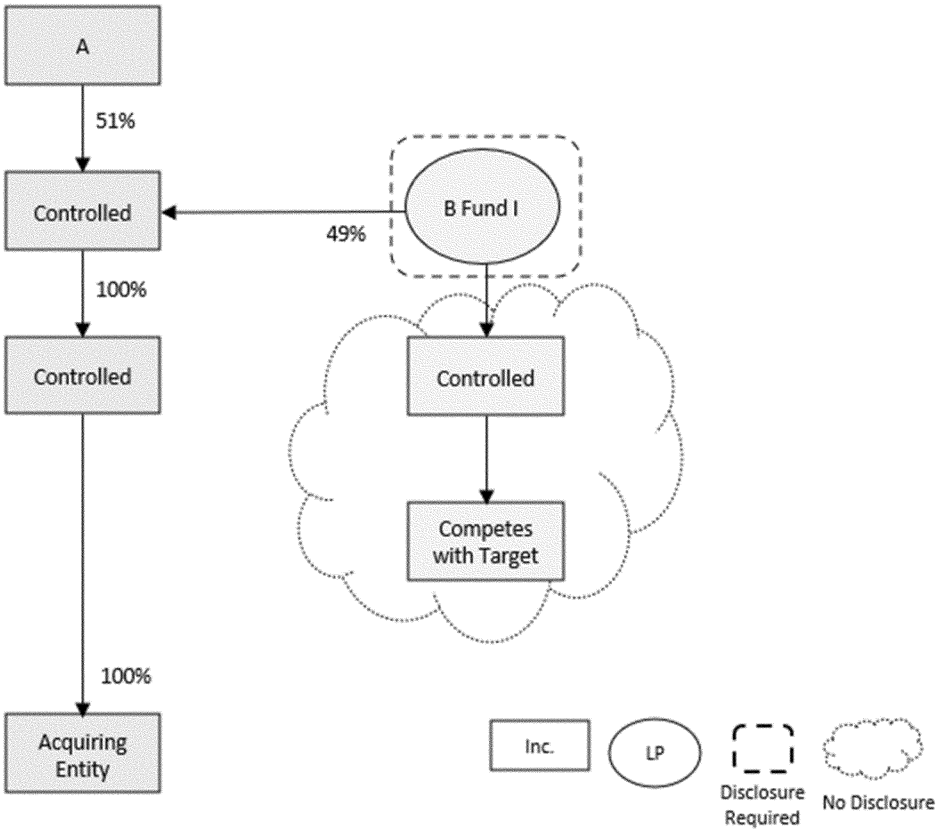


Figure 5a: Current Rules Do Not Require Disclosure of B Fund as a Co-Investor in the Acquisition; No Ability for Agencies to Know to Research B Fund's Other Holdings



As discussed in section II.B.1., and illustrated in Figure 5a, individuals or entities that have significant rights or holdings in entities related to the acquiring entity may also take active positions in or exert control over competitively significant businesses, including competitors, and the disclosure of these relationships could surface antitrust risks that require the Agencies' attention during the initial antitrust review. Because information that reveals whether there are existing investment relationships between the acquiring person and the target is necessary and appropriate for the Agencies' initial antitrust review, the Commission adopts this change as proposed. As a result, as shown in Figure 5b, the Agencies will receive the information necessary to determine whether the acquisition of the target by the acquiring entity may violate the antitrust laws.

Figure 5b: Final Rules Require Disclosure of B Fund; Agencies Know to Research B Fund's Other Holdings



In objecting to these proposals, commenters stated that identification of these additional minority holders would be burdensome. The Commission notes that, rather than merely reviving an expansive requirement to disclose all the minority investors of entities within the acquiring person, it proposed a more tailored instruction to require disclosure only of the entities related to the transaction. Given this limitation and the information gaps caused by vast changes to the M&A landscape discussed in section II.B.1., the Commission believes that the identification of the minority holders of the entities that are related to the transaction is necessary and appropriate and should be contained in an HSR Filing. Further, if the acquiring person does not have knowledge of the identity of the minority investors, it can so indicate and explain, just as acquiring persons currently do when the minority investors of the UPE or acquiring entity are unknown.[333] For example, acquiring persons that have publicly traded UPEs routinely note that they do not have information about minority holders beyond what is reported to the SEC.

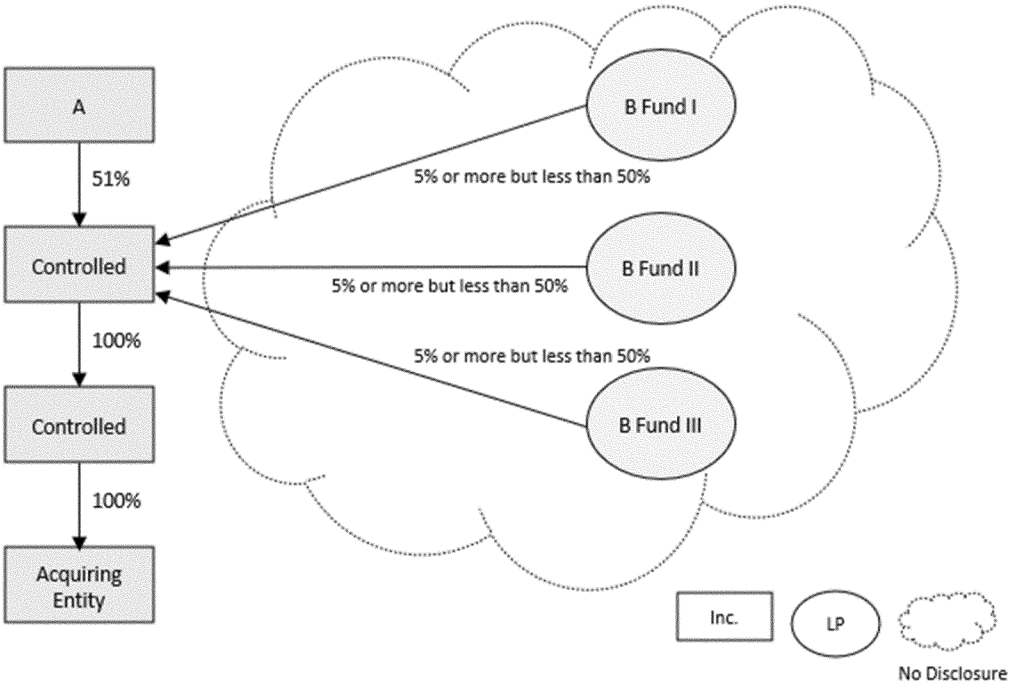
One commentor stated that the ''direct or indirect'' and ''control or controlled by'' language was broad and would require substantial time and resources to navigate. The Commission disagrees and notes that this requirement does not require a broad analysis of various theories of control but rather requires a determination of ''control'' as defined by § 801.1(b). The proposed instruction stated that the controlling relationship can be either direct or indirect to make clear that the requirement was not limited to entities just one level above or below the acquiring entity. For example, in a common scenario involving multiple shell entities, the acquiring UPE controls an intermediary entity that controls an intermediary entity that controls the acquiring entity, as shown in Figure 6a below. The Instructions contained in the final rule require disclosure of minority holders of five percent or more of each of those intermediary entities, subject to the limitations on disclosure of limited partners discussed below in section VI.D.1d.ii., as shown in Figure 6b. Control is a long-standing concept in the Rules, and the determination of control in this context is consistent with control determinations that filers need to make for a variety of items currently included in the Form and Instructions.

The Commission received suggestions to change the existing five percent threshold but declines to adopt this change. Because of the complexity of investment structures, minority investors with even low equity stakes can have formal rights to direct or influence the strategic decisions of the company, informal channels to exert influence, or the right to obtain sensitive business information about the entity in which they are invested. Further, as illustrated in Figures 6a and 6b, investment groups may be broken up

[333] See also the discussion of non-compliance in section VI.A.5.

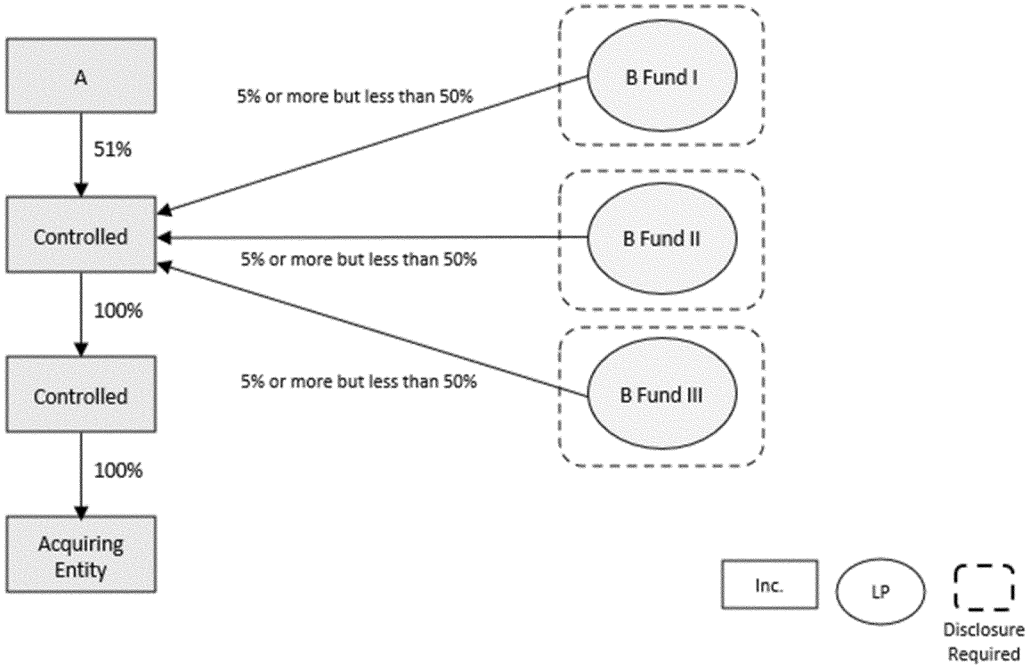
across multiple entities that are, for HSR purposes, separate persons.[334] These types of organizations can take active positions in multiple companies in the same or related industry, a trend that the Commission and commenters have observed. As a result, the Agencies need to know who these investors are in order to determine whether the acquiring person has connections to the target's business that could have competitive effects.

Figure 6a: A Single Investment Group May Divide Its Investment; Current Rules Do Not Require Disclosure if Investments Are Not Made in A or Acquiring Entity



[334] In 2020, the Commission proposed changing the HSR Rules to require aggregation of such interests when determining whether a filing must be made. 85 FR 77053 (Dec. 1, 2020). The Commission has not adopted any of those proposals. This more modest proposal to identify minority shareholders does not create any new obligations to file but does provide the Agencies with the identity of funds and other investors that hold, or will hold, interests in entities related to the acquiring entity through multiple HSR persons, allowing for further investigation as warranted.

Figure 6b: Final Rules Require Disclosure Regardless of the Entity In Which B Fund Invests



The Commission disagrees with the commenters' assertions that this information is not necessary to assess the competitive effects of the filed for transaction and is beyond the authority of the Commission. As discussed in section II.B.1., that analysis requires the Agencies to understand the scope of the acquiring person's involvement in the business of the target. Minority holders of entities within the acquiring person that are related to the acquiring entity may have the ability to influence decision-making of the acquiring entity and target post-acquisition. Therefore, they are functionally ''in the deal'' and their existing business relationships are relevant to a thorough antitrust analysis of the transaction. The increasing complexity of corporate structures and investment vehicles has increased the number of transactions with these types of minority interest holders, and the Commission has determined that the Agencies need to update the information requirements to keep pace with these changes.

The Commission finds the additional critiques of the proposal unpersuasive as well. The Commission addresses arguments about chilling deal volume and investment levels in section III.C.2. above. As to commenters opposing this particular change to the Instructions, the Commission is unaware of any evidence that fundraising or deal volume was negatively affected during the period prior to 2011 when HSR rules required broader disclosure of minority investors, nor that such activity increased when the requirement was dropped. Given the many other factors that influence the level of investment and M&A activity generally, the Commission believes it is unlikely that the disclosure of minority holdings in parties involved in reportable transactions has any measurable effect on dealmaking or investment levels.

Further, commenters objecting to the Agencies' need for identification of additional minority interest holders also offered contradictory critiques, with some stating that the Commission did not identify transactions where the minority interest holders were relevant to the competition analysis, and others stating the fact that the Commission offered two examples demonstrated that the current Form and Instructions provided the Agencies with sufficient information. First, cases cited in the NPRM provide examples of enforcement actions brought by the Agencies on various legal theories and fact patterns and do not necessarily reflect cases that were discovered through the HSR process. Second, the need for this information is obvious and its relevance plain: the Agencies need to know who will be making decisions for the combined entity post-acquisition. For example, the hypotheticals discussed above demonstrate that existing information gaps in the current Form leave the Agencies without enough information to even know to ask additional questions about additional individuals and entities within ''A.'' In the hypotheticals above, ''B'' could hold up to a 49.9% stake in an entity related to the transaction and functionally jointly control the acquiring entity along with ''A.'' Or ''B'' could hold only 5% but have ancillary rights or outsized influence over the operations of the acquiring entity (and thus the target after consummation). Or ''B'' could be its own person for HSR purposes, but one of several related entities that each has a minority interest that, when aggregated, account for a significant, or even majority, stake in the acquiring entity. In any of these scenarios, as well as many others, the identity of the minority interest holder would be critical to understanding the competitive implications of the transaction. Though the filing requirement falls on ''A,'' ''B'' has a seat at the table, and the Agencies must be able to investigate whether ''B'' has ties

to the business of the target. If the Agencies are not alerted to the existence of ''B'' on the Form, there is no ability to screen for potential issues that arise from ''B's'' involvement in both the acquiring entity and, upon consummation, the target.

Regarding concerns about privacy, the Commission notes that the contents of HSR filings are confidential.[335] Unlike requirements for disclosure made by private parties or government rules promulgated to require public disclosure, information included in HSR filings is protected by statute. Additionally, disclosure of minority investors, other than limited partners, which are discussed below, is already required by the current Form. The proposal to require identification of additional minority investors, including some limited partners, is an incremental expansion of what is currently required (and for corporate entities, less than what was required under the HSR Rules from 1978 to 2011). Additionally, the Agencies often require disclosure of an even broader group of minority investors, including limited partners, in response to a Second Request, as discussed in more detail below. The proposed requirements, therefore, did not introduce any new privacy concerns, and commenters did not offer any evidence that the current disclosure rules have created any substantive issues related to privacy.

The Commission further notes that the proposed requirements do not require the acquiring person to ask the minority investors for any information. Therefore, completion of the Form itself should impose no burden on the minority investors themselves. Only if the identity of the minority investor reveals a competitively relevant connection and an investigation is opened would the investor potentially have any cost. These costs are not imposed by the information requirements of Form and Instructions but rather by a potential investigation or enforcement action for a violation of the antitrust laws. Disclosure of an existing business or financial relationship in an entity that is engaging in an HSR-reportable transaction is not an improper burden and allows the Agencies to fulfill their statutory mandate to scrutinize every filing to determine whether it may violate the antitrust laws.

(b) Identification of Limited Partners

In addition to increasing the number of entities for which minority shareholders would need to be identified, the Commission also proposed requiring the identification of minority investors of limited partnerships that held 5% or more, in addition to the general partner. Filing persons are currently only required to identify the general partners of limited partnerships, but not limited partners, regardless of the percentage held. After considering the comments received regarding this proposal, the Commission adopts a modified requirement to identify only the general partner and limited partners that have certain rights related to the board of directors (or similar bodies) of entities related to the acquiring entity.

The current requirement to identify only the general partner of limited partnerships, and not its minority investors, was based on the understanding that limited partners had no control over the operations of the fund or portfolio companies.[336] As discussed above and in section II.B.1., the operations and investments of limited partnerships and limited partners cannot be easily generalized. Though some argue that limited partners may have limited influence over investment or operational decisions, this is not universally true. Limited partnerships often file for acquisition of control of entities. Investment groups, which utilize limited partnerships, often make investments in specific industries, leaving open the possibility that there is a competitive relationship between these investments and the target of the filed-for transaction.

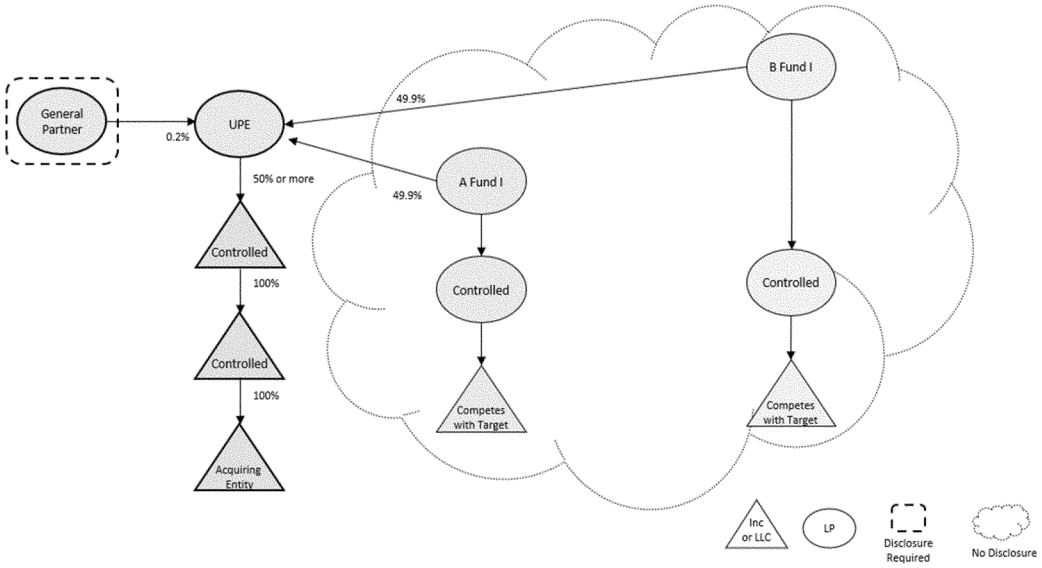
Further, the Commission has learned through its work that limited partnerships are not exclusively used as vehicles for diffuse groups of passive investors to invest their capital. Instead, some limited partnerships function as aggregation vehicles that allow private equity or other investor groups to direct the strategic business decisions of the portfolio companies in which they invest. The decision to organize as a limited partnership rather than an LLC or incorporated entity may be driven not by how the entity will function in the marketplace but by other factors, such as tax and liability.

The scenario in Figure 7a illustrates how the current Form and Instructions' lack of information about limited partnerships can affect a preliminary antitrust assessment. ''A'' and ''B'' form a new limited partnership that will be an acquiring person. ''A'' and ''B'' will each hold 49.9% of this entity and will have rights related to the board (or similar bodies) of entities related to the transaction. The remaining 0.2% will be held by the general partner. Pursuant to the current Instructions, this newly formed acquiring person would not be required to provide any information other than the name and address of its general partner when making a filing for a reportable transaction.

[335] 15 U.S.C. 18a(h).

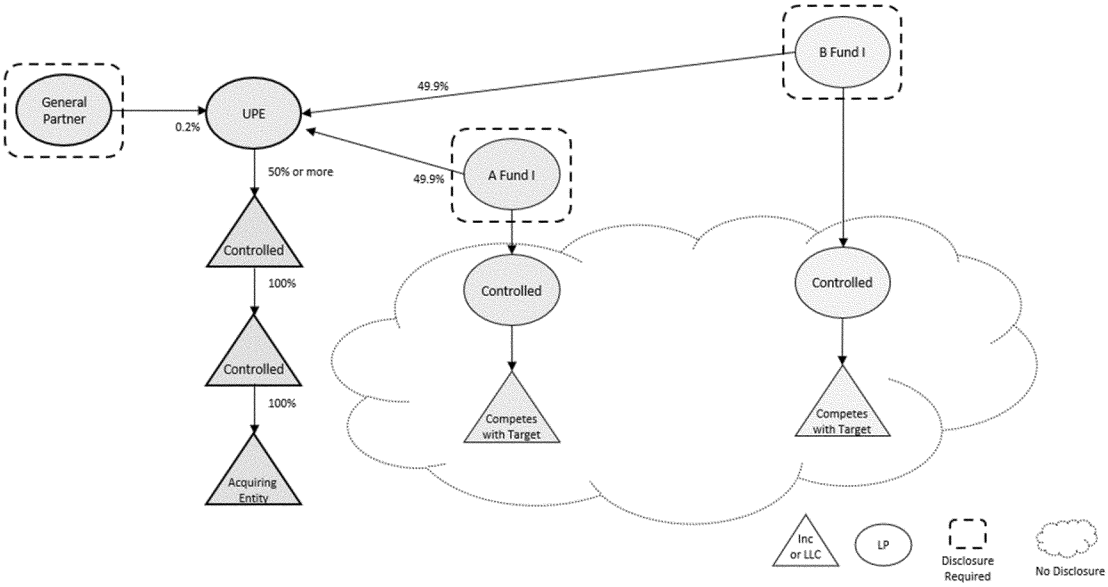
[336] 75 FR 57110, 57118 (Sept. 17, 2010) (proposed rule), *adopted* 76 FR 42471 (July 19, 2011).

Figure 7a: Current Rules Only Require UPE to Disclose Name and Address of Its General Partner; No Disclosure that A and B are Functional Buyers of Target



Compounding the difficulty in understanding the scope of the acquiring person's relationships, A Investment Group and B Investment Group may have used a code name for the transaction, such as ''Project Alpha,'' and also used that code name to name the newly created entity. In this scenario, the Agencies could receive a filing from Alpha Fund, L.P., that only discloses that it has a general partner, Alpha GP, L.P. There is no requirement that Alpha Fund, L.P. disclose that A Investment Group and B Investment Group each hold nearly 50% and will effectively co-own and manage the target after consummation. A Fund I or B Fund I could be head-to-head competitors of the target (or control competitors of the target) or have some other competitively significant relationship with the target. But the current Form would not make the Agencies aware of their significant stake in Alpha Fund, L.P. As shown in Figure 7b, the final rules address this by requiring the identification of A Fund I and B Fund I (and their affiliations with A Investment Group and B Investment Group, if known to UPE), allowing the Agencies to research whether the transaction may violate the antitrust laws.

Figure 7b: Final Rules Require UPE to Disclose Name and Address of Its General Partner and the Investment of A Fund I and B Fund I; Agencies Know to Research Holdings of A and B

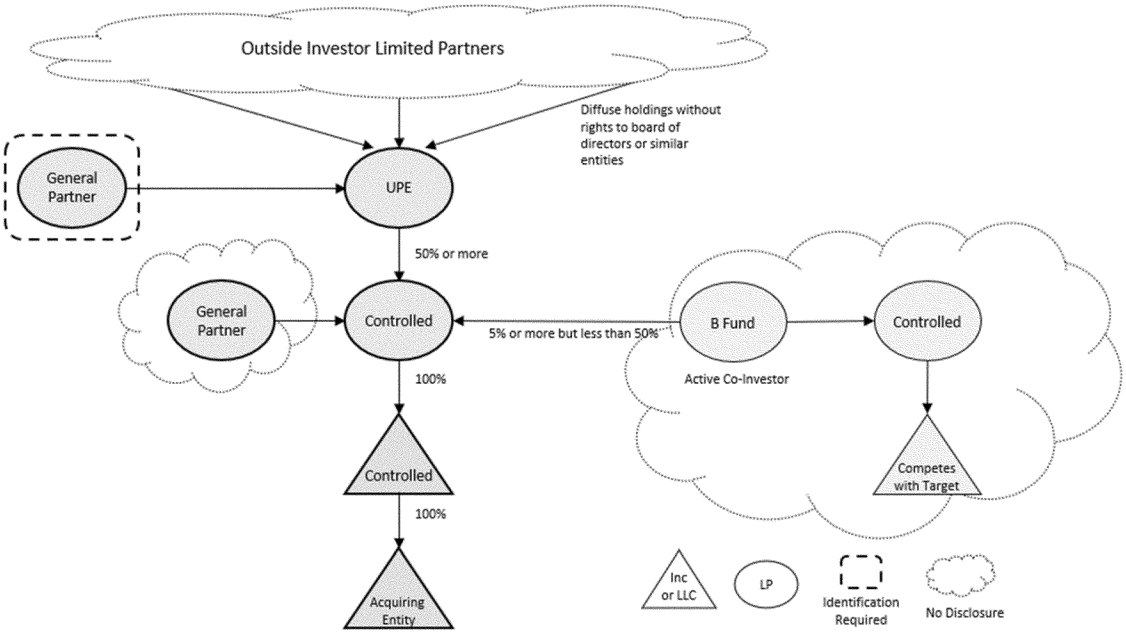


The Commission notes, as did one commenter, that in some instances the Agencies may receive some disclosure through the reporting of associate overlaps in current Items 6(c)(ii) or 7(b)(ii) and 7(d). However, many

investment groups are set up such that the associate definition, which focuses on entities, does not apply, even though the same individuals may be managing multiple funds. The Commission considered changing the definition of associates but determined that, at this time, it would be less complex and less burdensome on filers to merely require the identification of certain limited partners, which the Commission believes will allow the Agencies to use other sources to conduct a preliminary assessment of the competitive implication of these minority holders. If this proves to be insufficient, the Commission may revisit the requirements in future rulemakings.

Despite the need for identification of some limited partners, the Commission understands that there are still many limited partners who are essentially ''silent'' investors that do not participate in management decisions. They hold only financial interests for the purpose of earning a return on their investment and do not hold additional rights or participate in the governance or business operations of the limited partnership or the investments of the limited partnership. Therefore, the Commission adopts an incremental change for the identification of limited partners, implementing in part the suggestion of one commenter to require only limited partners that have certain rights related to the board of directors or similar bodies of entities related to the acquiring entity.[337] The hypothetical in Figure 8a shows a structure where the UPE of the acquiring person is a limited partnership in which its limited partners do not have any rights related to the board of directors or similar bodies of any of the UPE, Acquiring Entity, or either of the two Controlled entities between them. Additionally, UPE controls a limited partnership in which B Fund, an active co-investor for the transaction, has made its investment. Currently, UPE is only required to disclose its general partner.

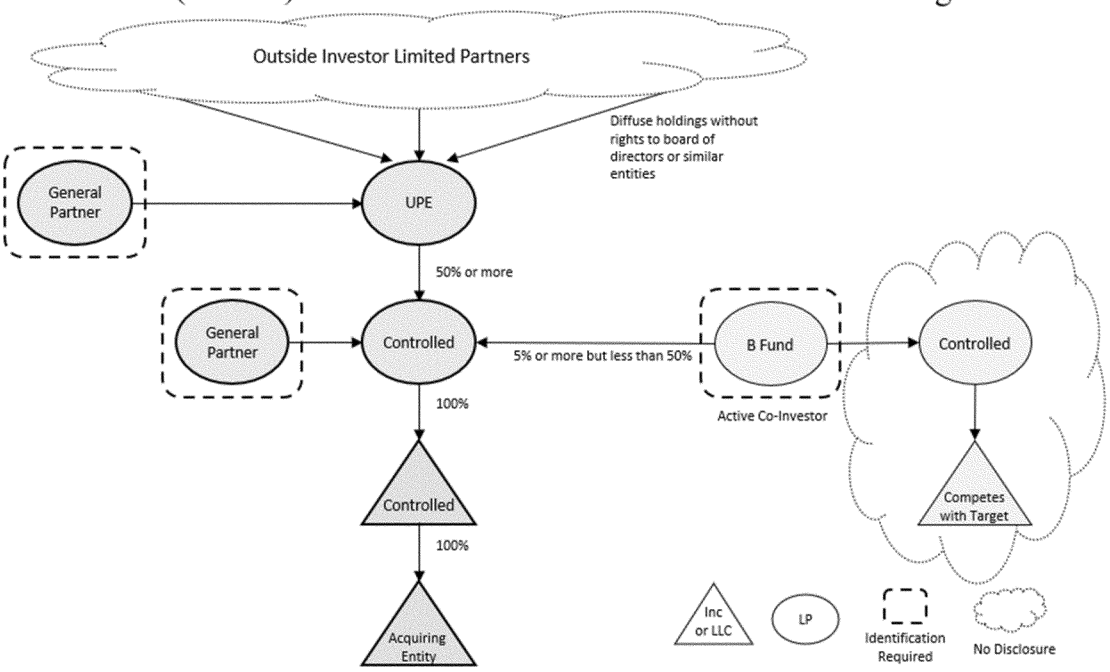
Figure 8a: Current Rules Only Require UPE to Disclose the Name and Address of Its General Partner



As shown in Figure 8b, the final rules would not require the disclosure of the ''Outside Investor Limited Partners'' because none has any rights to the board or similar body of an entity related to the acquiring entity. In contrast, UPE would need to disclose that B Fund is a limited partner of the Controlled entity as well as the general partners of UPE and Controlled LP.

[337] Comment of Dechert, Doc. No. FTC–2023–0040–0659 at 11 (commenting that it is not clear why a broad requirement to disclose all limited partners who hold interests of five percent or more is necessary to identify a potential competitive concern irrespective of such limited partners' ability or inability to participate in the management or control of the applicable fund, general partner, or acquired business).

Figure 8b: Final Rules Require UPE to Disclose General Partners and its Active Co-Investor (B Fund) But Not Passive Limited Partners or the Holdings of B Fund



In the Commission's experience, competitive concerns that arise from limited partners holding interests in the acquiring person most frequently stem from those limited partnerships that act as vehicles for investor groups to manage, direct, or influence the portfolio companies in which they invest. The Commission has determined that it is not necessary to know the names of limited partners that do not also have certain management rights and the final rule does not require disclosure of their minority interests.

The Commission expects that this modification will address concerns of commenters that disclosing limited partners would require investment firms to renegotiate agreements with limited partners. As discussed above, there is no restriction on the Agencies' ability to require disclosure of the identity of limited partners today during an in-depth investigation of the transaction. As a result, limited partners should be aware that their holdings may be relevant to an antitrust review of any transaction involving one of their investments. Indeed, the Commission has brought enforcement actions against acquisitions involving minority holdings of limited partners in competing businesses.[338] As the agencies charged with enforcing the antitrust laws, the Agencies have the authority to investigate the commercial dealings of limited partners for potential law violations regardless of any private agreements that promise non-disclosure. Therefore, any deficiency in agreements to permit disclosure to government agencies already exists. Further, if disclosure is the source of the Agencies' being made aware of a potential competitive concern with the transaction, any cost to the limited partner related to the completion and submission of the HSR Filing is justified because the information is necessary to determine whether the transaction may violate the antitrust laws. Nonetheless, the Commission has modified the requirement to reduce the type of limited partners that must be disclosed, focusing only on those with the ability to participate in management or control. On this basis, filers can exclude limited partners who serve as passive investors, who are essentially the customers of private investment firms, according to one commenter. To the extent that these limited partners do not participate in the management of the filing person, they need not be disclosed as a minority holder.

(iii) Limiting Requirements for Acquired Persons

Finally, the Commission proposed limiting the reporting requirements for the acquired person. Currently, the acquired person must identify the name and headquarters address of all holders of 5% or more but less than 50% of the acquired entity, along with the percentage held. If the acquired entity is a limited partnership, only identification of the general partner and its headquarters address is required. The Commission proposed limiting this requirement to minority holders of the acquired entity that would hold an interest after that consummation or would receive an interest in another entity within the acquiring person as a result of the transaction. However, the proposed requirements to identify certain limited partners also applied to the acquired person, if the minority investors will stay with the target post-acquisition. The Commission adopts this proposal with modification.

The proposed limitation to identify only minority interest holders of the target that will remain invested after consummation is intended to reduce the cost of complying with the final rule for the acquired person. The Commission has determined that the identity of any minority interest holder of the target that will cease to be involved with the target or acquiring person post consummation has limited relevance to understanding who could influence decision-making of the business post-

[338] *See, e.g., In re Red Ventures Holdco, LP,* No. C–4627 (F.T.C. Nov. 3, 2017) (overlapping limited partnership holdings violated section 7); *In re TC Group, L.L.C.,* No. C–4183 (F.T.C. Mar. 16, 2006) (acquisition involving minority stake giving two private equity investors seats on the boards of competitors).

acquisition. The Commission adopts this portion of the proposed rule. It modifies the proposed instruction to reflect the modification it adopts for the identification of limited partners, as described above. Thus, the final rule will require the acquired person to only identify minority holders of 5% or more if such holder will continue to be invested in the target or will acquire an interest in an entity within the acquiring person. If the target is a limited partnership, only limited partners (1) that hold 5% or more in the acquiring entity, (2) will continue to hold an interest in the acquired entity, or acquire an interest in the acquiring person, after the transaction is consummated, and (3) will have that have certain rights related to the board of directors or similar bodies of entities related to the acquiring entity will need to be identified. If the acquired person does not have this information, it can so note in an endnote.

The Commission also notes that one commenter focused on the requirement to identify roll-over investors, stating it would be a new burden that would discourage continued post-transaction investment. The Commission disagrees with this assessment. Currently, the acquired person already must identify all 5%–49.9% holders of the acquired entity, including roll-over investors. Further, the Commission once again notes that the amount of information required is limited; only the name of the minority interest holder (and the name of the master limited partnership, fund, or investment group, if applicable), its headquarters address, the name of the acquired entity it holds an interest in, and the percentage held must be disclosed.

2. Acquiring Person and Acquired Entity Structure

The Acquiring and Acquired Person Structure sections of the Form and Instructions require the reporting of information currently required by Items 1(f), 4(a) and (b), and Item 6(a). The Commission proposed that filing parties provide more information about the structure of the acquiring person and acquired entity, as well as the names under which they do business. The Commission also proposed a clarification regarding annual reports and audit reports of natural person UPEs. As discussed below, the Commission adopts some of these proposals without change and some with modification.

a. Entities Within the Acquiring Person and Acquired Entity

This section contains information currently required by Items 1(f) and 6(a) of the current Form. The Commission proposed requiring filing persons to organize the list of controlled entities by operating company or business, and, for each such operating company or business, the Commission proposed that filers identify the name(s) by which the company or business does business, as well as any name(s) by which it formerly did business within the three years prior to filing. The Commission adopts the proposal with modification.

The Commission received several comments opposed to this proposal. One commenter stated that the Agencies do not need to know the relationships between and among all related entities for its initial review of the HSR filing. The commenter asserted that the majority of covered entities will likely have no overlapping activities with the acquired company, and thus learning about them adds no value to the Agencies' initial screen. The Commission disagrees that the Agencies do not need this information and that it adds no value to the initial screen. This is the very information that allows the Agencies to understand what businesses are involved in the reported transaction.

The Commission does, however, make several modifications to these proposals that should reduce the cost of providing this information. The Commission adopts the proposal to require DBA names but does not adopt the proposal to adopt ''formerly known as'' (FKA) names. One commenter noted the difficulty of providing ''doing business as'' names for filing parties that do not maintain such records, but the Commission believes these DBA names will be of great value to the Agencies in the initial waiting period. Businesses create (or change) DBA names for a variety of reasons and may be required to register these names with State or local authorities. One commenter objected to the three-year period, and, as part of its overall efforts to reduce costs associated with an HSR Filing, the Commission eliminates this lookback so that filing parties must only provide this information as it stands at the time of filing.

Another commenter recommended that for executive compensation transactions the filing persons be permitted to dispense with the requirement to report ''doing business as'' names, assuming certain conditions are met. They stated that these transactions are unlikely to generate meaningful antitrust issues but that requiring prior business names will add materially to the burden on the acquired side without a corresponding benefit. The Commission agrees and as part of its overall effort to reduce cost, adopts the modification to allow both filing parties in select 801.30 transactions (which include those related to executive compensation) to provide this information as kept in the ordinary course without DBA names.

Finally, one commenter noted that the proposed rule appears to use the terms ''operating business,'' ''operating entity,'' and ''operating company'' interchangeably. The commenter requested clarification of the definitions or adoption of one term for consistency. The Commission agrees that using these three terms interchangeably is confusing and thus adopts ''operating business'' to capture entities that comprise distinct operations. Under this modification, filing parties need to organize their response by operating business(es) whether they are corporations, non-corporate entities, or assets that function as an operating business.

In sum, the Commission adopts modifications that require filing persons, except for those in select 801.30 transactions, to organize controlled entities at the time of filing by operating business and, for each such operating business, identify the name(s) by which the operating business does business. For example, a fund must organize its response by portfolio company(s), and a conglomerate must organize its response by business(es).

b. Annual Report and Audit Reports

Information for this section is currently required by Items 4(a) and (b). The Commission proposed clarifying the current instructions regarding which annual reports and audit reports are required from natural person UPEs. Currently, natural person UPEs, in lieu of personal financial documents, must produce financial documents for the highest-level entity(s) within their person. In addition, natural person UPEs must produce the same additional reports that non-natural person UPEs must produce: for acquiring persons, the reports of the acquiring entity(s) and any entity controlled by the acquiring person whose dollar revenues contribute to an NAICS overlap; and for acquired persons, the reports of the acquired entity(s). The Commission proposed new language to make this requirement clearer and the Commission adopts this change with modification.

The Commission received one comment that supported the proposal. Another commenter suggested two

revisions to the proposed Instructions. This commenter first suggested that for natural person UPEs who filed as acquired persons, the instructions should only require the most recent annual reports for the highest-level entity the Natural Person controls that includes the assets or entities being sold. Second, as a general matter, the commenter stated that persons filing notification should not be required to provide annual reports for entities that have less than $10 million in total assets, unless that entity's revenues contribute to a competitive overlap between the parties.

In considering the two suggested revisions in this comment, the Commission agrees that it is sufficient for the UPE of the acquired person to provide financial reports for only the highest-level entities that control the acquired entity, as appropriate, in lieu of providing personal financial documents. The Commission also has determined that this limitation is appropriate for acquiring persons with natural person UPEs as well. Therefore, the Commission adopts this suggestion, and natural persons, in lieu of providing personal financial statements, will need only provide financial reports for the highest-level entities that control the acquiring entity or acquired entity, as appropriate. The financial information for these highest-level entities should be provided in this section and not the UPE Details section, as discussed in section VI.D.1.

The Commission declines to adopt the suggestion that persons filing notification should not be required to provide annual reports for entities that have less than $10 million in total assets, unless that entity's revenues contribute to a NAICS overlap or any overlap identified in the Overlap Description. ''The person filing notification'' is a defined term for the purpose of the Instructions and is limited to the UPE. Therefore, other than for natural persons, the proposed Instructions only require reports from the UPE and, for the acquiring person, acquiring entity(s) and entities that contribute to a NAICS overlap, and for the acquired person, the acquired entity(s), which is consistent with the current requirement. The Commission finds these reports valuable, regardless of whether those entities have $10 million in assets.

3. Additional Acquiring Person Information

The Commission proposed requiring additional information about the acquiring and acquired person. These proposals included a description of the ownership structure of the acquiring person and acquiring entity as well as an organizational chart if the acquiring person UPE is a master limited partnership or fund, information about other types of interest holders that may exert influence over the acquiring person, and the identification of officers, directors, and board observers of the acquiring person and acquired entity. As discussed below, the Commission adopts some of the items as proposed, adopts some of the proposals as modified, and does not adopt others.

a. Ownership Structure

The Commission proposed that acquiring persons provide a description of the ownership structure of the acquiring entity and, for fund or master limited partnership UPEs, an organizational chart sufficient to identify and show the relationship of all the entities that are affiliates or associates. The Commission also proposed that acquired persons describe the ownership structure of the acquired entity.

The Commission did not receive any comments regarding the requirement to provide a description of the acquiring and acquired entities' ownership structure. The Commission believes that such descriptions will provide information and nuance about ownership structures that may not be clear from a simple list of minority holders. Moreover, descriptive responses allow filers to offer clarification about the structure, including whether the ownership structure is subject to change between filing and consummation of the transaction. As a result, the Commission adopts this item as proposed for the acquiring person. However, this information is less relevant from the acquired entity. As part of its efforts to reduce the cost related to filing where possible, the Commission does not adopt the proposal for the acquired person.

As for the proposed requirement for the acquiring person to provide organizational charts, commenters noted that organizational charts are not always kept in the ordinary course of business, and structures may be so complex that they cannot be synthesized into a chart. The Commission acknowledges that there may be some cost associated with creating organizational charts just for the purpose of making an HSR Filing and modifies this item to require charts that show the relationship of entities that are affiliates or associates if such charts exist, even if they were created for other purposes. The Commission declines to adopt the suggestion to limit this requirement to transactions where there is an identified NAICS or product or service overlap. These charts are necessary for staff to understand the totality of the transaction, including the role of key decision makers and their responsibilities relative to the business lines under review.

The complex structure of investment entities is not adequately captured by the current Form, and there is often no other source for Agencies to learn of these relationships. Information about the acquiring entity's ownership structure is therefore necessary and appropriate for the Agencies to evaluate the transaction at issue. The Commission has modified the proposal to limit the reporting costs by requiring only the acquiring person to provide a description of its ownership structure and to provide organizational charts only if they exist.

b. Other Types of Interest Holders That May Exert Influence

The Commission proposed an Other Types of Interest Holders that May Exert Influence section that would have required the acquiring person to identify certain individuals or entities, beyond those with the minority interests discussed above, that may have material influence on the acquiring entity and entities related to it. These included certain individuals or entities that (i) provide credit; (ii) hold non-voting securities, options, or warrants; (iii) are board members or board observers or have nomination rights for board members or board observers; or (iv) have agreements to manage entities related to the transaction. As discussed below, while understanding these relationships can be very important in assessing the competitive effects of certain transactions, the Commission has elected not to adopt proposals (i), (ii), and (iv) at this time. As discussed in section VI.D.3.c., the Commission adopts with modification the proposal to require identification of officers and directors, which incorporates some of proposal (iii).

The Commission received several comments in support of the proposed change to disclose other types of interest holders. One commenter stated that disclosure of these interest holders would be helpful to close a loophole when the filing parties may have influence or joint profit maximizing incentives with rivals. Another commenter noted that the information would also enable the Agencies to assess conflicts of interest or the potential for inappropriate sharing of competitively sensitive information. Other comments highlighted the

importance of identifying situations in which a single creditor to competing firms could have an incentive to facilitate their coordination or collusion as well as situations in which a private lender may assert control or an investor may have a dual role as private provider of leveraged loans to finance buyouts.

The Commission also received several comments opposed to these proposed changes. Critics noted that some of this information may not be available at the time of filing or would be burdensome to collect and report. Others questioned the utility of the information. Another commenter noted that it will not be readily apparent whether identified entities or individuals have overlaps, supply, or other relationships relevant to the target.

In regards to identifying certain creditors, commenters stated that in the vast majority of credit arrangements, the creditor's rights and financial incentives are distinctly different than those of equity holders and that many creditors are unable to control investment decisions. In addition, one commenter observed that these disclosure requirements could impede access to credit, which would seriously impact private equity as its deals frequently rely on third-party financing. Several commenters also expressed concern about the burden of identifying and describing complex credit arrangements, particularly for infrequent filers.

Regarding the proposed requirement related to non-voting securities, options, or warrants, one commenter questioned the necessity of the information to examine the anticompetitive effects of any proposed transaction, noting that, in exempting acquisitions of non-voting securities from filing, Congress must have concluded, based on the legislative history, that such acquisitions pose no anticompetitive threat. No specific comments were received with respect to the proposed requirement to identify individuals or entities that have agreements to manage entities related to the transaction.

The Commission disagrees with assertions that information about individuals or entities that can influence the acquiring person through mechanisms such as credit relationships, non-voting interests, or management contracts is not relevant to the assessment of the competitive effects of a reported transaction. Further, the Commission notes that the HSR Act specifically defines voting securities as securities which at present or upon conversion entitle the holder the right to vote for the board of directors.[339]

Nevertheless, the Commission acknowledges that the mechanisms of influence or managerial control are often bespoke and vary from entity to entity. The proposed rule was intended to sweep broadly but in a manner that was straightforward and relatively uncomplicated for filers to navigate. The comments raised issues that warrant further consideration. Given the other proposals that the Commission does adopt, particularly identification of additional minority interest holders, information about officers and directors of entities related to the acquiring entity, and the collection of additional documents, the Commission has decided not to adopt the proposals related to credit relationships, non-voting securities, and management agreements at this time. If these additional requirements still leave significant gaps in information that impede the Agencies' ability to screen for transactions that warrant additional investigation, the Commission may revisit these proposals in future rulemakings.

c. Officers and Directors

The Commission proposed adding a section that would have required the identification of the officers, directors, or board observers (or in the case of unincorporated entities, individuals exercising similar functions) of all entities within the acquiring person and acquired entity. Further, the proposal required for those individuals, the identity of other entities for which those individuals currently serve, or within the two years prior to filing had served, as an officer, director, or board observer (or in the case of unincorporated entities, roles exercising similar functions). After consideration of the comments and in light of the varied roles that religious or political non-profit organizations can play, the Commission has determined to narrow this requirement to (1) eliminate reporting related to board observers; (2) limit reporting to certain entities within the acquiring person (including officers and directors of the acquired entity who will continue to hold one of these positions post-consummation, if the acquiring person has filed for the acquisition of control); (3) only require identification of officers or directors that serve in those roles at the target or entities that are in the same industry as the target; and (4) exempt any non-profit entity organized for a religious or political purpose, even if that entity carries on substantial commerce, as described below.

Several commenters wrote in support of the proposal, recognizing the value to the Agencies' understanding of the ownership and management structure of companies involved in the transaction. One commenter stated that common board members at intermediate levels of ownership can influence competition directly. Another commenter also noted that private equity minority investment interests can confer rights to appoint board members or allow board observers that create anticompetitive opportunities to exert coordinated market power. This comment further explained that some entities place the same person on several boards to coordinate business strategies across those entities even where they hold only minority positions. The Commission agrees that, due to the influential impact that officers and directors can have on competitive decision-making of entities within the acquiring person, this information is relevant to the Agencies' initial antitrust assessment of the acquiring person's acquisition of interests in the target. The same commenter recommended that the Commission require disclosure of board membership information for any prior acquisitions identified in the HSR Filing. Because this requirement has been designed to identify potential competitive concerns between acquiring person and target at the time of filing and going forward, the Commission declines to expand the final rule to require this historical information.

However, the majority of the comments related to this proposal suggested significant modifications, either by eliminating the requirement in its entirety or acknowledging the relevance of the information but urging revisions to more narrowly tailor the requirements to achieve the Agencies' objectives. Critics across both of these groups raised some common issues.

Some commenters questioned the Commission's authority to require information on common officers and directors in an HSR Filing to enforce section 8 of the Clayton Act, pointing to the absence of any reference to section 8 or interlocking directorates in the HSR Act or in the Commission's original Statement of Basis and Purpose issued with the final HSR rules in 1978. A law firm commenter stated that legislative statements support that Congress disavowed any intention that premerger notification be used to allow the accumulation of information on businesses for general enforcement purposes, and the commenter asserted that the HSR Act is concerned only with potential violations of section 7. Another commenter wrote that even if it was appropriate to enforce section 8 using the HSR Act process, the

[339] 15 U.S.C. 18a(b)(3)(A).

proposed instructions went beyond the text of section 8 by requiring information about unincorporated entities as well as historical information.

Additionally, several commenters questioned the Commission's legal basis for the requirement to report officers and directors. For example, one commenter stated that this requirement had no bearing on the antitrust analysis of transactions under section 7 and that the NPRM does not provide evidence that the Agencies have missed anticompetitive interlocks due to lack of information in HSR Forms. One commenter stated that the NPRM does not identify any cases where a court stated that this information has relevance for review under section 7 of the Clayton Act.

The Commission disagrees that the identity of officers and directors is immaterial to an analysis of whether an acquisition may violate section 7. As described in sections II.B.1 and VI.D.1.d.ii, and elsewhere, the structures of entities have become more complex, allowing for the levers of influence and managerial control to be distributed through a variety of mechanisms beyond controlling equity stakes, or even minority equity stakes. The important role of board members in particular has been recognized in court cases and the focus of consent decrees to resolve competitive issues.[340]

Further, contrary to assertions that the HSR Act limits the Agencies to evaluating whether a notified transaction may violate ''Section 7,'' the HSR Act explicitly directs the Agencies to promulgate rules necessary and appropriate to determine whether a notified acquisition may, if consummated, violate the ''antitrust laws.'' [341] The HSR Act amended the Clayton Act, and the term ''antitrust laws'' is defined in the Clayton Act to include the Sherman Act and the Clayton Act, including section 8's prohibition on interlocking directorates.[342] As discussed in the NPRM, when the Agencies do become aware of existing or potential interlocks created by a reported transaction, they typically seek to remediate them consistent with the Agencies' enforcement authority and before consummation of the transaction. Counter to suggestions that the proposal sought to create a ''dossier'' on the filing parties for general enforcement purposes, this information is relevant to enforcing the antitrust laws with respect to the transaction under review.

Moreover, while a notified transaction could create a violation of section 8 as described in the NPRM, the same competitive concerns that underpin section 8 are also relevant to whether a transaction would violate section 7. In fact, as highlighted by some commenters, section 8 does not necessarily cover all officer and director relationships that may give rise to competition issues. But that does not mean that these relationships are benign or that they do not create the same opportunities or incentives to coordinate competitive decision-making, for example, if the CEO or director of the acquiring entity serves as a member of the board of a rival of the target. In this scenario, section 8's thresholds for strict liability may not capture this relationship, but it would be relevant to analysis under section 7, particularly in nascent markets where one of the entities involved does not meet the minimum sales trigger for application of section 8.[343] That risk alone is relevant to the Agencies' assessment of whether the transaction is likely to substantially lessen competition or tend to create a monopoly in violation of section 7, regardless of whether the interlock is of the type that violates section 8. It is in part because the Agencies cannot rely on section 8 compliance to capture all relationships that create interlocks between entities with competitive relationships that the Commission proposed the new section.[344]

Currently, the Agencies cannot screen for these relationships unless they are mentioned in the transaction documents submitted with the HSR Filing, and often they are not. This information is often not publicly available from any source other than the filers. As explained in the NPRM, information on the identity of officers and directors will help the Agencies identify potential anticompetitive harms that may arise from the proposed transaction.

Additionally, identification of these individuals will assist the Agencies in determining whether the filers have had an opportunity to improperly share confidential information or integrate their businesses before the HSR Act's waiting period expires. For the Agencies to conduct a thorough premerger review, the business operations of the two filing entities must maintain their premerger competitive status quo until the HSR waiting period expires. When the Agencies are aware that there are common officers and directors, they may investigate whether there are on-going communications or interactions affecting the premerger competitive status quo, for example, by interfering with the other filer's competitive decision-making or placing executives from one entity into management positions at the other.[345] The Commission believes that information about these relationships is relevant to ensuring that the parties are complying with the requirements of the HSR Act to hold their operations separate and continue to compete until the expiration of the waiting period. This is true regardless of the antitrust risk presented by the transaction or the possibility that these relationships are improper interlocks; parties must wait until the waiting period has expired to begin integrating operations. Violations of the

[340] *See, e.g., In re Red Ventures Holdco, LP,* No. C–4627 (F.T.C. Nov. 2, 2017) (complaint) (overlapping limited partnership holdings that provided board seats violated section 7); *In re TC Group, L.L.C.,* No. C–4183 (F.T.C. Mar. 16, 2006) (complaint) (acquisition involving minority stake giving two private equity investors seats on the boards of competitors); *In re Time Warner Inc.,* No. C–3709 (F.T.C. Sept. 12, 1996) (analysis to aid public comment) (walling off two individuals and one entity to prevent them from influencing officer, directors, and employees of competitor and its day-to-day operations). *See also* cases cited in section II.B.1.

[341] *See* 15 U.S.C. 18a(d)(1).

[342] *See* 15 U.S.C. 12.

[343] Section 8 of the Clayton Act, 15 U.S.C. 19, prohibits, with certain exceptions, one person from serving as an officer or director of two competing corporations if two thresholds are met. Competitor corporations are covered by section 8 if each one has capital, surplus, and undivided profits aggregating more than $10,000,000 with the exception that no corporation is covered if the competitive sales of either corporation are less than $1,000,000. In accordance with section 8(a)(5), the Commission adjusts these thresholds annually based on changes in gross national product. The thresholds in effect for 2024 are $48,559,000 and $4,855,900 respectively. 89 FR 3926 (Jan. 22, 2024).

[344] Commenter International Bar Association notes that beginning in September 2023, the European Union requires merging parties to provide information on any current interlocking directorships, and that Brazil requires similar information for both fast-track and regular notifications. *See* Comment of Int'l Bar Ass'n, Doc. No. FTC–2023–0040–0687 at 16–17. While this is not a basis for the final rule, the Commission notes that this information is relevant to competition issues examined in other jurisdictions.

[345] The Agencies' concern about premature coordination between merging firms, referred to as ''gun jumping,'' dates back many decades, and they have brought enforcement actions for violations of the HSR Act, as well as other antitrust laws that prohibit competitors from acting jointly prior to consummation of any acquisition. *See also* Note by the United States to the OECD, Suspensory Effects of Merger Notifications and Gun Jumping (Nov. 27, 2018) (DAF/COMP/WD(2018)94), *https://www.ftc.gov/system/files/attachments/us-submissions-fjun-2010-present-other-international-competition-fora/gun-jumping_united_states.pdf.* For a discussion of cases prior to 1995, see Mary Lou Steptoe, Acting Dir., Bureau of Competition, Fed. Trade Comm'n, Prepared Remarks Before A.B.A. Sec. Antitrust L. Spring Meeting, 1994 WL 642386 (Apr. 7, 1994).

stay provisions of the HSR Act are subject to civil penalties.[346]

Two commenters objected to requiring board observer information as outside the scope of section 8 and not related to the Agencies' antitrust assessment of the transaction. The Commission is aware that board observers do not have the same rights and duties as officers or directors. Comments submitted in response to the Commission's December 2020 Advance Notice of Proposed Rulemaking stated that individuals serving as board observers typically receive the same information as the board of directors but there may be ways to exclude them from reviewing privileged or competitively sensitive information. Consequently, the Commission views the risks of sharing competitively sensitive information or changing competitive decision making via board observers to be lower than the risk present with officers and directors. As a result, the Commission agrees that the need for information about board observers is not as great at this time for the purpose of the Agencies' premerger risk assessment, and the final rule does not require filers to identify individuals who have these rights.

In addition to comments related to the authority [347] and purpose of the proposed rule, several commenters raised concerns about the burden of collecting this information, especially historical information about individuals no longer serving in one of these roles, noting that it has little relevance and would be burdensome to collect. One commenter suggested that the requested information on officers and directors be limited to any positions they currently serve or expect to serve in the future. Another comment agreed, noting that current and expected future overlaps are relevant for assessing interlocking directorships and coordinated effects, but that detailed and historic information across all entities of the company has minimal relevance to the antitrust assessment of a particular transaction. Citing practical concerns, another comment noted that there should be no requirement to collect post-departure information from former personnel.

Other commenters stated that the burden of collecting any information about officers and directors was not justified by the benefit to the Agencies' review of any reported transaction. Some cited the higher burden of this requirement for large companies. For instance, one commenter noted that, in some instances, the individuals that would be identified would not be relevant to the Agencies' premerger review because, for small subsidiaries within a large entity's corporate structure, an officer might be someone who merely drew up the paperwork forming the entity whose role would not be relevant to the Agencies' antitrust assessment. Another suggested limiting this requirement to certain revenue thresholds or entities with overlaps or other relationships.

Additional commenters objected to having to report information regarding any individual's board membership or other association. They raised concern that this requirement could sweep in memberships with religious, political, or other non-commercial groups. One commenter stated that some of these individuals do not want to share information about their membership in certain organizations. The Commission has no intention of forcing disclosure in the HSR Filing of any officers or members of the governing board of non-commercial entities, or other non-profit entities with a religious or political purpose. The Form and Instructions that are part of this final rule counsel filers not to report any individual's role as a director, officer, or member of a non-profit entity organized for a religious or political purpose, even if that entity carries on substantial commerce. Filers who would otherwise be required to report these affiliations are excused from such reporting.

In response to the comments and to better tailor this requirement to the purpose of premerger review, the Commission has further decided to limit this requirement in several ways. First, the Commission has eliminated the requirement to identify officers or directors of acquired entities; the requirements of the final rule related to reporting information for officers and directors will apply to the acquiring person only. Second, the Commission limits the entities within the acquiring person to entities that (1) have responsibility for the development, marketing, or sale of products or services that are reported overlaps identified in the Overlap Description or supply relationships identified in the Supply Relationships Description or (2) directly or indirectly control or are controlled by the acquiring entity. If any of these entities is a non-profit entity organized for a religious or political purpose, even if that entity carries on substantial commerce, no reporting is required for individuals serving as officers or directors. Third, the Commission has limited the lookback periods contained in the proposed rule. For entities in category (1), filers will report officers and directors serving within three months prior to the HSR Filing. For category (2), there is no requirement to lookback to any individual who is no longer serving as an officer or director at the time of the HSR Filing but filers must consider individuals who have not yet officially taken the relevant positions. Fourth, the acquiring person will only be required to report the names of officers and directors of these entities if those individuals also serve as an officer or director of an entity that derives revenue in the same NAICS code (or is in the same industry) as the target at the time of filing and the name of such other entities. This will result in a list of only those individuals with the relevant connection.

As noted elsewhere, the Commission has carefully evaluated each of the requirements of the proposed rule in light of the comments and adjusted the final rule to calibrate information requirements to antitrust risk, burden, and importance to the Agencies' ability to screen for transactions that may violate the antitrust laws. On balance, the Commission has determined that an analysis of the board of the target entities is less probative in analyzing the potential effects of the transaction than is an analysis of certain entities within the acquiring person. Many filings are for acquisitions of control, and therefore the officers or directors of the target often change upon consummation. For those transactions where control is not being acquired, the acquired person may not be a party to the transaction, making the burden of collecting the information in the period of time between when it receives the required notice letter and when its filing is required higher than that of the acquiring person, which generally controls the timing of its filing. As a result, the Commission has not adopted the proposal for the acquired person.

For the acquiring person, as discussed elsewhere, due to the competitive significance of entities with products or services in development that have not

[346] 15 U.S.C. 18a(g)(1). *See, e.g., United States* v. *Legends Hospitality Parent Holdings, LLC,* No. 1:24–cv–5927 (S.D.N.Y. filed Aug. 5, 2024) (seeking civil penalties for obtaining beneficial ownership of acquired person prior to expiration of HSR waiting period); *United States* v. *Duke Energy Corp.,* No. 17–cv–00116 (D.D.C. Apr. 7, 2017); *United States* v. *Input/Output, Inc.,* No. 1:99–cv–00912 (D.D.C. May 13, 1999).

[347] Comment of A.B.A. Antitrust L. Sec., Doc. No. FTC–2020–0086–0015 at 10 (board observers generally receive the same information that a director would except when there are conflict-of-interest issues or when the information concerns competitively sensitive topics); Comment of Comput. & Commc'ns Indus. Ass'n, Doc. No. FTC–2020–0086–0002 at 11 (board observers are usually entitled to the same information as board directors although companies have more leeway to exclude observers from privileged or competitively sensitive information).

yet generated any revenue, the Commission declines to adopt a de minimis revenue requirement for this information but agrees that information related to officers and directors is most relevant to the antitrust assessment when the companies have an existing business relationship or are related to the entity making the acquisition. Thus, the Commission modifies this proposal to look only at those entities within the acquiring person that are responsible for the development, marketing, or sale of the products or services identified in the Overlap Description or the Supply Relationships Description, or directly or indirectly control or are controlled by the acquiring entity. This modification addresses commenters' concern about potentially needing to report information on many officers and directors, especially across larger or more diffuse organizations with many subsidiaries irrespective of antitrust risk. So modified, this requirement would focus the Agencies' inquiry on those entities that would be most likely to have a competitively important relationship with the target post-consummation.

The Commission believes that limiting this information requirement to those entities for which the acquiring person and the target have reported overlaps or supply relationships in the same sector as well as the entities that are related to the acquiring entity provides information the Agencies need for premerger screening. As modified, this requirement properly targets the information that reveals any antitrust risk that common officers and directors could act to undermine competition during the waiting period or post-consummation. The Commission acknowledges that there may be other such relationships involving the parties to the transaction that may be relevant to the competition assessment under section 7 or that present section 8 concerns but agrees that the Agencies can continue to collect this information only for those transactions that are flagged for closer review. While the final rule may impose a higher cost to large companies with many competitively relevant business lines, the Commission believes that the benefit to the Agencies is necessary and proportionate: it is more difficult for the Agencies to discover on their own all the individuals who serve in these key roles at different levels of larger companies when those companies have many business lines related to the target.

The Commission has also considered comments related to the proposed lookback period, and, in light of these concerns and to minimize the cost of collecting historical information about officers and directors, the Commission has modified this requirement to shorten the lookback period to three months before the filing date. The Commission believes providing information about individuals who served in one of these positions recently, but not at the time of the filing, is sufficient to identify those individuals who would have been in a position to share competitively sensitive information during a due diligence or negotiation phase for the transaction. It will also serve as a disincentive for these individuals to step down temporarily to avoid disclosure on the HSR Form.

Once the relevant entities and individuals have been identified (and excepting any non-profit entities organized for religious or political purposes), the acquiring person must determine whether those individuals also serve as an officer or director (or in the case of unincorporated entities, roles that serve similar functions) of another entity that derives revenue in the same NAICS codes as the target. If NAICS codes are unavailable, reporting should be based upon the industry overlaps, to the knowledge and belief of the acquiring person or the officer or director. Only if an individual serves in such capacity does the acquiring person need to provide the name of that individual, along with the name of the entity within the acquiring person they serve as an officer or director, their title at that entity, and the name of the other entity for which they serve as an officer or director (and excepting any non-profit entity organized for religious or political purposes). The Commission believes that these limitations will allow the Agencies to have information about key affiliations with other businesses in competitive overlap relationships while limiting the burden on filing parties and their officers and directors.

Finally, commenters representing the pharmaceutical industry voiced concerns about the applicability and effects of the proposed instruction on reportable transactions in the pharmaceutical and biomedical sectors. For example, one pointed out that biotech firms generally rely on a small cadre of qualified directors and officers who have the appropriate business background and stated that disclosure of these positions in an HSR Filing would discourage highly sought-after experts and specialists from accepting biotech leadership roles. Another explained that many pharmaceutical transactions that trigger HSR Filings involve only the acquisition of exclusive licenses, where the parties remain as independent firms post-transaction. This commenter also objected to reporting this information for acquisitions of companies with no sales.

The Commission is aware, from its own experience and from research done by others,[348] that there are individuals who serve on the boards of multiple life science companies. The final rule does not impose a disproportionate obligation for companies operating in this sector; these individuals are obligated to comply with the antitrust laws regarding interlocks as much as individuals serving in other sectors. The Commission does not agree that there is a unique risk that disclosure of recent, current, or future leadership positions will limit the number of talented and qualified individuals who are available to serve as officers or directors in the biopharma or life sciences sector beyond whatever limits the antitrust laws impose. Many sectors prefer knowledgeable professionals with distinct credentials and experience to serve as board members. Moreover, the cost of reporting these relationships is directly related to the number of reportable transactions that occur each year in this sector and the number of existing or potential relationships. The Commission does not believe that HSR reporting requirements will improperly deter qualified individuals from serving on the boards of these or any other companies.

The Commission believes that the modifications made to the final rule will ensure that the Agencies receive the information about recent, current, and future officers and directors that may create opportunities for anticompetitive harm under any antitrust law, including section 7 of the Clayton Act, section 1 of the Sherman Act, or the HSR Act itself. The Commission disagrees that the instruction will newly create a chilling effect on lawful and procompetitive activity or board membership. When individuals agree to serve as board members, they take on fiduciary responsibilities that statutory and common law require. Separate from any HSR requirements, these fiduciary duties require directors to, inter alia, act in the best interest of the organization and to ensure that the organization follows applicable laws.[349] Courts have found that directors may breach their duty of loyalty if they do not make a good faith effort to provide adequate

[348] *See* Lemley, *supra* note 316.

[349] Jeremy S. Piccini, ''Director Liability, the Duty of Oversight, and the Need to Investigate,'' Bus. L. Today 1 (Feb./Mar. 2011).

oversight and monitoring.[350] A merger or acquisition that requires reporting under the HSR Act is not an insignificant occurrence. When an organization to which an individual owes a fiduciary duty is involved in a reportable transaction, it is reasonable to expect those individuals to exercise their duties of care and loyalty by participating in compliance activities. Moreover, individuals who serve on boards must comply with the prohibitions in the antitrust laws that relate to interlocks and should be aware of how their role in a senior leadership position is relevant to the Agencies' assessment of proposed transactions. These risks exist without regard to the disclosure of their board position in an HSR Filing. Given the responsibilities that board members already carry, the Commission believes that the reporting requirement is reasonable and appropriate, particularly when balanced against the increased transparency and value it provides to the Agencies' premerger antitrust analysis.

In sum, the Commission has determined that the reporting requirements for UPEs contained in the final rule are necessary and appropriate to enable the Agencies to identify transactions that may violate the antitrust laws because the acquiring person and the target have existing business relationships, including through shared individuals or entities, that must be considered as part of that assessment, and that these requirements, as modified, have been tailored to reduce the cost of reporting as much as practicable.

E. Transaction Information

This section of the Form and Instructions reorganizes, clarifies, and expands the information required in the initial portion of the current Form as well as in Items 2, 3, and 5. The Commission proposed new sections to facilitate the reorganization, clarification, and expansion of these items and received comments on certain portions of the Transaction Information section. As discussed below, the Commission adopts some of these proposals without change and some with modifications.

1. Parties

This section requires the information currently mandated by Item 3(a). The Commission did not propose and does not adopt any material changes to the information required by this item.

2. Transaction Details

This section requires the information currently mandated by Items 2(b), 2(c) and 2(d). The Commission did not propose and does not adopt any material changes to the information required by these items. The Commission notes that the requirement to indicate the notification threshold in Item 2(c) is not applicable to the acquired person and is therefore excluded from the Form and Instructions for the acquired person. The Commission did not propose and does not adopt any material changes to the information required by this item.

3. Transaction Description

This section requires the information currently mandated by Items 2(a) and Item 3(a). The Commission did not propose and does not adopt any material changes to information required by these items. The Commission also proposed requiring the acquiring person to describe the business operations of all the entities within the acquiring person, which it adopts with modification, as discussed below.

a. Business of the Acquiring Person

The Commission proposed requiring the acquiring person to briefly describe the business operations of all entities within the acquiring person to provide a clear overview of all aspects of the acquiring person's pre-transaction business. The Commission adopts the proposal with modification.

The Commission received two comments expressing general support for the proposal, with one noting that the change is essential to ensuring that the Agencies can meet the statutory deadline. One law firm commenter was critical of the burden that the proposal would impose, stating that companies may have several dozen subsidiaries and written descriptions as to each of the respective business operations is not information readily maintained in the ordinary course of business and could be incredibly burdensome to collate.

The Commission adopts a clarified version of this requirement. The proposal was intended to require a short description of the operating businesses within the acquiring person, not an entity-by-entity description. The Commission understands that a single operating business may comprise multiple entities, such as shell entities or separate entities for each location of the business. Therefore, the Commission amends the requirement to remove ''of all entities within'' to make clear that the acquiring person does not need to describe its operations on an entity-by-entity basis.

Understanding the business of the acquiring person is necessary to understanding the potential competitive implications of the transaction. Investment groups often control multiple portfolio companies across many lines of business. Similarly, some corporations also have multiple and varied operations. These other operations may be related to the operations of the target, even if they do not directly overlap with it. Therefore, particularly for acquiring persons with complex structures or many businesses, knowing just the business of the acquiring entity is not sufficient for the Agencies to evaluate the impact of the acquiring person merging with or acquiring an interest in the target. The scope of the acquiring person's holdings is often not publicly available, necessitating the Agencies receiving the information from the acquiring person itself.

b. Business of the Target

This section requires the information currently required by Item 3(a). The Commission did not propose and does not adopt any material changes to the information required by this item.

c. Non-Reportable UPEs

This section requires the listing of non-reportable UPEs, which is currently required by Item 2(a). The Commission did not propose and does not adopt any material changes to the information required by this item.

d. Transaction Description

This section requires the information currently mandated by Item 3(a). The Commission did not propose and does not adopt any material changes to the information required by this item.

e. Related Transactions

This section requires filing persons to identify related transactions, and the Commission proposed a list of common circumstances in which multiple filings are required to guide filing parties in their responses. Although Item 3(a) of the current Form asks parties to indicate whether there are additional filings related to the transaction, filers sometimes overlook this requirement. The Commission received three comments in support of the proposed changes, with one of these commenters

[350] *See Marchand* v. *Barnhill,* 212 A.3d 805, 824 (Del. 2019) (reversing dismissal of stockholder's claims that directors breached their duty of loyalty by failing to establish a reasonable system of controls and reporting regarding food safety in connection with listeria outbreak); *In re Boeing Co. Derivative Litig.,* No. CV 2019–0907–MTZ, 2021 WL 4059934, at *33 (Del. Ch. Sept. 7, 2021) (finding that plaintiffs stated a claim that board breached its duty of oversight by failing to establish a reporting system for airplane safety).

noting that they appear to be reasonably designed to provide potentially helpful clarification. The Commission adopts this requirement as proposed.

f. Transactions Subject to International Antitrust Notification

The Commission proposed creating a Transactions Subject to International Antitrust Notification section that would require parties to identify the jurisdictions where each filing person has already filed or is preparing notifications to be filed as well as a list of the jurisdictions where it has a good faith belief it will file. The Commission adopts this requirement as proposed, but only for the acquiring person.

Although the Form currently asks filing parties to voluntarily identify other jurisdictions in which filings will be made, most filers do not disclose the information even though more and more transactions are subject to review in multiple jurisdictions around the world. As noted in the NPRM, in order to fully benefit from inter-agency consultations, the Agencies need to know as early as possible which foreign jurisdictions may also be evaluating a proposed transaction.

The Commission received two comments in opposition to this proposal. One commenter expressed concern about the effects of inter-agency consultations, and another recommended maintaining the status quo where filers voluntarily identify other jurisdictions where the transaction will trigger premerger notification under the laws of that jurisdiction. Both stated that the proposal would only impact international companies, which might be forced to speculate about potential foreign filings. The Commission acknowledges that the proposed requirement will have a greater impact on companies with operations outside the United States. But the Commission disagrees that it is asking parties to speculate about potential foreign filings; however, it has determined that it is sufficient for the information to be provided only by the acquiring person. As stated in the NPRM, the text of the proposed rule provides flexibility for parties who, at the time of the HSR Filing, may not have yet identified all the other jurisdictions where they will file. Indeed, the final rule specifies that filing parties can respond based on their good faith belief, which provides filing parties with the ability to respond based on their knowledge at the time of filing. Otherwise, the requirement asks for facts that are already known: the jurisdictions where the party has already filed and the ones for which it is preparing a filing. The Form also affords parties the option to voluntarily make certain waivers related to other jurisdictions, as discussed in section VI.K.3. Accordingly, knowing which other jurisdictions are reviewing the transaction can expedite the waiver process if the parties intend to provide a waiver after filing.

Given the importance of knowing which foreign jurisdictions may also be evaluating a proposed transaction and the benefits to the Agencies and the parties of early case-specific cooperation facilitated by waivers, the Commission adopts this necessary change as proposed for the acquiring person. However, because filing parties often coordinate their notification to other jurisdictions and in order to further reduce the burden on acquired persons, the Commission does not adopt the change for acquired persons because it is sufficient to obtain this information from only one filing party.

4. Additional Transaction Information

a. Transaction Rationale

The Commission proposed that the acquiring and acquired person be required to describe all strategic rationales for the transaction. These rationales would include those related to, for example, competition for current or known planned products or services that would or could compete with a current or known planned product or service of the other reporting person, expansion into new markets, hiring the sellers' employees (so-called acqui-hires), obtaining certain intellectual property, or integrating certain assets into new or existing products, services, or offerings. The Commission also proposed that the filing person identify which documents submitted with the HSR Filing support the rationale(s) described in the narrative. The Commission adopts the requirement as proposed but does not require the information from select 801.30 transactions.

The Commission received several comments supporting disclosure of transaction rationales. Individual commenters described the changes as common-sense requirements and noted the need to ensure each party in the transaction explains the reasoning from their perspective. One commenter stated that mergers may be beneficial to an acquiring company for anticompetitive reasons that might not be immediately apparent from a surface-level analysis of market shares and concentration in a particular market, and that requiring a firm to submit its justification for the strategic wisdom of a particular transaction would help diminish the role of guesswork in the Agencies' review of a proposed merger.

Commenters opposing disclosure of transaction rationales focused on the evolving nature of the information, which may very well differ across the various personalities and business roles that span an organization and which in some instances may be only discovered in the course of post-signing diligence. The Commission understands that there may be many goals for the transactions and that different perspectives within the filing person may be difficult to resolve. But that is precisely the problem that this requirement is intended to resolve. The Agencies are not in a position to understand which rationales are predominant nor choose among different rationales presented in the other materials submitted with the notification, such as transaction-related documents, without additional context. That is why the Commission believes that requiring filers to point to documents or other materials in the HSR Filing that support the stated rationale would help resolve any uncertainty about which rationale (or rationales) may predominate. The Commission also understands that rationales may change throughout the diligence process. The parties are not required to wait to file their notification until they have settled on a single or predominant rationale.

Others described the request as unfair because in the past the merging parties' strategic rationale for the transaction has only been revealed after the Agencies have sued to block a deal. The Commission disagrees that the parties lack rationales for the transaction until they are before a court defending a lawsuit, or that it is unfair to require them to state each strategic rationale for the transaction known at the time of making an HSR Filing. Indeed, each filer may have different reasons for entering into the transaction. Whatever the reasons for agreeing to the transaction, that is the information the Agencies seek. Knowing why each party sees the transaction as beneficial is highly relevant to the initial antitrust assessment and may cause the Agencies to determine, relying on the documentary support for that rationale, that the transaction does or does not warrant additional investigation.

In addition, commenters noted that a description of transaction rationales would be burdensome to generate and duplicative of other materials submitted in the HSR Filing, particularly documents responsive to current Item 4. The Commission acknowledges that there is some cost to filers to provide a description of strategic rationales but

disagrees that it is duplicative. There is no current requirement that the parties describe the rationale for the transaction, and for many transactions, there are no documents or other information submitted with the HSR Filing that reference a rationale. For these filings, the Agencies do not know what benefits either party hopes to achieve through the transaction. Alternatively, where there are many different rationales discussed in submitted materials, the Agencies lack the context to know which ones predominate or reflect the views of the organization. Requiring each filer to describe each strategic rationale for the transaction provides the Agencies with a starting place to understand the motivation behind the transaction without having to make judgments about which ones are still under consideration. Given the Agencies' experience with asking this question during the initial waiting period or reviewing other white papers that the parties voluntarily provide, the Commission believes that the cost of supplying a transaction rationale will be minimal and, in any event, is necessary for the Agencies to determine whether the transaction may violate the antitrust laws. Filers are invited (but not required) to copy and paste text or provide a summary from documents produced with the HSR Filing and reference the specific portions of those documents where the discussion of that rationale exists. However, if documents provide inconsistent rationales, filers should address these inconsistencies. The Commission believes that relying on statements contained in documents submitted with the HSR Filing will reduce the burden of preparing the filer's description of rationales for the transaction.

One commenter requested clarification as to whether the proposal contemplates a single consistent response submitted by all parties notifying the same transaction (in the context of a simple acquisition, buyer and seller) or whether it contemplates that each notifying party submits a separate narrative, noting that the motivations of buyers and sellers may diverge. The Instructions clarify that each filing party is required to submit a description of its strategic rationales because it is important to have such a description from both sides of a given transaction.

Another commenter suggested that to reduce burden the Commission should only require the acquiring person to submit its transaction rationale, reasoning that the acquiring person's strategy is the most competitively relevant and that the seller's rationale for a transaction is often no more than obtaining cash to distribute to investors or to use for unrelated business purposes. The same commenter suggested that the instruction be limited to requiring a brief description of the primary strategic rationale for the transaction. For the reasons outlined above, the Commission declines to adopt these suggestions but notes that a brief description of the transaction rationale is sufficient so long as it is accurate and does not conflict without explanation with stated rationales in documents submitted with the HSR Filing.

b. Transaction Diagram

The Commission proposed a new requirement that filing persons provide a diagram of the deal structure along with a corresponding chart that would explain the relevant entities and individuals involved in the transaction. The Commission adopts this proposal with modification.

The Commission received many comments in support of this proposal, all of which noted the value of such materials to the Agencies as they work quickly to assess the transaction. One commenter stated that without a diagram of all the entities and their relationships it can be hard to understand what's going on. Another highlighted that the proposed requirement would leverage documentation that often already exists. Noting that transaction diagrams can sometimes be incomplete or inaccurate, a law firm commenter suggested that this proposed instruction be modified to require the submission of the most recent diagram of the transaction, but only to the extent that such a diagram already exists and is not materially inaccurate. Finally, two commenters expressed general support for the proposal.

Three commenters opposed the proposal on the grounds that it would unnecessarily increase the burden on filing parties. One commenter stated that these materials are often not maintained in the ordinary course of business or created in the course of a deal negotiation. Another noted that deal structure may not be ''set in stone'' even after signing. In addition, another commenter pointed out that, besides burdening the parties, the proposal would increase the burden on Agency staff reviewing the information, adding that the additional information is not likely to be any more informative to the Agencies than the information already required under the current HSR Form.

Two commenters proposed modifications in light of the fact that many times these charts are drafted by outside tax advisors to show the pre-transaction reorganization needed to achieve the desired tax structure and benefits and that the charts sometimes include detailed tax advice that is protected by the attorney-client privilege or otherwise commercially sensitive. A law firm commenter suggested modifying the instructions to permit parties to redact, omit, or simplify any diagram, to exclude information that relates solely to tax considerations. Another commenter noted that where the details of the pre-transaction reorganization are irrelevant to the antitrust assessment of the transaction, such as where all or a majority of the outstanding equity of a target is being acquired, less detailed diagrams should provide the agencies with the desired information.

The Commission acknowledges the cost of having to create both a diagram along with a corresponding chart explaining the relevant entities and individuals involved in the transaction. Although such information would be materially useful to the Agencies, the Commission adjusts the proposal to require only the acquiring person in non-select 801.30 transactions to provide a diagram of the deal structure and only if one exists. That is, filers are not required to create a diagram or a chart solely for the purposes of submitting an HSR Filing. The Commission believes that such a diagram would be useful even if prepared for other purposes. With regard to privileged materials, HSR Rules already accommodate withholding certain material based on a claim of attorney-client privilege; if such a claim is made with respect to transaction diagrams, the filer can follow those requirements.

In sum, the Commission has determined that the transaction information requirements contained in the final rule are necessary and appropriate to enable the Agencies to fully understand the scope of the transaction being considered and to identify those that may violate the antitrust laws, and that the requirements, as modified, have been tailored to reduce the cost of reporting as much as practicable.

F. Joint Ventures

This section requires information currently mandated by Item 5(b) of the Form. As discussed in section VI.J.1.f, the Commission adopts the proposal to eliminate the use of 10-digit NAPCS codes, including in this section. The

Commission did not propose and does not adopt any other material changes to the information required by this item. The Commission notes that no acquired person filings are required for joint ventures, so this section is not included in the Form or Instructions for acquired persons.

G. Business Documents

The Commission proposed a Business Documents section that would require the submission of documents currently required by Items 4(c) and 4(d) of the Form as well as additional categories of documents. Specifically, the Commission proposed expanding the current requirement found in Item 4(c) to the ''supervisory deal team lead(s);'' altering the language of current Item 4(d)(ii); requiring the production of certain ordinary course documents; requiring drafts of Transaction Related Documents; and requiring an organizational chart of authors and recipients. As discussed below, the Commission adopts some of these requirements with modification and does not adopt others.

As noted in the proposed rule, the Agencies compared documents they have received over the years in response to Second Requests with those submitted in the HSR Filing and assessed whether having certain types of documents at the beginning of the waiting period would have changed the Agencies' determination of whether and how to move into an in-depth investigation of the transaction. As a result of this review, the Commission identified documents that are not required by the current Form but would have been highly probative to the initial antitrust assessment of the transaction during the initial waiting period.

1. Transaction-Related Documents

a. Competition Documents

In the proposed rule, the Commission proposed expanding the documents currently required by Item 4(c) of the Form, which are prepared by or for officers and directors for the purpose of evaluating or analyzing the transaction. Since the beginning of the premerger notification program, these transaction-related documents have been a key screening tool for the Agencies to determine whether the transaction may violate the antitrust laws because they discuss the acquisition with respect to market shares, competition, competitors, markets, potential for sales growth or expansion into product or geographic markets. The Commission proposed requiring the filing person to submit such documents prepared by or for supervisors of the team of individuals working to complete the transaction, which the Commission referred to as the supervisory deal team lead(s).

In response to comments that the proposal was not clear about whom the Commission intends for filers to search for responsive documents and information in addition to officers and directors, the Commission has introduced a definition of supervisory deal team lead and limited the term to just one person. As discussed in section VI.A.1.g., the Commission believes these changes will provide clarity for filing parties. The Commission now turns to comments that were not directed at the definition of supervisory deal team lead but concerning the requirement to submit documents prepared by or for someone other than officers and directors.

The Commission received one comment from State antitrust enforcers supporting the proposal, but other commenters expressed concerns about the costs associated with identifying, collecting, and producing documents from the supervisory deal team lead. Certain commenters stated that expanding 4(c) to include documents to and from supervisory deal team lead(s) would create a significant burden to filers that is not justified by any benefit to the Agencies. One commenter said that adding documents from these individuals would not likely generate material that would allow staff to better assess the need for Second Requests.

The Commission disagrees that adding documents prepared by or for the senior leader of the deal team would not likely generate additional key documents to help staff better assess whether to issue Second Requests. Since the beginning of the premerger notification program, 4(c) documents have been a principal source of information that allows the Agencies to identify those transactions that may violate the antitrust laws and that require a more in-depth review through the issuance of Second Requests. Based on documents submitted in response to Second Requests, it is the Agencies' experience that someone other than an officer or director is often in charge of the deal team and this person typically has additional documents that would be responsive to 4(c), but the documents have not been transmitted to an officer or director at the time of the HSR Filing. This is even more likely to be true when the HSR Filing occurs before due diligence is complete or a final agreement is executed. Requiring the submission of transaction-related documents prepared by or for the supervisory deal team lead would result in the Agencies receiving additional probative documents that speak directly to whether the transaction may or may not violate the antitrust laws even if the document has not been shared with an officer or director prior to filing the notification. Based on the Agencies' experience, the analysis of the transaction's competitive implications contained in these documents is extremely probative.

Certain commenters explained that the addition of the supervisory deal team lead to the existing officer and director custodians, combined with the other new document requirements, would require filers to submit a significantly larger volume of documents. One commenter estimated that adding documents from the supervisory deal team lead(s) as well as draft documents as proposed in the NPRM may increase the number of documents submitted with each filing by tenfold or greater. Another comment pointed out that adding supervisory deal team lead(s) to Item 4(c) could also add a burden related to internal document preservation and retention. The comments did not provide specific estimates of how many additional documents or pages of materials adding a supervisory deal team lead may generate, however.

As discussed throughout this final rule, the Commission has taken steps to lessen the costs identified by commenters. After careful consideration of the comments, the Commission has modified this proposal to reduce the cost associated with requiring 4(c) documents by limiting new custodians to be searched to a single individual, the supervisory deal team lead. This modest expansion of custodians by one individual is necessary because documents responsive to Item 4(c) are some of the most relevant material that staff receives, and based on the Agencies' experience there are also probative documents containing 4(c) content generated by and for the supervisory deal team lead that, if submitted with the HSR Filing, would allow staff to better gauge the competitive implications of the transaction—as understood by the filing person—and conduct a more informed, efficient screening analysis.

Another concern articulated by a small number of commenters was that documents created by or for the supervisory deal team lead may convey information that does not reflect the actual assessment of the proposed merger at senior levels. As one commenter explained, the Agencies may draw conclusions that do not actually

align with the documents provided to or sent by the personnel that can make final decisions for an entity, such as officers and directors. The Commission acknowledges this concern but believes that the exclusion of these documents from HSR Filings is often technical and simply a matter of timing. HSR Rules do not require filers to complete due diligence or sign an executed agreement before filing a notification. Even the modification discussed in section V.D. which requires filing parties to have agreed to key terms of the transaction still allows parties to file prior to the completion of all diligence and negotiation. In the Agencies' experience, staff often receives these 4(c)-type documents in response to a Second Request and finds that the reason they were not submitted with the filing was that they had not been shared with any officer or director at the time of the HSR Filing but were eventually shared with them. Even if such documents were never shared with an officer or director, any document that is responsive to 4(c) and was only shared with the supervisory deal team lead—the person who has primary responsibility for supervising the strategic assessment of the deal—is still highly probative of whether the transaction is likely to violate the antitrust laws.

The Commission believes that by limiting this requirement to the individual who has primary responsibility for supervising the strategic assessment of the deal, and who would not otherwise qualify as a director or officer, it has been tailored to provide a benefit to the Agencies with minimal cost to filers. In the situation where the only individuals supervising the strategic assessment of the deal are already either an officer or director, this requirement will not require searching for responsive documents from anyone new. As discussed above, to the extent that the supervisory deal team lead has responsive documents, it is just often a matter of timing that the document is not submitted with the HSR Filing. Rather than requiring parties to complete their due diligence and provide all responsive transaction assessments provided to key decision makers prior to filing, the Commission has determined that also requiring documents provided to the supervisory deal team lead is the most direct way to obtain these highly relevant assessments of the transaction with the HSR Filing. The cost associated with searching one additional individual for these documents is necessary and appropriate given their importance to the Agencies in quickly identifying those transactions that warrant a closer look. Thus, the Commission adopts this proposal as modified in the final rule.

b. Drafts

The Commission proposed requiring drafts of responsive transaction-related documents if that draft document was provided to an officer, director, or supervisory deal team lead(s). The Commission does not adopt the proposal at this time.

As explained in the NPRM, filers are currently required to submit draft versions of documents responsive to Items 4(c) or 4(d) only if there is no final version or if the draft was sent to the board of directors. Under this guidance, if a not-final version of a document is sent to the board of directors, it ceases to be a ''draft'' and must be submitted, even if a final version is also submitted. Based on the Agencies' experience with receiving other drafts of documents during a Second Request investigation, in some cases prior draft versions have been edited to remove candid assessments of factors relevant to competition prior to circulation to officers or directors.

The Commission received numerous comments on this proposal, raising four principal issues: (1) the burden of producing draft transaction-related documents is not justified by the benefit to the Agencies; (2) such drafts do not reflect sufficient deliberation to be probative of antitrust risk; (3) the term ''drafts'' is not defined in the NPRM and has no common meaning; and (4) requiring the production of drafts would chill internal discussions related to the strategic assessment of the transaction. These concerns are discussed in turn.

First, some commenters emphasized the burden of producing drafts, noting that filing parties will need assistance from counsel and may have to use e-discovery or forensic collection tools to capture all drafts. Requiring drafts, one commenter stated, would significantly increase the volume of documents produced; another commenter noted that it is not uncommon for the authors of these documents to prepare many discrete drafts as part of the drafting process. Some commenters underscored that Agency staff would also face the challenge of reviewing these additional documents. Another commenter pointed out that the proposal would disproportionately affect smaller businesses, which may not have staff lawyers or the ability to incur hundreds of thousands of dollars in legal fees.

In addition, some commenters expressed doubt regarding the probative value of drafts. Drafts may be duplicative, they noted, and often include boilerplate language that may not be accurate as well as incomplete thoughts, dummy slides, and placeholders. One commenter observed that the Agencies do not typically request drafts during the initial waiting period, and that it is exceedingly rare for Agency staff to use a draft document as a deposition exhibit or in any subsequent litigation.

Commenters also sought guidance from the Agencies regarding what constitutes a ''draft'' transaction-related document. In the context of a shared document platform, where several contributors may be working on a document simultaneously, one commenter asked if each saved iteration would be considered a draft that must be produced. Another commenter asked whether a document is considered to be ''submitted'' to an officer, director, or supervisory deal team lead if that individual simply has access to the document via a collaborative drafting tool. As a result of such vagueness, commenters noted, merging parties will face the enormous practical challenge of preserving all versions of documents, even at highly preliminary, incomplete stages. Moreover, such vagueness will lead to arbitrary and capricious enforcement of the requirement to submit drafts if Agency staff later discovers a draft document that they believe should have been submitted with the HSR Filing, according to one commenter.

Finally, some commenters raised concerns about the implications for internal deliberation during the drafting process. One commenter stated that the proposed requirement would chill open discussion ''for fear of creating documents that do not reflect the final thoughts of the company.'' Another commenter warned that it might cause some risk-averse businesses to remove officers, directors, and supervisory deal team leads from the document-drafting process.

Although several commenters recommended eliminating the proposed requirement entirely, the Commission did receive a few suggestions for ways to narrow the proposal. One suggestion was to limit drafts to specific types of documents identified by the Agencies as likely to contain probative information. Another commenter suggested requiring filers to submit the first draft, the last draft, and the final document. Alternatively, one commenter proposed that only the initial draft version submitted to an officer, director, or supervisory deal team lead be produced. None of the commenters supported the alternative proposed in the NPRM, which would require filing parties to

withhold drafts and submit them within 48 hours only if requested to do so by the Agencies.

Having carefully considered the comments, the Commission has decided not to adopt the proposed change to require draft documents at this time.

However, in light of concerns that the Agencies are receiving documents edited to remove candid assessments of the transaction and market competition, the Commission modifies its informal guidance regarding drafts that were shared with the board of directors or similar body. Currently, a document, even in draft form, that is shared with the board of directors (or similar) is responsive and no longer considered a ''draft.'' This distinction is based on the belief that if a document is shared with the board of directors, it is sufficiently reliable to be submitted with the HSR Filing. However, this guidance has sometimes been limited to require that the document be shared with the entire board. The Commission now clarifies that any Transaction Related Document (currently referred to as 4(c) and 4(d) documents) that was shared with any member of the board of directors (or similar body) is responsive and should not be considered a draft; rather, it should be treated as a final version and submitted with the HSR Filing as a Competition Document.

As explained in the NPRM, draft versions of responsive documents can contain highly relevant, probative, or candid statements about the transaction's competitive impact not reflected in the final version of the document, and in some cases, it appears that the final document has been edited to remove candid assessments of factors relevant to competition prior to circulation to officers or directors. The Agencies' experience is buttressed by multiple commenters, who similarly acknowledged that 'sanitizing' these documents in anticipation of antitrust investigation by the Agencies is a legitimate concern. The Commission believes that modifying its informal guidance, as well as obtaining additional documents and information as outlined in this final rule, including those shared with the supervisory deal team lead, will help ensure that the documents the Agencies review contain factual, accurate assessments of the strategic and competitive implications of the transaction.

c. Confidential Information Memoranda

This section requires information currently collected in by Item 4(d)(i) of the current Instructions. The Commission did not propose and does not adopt any material changes to the information required by this item.

d. Third-Party Studies, Surveys, Analyses, and Reports

This section requires information currently required by Item 4(d)(ii) of the current Instructions. The Commission did not propose and does not adopt any material changes to this item.

e. Synergies and Efficiencies

The Commission proposed a Synergies and Efficiencies section to collect the information currently required by Item 4(d)(iii) of the Instructions, with a proposed modification to clarify that forward-looking analyses are responsive. Although one comment expressed general support, some objected to the proposed modification, noting that it would expose firms' proprietary information. More generally, another commenter expressed concern that the burden of identifying the documents that relate to potential synergies or efficiencies would increase greatly if expanded to include supervisory deal team lead(s) and drafts, because synergy analyses in particular can generate a large number of drafts.

In light of the comments and to reduce the overall cost of the final rule as compared to the benefit this information would provide to the Agencies, the Commission does not adopt the proposed modification. However, the Commission declines to repeal the requirement to provide documents that reflect expected synergies and efficiencies, as the Agencies find these analyses to be relevant to understanding any such expected benefits of the transaction. Parties often provide more information about potential efficiencies than is strictly required by the Rules if they want the Agencies to consider such information during their initial review. Thus, the current language in the Instructions regarding synergies and efficiencies remains in effect as part of the final rule.

2. Plans and Reports

The Commission proposed requiring filers to submit two sets of plans and reports not created specifically for analyzing the filed-for transaction. First, it proposed requiring the submission of periodic plans and reports that discuss market shares, competition, competitors, or markets of any product or service that is provided by both the acquiring person and acquired entity, if those documents were shared with a chief executive officer of an entity involved in the transaction, or with certain individuals who report directly to such a CEO. Second, the Commission proposed requiring the submission of all plans and reports submitted to the board of directors (or, in the case of unincorporated entities, individuals exercising those functions) that discuss market shares, competition, competitors, or markets of any product or service that is provided by both the acquiring person and acquired entity. The NPRM called for all such plans and reports that went to the board, not merely those prepared on a periodic basis, because it is the Commission's experience that any report sent to the board reflects market intelligence that is important to the top decision-makers. As proposed, the Commission limited this document requirement to those materials prepared or modified within one year of the filing date of the notification. The Commission adopts the proposal with modifications explained below.

As explained in the NPRM, plans and reports prepared in the ordinary course often contain detailed assessments of core business segments, markets, competitors, other acquisition targets, and projections about future competitive dynamics—insights that have direct bearing on the Agencies' antitrust assessment of the transaction in the initial waiting period. Staff at the Agencies frequently request these documents voluntarily from filing parties early in their review to better understand and analyze the relevant markets at issue.

The Commission received several comments on these proposals. Some comments stated that the proposed requirement was overly broad and would create a significant burden for filers without commensurate benefit to the Agencies. In particular, for example, some comments said that this requirement would mean that filing company personnel must identify, collect, and produce responsive material from several individuals who are not currently searched for documents or materials submitted with an HSR Filing. These comments disagreed with the NPRM's statement that companies frequently collect these documents as part of the due diligence process for transactions. In addition, one commenter stated that, even if such documents were collected, the collection process would not occur in a systematic way to ensure compliance with HSR requirements. In order to effectively collect and produce responsive material, some comments contended that filers would need to use e-discovery and other forensic discovery tools, which are expensive and add

additional time. Certain comments explained it would be counterproductive and burdensome for the Agencies' staff to review and assess the significant volume of documents this new request will likely yield.

The Commission acknowledges that this proposal would have increased the costs for certain filers and has tailored the final rule to minimize these costs. For instance, commenters suggested that there would be additional costs to collect these types of documents, such as interviewing additional personnel, collecting additional documents for production, and having those documents reviewed by counsel, among other tasks. In response to these concerns, the Commission notes the revised requirement is very targeted: it applies only to documents that already exist and are dated within one year of filing, and that discuss overlapping products and services. But in response to concerns that a search for even this limited set of documents could require forensic document technology or other investments in discovery tools, the Commission modifies this requirement to limit the business executives whose files need be searched, dropping the need to collect and produce documents from any person who reports directly to the relevant CEO. As a result, this requirement will not require documents from any new custodians. With this modification, the Commission believes that the number of responsive documents will be reduced so that the burden on the parties to submit and the burden on staff to review these documents will be manageable.

The Commission believes that limiting responsive plans and reports to those shared with the CEOs and with the Boards of Directors of the entities involved in the transaction will still provide the Agencies with sufficient context necessary to determine whether the transaction is likely to violate the antitrust laws. Importantly, these individuals are often involved in preparing the HSR Filing and are the same individuals who are searched for other responsive documents, such as Competition Documents. From the Agencies' experience, those that report directly to the CEO typically collect and retain the types of reports that contain important and relevant business facts so that documents provided to the CEO contain important market analyses and facts that are highly relevant to the Agencies' initial antitrust assessment. They can be especially important for determining the scope of any investigation, potentially narrowing the areas of inquiry or identifying areas of emerging competition that are not otherwise discussed or described in documents generated in connection with evaluating the reported transaction.

The Commission has determined that at this time, requiring reports provided to lower-level executives who report to the CEO, as proposed in the NPRM, would add cost for filers, even those with known overlapping business lines who may expect that the Agencies will be taking a close look at the documents submitted with the HSR Filing.[351] The Commission is also mindful of the burden to the Agencies of receiving HSR Filings with many additional documents that must be reviewed during the initial waiting period. The Commission believes that getting ordinary course plans and reports from the Board of Directors and CEOs should be sufficient to provide staff with highly relevant information with important market context for other submitted documents and information, including the Overlap Description, without overwhelming the current level of staffing devoted to premerger review.

In addition to limiting the people who must provide plans and reports, the Commission has also determined that these documents are not required for select 801.30 transactions. As discussed above, select 801.30 transactions are those where the Commission believes that certain requirements of the final rule are unlikely to provide information necessary to determine whether that transaction may violate the antitrust laws. Not requiring plans and reports for HSR Filings of select 801.30 transactions is another way the Commission is lessening cost based on the lower likelihood that the transaction may violate the antitrust laws.

Other commenters mentioned that responsive plans and reports are unlikely to contain only information about the specific products or services offered by the other filers and this requirement would thus sweep in irrelevant information. One such comment noted that the material received would contain much irrelevant material that would lack sufficient probative value. The Commission disagrees that requiring the plans and reports at issue will generate irrelevant documents. Based on the Agencies' experience, plans and reports, taken as a whole, are highly relevant to staff's analysis of the nature and scope of product or service markets, geographic markets, competitors and competitive dynamics in the industry, new or potential entrants that could mitigate competition concerns, among other key considerations that could determine whether the transaction may violate the antitrust laws. Documents that were created in the ordinary course of business and not solely for the purpose of evaluating the transaction frequently contain important discussions about development efforts for non-commercial products or services or explain competitive dynamics in a broader way that would reveal ways that the transaction could impact non-horizontal competition. In addition, they may identify potential entrants or emerging threats, or discuss other potential acquisition targets. In the Agencies' experience, such plans and reports provide market facts and long-range assessments that bear directly on whether the transaction is one that may violate the antitrust laws in ways described in section II.B.4. Staff has routinely requested that filers provide these documents on a voluntary basis during preliminary-phase investigations, however, because of the voluntary nature of the request there is no requirement that filers produce all or even any of these materials.

Moreover, the modifications the Commission has made to the final rule ensure that the plans and reports are relevant to understanding the nature and extent of existing competition between the merging parties. The only filers who must provide these documents are those involved in transactions in which both parties provide the same types of products or services or that are known to be under development. The Commission acknowledges that these plans are also important to investigate competitive effects in transactions involving supply relationships but has limited this request in the interest of administrability, efficiency, and reducing cost. Transactions between two entities that currently compete (or have pre-revenue products in development that will result in direct

[351] In the final rule, the Commission adopts the suggestion of one commenter to limit plans and reports to those provided to the CEO but declines to seek another round of public comment before finalizing this requirement as modified. Another commenter suggested that the Commission only require these documents that were provided to the board and not to the CEOs. The Commission declines to adopt this suggestion because it believes that excluding CEOs would prevent the Agencies from having the type of relevant information that is routinely provided to senior leaders related to markets with overlapping products and services. Based on its cumulative experience in collecting these types of documents during merger investigations, the Commission has determined that it is necessary and appropriate to collect a limited set of plans and reports that were provided to the highest level of decision-makers, including the CEOs, because they contain important context for conducting the Agencies' initial antitrust assessment of the transaction.

competition soon) typically warrant a close look during the initial waiting period. For these transactions, filers need provide only the plans and reports that discuss market shares, competition, competitors, or markets for those overlapping lines of business created within a year of filing. This is exactly the kind of information the Agencies rely on to determine whether to investigate a transaction during the initial waiting period because it provides key information about the competitive landscape at issue in the transaction. While the Commission acknowledges there may be select portions of these responsive documents that do not contain relevant information, it is often the case that responsive documents contain non-responsive portions. Therefore, the Commission adopts this requirement with a clarification that the relevant products and services are those that both the acquiring person and target produce, sell, or are known to be developing.

One commenter explained that this requirement means filers must self-assess the products and services in which they overlap, and filers may disagree on the existence or degree of the overlap. The Commission agrees that this requirement requires a self-assessment by each party and does not expect that the products and services that are identified in the Overlap Description by each filer will always align, since the acquired person may not have complete information about all the products and services that the acquiring person offers or is developing. The Commission expects that the acquiring person, through its normal diligence of the target, will have a more fulsome understanding of the target's products and services, including those under development. However, as discussed in section VI.I.1., filers should not exchange information with each other when responding to the Overlap Description and each filer may refer to any submitted business document that supports the analysis of overlaps contained in the Overlap Description. In this way, the Commission expects that the analysis of markets reflected in the submitted plans and reports will be reflected in each party's assessment of overlaps contained in the Overlap Description. As is currently the case with a filer's identification of overlapping NAICS codes and for the new requirement to provide an Overlap Description, the Commission will rely on the good faith of the filer to provide accurate information.

Another commenter explained that ordinary course documents not prepared for the transaction are arguably outside the HSR statutory mandate because the Commission had previously declined to adopt a proposal to include such ordinary course documents. The Commission's 1976 proposal had contemplated filers providing, among other items, copies of studies, surveys, analyses, and/or reports prepared by or for the company in the three years before filing, which contain information regarding market shares, competition, competitors, markets and more in relation to any product or service currently made or sold by the other filing party. The Commission states that merely because it declined to require the submission of ordinary course documents with the HSR Filing in the past does not mean it lacks the authority to do so now. The Commission believed that it had the statutory authority to require ordinary course documents in 1976 when it first set up the premerger review program but determined that excluding these types of documents was unlikely to impede effective premerger review.

The Commission believes that it is now necessary and appropriate to require such documents to be submitted with the HSR Filing. As discussed in section II.B., many aspects of the economy, deal structure, and technology have changed dramatically since Congress passed the HSR Act. Based on their experience, the Agencies know that ordinary course documents often contain important horizon-scanning discussions, including market intelligence about other competitors in the market or emerging competitive threats, and that these high-level plans and reports provide important information about the competitive dynamics that may be affected by the transaction. Indeed, these documents often identify other competitors, including their strengths and weaknesses, and this information is highly probative of the competitive assessment of the transaction. Moreover, with the practical limitation to collect and submit only documents that were shared at the highest levels of management—those provided to the CEO or the Board of Directors—the Commission believes the final rule carefully balances the burden of this requirement (for the parties and the Agencies) in light of their clear relevance to the antitrust assessment of the transaction.

One comment noted that requiring plans and reports would be inconsistent with international jurisdictions' merger control regimes. However, the Commission does not find the issue of varying international jurisdictions' document requirements for government merger review dispositive. Each jurisdiction establishes, for itself, the information needed for the particulars of their laws, economies, and priorities. The Commission relies on its own experience in enforcing the U.S. antitrust laws, in light of binding precedent, to assess the most relevant and probative information to determine whether an acquisition may violate those laws. Based on its own experience and expertise in enforcing the U.S. antitrust laws, the Commission has determined that due to the changes in corporate structure and market dynamics described in section II.B., it is now necessary and appropriate to collect a limited set of plans and reports with the HSR Filing.

A smaller set of comments stated that the terms used in the new proposed requirements were vague and unclear. For example, one comment said that the proposed instructions do not provide a clear definition of ''semi-annual and quarterly'' or ''plans and reports,'' which creates uncertainty and compliance risks for filers. Another comment said that the expanded requirements will create uncertainty because they do not directly reference the transaction under review or documents shared during the due diligence process, which would lead filers to make subjective determinations as to which materials are responsive.

The Commission disagrees that there is uncertainty or ambiguity about what is responsive. As stated in the NPRM, regularly prepared plans and reports are high-level strategic business documents created not in contemplation of the transaction but in the ordinary course of business within one year of filing and that are prepared at regular intervals. Responsive plans and reports will discuss market shares, competition, competitors, or markets of any product or service that is provided by both the acquiring person and acquired entity, if those documents were shared with a CEO of an entity involved in the transaction, or of any entity it controls or is controlled by. Targeting documents that discuss market shares, competition, competitors, or markets tracks similar language in Item 4(c) of the current HSR Form, which in the Commission's experience is familiar to many filers and uses phrases that are known to businesspeople. The NPRM references to semi-annual and quarterly rely on standard terms that are routinely used in document requests sent to filers and third parties by the Agencies during their investigations. In the interest of clarity, however, the Commission notes that regularly prepared documents

include those that are produced at regular intervals, such as ''annual'' (once a year), ''semi-annually'' (two reports or plans each year), and ''quarterly'' (once every quarter or every three months). To help resolve any remaining uncertainty, the Commission clarifies that regularly prepared plans and reports are those that are prepared by the filers in the ordinary course and at regular intervals and does not include special reports prepared for a specific purpose. Filers should submit one year's worth of annual, semi-annual, or quarterly plans or reports provided to a CEO but do not need to submit plans or reports that are produced more frequently, such as monthly or weekly. The Commission clarifies that filers should submit all plans and reports provided to the Board of Directors and not only those that are regularly prepared. These documents, which were shared at the highest level of decision-making, may include special reports if they contain responsive material.

Yet other commenters were concerned that requiring plans and reports would raise confidentiality concerns, forcing filers to disclose potential transactions to employees before they are ready to do so. As modified, this requirement alone would not lead other personnel to become aware of the transaction prematurely. The Commission believes that plans and reports can be obtained from these CEOs and Board members in a way that does not necessitate divulging the transaction to other executives and businesspeople who do not otherwise know about the pending transaction. Finally, the Commission notes that plans and reports are also not required in filings for select 801.30 transactions.

Certain comments that opposed the requirement to submit plans and reports also offered suggested modifications. One of these comments recommended that the Commission tailor the requirements to clarify that it is limited only to the filing party's products and services in the United States and that filers need only produce documents, or portions thereof, that discuss specifically identified subject matter. Certain comments agreed that the Commission should allow filers to redact non-responsive materials from these documents. The Commission declines to adopt these suggestions because it finds that allowing filers to redact non-privileged information or information related solely to matters outside the United States on the basis of relevance would introduce too much uncertainty into the value of these documents, leaving Agency staff with incomplete, piecemeal material. Agency staff is experienced with reviewing documents that contain relevant as well as non-relevant content and the Commission believes it is important for documents be produced as they were shared with the relevant decision-makers, properly redacted for privilege only.

The Commission also considered alternatives proposed by commenters. One commenter explained that the Agencies could request filers to submit these documents on a voluntary basis, because those requests are narrowly tailored and have historically followed initial substantive discussions between filers and Agency staff. When used in combination with withdrawing and refiling, this process would provide the Agencies, the commenter said, with at least 30 days to review and analyze strategic plans before issuing Second Requests. The Commission disagrees that it is sufficient to continue to obtain plans and reports on a voluntary basis after staff has identified that they are needed because there is no obligation for filers to comply, substantially or minimally, with such a request for information prior to the expiration of the initial waiting period. In the Agencies' experience, even when parties are asked to provide these documents on a voluntary basis, they are often do not provide them prior to the end of the first review period (either 30 or 15 days) and often choose to pull and refile their notification in order to submit these and other materials that were requested on a voluntary basis. Moreover, in the Agencies' experience, these particular documents contain important information that is currently missing from the HSR Filing that would identify the transaction as one that requires a closer look.

Another comment suggested that Agencies could get these documents using Second Requests as they do now. While either Agency can obtain these documents through the issuance of Second Requests, the Commission believes that the probative value of these documents makes them necessary for staff's initial screening assessment, both because they can identify different areas of antitrust risk, including for areas of future competition, and because they may contain additional information about the business lines of interest that may alleviate the need to issue Second Requests or narrow their scope. As discussed above, because issuing Second Requests is time- and resource-intensive for both the parties and the investigating agency, is it not a substitute for having additional information in the HSR Filing that minimizes the need to issue Second Requests at all. Having additional relevant and targeted information on the front-end benefits both the Agencies and the parties because it allows the Agencies to focus on the most concerning transactions, and allows parties to avoid Second Requests when they are not warranted, and thereby avoid unnecessary expense and delay.

Finally, certain comments discussed earlier also suggested not adopting the proposed requirement at all. In light of the Agencies' experience with the probative value of high-level ordinary course documents and their belief that having them would provide necessary context to other material submitted with an HSR Filing, the Commission declines to dismiss the requirement altogether. The Commission believes this final rule, as modified, reflects a reasonable balancing of the importance of these documents to a premerger assessment and the burden of requiring them for any transaction where filers have overlapping business lines. The Commission has in considered the specific concerns raised by comments and tailored the requirement to preserve the important benefit to the Agencies while mitigating the cost to filers (and to the Agencies).

3. Organizational Chart of Authors

As the final part of its Business Documents section, the Commission proposed requiring an organizational chart(s) that would reflect the position(s) within the filing person's organization held by identified authors and, for privileged documents, recipients of each document submitted with the HSR Filing. The Commission also proposed requiring the filer to identify the individuals searched for responsive documents. The Commission does not adopt this proposal.

The Commission received several comments opposing this proposed instruction, with commenters noting that many companies do not maintain these types of organizational charts in the ordinary course of business, and to the extent they do, such charts are often incomplete or inaccurate. According to one commenter, such charts would need to be prepared solely for the purpose of the HSR Filing, which would be time-consuming. Other commenters pointed out that authors of certain documents may not even be employees of the filing entity, thereby complicating the certification of the filing.

In addition, multiple commenters questioned the Agencies' need for organizational charts to determine whether to issue a Second Request. As one commenter noted, it is unclear why organizational charts will assist staff in

assessing whether a particular transaction merits further review as opposed to their value for identifying potential custodians for a potential Second Request.

As to the proposed requirement to identify the individuals searched for responsive documents, one commenter stated that parties may claim privilege on information regarding whose files were searched. Another commenter observed that, for the majority of HSR filings, documents are identified through targeted self-collection, directed and overseen by legal counsel, rather than running Second Request-style searches through custodial files. The same commenter cautioned that the proposed disclosure requirement would disincentivize companies to err on the side of over-collection so as not to raise a red flag to the Agencies or suggest that the persons searched should be custodians in a Second Request.

Finally, as an alternative to providing an organizational chart, one commenter suggested requiring parties to identify the person who supervised the drafting and the person to whom that drafter directly reports.

After considering the comments and weighing the benefit to the Agencies during the initial waiting period in light of the cost of complying, the Commission does not adopt this proposal. As discussed in section VI.A.3., elsewhere the final rule requires filers to identify authors of documents if the filer has identified a NAICS overlap, product or service overlaps in the Overlap Description, or a supply relationship in the Supply Relationships Description. The Commission has determined that author information is not relevant for all filers and that limiting author information in this way provides sufficient benefit to the Agencies while reducing the cost for filings without such relationships.

In sum, the Commission has determined that the requirements to submit business documents contained in the final rule are necessary and appropriate to enable the Agencies to identify transactions that may violate the antitrust laws and to provide important information about each party's view of market realities and that these requirements, as modified, have been tailored to reduce the cost of submitting responsive documents as much as practicable.

H. Agreements

The Commission proposed an Agreements and Timeline section to require filing persons to provide a term sheet or draft agreement that reflects sufficient detail about the proposed transaction to demonstrate the transaction is more than hypothetical, if a definitive agreement has not been executed. In addition, the Commission proposed additional changes to require the submission of the entirety of all agreements related to the transaction and a new requirement to submit other agreements between the filing persons that are not related to the transaction, as well as a timetable for the transaction. As discussed below, the Commission adopts some proposals with modification and does not adopt the requirement to submit a timeline.

1. Transaction-Specific Agreements

The Commission proposed requiring filing persons to produce all documents that constitute the agreement between the acquiring person(s) and the person(s) whose assets, voting securities, or non-corporate interests are to be acquired, inclusive of schedules, exhibits, and the like, that relate to the transaction, regardless of whether both parties to the transaction are signatories. Further, consistent with the proposed changes to § 803.5, the Commission proposed requiring the most recent draft agreement or term sheet, if filers were not submitting a definitive agreement. The Commission adopts the requirements with modification.

Currently, only the production of certain schedules is required, although many filers do provide schedules regardless. As noted in the NPRM, in the Commission's experience, the structure of transactions has become increasingly complex, often comprising not only multiple agreements between the filing persons but also agreements with third parties. Understanding the entirety of the transaction, including but not limited to non-competition and non-solicitation agreements and other agreements negotiated with key employees, suppliers, or customers in conjunction with the transaction, is crucial to determining the totality of the transaction and assessing during the initial waiting period the transaction's potential competitive impact.

The Commission received one comment in support of this proposal. The State antitrust enforcers wrote in support of the request for non-competition agreements, noting that non-compete clauses that bind employees post-employment prevent new businesses from emerging and stifle entrepreneurship and innovation. One commenter opposed the proposal, noting that this requirement will significantly increase the burdens for filers and recommended requiring that notifying parties provide a descriptive index of such agreements from which investigating staffs could identify specific agreements that they require (with translations if needed). Another commenter expressed the concern that, as written, the proposed instruction would capture clean-team agreements, used by merging parties to reduce the antitrust risk associated with exchanging competitively sensitive information, as well as confidentiality agreements that include similar antitrust safeguards, and that in doing so this proposal might have unintended effects. The commenter cautioned that in response some parties might forgo using clean-team agreements entirely, on the thinking that including a clean-team agreement in the HSR filing would signal a larger competitive concern than actually exists.

The Commission finds that having the complete set of documents that will govern the transaction is necessary to understand the potential effects of ''the transaction.'' Therefore, it does not adopt suggestions to provide an index in lieu of the actual documents that constitute the agreement. In the Commission's experience, voluntary production of documents can delay the review of transactions within the initial waiting period. The Commission does limit the requirement to those agreements that will be in effect on and after closing, with the intention of excluding agreements such as clean team agreements. The Commission also adopts the clarification, discussed in section V.D., that the requirement relates to the transaction that the parties intend to consummate.

The Commission also proposed requiring that, if there is no definitive executed agreement, the filing parties provide a copy of the most recent draft agreement or term sheet that provides sufficient detail about the scope of the entire transaction that the parties intend to consummate. As discussed in section V.D., the Commission is modifying the proposed instructions in response to certain comments that requested clarification. One commenter sought clarity on what constitutes ''sufficient detail'' about the scope of the transaction, noting that certain transaction details are often not fully determined at the time of signing a definitive agreement or filing HSR, but also may not be necessary to determine whether to issue Second Requests. The same commenter cautioned that the proposed requirement will likely cause undue delays and risk unnecessarily increasing the overall timing to close a transaction especially in instances where parties intend to file on the basis of a letter of intent.

To address this concern, the Commission has revised the Instructions to describe what would be sufficient:

> some combination of the following terms: the identity of the parties; the structure of the transaction; the scope of what is being acquired; calculation of the purchase price; an estimated closing timeline; employee retention policies, including with respect to key personnel; post-closing governance; and transaction expenses or other material terms.

The Commission notes that these examples are meant to be illustrative and not exhaustive.

2. Other Agreements Between the Parties

The Commission proposed requiring filing persons to submit all agreements between any entity within the acquiring person and any entity within the acquired person in effect at the time of filing or within the year prior to the date of filing. The Commission adopts the proposal with a significant modification to reduce the burden that would have been associated with producing copies of these agreements with the HSR Filing.

As explained in the NPRM, understanding the scope of any existing contractual relationships between the filers, such as an existing customer-supplier relationship, would materially assist the Agencies' review by revealing any business interactions or relationships that exist prior to the transaction and that may be affecting premerger competition, which is material to assessing how the transaction may affect post-acquisition competition.

The Commission received two comments in support of the proposed requirement. The State antitrust enforcers noted that it would shed light on any licensing or supply agreements, as well as any non-compete agreements, between the parties. A union commenter also supported the request and suggested expanding it for certain non-compete and non-solicitation agreements. The commenter noted that the filing parties might have such agreements related to the products, but these agreements might be with third parties and not between the filing persons. In addition, the same commenter suggested requiring parties to submit copies of collective bargaining agreements, at least with any common unions.

Several commenters, however, objected to the burden the proposed requirement would impose, particularly in industries where companies rely heavily on agreements with other industry participants to do business. One commenter noted that broadband and telecommunications providers routinely have myriad agreements with each other, covering a wide range of aspects of the services they offer. The commenter stated that many, if not most, of these agreements have little potential to create competition concerns, and in fact many are pro-competitive. Another commenter stated that, in the wireless communications industry, some pairs of wireless carriers might have up to 1,000 agreements to which they are both parties.

A few commenters recommended modifications of the proposed instruction to reduce the burden. One commenter suggested relying on the Competition Descriptions or excluding de minimis agreements and only requiring ''Material Other Agreements,'' which would be defined as exceeding in value some percentage of entity revenues. Another commenter recommended only requiring the production of three categories of pre-existing contracts between the acquiring person and the acquired entity or assets: (i) noncompete agreements in effect within one year of filing, (ii) non-solicitation agreements in effect within one year of filing, and (iii) supply or license agreements that generated annual revenue of $10 million or more within one year of filing. The commenter also suggested clarifying that purchase orders do not need to be produced, nor do contracts that have expired or terminated before the filing date. A third commenter also recommended limiting the requirement to contracts that are material in terms of dollar value. In addition, the commenter proposed that notifying parties be permitted to exclude standard-form agreements that they use with numerous other counterparties.

In light of the comments, the Commission has made significant modifications to this proposal. First, the Commission has determined that only one party need provide this information; in accordance with its general approach, the Commission has determined to require only the acquiring person to indicate if there are existing agreements between the parties. Second, the acquiring person will not be required to provide the agreements, but rather only to answer whether any such contractual agreements exist and, if so, to indicate via checkbox which types. The Commission has identified specific types of agreements that reflect a significant business relationship that is relevant to the premerger assessment: agreements with non-compete or non-solicitation terms; leases, licensing agreements, master service agreements, operating agreements, or supply agreements. If the there are other types of agreements, the acquiring person should indicate ''other.'' The Commission clarifies that these are agreements that the parties have with one another and which may affect the antitrust assessment of the reported transaction.[352] Third, the Commission has limited the requirement to those agreements that are between the acquiring person and the target, rather than the acquired person. This is the specific relationship that is of interest to the Agencies for the premerger assessment and should limit the information to those agreements most relevant to that analysis. These limitations should provide the Agencies with sufficient information to screen for transactions that may require further review due to existing contractual obligations, while relieving much of the cost associated with the requirement.

3. Timeline

The Commission proposed that filing persons provide a narrative timeline of key dates and conditions for closing. After careful consideration of concerns raised by commenters, the Commission does not adopt this proposal.

In the NPRM, the Commission reasoned that, just as it is critical for the Agencies to understand the totality of the transaction during the initial waiting period, it is critical to understand the timing of key milestones and the conditions to closing, which are often complex and not easily understood from the transaction documents themselves. The Commission suggested that this basic information would help the Agencies understand key deal milestones and better manage the timing and focus of the investigation during the initial waiting period.

The Commission received a few comments expressing general support for the proposal; however, one commenter raised concerns regarding the burden, noting that the proposed

[352] For example, a non-compete or non-solicitation agreement between two otherwise independent companies is indicative that the parties may have a competitively significant relationship, and in certain situations, may violate the antitrust laws. *See, e.g., United States* v. *Brown,* 936 F.2d 1042 (9th Cir. 1991). In a merger context, non-compete restrictions can implicate post-merger competition in ways that violate the antitrust laws. *See, e.g., In re ARKO Corp.,* No. C–4773 (F.T.C. Aug. 9, 2022) (final decision and order); *In re DTE Energy Co.,* No. C–4691 (F.T.C. Nov. 24, 2021) (decision and final order). Other agreements between the parties, including those related to distribution or licensing, can limit competition post-merger in ways that may violate section 7, including by increasing the risk of foreclosure. *See, e.g., FTC* v. *Tempur Sealy Int'l, Inc.,* 4:24–cv–02508 (S.D. Tex. filed July 2, 2024) (complaint) (alleging that buyer attempted to use existing distribution relationship to exclude rival mattress brands premerger).

requirement is broader and more onerous than the interrogatory that staff routinely requires during in-depth investigations. The same commenter suggested that this instruction be limited to requiring a brief description of the timetable for the transaction and a brief description of any termination fees, break-up fees, ticking fees, or similar arrangements.

After considering the comments and weighing the benefit to the Agencies of requiring a deal timeline in light of the cost of compliance presented by commenters, the Commission is not adopting this proposal. Even though the Agencies would benefit from knowing the timeline for the transaction to help manage their time and investigative resources during the initial waiting period, the Commission does not adopt the proposed change to require one. In the Agencies' experience, these timelines can change throughout the course of an investigation, although not typically within the initial waiting period. The decision not to require a timeline is one of the ways in which the Commission aims to lessen cost on all filers of preparing an HSR Filing and staff can continue to ask for (or parties can choose to provide) this relevant information when warranted.

In sum, the Commission has determined that the requirements for the transaction agreement and information about other types of agreements between the parties contained in the final rule are necessary and appropriate to enable the Agencies to understand the scope of the transaction as well as any existing business relationship that might be affected by the transaction and that these requirements, as modified, have been tailored to reduce the cost of reporting as much as practicable.

I. Competition Descriptions

The Commission proposed a new Competition Analysis section in the Instructions to require filers to provide three categories of narrative responses: (1) an Overlap Narrative, (2) a Supply Relationships Narrative, and (3) Information related to Labor Markets. As proposed, filers would provide, among other things, a description of their basic business lines as well as product and service information for all related entities; identify current and potential future overlaps and supply relationships between the filing persons; and provide information about their employees and what services these employees provide in areas where both parties employ the same types of workers. As noted in the NPRM, this information would supply crucial information about existing and future competitive relationships between the filing parties, which is the starting point for any assessment of whether the transaction may violate the antitrust laws.

As discussed in detail below, in the final rule the Commission does not adopt requirements related to Labor Market Information, and adopts requirements to submit an Overlap Description and a Supply Relationships Description with significant modifications. On the Form, this section is now labeled Competition Descriptions.

The Commission received several comments that supported the introduction of narrative responses. One commenter strongly supported the collection of information in narrative form related to products, services, workers, supply and distribution relationships, licensing, and industry and geographic overlaps, believing that this information is necessary to help the Agencies evaluate the effects of an acquisition more thoroughly and efficiently, and identify potential threats to competition. Another commenter suggested that pre-acquisition disclosure of vertical linkages is necessary for antitrust agencies to effectively assess the potential anticompetitive impact of these non-horizontal acquisitions. Another noted that, while HSR rules have always required parties to identify downstream products and revenues by NAICS and NAPCS codes, they have never required the disclosure of any information at all about input markets, including those for labor. It stated that this lack of information leaves initial filing screeners at a loss to spot these competition issues and potential violations, and further noted that this omission forces investigatory staff scrambling to ask companies to volunteer such critical input market information. The same commenter stated that the proposed rule would help narrow this information asymmetry and empower the Agencies to clearly identify impact in both output and input markets.

The Commission also received several comments that objected to the collection of this information in narrative form. In general, comments asserted that expansive narrative requirements are arbitrary and capricious because they would change HSR notification from an objective task to a subjective task, creating delays, disputes, and uncertainty with no countervailing benefit especially for those deals where no antitrust issues are present. For a number of reasons discussed in detail below, the Commission disagrees, but has nonetheless modified these requirements as appropriate to tailor them to their relevance in determining whether the transaction may violate the antitrust laws and warrant a Second Request.

Experience With Narratives

The Agencies have extensive experience reviewing narrative responses to requests for voluntary submissions from the filing parties during the initial waiting period (and to other types of investigative demands where responses can be compelled) and are aware of the effort required to produce them. From this experience, the Commission knows that when the parties submit this information on a voluntary basis during the initial waiting period—and it is complete and timely—narratives that discuss existing business relationships between the parties are critically important to determining whether there is a need to issue a Second Request. In the Agencies' experience, voluntary narrative responses are especially helpful in focusing any potential Second Request on the areas of competition most in need of in-depth review but just as often can lead staff to conclude that no Second Request is necessary. As discussed above in section III.A.2., when the Agencies engage with the parties during a withdraw-and-refile investigation, which typically involves the submission of some narrative responses from the parties, the transaction is more likely to proceed without the need for a Second Request.

But voluntary narrative responses often come late in the initial waiting period and are frequently incomplete. More importantly, staff only asks for additional information on a voluntary basis when it has determined, on the basis of other information contained in the HSR Filing, that the transaction may alter existing competitive conditions in a way that may violate the antitrust laws but that more information is needed. As discussed in section II.B., the current information requirements do not surface the facts that would flag transactions for certain types of violations, and for those filings staff has no basis to know that additional information is needed. Where there are deficiencies in the initial information requirements, resorting to collecting information on a voluntary basis does not cure the deficiency because staff will not know that relevant facts exist to flag the transaction for follow up.

The Commission believes that requiring additional information with the HSR Filing that would reliably reveal any existing business relationships between the filers is

necessary and appropriate to enable the Agencies to determine whether an acquisition may, if consummated, violate the antitrust laws. Because the information called for in the Competition Descriptions is provided directly by the parties to the transaction and is reflective of each filer's business operations, it is highly probative and reliable for the purpose of conducting a quick and thorough premerger assessment of existing and future business relationships between them. The information collected on the current Form does not reveal these relationships, yet these are the relationships that are foundational to flagging whether the transaction is one that warrants a closer look. As discussed in sections II.B.3. and 4., the need is especially great for information related to potential non-horizontal concerns because there is currently no information that specifically identifies existing supply relationships. Information about existing supply relationships will fill critical information gap in the current Form and provide a factual basis for the Agencies to screen for potential non-horizontal impacts during the initial waiting period.

Nonetheless, to make clear that the Commission does not require the parties to submit an antitrust analysis akin to a ''white paper,'' or hire counsel or experts simply to create narratives for the purpose of an HSR Filing, the Commission eschews the use of the term ''narratives'' and instead adopts the term ''description'' to better reflect the type of answer that is required. Filers should rely on business personnel to describe the products and services they offer (or that are under development) using terms and language that is natural in the marketplace. Given the breadth and tone of the objections to the proposed narratives, the Commission believes that commenters misunderstood what is sought. The Commission intends to collect factual information about overlaps and supply relationships via a written answer (as opposed to documents or data) but is not seeking opinions or arguments about what those facts should imply. While in other contexts a narrative response may contain opinions, tell a story, or take a position, the final rule does not require any of that from filers. Instead, filers should collect and report the type of information it provides to customers, suppliers, investors, or the public for purposes other than an antitrust analysis—to simply describe the products or services it offers for sale. This is the type of basic business description required by the final rule, and the Commission adopts with terms Overlap Description and Supply Relationships Description to address concerns that the final rule requires something other than that. Moreover, the Instructions ask filers to provide a brief description in an attempt to discourage lengthy responses or unnecessary commentary beyond what is strictly required. [353]

The Overlap Description is a key reform and is motivated by the Commission's experience over time with relying on NAICS codes to identify areas of horizontal competition. Based on its experience reviewing narrative responses submitted on a voluntary basis during the initial waiting period, the Commission has identified problems with relying exclusively on NAICS code overlaps as the basis for screening whether the merging parties are current competitors. While NAICS codes are well suited for reporting in some sectors, the Commission agrees that NAICS codes can be both overinclusive and underinclusive in reflecting whether the parties offer competing products or services to any set of customers. As discussed in section II.B.4., when it comes to certain sectors of the economy that are undergoing technological change or growth, including through the introduction of novel products or services, NAICS codes are especially unhelpful, and have not been updated to reflect current market offerings.

The mismatch between existing NAICS codes and market realities can be most acute in new sectors of the economy, for which there are not many codes. For instance, NAICS code 518210 is for companies that provide computing infrastructure, data processing, web hosting, and related services, which covers businesses as diverse as those providing data entry services, cloud storage services and cryptocurrency mining.[354] Included in this six-digit NAICS code are a whole array of businesses offering complex and evolving products, some of which may compete for the same customers but some of which surely do not. Adding further complexity, the Census Bureau provides cross-references to fourteen other NAICS codes with related business lines. This single category is very broad, potentially reflecting ''competition'' between the parties that does not exist in the marketplace. As a result, each filer in a transaction may report revenues in 518210 reflecting an ''overlap'' in their respective business lines, when in reality they offer very different products or service.

These cross-references create a different but equally vexing problem. For instance, NAICS code 541511 is for companies that offer custom computer programming services to meet the needs of a particular customer while NAICS code 513210 is for companies primarily engaged in software publishing. Here, a company that provides both standard and custom solutions may report revenues only in 513210 even if some of the companies it competes with would only report revenues in 541511, reflecting its focus on custom products. Overall, companies select their own NAICS codes for revenue reporting, introducing discretion into the use of this ''objective'' system of classification, which was established for a purpose other than identifying companies that offer competing products or services. As a result, companies that may regularly compete against one another may not identify any overlapping NAICS codes.

Despite these shortcomings, the Commission will continue to rely on NAICS code reporting for revenues and the identification of overlaps to give filers some common system of reference and because the identification of horizontal overlaps is a key screening step in the Agencies' initial antitrust assessment. But new sectors have emerged over the years and NAICS codes have not been refined or updated. Accordingly, the Commission has determined that receiving overlap information in description provided by the filer is necessary and appropriate to enable the Agencies to determine whether an acquisition may, if consummated, violate the antitrust laws. The Agencies may also use the Overlap Description to conclude that the parties are not current or future rivals because the exercise provides filers with an opportunity to correct any ''false positives'' that result from inaccurate reporting of NAICS revenue overlaps. As a result, the Overlap Description may contain a factual basis for the Agencies to determine, solely on the basis of information contained in the HSR Filing, that the transaction is not likely

[353] A significant number of filers who report NAICS overlaps initiate contact with the Agencies to provide supplemental information (often in the form of white papers) that supplies context for how they view competition, regardless of NAICS reporting. In the Agencies' experience, these presentations often contain descriptions of the parties' respective business operations as well conclusions that the parties would like the Agencies to reach to dismiss concerns about the transaction. The former is now required by the final rule while the latter is not.

[354] *See* U.S. Census Bureau, North American Industry Classification System, 51280 Computing Infrastructure Providers, Data Processing, Web Hosting, and Related Services (rev. Sept. 10, 2024), *https://www.census.gov/naics/?input=518210&year=2022&details=518210.*

to violate the antitrust laws at that time. In the Overlap Description, a filer can make clear that further investigation is unnecessary. Allowing the agencies to reach these conclusions at the outset is more efficient than having the parties provide the information at a later stage or requiring the Agencies to discover this information indirectly through document requests.

As the Commission acknowledged in the NPRM, the cost to filers to create these descriptions could be significant, especially for transactions involving close competitors with multiple overlapping product or service lines or those who operate in the same supply chain. But identifying those transactions that present broad and complex competition issues is a critical first step for the Agencies, and information from these descriptions is highly relevant to flagging the transaction as one that may violate the antitrust laws. Thus, the cost of providing these descriptions is proportional to the likelihood that the transaction is one that warrants a close look: the more extensive the existing competitive relationship between the parties, the more relevant these relationships are in identifying the transaction as one that warrants further investigation. It is also possible that these descriptions will provide important context for other information contained in the HSR Filing that would allow the Agencies to narrow any potential investigation to those areas of important existing or future competitive interaction, or to conclude that the transaction is not one that is likely to violate the antitrust laws. Thus, the descriptions are necessary and appropriate for the Agencies to assess the potential for anticompetitive impacts, including some indication of their scope. This information will also permit the Agencies to manage their resources appropriately, increasing overall efficiency. For example, if the Overlap Description identifies hundreds of products or services, the Agencies can devote sufficient staff resources to reviewing those areas of overlap to determine whether any rise to the level of requiring a Second Request investigation. On the other hand, if the notification identifies no areas of overlap, the Agencies may be able to quickly determine whether there are other materials in the filing that would nonetheless raise concerns about the competitive impact of the transaction.

It is appropriate for the filers to bear the burden of providing basic business information that they possess. It is unreasonable and inefficient to require the Agencies, who do not possess basic information about the filers' businesses, to expend resources gathering the information from outside sources, or to require the Agencies to issue a separate request for this critical information which only delays the review process and in turn the filers' ability to consummate transactions. Yet the status quo requires the Agencies to obtain basic business facts that are needed to evaluate transactions through voluntary requests to the parties or Second Requests. As one commenter noted, the Federal Rules of Civil Procedure encourage Federal courts to order civil discovery based on the obvious principle that the person already in possession of the information is in the best position to provide it, and properly so.[355] This principle is apt here.

The Commission also believes that parties will be able to reduce the cost of creating descriptions by drafting them during the period of due diligence when the companies are learning more about their respective business operations. Discovering the extent of existing business operations is key to the diligence process, and companies often create descriptions of their operations as part of the process.[356]

The Commission has made every effort to calibrate its need for the requested information and the availability of that information from the parties or from others, including the cost to filers associated with collecting information and creating the descriptive responses. For this reason, as discussed below, the Commission has decided to significantly modify certain aspects of the proposed descriptions, for instance when the information is duplicative of other information in the notification or when the information is available from a source other than the parties. In taking this approach, the Commission rejects alternatives suggested by commenters to reduce the cost by excusing transactions below a certain value or without a NAICS overlap, because it has found no basis for doing so. In the Agencies' experience, deal value is not a reliable indicator of the potential for antitrust harm,[357] especially when the transaction involves multiple business lines or when competition occurs in local markets.[358] Instead, the Commission has determined to excuse select 801.30 transactions from the requirement to provide Competition Descriptions. As discussed in section VI.A.1.f., these transactions rarely involve entities with existing competitive relationships and do not confer control, and thus the Commission has determined not to require these filers to provide descriptions of any existing business relationships, should they exist.

The Commission now turns to a discussion of both the general and specific objections to the Competition Descriptions requirements.

General Objections to the Competition Descriptions

Several commenters questioned the general utility of these requirements. One commenter suggested that burdening all filers with these descriptive requirements is not particularly well targeted to identifying acquisition-related antitrust concerns. Another stated that the information called for is duplicative of documentary materials that are now also required. Two other commenters suggested that the Commission continue to ask for this information on a voluntary basis and only for deals that have been flagged for closer review.

The Commission disagrees that the information required by the Competition Descriptions would be of little use or contain repetitive information. Requiring filers to provide a description of their existing competitive relationships is a key reform of the final rule to make the premerger review process more effective and efficient. Such descriptions should contain a factual summary of the parties' existing business relationships, which is critical information for identifying those transactions that require a closer look. This is information that is known to filers and bears directly on whether the transaction may violate the antitrust laws. The Commission has determined

[355] Fed. R. Civ. P. 26(b)(1) advisory committee note (2015) (identifying information asymmetry as a justification for placing a heavier burden on the party who has the information).

[356] When establishing the premerger regime, the Commission acknowledged that requiring information in the notification may actually reduce the cost associated with compiling it. 42 FR 39040, 39043 (Aug. 1, 1977).

[357] *See, e.g., United States* v. *Neenah Enterprises, Inc.,* No. 1:21–cv–02701 (D.D.C. Oct. 14, 2021) (complaint) ($110 million asset purchase); *In re Global Partners LP,* No. C–4755 (F.T.C. Mar. 2, 2022) (decision and final order) ($151 million acquisition); *In re ANI Pharmaceuticals, Inc.,* No. C–4754 (F.T.C. Jan. 12, 2022) (decision and final order) ($210 million acquisition); *United States* v. *Grupo Verzatec S.A. de C.V.,* No. 1:22–cv–01401 (N.D. Ill. Mar. 17, 2022) (complaint) ($360 million acquisition). Note that the value of the transaction is considered by some filers to be confidential information and is not always disclosed in public filings. *See FTC* v. *IQVIA Holdings Inc.,* No. 1:23–civ–06188 (S.D.N.Y. Dec. 29, 2023); *In re Lifespan Corp.,* No. C–9406 (F.T.C. Feb. 17, 2022) (complaint).

[358] *See, e.g., In re The Golub Corp.,* No. C–4753 (F.T.C. Jan. 20, 2022) (decision and final order) (divestiture of 12 supermarkets); *United States* v. *B.S.A. S.A.,* No. 1:21–cv–02976 (D.D.C. Mar. 15, 2022) (divesture of two business lines).

that it is necessary to require this descriptive information from filers because other information in the HSR Filing is not sufficient to screen transactions for all types of potential harm, and, as discussed above, staff cannot rely solely on voluntary collection of this information to flag the transaction for a closer review.

Moreover, as discussed elsewhere, the Commission intends to rely on information in the Competition Descriptions as the basis for determining whether the filer also has to provide other information required by the final rule. The Commission has determined that, for many additional information requirements, these descriptions (in addition to the NAICS code overlap reporting) will determine the scope of most of the other information requirements in the HSR Filing. It is appropriate for the Commission to condition additional information requests on the identification of an existing business relationship as the most effective way to calibrate the cost of reporting the antitrust risk associated with each transaction. In order to reduce the cost for filers whose transactions raise little to no antitrust risk, it is necessary that all filers go through the exercise of determining whether they are in a horizontal or supply relationship with the other party. Those filers who do not have such relationships will so indicate by responding ''none'' and will be relieved of the obligation to respond to other questions that are conditional on an affirmative response. Relying on this conditional response format is a key feature of the final rule to ensure that filers who do not have an existing business relationship with the other party (*e.g.,* as a competitor or supplier) have a lower cost associated with submitting an HSR Filing.

One commenter stated that because these descriptions are not prepared in the ordinary course, they cannot be required to be submitted with the notification. Further, this commenter stated that Congress only intended the Commission to collect information and documentary materials reasonably available to the reporting companies, suggesting that anything not kept in the ordinary course of business runs afoul of Congressional intent. The Commission disagrees with the commenter's reading of both the statute and the legislative history. The rulemaking provision in 15 U.S.C. 18a(d) contains no ordinary course limitation. To the contrary, it states that HSR filings shall be in such form and contain such documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable the Agencies to determine whether an acquisition may, if consummated, violate the antitrust laws. The commenter quotes the Commission's 1977 Notice of Proposed Rulemaking for the premerger notification rules when making this assertion, but in that notice, the Commission did not state that information reasonably available was limited to ordinary course documents.[359] Further, the Competition Narratives as adopted do not require any information that is not kept in the ordinary course of business of the acquiring or acquired person. These descriptions require parties to gather and present this information in a format that will permit the Agencies to understand their lines of business, areas in which the parties offer similar products and services, and relationships in the relevant supply chains.

The Commission also disagrees that businesses do not develop an understanding of their business operations in comparison to those of the other merging party ''in the ordinary course.'' In the Agencies' experience, businesses routinely conduct competitive assessments in which they compare their operations to those of others. These internal assessments of other market participants are often done long before any specific assessment of a particular transaction and may be contained in documents such as plans and reports. In the specific context of a proposed transaction, parties (especially those that are publicly traded) conduct due diligence assessments of prospective targets. These comparative assessments may be done specifically for the purpose of analyzing the filed-for transaction, and the Commission considers those to be in the ordinary course of acquisition planning. The descriptions required by the final rule would summarize these types of assessments and reflect their underlying business facts. In the Commission's view, this is exactly the type of materials the House conferees intended would be submitted with the notification: ''the very data that is already available to the merging parties, and has already been assembled and analyzed by them. If the merging parties are prepared to rely on it, all of it should be available to the Government.''[360]

Compliance Concerns

Some comments expressed concern that the descriptions would create HSR Act compliance issues, noting that, because the descriptions require subjective judgments, the Agencies have no objective standards or precedent against which compliance or substantial compliance could be judged. One commenter suggested that each of the descriptions may generate disagreements between the Agencies and the merging parties regarding the accuracy or completeness of the information provided, leading the Agencies to retroactively declare a notification to be incomplete and restarting the initial waiting period. One commenter stated that the descriptive responses will require extensive iterative discussions with PNO to determine compliance, which will delay the start of the waiting period. Others asserted that the Commission could deem a descriptive answer to be incomplete simply because staff disagrees with the assessment, or that the Agencies may be tempted to second-guess or nitpick the parties' responses, leading to uncertainty about deal timelines.

As discussed above, the Agencies have decades of experience with reviewing descriptive responses, including those submitted on a voluntary basis during the initial waiting period and in response to Second Requests. In fact, staff routinely seeks this information as the first supplement to the information contained in the HSR Filing for any transaction that is identified as requiring a closer look. But the current practice of permitting parties to submit descriptive responses on a voluntary basis while the waiting period is underway has encouraged parties to submit incomplete responses or submit them at a time when staff is unable to verify the information before it must make a determination whether to issue Second Requests. Any deficiency in a voluntary descriptive response prevents staff from being able to quickly determine whether the Agency should issue a Second Request to require a more complete narrative answer.

The Commission believes that requiring Competition Descriptions to be submitted with the HSR Filing provides the proper incentive for filers to submit a complete and accurate response, one that is certified by the responsible executive who signs the notification and that is available at a time when the information can be reviewed and assessed by staff. The certification allows the Commission to accept filings containing descriptive responses and to start the waiting period. If, upon reviewing the notification, staff determines that the

[359] 42 FR 39040, 39043 (Aug. 1, 1977).

[360] 122 Cong. Rec. 30877 (1976) (remarks of Rep. Rodino).

descriptive responses are directly contradicted by other information submitted with the notification, staff may request supplementary information to explain the contradictions, which could require a restarting of the waiting period. If the notification contains no such materials that call into question the reliability of the descriptions, any supplementary submissions to clarify or correct them would likely not require a restarting of the waiting period under the Act.

Other comments raised compliance concerns related to who must help prepare the information. Some comments stated that the descriptive responses will require filers to hire expensive antitrust counsel, and possibly an expert economist, to draft the descriptions prior to filing. According to one commenter, filing parties will be forced to engage antitrust counsel, economists, and other professional class consultants on every deal, regardless of its impact on competition. Another commenter suggested that hiring consultants to draft narratives may be prohibitive for some parties that may be most in need of a merger or affiliation. One comment noted that, as a practical matter, the only people who are eligible to certify the notification often lack personal knowledge necessary to opine about things like the relevant product market definition or the competitive effects of a transaction. The Commission disagrees that filers need to hire outside personnel, who do not know the filer's business operations and would need to be given the very information that the Competition Descriptions call for in order to draft them. As noted in the NPRM, those who author the descriptive responses should be the individuals who best know the business of the filing person. The Commission reiterates that the Competition Descriptions should be based on a businessperson's understanding of the filer's business operations and consistent with other business documents and materials submitted with the HSR Filing.

Other comments raised a related point, stating that the type of detailed, competitively sensitive information necessary to draft these narratives is often deliberately kept away from the business executives, which would require certain filing parties to employ antitrust safeguards to collect information without sharing confidential business information with or about one another. Several commenters asserted that providing customer contact information, including identifying specific individuals for Agency outreach, would create significant uncertainty and further increase the risk that confidential acquisition plans would be known more widely, or increase the risk of insider trading.[361]

As discussed in the section below, the Commission agrees that it is important to reduce the need to share information about the transaction more broadly than is necessary to complete an HSR Filing, but rejects the idea that companies are unfamiliar with managing these risks or that the rule would significantly increase them. Also, complying with securities laws to prevent insider trading in public shares is an obligation of every publicly traded company, and the rule does not increase the risk that those with knowledge of the deal will violate those laws. Nonetheless, in response to these concerns, as discussed below, the Commission has determined to modify certain requirements for the Competition Descriptions in order to reduce the need for filers to share information outside of the company, for instance with customers or suppliers. The Commission agrees that the process required to collect information for the notification should not require information-sharing beyond what is absolutely necessary. Specifically, the Commission has added to the instruction a statement that the parties should not exchange information for the purpose of responding to the Overlap or Supply Relationships Descriptions. The acquiring and acquired persons should each respond on the basis of information known to them in the ordinary course of their business or through normal transaction diligence. The Commission understands that, unlike the NAICS overlap identification, the filings may not identify the same products and services in the Competition Descriptions. This may require those contemplating a transaction to plan for limits on the flow of information about the deal, including ''clean teams'' and data rooms with limited access, but the Commission believes filers have experience with managing these risks and employ protections to prevent the sharing of information or disclosing knowledge of the deal beyond these limits. The Commission has determined that the requirement to prepare descriptive responses does not increase the risk that those protections will be breached or that filers will be required to change their approach to comply with the final rule. To the extent that this process reveals existing business relationships of which either or both parties were not aware, this is an appropriate outcome of requiring this analysis to be done prior to filing.

Another group of comments raised compliance concerns related to taking an affirmative position on specific elements of an antitrust violation, such as the definition of relevant markets and any competitive effects, impermissibly shifting the burden of proving such elements of an antitrust violation to the parties. For instance, one commenter read the rule as not requiring filers to define a relevant market or provide market shares but nonetheless objected that filers lack the benefit of established competition law principles to guide the scope of their responses. Others suggested that the Commission adopt the practice of the European Union and other regimes and make available written decisions about market definitions.

As stated in the NPRM, the Commission does not intend for the Competition Descriptions to contain an assessment of relevant markets or reference any ''market.'' The Commission understands that the determination of a relevant antitrust market is a fact-bound process that is the result of extensive information gathering, including from third parties (who may be other participants in the ''market''). Information contained in the notification has never been, and never could be, sufficient to determine whether a relevant antitrust market exists in which the transaction could potentially cause harm. Rather, the Commission intends the identification of competing products or supply relationships to be a statement of business fact, not a conclusion that there is a relevant antitrust market that comprises an area of effective competition.[362] The Agencies recently

[361] Commenter American Securities Association states that certain aspects of the proposed rule would require public companies to announce and file details with the SEC about signed deals, ''creating additional hurdles that will test investor confidence.'' Comment of Am. Sec. Ass'n, Doc. No. FTC–2023–0040–0682 at 2. Because the final rule does not change who is required to file notification under the Act, there are no new obligations to disclose transactions nor to make statements to the SEC. To the extent that this comment is based on a concern that the Agencies may flag additional deals as requiring Second Requests because they may determine that a particular transaction may violate the antitrust laws, that is the intention of the final rule and well within the Commission's authority under the Act, regardless of filers' obligations to make statements required by the securities laws.

[362] A party responding to an interrogatory under Rule 33 of the Federal Rules of Civil Procedure ''must furnish information that is available to it and that can be given without undue labor and expense,'' and a party must ''provide relevant facts reasonably available to it but should not be required to enter upon independent research in order to

Continued

released updated Merger Guidelines that contain a detailed discussion of how and why the Agencies undertake the exercise of defining markets.[363] Thus, the Commission disagrees that filers are unable to understand how information about whether and to what extent the merging parties are direct competitors factors into the Agencies' initial antitrust assessment.

Comparison to Other Jurisdictions

Some comments suggested that the Commission is improperly attempting to model the U.S. premerger notification regimes on those in other jurisdictions. The Commission rejects this suggestion. The purpose of this rulemaking is to maintain a premerger notification regime that fulfills the Agencies' congressional mandate to vigorously enforce the U.S. antitrust laws and prevent undue concentration in its incipiency. As the Commission noted in the NPRM, many other jurisdictions rely on submissions from the parties that contain basic information about business lines or company operations, and several require the parties to self-report overlaps.[364] The Commission expects that the burden on filers (or their counsel) with experience drafting these submissions for other jurisdictions will be comparatively low because of their familiarity with such drafting. This does not mean that the Commission is relying on the experience of other jurisdictions in enforcing their laws. Rather, the Commission is simply noting that the prevalence of descriptive requirements among other competition enforcers supports its belief that, for some filers, preparing descriptive responses is not a new exercise or overly burdensome. The Commission further notes that other businesses might be familiar with preparing a business plan or conducting a market research and competitive analyses, which would contain much of the same information as is required by the narratives.[365]

One commenter stated that pharmaceutical transactions are not acquisitions of other companies but instead involve exclusive licenses, which are not reportable in other jurisdictions. As a result, according to this commenter, the descriptive requirements introduce an entirely new and significant burden that will fall disproportionately on parties to pharmaceutical transactions. The Commission disagrees that there will be a measurably different impact on pharmaceutical companies. As discussed above, the requirement to submit Competition Descriptions is not dependent on having prepared similar materials for other jurisdictions, and there are many kinds of transactions that are not reportable in other jurisdictions for which the parties will now be required to submit a descriptive response. In addition, the Commission has no reason to exempt pharmaceutical licensing deals from any requirements of the Act because these transactions, like other reportable transactions, can raise antitrust concerns.[366] As the D.C. Circuit found when it upheld the Commission's authority to require the reporting of pharmaceutical licensing transactions, the Act does not prevent the Commission from adopting rules of general applicability and the Commission can rely on its experience in reviewing HSR Filings to adjust the HSR rules.[367] Certain sectors have more reportable transactions, but the Commission is not imposing different requirements on any sector. Nor should it remove information reporting requirements for those sectors where there are more reportable transactions merely because more companies in those sectors are involved in reportable transactions. Moreover, the Commission believes that complying with the Competition Description requirements for transactions involving licensing agreements will be less costly than for other types of transactions because those transactions are fairly limited in purpose as they relate to uses for the licensed technology.

After careful consideration of the comments raising general objections to requiring descriptions of existing business operations of the merging parties, the Commission has determined to require Competition Descriptions in the final rule due to the benefit they would provide to the Agencies. These responses will provide the Agencies with key information that is necessary to determine whether an acquisition, if consummated, may violate the antitrust laws. It is appropriate for filers to provide this information because they are in the best position to do so. Competition Descriptions will allow the Agencies to conduct a fact-based assessment of the antitrust risks posed by each transaction, rather than expend time and resources issuing voluntary access letters and Second Requests for information that bears directly on the determination that further investigation is warranted. Nonetheless, in light of the concerns expressed by commenters, the Commission has made significant modifications to these requirements to better calibrate the information that would be most beneficial to the Agencies while reducing the cost as much as practical, including excusing select 801.30 transactions from these requirements.

1. Overlap Description

The Commission proposed a new Overlap Narrative section that would require each filing person to provide an overview of its principal categories of products or services (current and planned) as well as information on whether it currently competes with the other filing person. The Commission further proposed that each filing person would describe its current and planned principal categories of products and services in a way that those business lines are referred to in the company's day-to-day operations, and identify any documents submitted with the HSR Filing that support information contained in the narrative. For each identified overlapping product or service, the Commission proposed that the filing person would also provide sales, customer information (including contacts), a description of any licensing arrangements, and a description of any non-compete or non-solicitation agreements applicable to the employees or business units related to the product or service.[368]

The Commission received numerous comments on this requirement. As one commenter noted, the Commission's original proposal in 1977 would have required a filer to identify its top five most significant competitors for overlapping operations. The Commission did not adopt this proposal, as well as other proposals, not because they were improper, as suggested by this commenter, but because the Commission determined at the time that it was important to reduce

acquire information merely to answer interrogatories.'' *Lynn* v. *Monarch Recovery Mgmt., Inc.,* 285 FRD. 350, 357 (D. Md. 2012) (citation and internal quotations omitted). Filers should take a similar approach to providing business facts here.

[363] *See* Dep't of Justice & Fed Trade Comm'n, Merger Guidelines 4.3 (2023).

[364] NPRM at 42180.

[365] The Small Business Administration provides guidance for how to conduct market research and find a competitive advantage, including links to free government databases and resources to help with that assessment. *See* U.S. Small Bus. Admin, ''SBA Business Guide, Market research and competitive analysis'' (last updated May 31, 2024), *https://www.sba.gov/business-guide/plan-your-business/market-research-competitive-analysis#id-use-market-research-to-find-customers.*

[366] *See, e.g., In re Sanofi Corp.,* No. 9422 (F.T.C. Dec. 11, 2023) (complaint) (transaction abandoned); *FTC* v. *Mallinckrodt ARD Inc. (f/k/a Questcor Pharms., Inc.),* No. 1:17–cv–120 (D.D.C. Jan. 30, 2017) (stipulated order for permanent injunction and equitable monetary relief).

[367] *PhRMA,* 790 F.3d at 201.

[368] NPRM at 42196.

the overall burden of complying with notification requirements,[369] which were unfamiliar to the M&A business community at that time. After forty-five years of experience with reviewing thousands of transactions each year, the Agencies are now well aware of the importance of understanding who the parties view as their competitors, especially if that group includes the other merging party, because it is relevant to whether the transaction may violate the antitrust laws.[370] The need for this self-identification of competitors has grown over time as NAICS codes and other information do not always provide a consistent and reliable benchmark for filers, resulting in over- or under-reporting of competitive overlaps. In this rule, filers are merely required to describe each of the principal categories of products and services they offer, and list and describe each product or service that they both provide to the market. The Commission believes that in light of the shortcomings of other more objective reference points, it is necessary to require filers to identify whether they offer products or service that compete with the other filing party.

Several comments pointed to the burden of providing an Overlap Description for all filings. For instance, one commenter stated that the proposal lacks a relevance test or de minimis threshold so that companies will be required to delve deep into complex corporate structures to identify individual products and services offered by their subsidiaries. Another raised concerns that providing a detailed analysis of competitive dynamics in each of these theoretical segments, particularly in transactions that are occurring in manifestly competitive environments, is wasteful and unduly burdensome.

As discussed above, in light of concerns about the cost this requirement places on all filers, the Commission has modified its proposal in several ways to reduce the cost on filer. First, it has decided to limit the requirement to report planned or future products to those referenced in another document submitted with the HSR Filing. The Commission has also eliminated the requirement to provide an estimate of how much of the product or service each customer category purchased or used monthly for the last fiscal year. And rather than require reporting for the two most recent fiscal years, the Commission has limited reporting to the most recent fiscal year. In addition, the Commission has decided not to require sales information in units—only dollars. It has also eliminated the requirement to provide individual contact information for customers. Additionally, the Commission has eliminated the requirement to describe licensing agreements and non-compete or non-solicitation agreements in this section. These changes are discussed in greater detail in the sections that follow. Finally, the Commission has decided not to require Overlap Descriptions for select 801.30 transactions. In the Commission's experience, these filings almost never report overlaps on the basis of NAICS codes and there is no reason to think that requiring this class of filers to provide a descriptive confirmation would provide a benefit to the Agencies that would enhance premerger screening of this particular set of transactions.

At this time, the Commission lacks a basis to excuse other categories of filings either on the basis of complexity of the filer's corporate structure or the general robustness of competition in the markets in which the filers compete. In fact, complex corporate structures can make it much harder for the Agencies to discover competing lines of business from any source other than the filers. When information in the HSR Filing is inconclusive, staff often must try to discover these existing relationships based on imperfect information from public sources, the parties' submitted documents, and other sources of market information, such as third parties. Requiring filers to provide a description of any overlap is a much more direct, efficient, and reliable way to get this critical information because it will be coming from the parties. If the parties are aware of other companies that also provide products or services that compete, they can (but are not required to) provide that information as part of their descriptive response. If this requirement creates a significant cost to filers, it is due to their significant pre-acquisition business relationships, meaning that the effort to provide the description is directly proportional to the risk that the transaction may violate the antitrust laws.

After careful consideration of the comments, the Commission has made significant modifications to the Overlap Description to reduce the cost to filers while also providing a factual basis for identifying whether the filing parties are actual or potential competitors. This information will improve Agency decision-making during the initial waiting period. Modifications reflected in the final rule are discussed below.

a. Identification of Current or Future Overlaps

The Commission proposed that each filing person provide a brief overview of its principal categories of products and services (current and planned) as well as information on whether it currently competes with the other filing person. As noted in the NPRM and discussed above, such information is core to the Agencies' substantive antitrust analysis during the initial waiting period and is not readily accessible from sources other than the filers themselves.[371] A comment from State antitrust enforcers supported the requirement for additional information about present and potential horizonal competitive overlaps, noting that State antitrust enforcers are particularly concerned with acquisitions of potential or nascent competitors and the protection of rivalrous innovation. As fellow enforcers of the Federal antitrust laws, they noted that most research and development (''R&D'') pipelines are known only to the companies and that disclosing current or known plans, including R&D efforts, up front would ensure effective deal reviews. They noted that, at times, deals that appear benign may mask significant anticompetitive effects lurking below the surface. Sophisticated incumbent companies have a greater incentive and more developed means to detect industry developments—and a correspondingly far-reaching ability to curb competition in ways that harm consumers.

As discussed in section II.B.4., the Agencies currently lack a sufficient basis from information in the notification to determine if the transaction is likely to violate the antitrust laws by eliminating on-going innovation competition, a potential competitor, or a nascent competitive threat that has yet to make sales. Without information that indicates there are known areas of competition based on expected revenues, this will continue to be a blind spot that results in less-than-optimal enforcement on this basis. Because these areas of potential or emerging competition are typically not well-known to others uninvolved in the transaction, the Agencies do not have a source for this information other than the filing parties.

The need for information related to planned products and services is especially important for transactions in which one (or both) filers already have

[369] *See* 42 FR 39040, 39043 (Aug. 1, 1977).

[370] *See, e.g., Illumina, Inc.* v. *FTC,* 88 F.4th 1036, 1049 (5th Cir. 2023); *FTC* v. *Whole Foods Market, Inc.,* 548 F.3d 1028, 1045 (D.C. Cir. 2008) (Tatel, J., concurring in judgment).

[371] NPRM at 42196.

a dominant position and the other party has planned products that could soon be introduced to the market to provide some level of competition to the dominant player. According to the State antitrust enforcers, acquisitions of potential or nascent entrants may empower already dominant incumbents to discontinue either the target firm's or its own innovation, thereby eliminating existing and future competition between the merging parties and information supplied by the Overlap Description is critical for the Agencies to analyze acquisitions affecting potential competition or present rivalrous innovation.

Other commenters object to the requirement to identify overlaps based on planned products or services under development by the other party. One pointed out that many companies have a pipeline of product ideas that may or may not result in an actual product sold to customers. Others indicated that in the pharmaceutical and biotechnical sectors, this information would be speculative at best for many ongoing R&D initiatives. The Commission acknowledges that the assessment of when a planned product or service will start generating revenues is likely imprecise, and that products in development often do not meet important deadlines for commercial release. But the Commission disagrees that companies with extensive R&D pipelines are unfamiliar with these drawbacks or that imprecision prevents them from having target launch dates based on their best information. In the Agencies' experience, companies with ongoing product development efforts routinely adjust expected timelines to commercialization based on new information. In particular, as part of preparing for the transaction, many of these companies prepare an assessment of the target's products, including products in development. Products in development can compete with other products in various stages of commercialization, forming the basis for antitrust liability in certain circumstances.[372]

Nonetheless, to provide an objective reference point that would determine whether a filer would need to include a product in development as part of its descriptive response, the Commission modifies this requirement to limit the reporting of current or known planned products or services to those that are reflected in documents submitted with the filing. This limitation should serve to reduce the cost and increase the certainty that the planned product or service is likely to be introduced. In particular, plans and reports provided to the CEOs and Boards of Directors and submitted with the HSR Filing would likely provide a solid reference point for filers to determine if the planned product is sufficiently likely to meet targets for commercial introduction because it is discussed in these high-level reports shared with key decision-makers.

In addition to the objections discussed above, several commenters objected to the specific requirements of identifying overlaps or customers based on sales information, which might include sales generated in markets outside the United States. One commenter stated that the requirement to provide historical information should be limited to sales and customers from U.S. operations and should be further limited to sales information based solely on sales by dollars, not additionally by units. The Commission declines to limit the Overlap Description to U.S. sales information. Many transactions every year involve industries whose companies compete on a global basis such that the relevant antitrust markets in which they compete are broader than the United States or involve facilities or customers that are located outside the United States.[373] Having this information is critical to the Agencies' assessment during the initial waiting period.

The Commission agrees with the other modification suggested by one commenter to limit this requirement by reporting revenues only based on sales by dollars and not also by units. As the commenter notes, in many service sectors such as healthcare or professional services, the concept of ''units'' is arbitrary and estimates would be both burdensome and unreliable. The Commission believes that it is less costly for filers to rely on only one measure of sales and that reporting by other measures in addition to sales often does not lead to different results. Thus, the Commission does not adopt the requirement to report sales based on units in addition to dollars and limits the reporting of sales and customer information only to dollar sales.

To further reduce the cost of collecting data to support the Overlap Description, the final rule requires the reporting of sales data only for the most recent fiscal year, down from the last two years as proposed. This limitation parallels other reporting requirements that are similarly limited to the most recent fiscal year.

The commenter also suggested that, in order to prevent the sharing of information between existing competitors that would inadvertently increase the risk of anticompetitive coordination, the information required by the Overlap Description be limited to information within the knowledge, information, or belief of the person filing. The Commission confirms that filers should prepare the Overlap Description based on the knowledge and belief of the filing person.

b. Customer Information

The Commission proposed that, for each principal category of products and services and each overlapping product or service, filers (a) describe all categories of customers, including an estimate of monthly sales or purchases in each category; (b) contact information (including the individual's names, title, phone, and email) for the top 10 customers (based on units and sales) for the last year, and the top 10 customers in each customer category.

Some individual commenters supported this proposal, urging the Agencies to take steps to better understand the impact of acquisitions on those most affected by them, including customers. Other comments raised concerns about the type and amount of information collected about customers, as well as the risks associated with identifying them in an HSR Filing, including providing individual contact information. One commenter asserted that the Agencies' stated intention to contact customers during the initial waiting period raises serious confidentiality concerns and places a transaction at considerable risk. Another commented that there may be legitimate business justifications for not disclosing a potential transaction internally or to commercial partners at the time of filing, and requiring specific contact information practically necessitates such disclosures to maintain employee and customer relations. According to another commenter, for the vast majority of transactions, customer information is not required to make an assessment that the transaction requires Second Requests, and thus the Agencies should

[372] *See, e.g., Illumina* v. *FTC,* 88 F.4th at 1050.

[373] *See, e.g., Polypore Int'l, Inc.* v. *FTC,* 686 F.3d 1208 (11th Cir. 2012); *FTC* v. *Wilh. Wilhelmsen Holding ASA,* 341 F. Supp. 3d 27 (D.D.C. 2018); *FTC* v. *Tronox Ltd.,* 332 F.Supp.3d 187 (D.D.C. 2018); *In re Nvidia Corp.,* No. 9404 (F.T.C. Dec. 2, 2021) (complaint)*; United States* v. *ZF Friedrichshafen A.G.,* No. 1:20–cv–00182 (D.D.C. Jan. 23, 2020) (complaint); *United States* v. *United Techs. Corp.,* No 1:18–cv–02279 (D.D.C. Oct. 1, 2018) (complaint); *United States* v. *Novelis, Inc.,* No. 1:19–cv–02033 (N.D. Ohio Sept. 4, 2019) (complaint); *In re Corpus Christi Polymers LLC,* No. C–4672 (F.T.C. Feb. 20, 2019) (decision and final order): *In re Quaker Chem. Corp.,* No. C–4681 (F.T.C. Sept. 9, 2019) (decision and final order).

continue to ask for customer contact information on a voluntary basis only when it may be necessary.

After considering these comments and others, the Commission modifies the amount of information required in the Overlap Description related to customers but has determined that some information related to customers is important for the initial antitrust assessment of the transaction. The Agencies will continue to reach out to customers in order to get their input and reactions to reportable transactions as time and resources allow during the initial waiting period regardless of whether they are referenced in the notification. Contacting customers to learn about the business lines of the filing parties is often the very first thing staff does to begin the investigation of a potentially problematic transaction. As discussed in section III.C.1., the Agencies routinely contact many customers of the filing parties, often without the filing parties' knowledge, during the course of an investigation, especially if the initial waiting period is prolonged by a withdrawal and refile.

There is nothing improper about the Agencies' contacts with third parties to learn facts about the industry or the operations of the filing parties. The HSR Act contains strict limits on the disclosure of information submitted or collected during an investigation,[374] and unauthorized disclosure carries criminal penalties.[375] At all times during the investigation, Agency staff comply with these requirements. For example, when contacting customers or other market participants, Agency staff may disclose that the agency is conducting a nonpublic investigation of the proposed transaction, but Agency staff will not disclose any information contained in an HSR Filing without a waiver.

Although collecting more information from filers in the HSR Filing should reduce the Agencies' reliance on contacting third parties to learn basic business facts about the merging parties, conducting outreach with third parties is an essential task of premerger screening to ensure that the Agencies' antitrust assessment fully considers any potential impact of the transaction on other market participants.[376] Because transactions may not have been publicly disclosed, it is imperative that the Agencies initiate contact with third parties and not wait for them to reach out. The Agencies routinely conduct public research to learn about customers for potential outreach, regardless of whether the filing parties have provided their contact information. Moreover, customer information is typically in the agency's first request to filers to submit additional information on a voluntary basis during the initial waiting period. At times, filers have anticipated this voluntary request and provide this information quickly, sometimes the same day. However, this is not universally true and any delay in obtaining this information about top customers is inefficient and undermines the Agencies' ability to conduct third-party outreach. While the Agencies may be able, on their own, to identify some customers of the filing parties, it is important that such third-party outreach also include those customers most affected by the transaction, that is, those customers who are most reliant on the filing parties to conduct their own business.

Nonetheless, in light of concerns about identifying particular individuals as customer contacts, the Commission does not adopt that requirement as proposed. Instead, the Commission modifies the requirement so that filers must identify customers by company name without providing contact information for any individual employed by the company. The Commission believes that company contact information has value even without knowing the name or title of the individual at the customer business that is most knowledgeable about the existing business relationship with the filer. Moreover, knowing which companies are top customers provides important context to determining whether any particular customer may be affected by the elimination of competition between the parties and is additional information beyond knowing what the overlapping product or service is.

To further reduce the cost of providing information related to customers, the Commission has modified this requirement so that filers do not have to estimate monthly purchases or sales by customer category as proposed. Filers will be required to describe all categories of customers without providing specific sales or purchase estimates by category. Simply describing categories of customers will enable the Agencies to determine if there are unique end-uses for the product, possibly reflecting some degree of non-uniform demand that would indicate limits on substitutability across different customers. Qualitative descriptions of customer categories are sufficient for the Agencies to determine, at a preliminary stage, whether demand is segmented, a fact that is important for gauging potential competitive effects of the transaction. Relatedly, this additional information may help eliminate or reduce antitrust concerns if the parties serve very different customers or customer categories.

With these significant modifications, the Commission adopts the requirement that filers providing an Overlap Description also include some information about customers for those products or services.

c. Descriptions of Agreements With the Other Filing Party

The Commission proposed that as part of the Overlap Description, for each overlap product or service identified, filers would provide a description of certain competitively significant agreements between the filing parties, such as licensing arrangements and any non-compete or non-solicitation agreements applicable to employees or business units related to the product or service.[377]

One commenter supported the collection of information related to existing agreements between the filing parties because it may be relevant to an assessment of whether something short of a full merger may be sufficient to enable the parties to realize the potential procompetitive benefits of a transaction without potential competitive harm. No commenter specifically objected to this particular requirement of the Overlap Description. However, in light of objections to the overall cost of the final rule, the Commission does not adopt this proposal at this time. Instead, the Commission believes that the requirement, discussed in section VI.I.1, to indicate via check boxes whether certain types of agreements exist between the acquiring person and target will alert the Agencies to transactions that may require further investigation.

2. Supply Relationships Description

The Commission proposed to require each filing person to provide information about existing or potential purchase or supply relationships between the filing persons. This description would require filers to describe each product, service or asset (including data) that the filer sold, licensed or otherwise supplied, to the other party or to any other business that, to the filer's knowledge or belief, uses its product, service, or asset to compete with the other party's products or services, or as an input for a product or

[374] 15 U.S.C. 18a(h).

[375] *See* 18 U.S.C. 1905, 15 U.S.C. 50.

[376] Some commenters believe that the Agencies have been insufficiently attentive in the past to those most affected by harmful consolidation.

[377] NPRM at 42196.

service that competes with the other party's products or services.[378] Similar information is required for purchases from the other party. According to the NPRM, this information would allow the Agencies to identify whether the transaction would create opportunities for post-acquisition foreclosure of rivals arising from vertical or diagonal relationships.[379] As discussed in section II.B.3., current information requirements do not provide a factual basis to alert the Agencies that there is an existing supply relationship that might require a closer look to determine whether the transaction is likely to violate the antitrust laws.

As noted in the NPRM, in the past the Commission had required filers to provide similar information about vertical vendor-vendee relationships, but the requirement was eliminated in 2001; since that time, filers have provided no specific information related to existing vertical or other supply relationships. Several commenters objected to including this information again, noting that vertical concerns will not be a feature of most transactions, and information related to these issues is more appropriate for a Second Request once the Agencies have determined that the transaction genuinely raises vertical foreclosure concerns. One commenter stated that information about sales to and purchases from non-transacting parties has limited, if any, relevance to the transaction and is thus outside the scope of the Act. Another noted that concerns about unwinding already-consummated transactions that motivated the Act are not present in non-horizontal transactions, and urged the Agencies to exempt purely non-horizontal transactions from the reporting requirements of the Act on that basis.

Other commenters supported the reintroduction of the requirement to report information related to key supply relationships, suggesting that descriptive responses should provide a more accurate and complete basis for screening transactions. One commenter commended the Commission for recognizing the need to request information about input markets and noted the historical lack of such information has resulted in an information asymmetry between the Agencies and filing parties. Others identified industry-specific concerns related to non-horizontal implications of acquisitions. One commenter cited the example of the seed industry, commenting that to understand market power in that industry the Agencies must have information regarding the unique supply, distribution, and licensing dynamics that are present. Another commenter discussed the proposal's impact on private equity firms, claiming it is common for firms to have portfolios that include upstream and downstream segments, a structure that can incentivize preferential treatment between portfolio companies in ways that disadvantage rivals.

State antitrust enforcers also supported the need to better understand any supply relationships, including through the collection of information regarding data assets. They explained that the merger of two firms' complementary data sets can create, augment, and maintain market power. As antitrust enforcers, they stated that they also seek to understand how the target's data can be combined with the buyer's, and whether the combined data can be used to leverage power into further applications. To fully account for the potential that the combination of the buyer's and seller's data could be leveraged into additional applications, the State antitrust enforcers recommended the Commission consider whether these requests should be expanded beyond the related purchases and related sales narrative.

After considering the concerns raised by commenters on both sides, the Commission has determined that the final rule will require, once again, the submission of information related to supply relationships. Contrary to assertions that the Agencies rarely challenge, and even more rarely prevail against, non-horizontal acquisitions, the Agencies have blocked several non-horizontal mergers since 2021 and have another challenge pending review.[380] The Commission specifically rejects the suggestion that the final rule exempt non-horizontal mergers from the reporting requirements of the Act. Such an exemption would abrogate the Agencies' direct Congressional mandate not to ignore mergers that do not involve horizontal competitors. With the 1950 amendments to the Clayton Act, Congress made clear that section 7 applies not only to mergers between actual competitors but also to vertical and conglomerate mergers.[381]

The Commission observes that mergers that create a risk of non-horizontal concerns are more varied in their effects, with the over-arching concern being the risk that the transaction provides the merged firm with the ability and incentive to foreclose rivals. According to controlling precedent, there are myriad ways in which the merged firm could engage in foreclosing behavior, such as by making late deliveries or subtly reducing the level of support services.[382] In light of that variety of potential mechanisms, it is important to have some basis to assess whether the transaction creates a risk that the merged firm may limit access to products or services that its rivals use to compete.[383]

Some commenters questioned whether, as a practical matter, filers will be able to gather the information required by the Supply Relationships Description. For instance, one commenter stated that providing this information would require filers to create a new tool for tracking related sales and purchases, while another noted that, especially for retailers who are often ''price takers,'' there may be no need internally for conducting this type of analysis, meaning it would be undertaken solely to comply with the Act for reporting transactions. Two other commenters stated that this narrative is duplicative of document requests and thus should be eliminated.

The Commission disagrees that the new Supply Relationships Description requires special reporting tools or is duplicative of document requests. In the Agencies' experience, documents submitted with the HSR Filing often do not contain references to key suppliers or purchasers, or the documents do not

[378] *Id.* at 42196–97.

[379] *See* Dep't of Justice & Fed Trade Comm'n, Merger Guidelines 2.5 (2023).

[380] *See* Press Release, Fed. Trade Comm'n, ''Statement Regarding Illumina's Decision to Divest Grail'' (Dec. 18, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/12/statement-regarding-illuminas-decision-divest-grail*; *In re Lockheed Martin Corp.,* No. 9405 (F.T.C. Jan. 25, 2022) (complaint alleging merger would enable missile systems manufacturer to use control over missile propulsion systems to harm rival defense prime contractors) (transaction abandoned); *In re Nvidia Corporation,* No. 9404 (F.T.C. Dec. 2, 2021) (complaint alleging merger would give chip manufacturer the ability and incentive to use control over microprocessor design technology to undermine competitors) (transaction abandoned); *In re Microsoft Corp.,* No. 9412 (F.T.C. Dec. 8, 2022) (complaint). *See also FTC* v. *Procter & Gamble Co.,* 386 U.S. 568, 577 (1967) (whether classified as horizontal, vertical, conglomerate or other, all mergers tested by the same standard under section 7).

[381] *Brown Shoe Co.* v. *United States,* 370 U.S. 294, 317 (1962) (explaining that by the deletion of the acquiring-acquired language in the original statutory text, Congress hoped to make plain that section 7 applied not only to mergers between actual competitors, but also to vertical and conglomerate mergers whose effect may tend to lessen competition in any line of commerce in any section of the country). *See also* H.R. Rep. No. 1191, at 11 (1949).

[382] *See Illumina, Inc.* v. *FTC,* 88 F.4th 1036, 1053 (5th Cir. 2023).

[383] *See* Dep't of Justice & Fed Trade Comm'n, Merger Guidelines 2.5 (2023).

provide sufficient context to understand whether the merged firm will have the ability to foreclose key inputs in violation of the antitrust laws. Nor does the Commission agree that companies are unaware that they are in an existing supply relationship or that there would be no records for a company to determine that it has purchases from or sales to another company. As with the Overlap Description, requiring filers to provide a brief description of any sales or purchase relationship is a much more direct, efficient, and reliable way to get this critical information because it will be coming from the parties and does not require staff to interpret references in documents to these types of relationships. Even given the expansion of document requirements in the final rule, this specific information that describes an existing business relationship in the same supply chain is unlikely to be revealed in transaction-specific documents or those generated in the ordinary course. This is especially true because the Supply Relationships Description requires each filer to identify whether it supplies not just the other party but a different company that competes with the other party.

Two commenters urged the Commission to narrow the scope of the required information by adopting a limitation for de minimis levels of related sales or related purchases, for example by restricting requirements to those related sales or purchases generating over $10 million in U.S. revenue in the past fiscal year. One commenter noted that the pre-2001 reporting for vendor-vendee information was limited to transactions between the parties and to purchases or sales over $1 million, and stressed the need for the Agencies to establish a similar objective criteria to guide filers and avoid reporting thousands of routine or competitively benign purchases. Another commenter questioned the need for the Commission to revive a request that it deemed insufficient as a screen for potential non-horizontal relationships.

After careful consideration of these comments, and in light of the Commission's intention to reduce cost wherever practical, the Commission has made several modifications to the Supply Relationships Description. As with the Overlap Description, the Commission declines to exclude information related to sales outside the United States. Here too, such an exclusion is not justified for the significant number of transactions for which sales occur outside the United States and yet the transaction has sufficient nexus to the United States to require reporting. Nonetheless, the Commission has determined that the rule should include a de minimis exclusion to reduce the cost of collecting information related to competitively insignificant sales or purchases. The final rule excludes reporting unless the product, service, or asset (including data) represented at least $10 million in revenue. In order to ensure that the de minimis exclusion does not cause filers to underrepresent their own production or capacity to supply the market, the de minimis amount is inclusive of internal transfers within the filing person. That means that when applying the de minimis exclusion, the filer should include the value of the product that it supplies to itself because that reflects the filer's ability to meet the demand for the product. For example, if the acquiring firm sells Product X to the target, when calculating the total revenue for Product X to determine whether Product X represents at least $10 million in revenue, the filer must include its own consumption of Product X and sales of Product X to anyone else. If all of the filer's sales (including internal sales) of Product X represent less than $10 million in revenue, the filer does not need to respond to the Supply Relationships Description for sales of Product X.

As with the Overlap Description, several commenters objected to the Supply Relationships Description on the grounds that it is subjective and burdensome and that it would require premature disclosure of the deal or improperly shift the burden of proving an antitrust violation from the Agencies to the filing parties. Accordingly, the Commission has determined to make similar modifications to the Supply Relationships Description as it did for the Overlap Description, in order to reduce the cost of reporting. Specifically, the final rule limits the reporting period to the most recent fiscal year and requires reporting for sales only in dollars, not also in units. It also eliminates the requirement for contact information for individuals at customers or suppliers, requiring only the identity of the company to limit the risk of inadvertent disclosure. With these modifications, the Supply Relationships Description will provide a factual basis to determine whether the transaction requires a closer look to assess the risk of foreclosure, while minimizing the cost as much as practicable.

3. Labor Markets Information

The Commission proposed creating a new Labor Markets Information section within the Instructions that would require each filing person to provide certain information about its workers in order to screen for potential labor market effects arising from the transaction. As noted in the NPRM, the Agencies have increasingly recognized the importance of evaluating the effect of mergers and acquisitions on labor markets.[384] Yet, as noted in section II.B.2., the Agencies' HSR Form does not collect information from filers about their employees or the type of work that their employees do that would allow the Agencies to identify the parties as competitors for certain labor services, raising challenges for the effective enforcement of section 7 to protect competition that benefits workers.[385]

Within the Labor Markets section, the Commission proposed requiring each filing person to (1) provide the aggregate number of employees for each of the five largest 6-digit Standard Occupational Classification (SOC) codes; (2) identify the top five largest 6-digit SOC codes in which both parties employ workers, and for each of these SOCs, list the overlapping ERS-defined commuting zones and the total number of employees within each commuting zone; and (3) identify any penalties or findings that were issued against the acquiring person or acquired entity by the DOL's Wage and Hour Division, NLRB, or OSHA during the five-year period before the filing.[386]

The Commission received many comments focused on the labor market proposals. Several commenters, including hundreds of individual commenters, supported the Agencies' attention to the potential for merger-induced harm in labor markets and the requirement that parties submit information about their employees for premerger screening. Supportive commenters stated that filers have sophisticated legal and accounting personnel and systems to minimize the burden on the companies of collecting and reporting employee information. Other commenters asserted that requesting labor market information in the earlier stages of merger review would lead to a more efficient and uniform process that could result in the Agencies' termination of the HSR waiting period prior to the end of the initial 15 or 30 days in a greater number of mergers where no labor market issues exist.

[384] NPRM at 42197.

[385] 15 U.S.C. 18.

[386] NPRM at 42197–42198.

Other commenters, including law firms, private equity and venture capital groups, and industry groups, raised broad objections to the Commission's proposal to collect labor market information in the HSR Form. These organizations argued that the effort required by the Labor Markets section would be significant and would greatly increase costs for companies wishing to engage in reportable transactions. Moreover, they argued that this increased burden was not justified by the utility of the employee information required by the proposed rule for antitrust screening. Some commenters stated that the increased burden of complying with these reporting requirements would have a chilling effect on transactions.

In light of the comments, as well as the Agencies' recent experience in identifying and investigating transactions that may harm competition for workers, the Commission has determined not to require specific information about employees at this time. After considering several options to collect worker information that would be specific enough to allow the Agencies to screen for potential labor market effects without unduly burdening filers, the Commission has determined that the Agencies will rely on other information required by the final rule to identify transactions that require an in-depth investigation for potential labor market effects. This includes the new Competition Descriptions, which together will provide the Agencies with a better understanding of the premerger competition between the merging parties. The Commission believes that this information is likely to reveal those transactions where the filers are likely to compete for workers that do the same or similar types of jobs because they supply similar or related products or services. In addition, the new document requirements, including plans and reports and additional transaction-related documents, should reveal whether the parties view themselves as competing for labor services. From these documents, as well as a description of the rationale for the transaction from the buyer, the HSR Filing should reveal whether the buyer anticipates any impact on workers or labor costs as a result of the transaction.

The Commission acknowledges the need to obtain detailed information about employees for some transactions during the merger review process and will continue to consider whether it is appropriate, on a case-by-case basis, to require the production of such information in a Second Request.

a. Worker and Workplace Safety Information

The Commission proposed to create a Worker and Workplace Safety Information section that would require filing persons to identify any penalties or findings that were issued against the acquiring person or acquired entity by the U.S. Department of Labor's Wage and Hour Division, the National Labor Relations Board, or the Occupational Safety and Health Administration during the five-year period before the filing. Several commenters supported the inclusion of the Worker and Workplace Safety Information, noting that the information could prove indicative of a concentrated labor market and market power. One commenter stated that it had previously alleged that repeated and widespread labor law violations constituted direct evidence of labor market dominance that could be relevant to merger analysis. Others noted that this information is often known to the filers and may be indicative of a concentrated labor market.

Some commenters urged the Commission not to require the submission information about past workplace violations due to the lack of a clear nexus between labor law violations and merger analysis. Other commenters stated that labor law violations may be tied to issues that are irrelevant to market power, such as the presence of an organized labor group that is more inclined to report potential violations, and the requirement should be limited to the industries where violations are more prevalent. Some stated that the existence of labor law violations was government data that was already available to the Agencies without placing the obligation on parties to report such violations.

The Commission acknowledges that information regarding some of these violations may be publicly available or otherwise available to the Agencies. The U.S. Department of Labor and the National Labor Relations Board maintain public accessible databases containing labor enforcement case information on their respective websites.[387] In addition, the Agencies have each established Memoranda of Understanding (MOUs) with the Department of Labor and the National Labor Relations Board that would allow for the Agencies to obtain relevant non-public information regarding labor law violations.[388] Accordingly, when the Agencies identify potential harms to labor market competition through information contained in the HSR Filing or through other means, they can seek information on labor violations from publicly available sources, from the Department of Labor and the National Labor Relations Board under their respective MOUs, and when appropriate, from the filers on a voluntary basis or in response to Second Requests. Because this information may be available to the Agencies through means that would not require filers to provide this information in the HSR Filing, the Commission does not adopt the requirement for filers to submit information on worker and workplace safety, and it is not required by the final rule.

b. Requests To Expand Requirements for Information Related to Labor Markets

Some commenters encouraged the Commission to request more information about employees, including the merging companies' histories of labor law violations dating back ten years rather than only five years; information about their remote, temporary, or contract workers; and the merging companies' union avoidance activities and expenditures. Certain commenters encouraged the Agencies to consider the role of unions and collective bargaining to accurately assess employer market or monopsony power. In particular, commenters suggested that the Agencies could collect the following information to animate such an analysis: (1) a list of unions at controlled entities, associates, and franchisee/cooperatives; (2) copies of collective bargaining agreements, at least with any common unions; and (3) a narrative describing any opposition to

[387] *See* U.S. Dep't of Labor, ''Enforcement Data,'' *https://enforcedata.dol.gov/Enfdata/search.php*; Nat'l Labor Relations Bd., ''Case Search,'' *https://www.nlrb.gov/search/case.*

[388] *See* Press Release, Fed. Trade Comm'n, ''FTC, Department of Labor Partner to Protect Workers from Anticompetitive, Unfair, and Deceptive Practices'' (Sept. 21, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-department-labor-partner-protect-workers-anticompetitive-unfair-deceptive-practices*; Press Release, Fed. Trade Comm'n, ''Federal Trade Commission, National Labor Relations Board Forge New Partnership to Protect Workers from Anticompetitive, Unfair, and Deceptive Practices'' (July 19, 2022), *https://www.ftc.gov/news-events/news/press-releases/2022/07/federal-trade-commission-national-labor-relations-board-forge-new-partnership-protect-workers*; Press Release, U.S. Dep't of Justice, ''Justice Department and National Labor Relations Board Announce Partnership to Protect Workers'' (July 26, 2022), *https://www.justice.gov/opa/pr/justice-department-and-national-labor-relations-board-announce-partnership-protect-workers*; Press Release, U.S. Dep't of Justice, ''Departments of Justice and Labor Strengthen Partnership to Protect Workers'' (Mar. 10, 2022), *https://www.justice.gov/opa/pr/departments-justice-and-labor-strengthen-partnership-protect-workers.*

efforts to unionize, including union avoidance activities and expenditures. The Commission acknowledges the utility of collecting this information for some transactions during the merger review process but does not believe that this information is necessary for all filings at the screening stage. As a result, the Commission has not included requirements for this information in the final rule but will continue to consider whether it is appropriate, on a case-by-case basis, to request such information during the investigation of the transaction.

In sum, the Commission has determined that the requirements of the final rule to provide descriptions of areas of competitive interaction between the parties are necessary and appropriate to enable the Agencies to identify transactions that may violate the antitrust laws and that the requirements, as modified, have been tailored to reduce the cost of reporting as much as practicable.

J. Revenues and Overlaps

The Commission proposed a Revenues and Overlaps section to collect information currently required by Items 5(a), 6(c), 7, and 8, subject to proposed modifications. The Commission proposed substantive changes to the reporting of revenue by NAICS code, how NAICS overlaps of controlled entities are reported, which minority-held entities must be reported, and which prior acquisitions must be reported. As discussed below, the Commission adopts some of the changes as proposed, adopts others with modifications, and does not adopt others.

1. NAICS Codes

In the NPRM, the Commission proposed several changes related to revenue reporting. One of the changes was ministerial in nature—adopting the 2022 version of the NAICS codes. This proposal received no comments, and the Commission adopts it as proposed.

The Commission proposed other, non-ministerial changes to revenue reporting that reflect a substantively different approach to revenue information by: (1) eliminating the requirement that filing persons provide the precise amount of revenue attributed to each NAICS code and instead report revenues within ranges; (2) reporting NAICS codes on a descriptive basis through engagement with individuals familiar with the business operations of each operating company and providing additional information if more than one code would be appropriate; (3) requiring acquiring persons and acquired entities with more than one operating company or unit to identify which entity(s) derives revenue in each code; (4) requiring acquiring and acquired persons to report NAICS codes for certain pipeline or pre-revenue products; (5) clarifying that the acquired person must report the NAICS codes relevant to the acquired entity(s) at the time of closing; and (6) eliminating the requirement for filing persons engaged in manufacturing to provide revenue by NAPCS-based codes. As discussed below the Commission adopts some of these changes, adopts a modified version of others, and does not adopt certain of these proposed changes.

a. Reporting Revenues in Ranges

The Commission received several comments in support of the proposal to eliminate the requirement that filing persons provide the precise amount of revenue attributed to each NAICS code and instead report revenues within one of five ranges. One commenter stated that the introduction of levels proposed in the NPRM will simplify compliance with the NAICS allocation requirement. Two other commenters expressed general support for the proposed set of reorganized revenue information. The Commission did not receive any comments opposed to this change and adopts it as proposed.

b. Reporting Revenues on a Descriptive Basis

Regarding the proposal to report NAICS codes on a descriptive basis through engagement with individuals familiar with the business operations of each operating company and provide additional information if more than one code would be appropriate, two commenters objected on the grounds that it would be overly burdensome. One commenter noted that many NAICS codes are broad and disconnected from the modern economy, making it difficult to determine whether a particular code applies. The other commenter objected to the proposal to list all the codes that describe the products or services offered, explaining that it would be extremely difficult to comply with when relying on personnel at various operating companies that have varying familiarity with the NAICS system. The same commenter noted that if the Agencies are concerned about missing potential overlaps, the Overlap Description is a more effective way to address that concern.

The Commission acknowledges the concerns about cost and adopts this proposal with modifications. As noted in the proposed rule, in the Commission's experience, reliance on financial records often results in under-reporting or reporting revenues in codes that may not actually be descriptive of the products or services provided. Having knowledgeable business personnel select the appropriate NAICS codes that best describe the filer's business lines is the best way to ensure that the NAICS code revenues contained in the HSR Filing reflect the full range of products and services offered from a business perspective. However, the Commission will not require a particular methodology to collect NAICS codes and notes that the intent of this change is to have filers report codes that descriptively represent their revenues, and not need to rely on how they are captured in financial systems.

c. Identifying Entities That Derive Revenues in Each Code

Two commenters objected to the proposed requirement to report NAICS information separately by operating entity. Each of the commenters asserted that this additional requirement would likely create significant new burdens, in particular for larger companies with numerous subsidiaries. While this type of reporting may be more difficult for those with numerous subsidiaries, these are exactly the filings for which the Agencies cannot determine which entities generate revenues that are related to those of the other party. When parties report revenues by entity, the Agencies can quickly home in on which business lines are competitively relevant. The Commission notes that some filers already provide revenues in this way and it is extremely useful to the Agencies when they do. Although the Commission acknowledges that this proposal may be more difficult for some filers, it is necessary for the Agencies to have at the outset a clear picture of how revenues are generated within the filing person. The Commission adopts this change as proposed.

d. Reporting Revenues for Pre-Revenue Products or Services

The Commission received several comments regarding the proposal to require acquiring and acquired persons to report NAICS codes for certain pipeline or pre-revenue products. A group of State antitrust enforcers supported the proposal, noting that they are particularly concerned with acquisitions of potential or nascent competitors and the protection of rivalrous innovation. Critics of the proposed requirement expressed concerns about compliance. One commenter pointed out that the Commission did not provide a clear standard for what ''under development''

means or what information the acquiring person must have to ''know'' about the target's product pipeline. Other commenters noted that classifying pre-revenue products or products under development is inherently speculative and that the NAICS classifications sometimes lag changes in technology and business.

The Commission acknowledges the potential challenges in complying with this change and believes it is sufficient for the Agencies to rely on the Competition Descriptions section for information related to pre-revenue products or services. In the Overlap Description, filers are required to list and briefly describe each current or known planned products or services that compete or could compete with those of the other party. As a result, similar information related to potential NAICS code revenues would be largely duplicative. Given the Commission's interest in reducing the cost of complying with the final rule where the additional information provides little benefit to the Agencies, the Commission does not adopt this proposal.

e. Overlap Reporting Revenues as of Time of Closing

Regarding the proposal to clarify that the acquired person must report the NAICS codes relevant to the acquired entity(s) at the time of closing, the Commission did not receive any comments. The Commission adopts this item as proposed.

f. Eliminating Reporting by NAPCS Codes

Regarding the proposal to eliminate the requirement for filing persons engaged in manufacturing to provide revenue by NAPCS-based code, the Commission did not receive any comments. The Commission adopts this item as proposed.

2. Controlled Entity Geographic Overlaps

Information about the geographic areas related to overlapping products and services is currently required by Item 7. The Commission proposed modifying these requirements to: (i) add a requirement to provide the name(s) by which entities have done business within the last three years, (ii) require the filing person to identify the overlapping entity within its own person, rather than the other filing person, (iii) update the NAICS codes that require geographic reporting at the street address level, (iv) require the identification of locations of franchisees for certain NAICS codes, and (v) add a requirement to provide geolocation data. As discussed below, the Commission adopts the some of the proposals as proposed, some with modification, and does not adopt others.

a. NAICS Overlaps of Controlled Entities

The Commission proposed several changes to the information concerning NAICS overlaps of controlled entities. First, the Commission proposed requiring the acquiring person to identify the entity(s) within its own person that has operations in the same NAICS code as the acquired entity(s), and the acquired person to identify the entity(s) within the acquired entity(s) that has operations in the same NAICS codes as the acquiring person. Second, it proposed requiring the identification of ''doing business as'' or ''formerly known as'' names used within the last three years by entities with U.S. operations in overlapping NAICS codes. Finally, the Commission proposed that filing persons be required to identify the entity(s) that have U.S. operations in the overlapping NAICS code(s).

Regarding the proposal to require the identification of ''doing business as'' or ''formerly known as'' names used within the last three years by entities with U.S. operations in overlapping NAICS codes, the Commission received two comments. One commenter expressed support for the proposal, noting that information regarding how private equity portfolio companies are commonly known in the marketplace is necessary for the Agencies to assess potential anticompetitive overlaps. Another commenter, however, stated that the new requirement may be difficult for filing parties to meet if they do not maintain such records, meaning they would need to recreate the information for the HSR filing. The same commenter questioned the value of the information for entities beyond those that either (i) generate revenue that results in a NAICS overlap or (ii) are parties to Material Other Agreements.

The Commission believes ''doing business as'' names will be of great value to the Agencies in the initial waiting period and thus adopts the proposal to require filing parties to identify names by which entities do business at the time of filing. However, as part of its overall efforts to lessen costs, the Commission does not adopt the proposal to require ''formerly known as'' names.

Regarding the proposal to have each filing person only report entities within its own person that derive revenue in the overlapping NAICS codes, the Commission did not receive any comments. The Commission adopts this change as proposed.

Finally, regarding the proposal to require filing persons to identify the entity(s) that have U.S. operations in the overlapping NAICS codes, the Commission did not receive any comments. The Commission adopts this change as proposed.

In addition, one commenter suggested that the Commission require identification of overlaps at the 3-digit, rather than 6-digit level, stating that 6-digit NAICS codes are too narrow. While the Commission agrees that some 6-digit NAICS codes are too narrow to identify products or services that effectively compete in the market, it also finds that other codes are overly broad. Further, identification of overlaps also triggers the reporting of additional information, including geographic information, identification of authors of documents, production of certain annual reports, information about certain officers and directors, identification of certain prior acquisitions, and certain defense and intelligence contracts. Thus, the Commission declines to adopt this suggestion but notes that this final rule includes a Competition Descriptions section, as discussed in section VI.I, to address the shortcomings of revenue reporting by NAICS codes.

b. Geographic Market Information

The Commission proposed two changes related to geographic markets. First, the Commission proposed updating the list of NAICS codes for which locations need only be identified at the State level and NAICS codes for which street-level information would be required. These adjustments reflect the Commission's periodic review of which NAICS codes need more granular street, city, and State address information, and which NAICS codes need only be reported at the State level. Information about where each filer generates revenues is important to determining whether the parties sell or supply products or services in the same local markets. Geographic market information often provides a factual basis for the Agencies to conclude that the merging parties do not sell the same products in the same local areas. Keeping this information up-to-date allows the Agencies to rely on geographic market information to conclude that the transaction does not warrant the issuance of Second Requests.

The Commission received two comments regarding this requirement, one in support of it and one opposed. The supportive comment emphasized the need for street-level information in

the agriculture industry, where the relevant markets for evaluating competition tend to be local and regional due to the perishable nature of agricultural products. The Commission agrees that street-level information is key in local and regional markets and articulated this as the basis for the expansion of the requirement in the NPRM.

The comment in opposition to the proposal stated that it would impose additional costs on filing parties given the wide range of industries for which street-level information would be required. The Commission acknowledges the cost, but for the reasons discussed above, believes that street-level geographic information is necessary to the Agencies' ability to conduct appropriate premerger screening of transactions that are most likely to affect competition at a local level. The Commission adopts this change as proposed.

The Commission also proposed requiring filers to list locations where franchisees of the acquiring or acquired person (as appropriate) generate revenue in overlapping NAICS codes that require street-level reporting. The Commission did not receive any comments on this change and adopts it as proposed.

c. Geolocation

The Commission also proposed requiring filers to report latitude and longitude information for street addresses. The Commission received comments both in support and in opposition to this requirement. The supportive comment stated that many companies already keep lists of latitude/longitude waypoints, while the comment opposed stated that exceedingly few businesses maintain geolocation data in the ordinary course of business.

As helpful as this information would be to the Agencies, especially during the initial waiting period when the Agencies need to determine whether there are any geographic markets in which the parties compete, in its overall effort to reduce costs to filing parties, the Commission does not adopt this proposal. Agency staff can continue to pursue sources for this information when necessary and as time permits during the initial waiting period.

3. Minority-Held Entity Overlaps

The Commission proposed creating a Minority-Held Overlaps section to collect information related to minority holdings that is currently required by Item 6(c). Item 6(c) requires the identification of holdings of the acquiring person and its associates or the acquired entity (as appropriate) of greater than 5% but less than 50% if such holdings derive revenue in any of the same 6-digit NAICS codes (or industries) as the other party. In the NPRM, the Commission proposed eliminating the option to list all the minority-held entities, rather than just those that are in overlapping NAICS codes or industries. The Commission also proposed requiring filers to provide the names by which the listed entities do business, if known. The Commission adopts these changes as proposed.

Regarding the proposal to eliminate the option to list all minority-held entities, the Commission received three comments, one comment in support of the proposed change and two comments opposed to it. The supporter of the proposal stated that it is critical to understand a company's minority holdings, which may allow it to exercise a level of competitive control in a market. One commenter questioned the probative value of information about minority interests generally but did not address this specific proposal. Another commenter expressed concern that the proposal could lead to greater scrutiny of ''growth equity'' firms that primarily take minority stakes in companies, and asserted that it could have a chilling effect on certain investments.

The Commission addresses concerns that increased transparency may lead to more enforcement actions in section III.C.1. and states that the identification of overlapping minority holdings is a key reform of the final rule because where these relationships exist, the Agencies should scrutinize them as part of their premerger review. The Commission also emphasizes that filers are currently required to identify overlapping minority holdings. However, the current Instructions allow filers to identify all minority holdings rather than only those that overlap. The Commission has found that lists not limited to the overlapping entities hinder efficient screening for transactions that may require further investigation, resulting in extra effort even when it would not be required if the overlaps were known as well as not surfacing transactions that do have such overlaps. In contrast, when filers submit a list of only those minority-held entities that derive revenue in the same NAICS code, or are in the same industry as the other party, the Agencies can quickly focus in on holdings that could create a competitive concern. Additionally, as minority interest holders, the filers are in a better position than the Agencies to identify which, if any, of their holdings operate in the same space as the other party. Given the importance of this information to the Agencies, the Commission adopts this change as proposed.

Regarding the proposal to require filers to provide the names by which the listed entities do business, if known, one commenter supported the proposal while another stated that it may be difficult for filing parties to comply with if they do not maintain such records. As discussed in sections VI.D.1.d.(i) and (iii) and VI.D.2.a., the legal names of entities are not always directly related to the name by which the entity is known to the marketplace. Knowing the public-facing names of entities facilitates efficient review of transactions by the Agencies because those names may be better known to other market participants. For investors of 5% or more, the Commission believes this information should be readily available to filers. However, if this information is not known, a statement of non-compliance can be submitted with the filing, as discussed in section VI.A.5. Accordingly, the Commission adopts this requirement as proposed.

In sum, the Commission has determined that the reporting requirements for revenues and overlaps contained in the final rule are necessary and appropriate to enable the Agencies to identify transactions that may violate the antitrust laws in any line of commerce or section of the country and that the requirement, as modified, has been tailored to reduce the cost of reporting as much as practicable.

4. Prior Acquisitions

The Commission proposed creating a Prior Acquisitions section within the Instructions to collect information required by Item 8 of the current Form, as well as additional information. First, the Commission proposed requiring both the acquiring person and the acquired entity to provide information about prior acquisitions, expanding the current requirement that is limited to the acquiring person. Second, the Commission proposed extending the time frame to report prior acquisitions from five years to ten years. Third, the Commission proposed eliminating the dollar threshold for listing prior acquisitions, which currently limits reporting to only acquisitions of entities with annual net sales or total assets greater than $10 million in the year prior to the acquisition. Fourth, the Commission proposed treating asset transactions involving the prior acquisition of substantially all of the assets of a business in the same manner as prior acquisitions of voting securities or non-corporate interests. The Commission also proposed requiring

filers to report whether all or substantially all of the acquired voting securities, non-corporate interests, or assets are still held at the time of filing. As discussed below the Commission declines to adopt several of these proposals and modifies others.

As noted in the NPRM, information about prior acquisitions has always been important for the Agencies, allowing them to identify strategies to gain market share through acquisitions rather than internal expansion or more vigorous competition. Filers have been required to provide information about prior acquisitions from the beginning of the premerger notification program. As discussed in section II.B.5., the Commission believes that additional information about prior acquisitions will reveal roll-up or serial acquisition strategies that have become increasingly prevalent in certain sectors as well as among certain investors and acquirors, and that have been an effective strategy for increasing concentration. A history of prior acquisitions in the same sector can provide an independent basis for the Agencies to take a closer look at the filed-for transaction to ensure that merger enforcement takes place at a time when it can be effective in preventing undue levels of market concentration.

Several comments provided general support for the Commission's efforts to expand this item. According to a group of State antitrust enforcers, details about a filing entity's prior acquisitions are vital for evaluating mergers and industry concentration trends. They contend that, in an era of so-called ''stealth acquisitions,'' premerger tools used by antitrust enforcers require sharpening. Another commenter also expressed this concern, observing a rise in serial acquisition strategies that are potentially aimed at sidestepping regulatory scrutiny.

Other commenters provided research supporting the proposed expansion of information about prior acquisitions. One commenter offered that his research supports claims made in the NPRM that prior acquisitions have important consequences for competition. He explained that even minor deals can produce major changes in market structure, firm behavior, and consumer welfare. Other commenters described their research or experience with roll-up acquisitions that have occurred in various sectors of the economy, explaining that more expansive disclosures of prior acquisitions will allow the Agencies to better identify serial acquisitions and their potentially anticompetitive effects.

But several comments raised broad objections to the Commission's proposal to collect additional information on prior acquisitions. Several comments broadly asserted that the burden of providing this additional information about prior acquisitions would be too high. One commenter asserted that expanding the information required would create a chilling effect that could discourage acquisitions of startups, as many potential acquirers of startups are likely to have made several small acquisitions in the technology sector. Similarly, some comments explained that the expansion of information related to prior acquisitions would have particular impact on specific industries or financial sectors, including pharmaceuticals, technology, agriculture, and private equity. Other commenters said that providing more complete information about prior acquisitions would reduce investments in startup companies. Finally, certain comments suggested that the proposed changes would adversely affect venture capital and funding acquisitions.

The Commission has addressed some of these general concerns in section III.C., as well as more detailed concerns about the cost to complete this requirement, below. It believes that many of these broad concerns are either not directly relevant to this rulemaking or otherwise in tension with historical reporting practice.[389] Nonetheless, the Commission has determined not to adopt most of the expansions contained in the proposed rule, including the extension of the lookback period from five to ten years or the elimination of the $10 million exception. Instead, the Commission adopts modest adjustments to the current requirements and extends the reporting requirement to prior acquisitions of the target. The adopted adjustments contained in the final rule include: (1) the elimination of the $1 million threshold for revenue when determining which overlapping NAICS codes are relevant; (2) the requirement to include prior acquisitions of assets or entities that also provide competing products or services listed in the filing person's Overlap Description; and (3) the proposal to treat prior acquisitions of substantially all of the assets of a business in the same manner as prior acquisitions of voting securities or non-corporate interests.

This information related to prior acquisitions will better reflect current market dynamics in the very lines of business that will be the focus of the Agencies' premerger assessment. The final rule does not require reporting on all prior acquisitions, only those in in business lines which the parties have identified as areas of overlapping current or future competition, either on the basis of NAICS code reporting or in the Overlap Description. This limitation focuses the required information on the specific antitrust risk that one or both parties have a pattern or strategy of rolling up competitors. It also alerts the agencies to potential changes in the competitive environment that may not be publicly available, which is valuable information in assessing whether or not the filed for transaction may violate the antitrust laws. In addition, parties are required to report only those acquisitions of U.S. entities or assets and foreign entities or assets with U.S. sales, thus targeting acquisitions that are likely to affect local markets within the United States. With these limitations, information collected about prior acquisitions is properly focused on the antitrust risk that the merging parties are pursuing a roll up strategy that is harming or could harm competition in the United States in violation of the antitrust laws.

As discussed in section II.B.5., the antitrust laws have always applied to anticompetitive serial acquisitions. In light of the increased use of these strategies and evidence of their harmful effects in certain sectors, there is a clear benefit to antitrust enforcement from disclosing prior acquisitions that may reveal a pattern or strategy of rolling up competitors in violation of the antitrust laws. This risk can be especially acute when the transaction involves a merger between 'consolidators,' with both firms having many prior acquisitions in the same lines of business. The final rule is properly tailored to focus on the risk that the transaction is part of such a strategy. Information about prior acquisitions need only be submitted for business lines that the parties have identified as areas of current or future competition. Moreover, any burden imposed by the additional reporting requirements would be limited. Based on the Agencies' experience, information about prior acquisitions is well-known to companies that are parties to an acquisition agreement, as this information is often collected as part of the due diligence process for the pending transaction. Other companies, even relatively small companies, routinely provide this information to the

[389] The Commission previously required information about prior acquisitions for a full ten years. The Commission is not aware of any evidence, and commenters did not point to any, of any noticeable impact on the level of startup activity or venture capital funding during that period.

Agencies in response to a Second Request.

The Commission acknowledges that this requirement imposes a new obligation on acquired companies but believes this information is necessary and appropriate for the Agencies to conduct their premerger review. Information about prior acquisitions is specifically targeted to uncover prior acquisitions where the parties have existing or emerging overlaps; if the acquired person completed many acquisitions over the past five years in these overlapping business lines, that information would be highly relevant to assessing the transaction's likely effect on future competition in those overlap sectors. Moreover, serial acquisition strategies may be going on simultaneously in a particular business line, and the acquired person's history would reveal whether the acquiring person is acquiring a firm that was also pursuing such a strategy.

The benefit to the Agencies from collecting this information from both parties is directly related to the number of prior acquisitions in the same business lines: the more acquisitions recorded during the prior five years, the more relevant is the information about them. Both the acquiring person and the acquired entity can and do make acquisitions that have an impact on the relevant competitive landscape. In addition, requiring this information from both filers may help deter acquisition strategies whereby a target buys several related companies that fall under the HSR thresholds and then the acquiring person purchases the target; the current rule does not reveal this history of prior acquisitions in the same business lines. Being able to clearly understand this history from the time a filing is made assists the Agencies in identifying a potential pattern of acquisitions in a particular industry that has contributed to a trend toward concentration or vertical integration that affects the competitive dynamics for the parties to the transaction, as well as the commercial realities of post-merger competition. One commenter suggested that parties report prior acquisitions only from the point in time when the current UPE acquired control of the acquiring or acquired entity, but this would limit the Agencies' ability to fully understand patterns and current competition. Thus, the Commission declines to further limit the requirement in this way.

The Commission also proposed expanding the time frame for reporting prior acquisitions from five to ten years to allow the Agencies to have a more complete understanding of how past acquisitions in the affected business lines affect the competitive landscape of the current transaction under review. Even though the Commission has required ten years of prior acquisition information on the HSR Form in the past, commenters questioned the expansion of the requirement now. Some comments focused on the added burden, noting that individuals who have institutional knowledge of past acquisitions may no longer be employed by the filing entity. Another comment pointed out that the Commission previously recognized that a ten-year lookback period was unduly burdensome when it reduced the information request from ten years to five years in 1987. The Commission acknowledges the cost associated with reporting many prior acquisitions, and after careful consideration of the comments, has determined not to require reporting for prior acquisitions occurring more than 5 years prior to filing.

But the Commission disagrees that concerns about roll-up strategies are not well-grounded in antitrust law. As discussed in section II.B.5., U.S. antitrust law clearly addresses concerns about the acquisition or maintenance of market power through serial acquisitions. As stated above, it is precisely this information that allows the Agencies to fairly measure the competitive landscape and on-going trends toward concentration in certain business lines, making the information relevant to the Agencies' initial antitrust assessment of the transaction. The Commission also disagrees that the HSR Act does not permit the Agencies to use section 7 of the Clayton Act to challenge serial acquisitions. Section 7 clearly prohibits acquisitions that were preceded by a series of acquisitions that rendered the market(s) under review concentrated,[390] and it is not improper for the Commission to require the reporting of prior acquisitions to better detect a pattern of acquisitions that may also violate other antitrust statutes, such as section 2 of the Sherman Act or section 5 of the FTC Act. Although the Commission agrees that the information submitted with the HSR Form must be used to examine the potential competitive impact of the filed-for transaction, it disagrees that the scope of section 7 is so limited as to prevent the Agencies (or other enforcers of the Federal antitrust laws) from alleging harm that derives from a cumulation of similar acquisitions in the same market.[391]

The Commission also proposed eliminating the $10 million threshold for identifying prior acquisitions and received several comments on this point. One comment urged the Commission to keep the existing limitation that requires reporting only those acquisitions of more than $10 million in total assets and annual net sales in the year prior to the acquisition as a way to eliminate the burden of reporting a large number of extremely small transactions that are competitively insignificant. One comment suggested maintaining the current $10 million threshold for prior acquisitions but exempting certain, specified NAICS codes related to emerging technology sectors from the threshold.

Yet another commenter suggested the Commission broaden its proposed rule to include prior acquisitions based on three-digit NAICS codes, rather than relying on six-digit NAICS code overlaps, which the commenter found to be often too narrow or imprecisely defined. The Commission acknowledges that three-digit NAICS codes would include more prior acquisitions and present a broader picture of the competitive landscape. But because prior acquisitions also include products or services described in the Overlap Description, which in some instances may encompass a broader set of acquisitions than reliance on NAICS codes alone, the Commission declines to use three-digit NAICS codes as the standard.

In sum, the Commission has determined that the reporting requirements for prior acquisitions contained in the final rule are necessary and appropriate to enable the Agencies to identify transactions in which the merging parties are engaged in a pattern or strategy of roll-up acquisitions and that the requirement, as modified, has been tailored to reduce the cost of reporting as much as practicable.

K. Additional Information

1. Subsidies From Foreign Entities or Governments of Concern

While the Commission did not receive any comments objecting to the proposed new defined terms ''foreign entity or

[390] *See United States* v. *Phila. Nat'l Bank,* 374 U.S. at 367. *See also Credit Bureau Reps., Inc.,* v. *Retail Credit Co.,* 358 F. Supp. 780, 794 (S.D. Tex. 1971), aff'd, 476 F.2d 989 (5th Cir. 1973).

[391] *See Brown Shoe Co.* v. *United States,* 370 U.S. 294, 334 (1962) (citing S. Rep. No. 81–1775, at 5 (1950) and H.R. Rep. No. 81–1191, at 8 (1949)). In particular, S. Rep. No. 81–1775, at 5 noted that where several large enterprises are extending their power by successive small acquisitions, the cumulative effect of their purchases may be to convert an industry from one of intense competition among many enterprises to one in which only a few large concerns supply the market.

government of concern'' and ''subsidy'' discussed in section IV.B., it did receive several comments about the reporting requirements included in the proposed Instructions. One commenter objected that the Committee on Foreign Investment in the US (''CFIUS'') already is tasked with the review of certain transactions involving foreign investment in the United States and that requiring information about foreign subsidiaries in the HSR form would add to the burden of notifying parties (and the Agencies) without providing concurrent value for the substantive antitrust analysis. In response to this comment, the Commission notes that it must defer to Congress in implementing the requirement to report information about foreign subsidies in the HSR Form.

Another commenter suggested introducing a de minimis threshold so that the reporting obligation is limited to only those subsidiaries from foreign governments and entities of sufficiently large amounts to potentially distort the competitive process in markets in the United States in which the merging parties compete. Citing the EU Foreign Subsidies Regulation as an example, this commenter claimed that such a threshold would save merging parties the burden of compiling small subsidy amounts that could not be expected to result in competition concerns. The Commission acknowledges that a de minimis requirement may indeed make sense as part of the information required, but Congress did not provide for a de minimis threshold, and the Commission does not yet have sufficient data to make that determination or establish an amount at this time. Once the Agencies have begun to receive information about foreign subsidies, the Commission can revisit this issue, if warranted.

Finally, a comment from a senator and a representative noted that information about the financing activities of merging parties would also be useful in addressing a host of national security challenges and encouraged the Agencies to share such information with other governmental bodies, including Congressional committees. The Commission agrees the Agencies should facilitate this kind of information sharing to the extent permitted by current law, regulations, guidelines, and practices governing information sharing within the Federal government.

2. Defense or Intelligence Contracts

The Commission proposed creating a Defense or Intelligence Contracts section that would require filing persons to report information related to certain contracts with defense or intelligence agencies to speed up outreach to those agencies related to the reported transaction. As proposed, both the acquiring and acquired person would have been required to identify whether they have existing or pending procurement contracts with the Department of Defense (''DoD'') or Intelligence Community (''IC''), as defined by 10 U.S.C. 101(a)(6) and 50 U.S.C. 3003(4), valued at $10 million or more, and provide identifying information about the award and relevant DoD or IC personnel. The Commission reasoned that for filings from companies that supply DoD or IC with products or services, this information would greatly enhance the Agencies' ability during the initial waiting period to identify and contact appropriate stakeholders within DoD or IC to seek their input as customers that might be impacted by the proposed transaction and to speak to knowledgeable experts about the products or services provided to the government by the parties. As discussed below and in response to concerns raised in public comments, the Commission adopts the proposal with modification.

The Commission received several comments on this proposal. One commenter stated that the Commission provides limited explanation of its authority or justification for this proposed requirement and that it does not explain its focus on these agencies. The Commission responds that it proposed special reporting requirements for the defense and intelligence agencies because they are often the only customer for products and services offered by defense companies, and a thorough review of these transactions is a priority for the Agencies. Products and services sold to DoD or the IC are often unique and not sold to any other customer. As noted in the NPRM, the Agencies regularly review filings from companies that supply the DoD or the IC with products or services, and it is important for them to be able to quickly contact DoD and IC staff to collect key insights and information to prevent mergers that may have an anticompetitive impact. A recent study by the General Accountability Office highlights the importance of DoD's input to the Agencies regarding potential competition risks to the defense industrial base and DoD programs.[392] The Agencies have relied on interactions with DoD personnel, and to a lesser extent IC personnel, to investigate and challenge defense mergers over the years. Without information about specific DoD or IC contracts or knowledge of which unit handles that contract, the Agencies often face difficulty and delay in identifying appropriate relevant personnel or stakeholders with knowledge of the contracts, programs, or products or services at issue.

Any delay in identifying the right DoD or IC personnel with deep knowledge of complex and highly sensitive programs hinders the Agencies' ability to identify and fully assess competition issues in the reported transaction that would impact DoD or IC programs or budget. The Commission has determined that to be fully proactive about these concerns, and to seek DoD or IC input at an early stage of the inquiry, parties with certain pending or current DoD or IC contracts need to provide that information with their notification. Although the Agencies are also attentive to any merger that may affect purchases by other parts of the government, these transactions involve products and services that are also sold to commercial customers and can be investigated using our standard approach.

Beyond this comment on the general focus of the requirement, commenters addressed three primary areas of concern: vagueness, confidentiality, and the burden of compliance. First, commenters expressed concern about the lack of clarity in the proposed rule, for instance pointing out that neither the NPRM nor the cited statutes define what constitutes a ''pending'' procurement contract. This commenter suggested that, to avoid this ambiguity, the new rule should apply only to active procurement contracts, not pending contracts. The Commission agrees there is a need to clarify which contracts should be reported and modifies the Final Rule to require reporting for (1) pending proposals submitted to the U.S. Department of Defense or any member of the U.S. intelligence community, as defined by 10 U.S.C. 101(a)(6) or 50 U.S.C. 3003(4), and (2) awarded procurement contracts with the U.S. Department of Defense or any member of the U.S. intelligence community, as defined by 10 U.S.C. 101(a)(6) or 50 U.S.C. 3003(4). The Commission declines to limit the reporting requirement to active contracts only. Submission of a proposal indicates that the filer is a competitor, regardless of

[392] *See* U.S. Gov't Accountability Office, Defense Industrial Base: DOD Needs Better Insight into Risks from Mergers and Acquisitions 28 (Oct. 2023) (GAO–24–106129).

whether it is ultimately awarded the contract. The Commission believes that these changes address some of the ambiguities raised by commenters.

According to one commenter, it is not clear what method of valuation should be used to determine if a contract is valued at $10 million or more, particularly for open-ended supply contracts. First, as discussed below, the Commission increases the threshold to $100 million. Second, the Commission clarifies that filers should use the maximum estimated quantity or value in their proposed or awarded prices to determine the estimated value of the contract. Otherwise, filers should use reasonable judgment in determining how to value their contracts and may explain the method of valuation used.

With respect to confidentiality concerns, one commenter stated that it is not clear how a company may provide this information without violating Federal laws and regulations restricting the dissemination of such sensitive information. Commenters proposed suggestions to avoid such conflicts. For instance, one suggested that the proposed instruction should be clarified to exclude any contracts that are classified or otherwise subject to a government-imposed duty of confidentiality. Another recommended that the Agencies consider the appropriateness and potential applicability of a national security exception to certain requirements within this proposed rule.

As an initial matter, the Commission notes that there is nothing in the HSR Act that overrides the protections due classified information, and the Commission specifically intends to not require the submission of classified information. To alleviate concerns about the sensitivity of the information related to these contracts, the Commission revises the Instructions to expressly state that parties should not include classified information but that they should note when responsive information is withheld on that basis. The Commission believes that this modification addresses the concerns raised in the comments and preserves protections for classified information. The Commission declines to adopt the proposal to exclude any contracts that are classified or otherwise subject to a government-imposed duty of confidentiality. The fact that the parties have submitted a proposal in response to a request from DoD or the IC or have an existing contract is not classified information. Such an exclusion is overbroad and would not allow the Agencies the benefit of reviewing non-classified information related to these pending proposals or active contracts. The Commission believes that the revision stating that parties should not include classified information in their submissions addresses this issue. For the same reason, the Commission declines to adopt the proposal to create a national security exception to the rule. The confidentiality provisions of the Act provide sufficient protection for any confidential but unclassified information about these documents. The Commission additionally notes that many of the products and services the Agencies investigate have similar national security implications even if they involve customers other than DoD or the IC.

As to the burden of complying with this requirement, one commenter noted that the requested information is often not maintained in the ordinary course of business, nor is it created in the course of a deal negotiation, and that due to confidentiality concerns, these data are often not centrally maintained and may not be known, even among senior leadership. To limit the burden, one commenter recommended that the requested information be limited to those DoD or IC contracts with a primary NAICS code for which the filing parties have identified NAICS overlaps or that the Agencies obtain this information from the Federal Procurement Data System.

To reduce the cost of complying with this request, and in light of the general concern that classified materials are not widely known or shared, the Commission makes two significant modifications to limit the scope of this requirement. In line with the proposal above, the Commission limits the set of responsive contracts to those involving a 6-digit NAICS industry code overlap or a product or service described in the Overlap Description or the Supply Relationships Description. The Agencies' need for information about pending or active DoD or IC contracts is directly related to the specific antitrust risks associated with the transaction, and limiting this information in this way targets the most relevant contracts, if they exist. In addition, in response to concerns that the $10 million de minimis level will require reporting for purchases by DoD or the IC of mundane products and services, rather than critical defense purchases, the Commission has determined to increase the de minimis threshold for these contracts from $10 million to $100 million. The Commission believes that this is the appropriate threshold for limiting this request to products that are uniquely sold to the DoD or the IC. The Commission declines to make any modification in response to the suggestion that the Agencies get this information from the Federal Procurement Data System. It is not feasible for the Agencies to rely on discovering critical DoD or IC proposals or contracts from this database for the purpose of identifying key personnel at those agencies and obtaining information about complex products and services during the initial waiting period. This information is known by the parties and easy to verify, especially with the limitation that the contracts be worth more than $100 million annually. Contracts or commitments of this size are likely subject to close monitoring.

In addition, to further reduce the burden of this requirement, the Commission excuses select 801.30 transactions from reporting information related to DoD or IC proposals or contracts. These transactions do not involve an agreement between the parties.

Finally, two commenters noted a typographical error in the proposed Instructions: the reference to 50 U.S.C. 3033(4) should refer to 50 U.S.C. 3003(4). The Commission revises the instructions to correct the typographical error noted by the commenters.

In sum, the Commission has determined that the reporting requirements for pending proposals and active contracts with DoD or the IC contained in the final rule are necessary to provide the Agencies with the ability to identify transactions in which the merging parties are providing critical products or services to the government and to quickly reach out to those agencies for their input. The requirement, as modified, has been appropriately tailored to reduce the cost of reporting as much as practicable.

3. Voluntary Waivers

The Commission proposed amending the Instructions to allow filing persons to waive the confidentiality provision contained in the Act, 15 U.S.C. 18a(h), for any non-U.S. competition authorities or State Attorneys General they identify. As stated in the NPRM, allowing filers to waive the confidentiality protections in the HSR Filing would provide an efficient mechanism for filers to consent to limited waivers of confidentiality at the outset of any agency review to facilitate early cooperation among competition enforcers. The proposed voluntary waivers would allow the Agencies to disclose the existence of an HSR Filing and the information contained in the HSR Filing, but only for those non-U.S. competition authorities or State Attorneys General identified by the filing person. The

Commission also proposed modifying the language that would inform filers about potential disclosures based on the waivers to track the language of the Act more closely. As discussed below, the Commission adopts this proposed change with modifications.

The Commission received three comments addressing this proposal. A group of State Attorneys General, who would be the recipients of HSR-related information if filers granted access on a voluntary basis, encouraged the Commission to consider three changes. First, they proposed requiring filing persons to identify the relevant States where the parties do business, regardless of whether they opt to provide waivers or check the box. Second, they encouraged the Agencies to, by default, disclose to the public the fact of filing and the expiration date of the waiting period. They argued that nothing in the HSR Act requires that the fact of filing and the waiting period be kept confidential and that this information should not be treated as such. The comment urged the Agencies to exercise their authority to disclose this information to the public or to the States. They recommended that to avoid disclosure, the parties should have to provide a basis for keeping the fact and timing of the filing confidential. If the Agencies adopted the second proposal, they also encouraged the Agencies to include a check box to allow parties to waive confidentiality of the information and documents filed with the notification so that these materials could be shared with affected States. Third, if the Agencies chose not to adopt the above recommendation regarding public disclosure, the State antitrust enforcers suggested disaggregating the check box into two separate boxes, one to allow disclosure of the fact of filing and the associated waiting period and another to allow sharing of the information and documents in the filing with affected State Attorneys General. They stated that disaggregating the check box increases the likelihood that States at least receive notification of the transaction.

The Agencies have historically not publicly disclosed or provided to the States or international enforcers information regarding HSR filings, including the fact that a filing was made and the waiting period, in the absence of a waiver from the parties. Without weighing on the merits of the States' legal arguments regarding the scope of the HSR Act's confidentiality protections, the Commission at this time believes it is appropriate to maintain its prior practice. The Commission does adopt the States' suggestion to disaggregate the waiver check boxes, which would allow for greater flexibility in providing the Agencies consent to disclose and provide filers with the option to disclose some information but not all information contained in the HSR Filing.[393] The waiver would apply only to those non-U.S. competition authorities or State Attorneys General selected by the filing person. The Commission declines to adopt the proposal by the State antitrust enforcers to require parties to identify the relevant States where they do business, regardless of whether they waive confidentiality. The Commission will likely receive much of this information through the new requirements contained in the final rule.

The Commission received two other comments on this proposal. One commenter expressed concern about confidential information becoming publicly known once it is shared more widely due to the increased risk of leaks. On this point, the Commission notes that these waivers are voluntary. The parties can decide not to waive confidentiality if they have concerns about confidentiality. Further, the Agencies take seriously the confidentiality requirements of the Act and require law enforcement colleagues to abide by these protections. In the many decades of case cooperation pursuant to voluntary waivers, these protections have worked to prevent improper disclosures. The Commission believes that concerns about an increased risk of leaking due to the option to waive confidentiality at the time of filing are unfounded.

Finally, according to one commenter, the proposed rule appears to contemplate a single check box that does not permit notifying parties to communicate their willingness to waive confidentiality as to some international competition authorities but not as to others. The Commission notes that this commenter misunderstands the requirement and clarifies that the voluntary waiver will only apply to those jurisdictions that the party affirmatively indicates in the HSR Filing. In addition, failure to check either box or indication of only a few jurisdictions for waivers does not prevent the parties from providing these waivers or adding jurisdictions later. The inclusion of these waiver options in the Form is simply meant to serve as an efficient mechanism for filers to provide their clear consent at the outset even if only on a limited basis.

The Commission did not receive any comments regarding the proposal to modify the language informing filers about potential disclosures based on the waivers to track the language of the Act more closely. Thus, the Commission adopts this change as proposed.

In sum, the Commission has determined that offering the option for parties to waive the confidentiality provisions of the Act to allow for the sharing of HSR materials with non-U.S. jurisdictions or State enforcers in the final rule will provide a benefit to the Agencies in facilitating case cooperation at an early stage in the Agencies' assessment of antitrust risk. The option, as modified, has been tailored to provide a clear choice for filers who wish to facilitate the sharing of information by providing a waiver.

4. Identification of Communications and Messaging Systems

In conjunction with the proposed requirement that filing persons certify they have taken steps to prevent destruction of relevant information, as discussed in section VI.L., the Commission also proposed that filers identify and list all communications systems or messaging applications on any device used by the filing person that could be used to store or transmit information or documents related to its business operations. The Commission does not adopt this proposal.

In the proposed rule, the Commission reasoned that, as companies have increasingly been relying on new forms of communication to do business and make key operational decisions, these communications systems have become an important part of the Agencies' investigations. In the Agencies' experience, these systems contain highly relevant information on the transaction itself, as well as on topics that are critical for the Agencies' assessment of the transaction such as competition, competitors, markets, customers, and industry characteristics. Nevertheless, many parties do not appear to fully understand or comply with document preservation obligations for these new modalities.

The Commission received several comments on this proposal, mainly regarding the burden of the request and its utility in screening for anticompetitive transactions during the initial waiting period. Multiple commenters expressed doubt about the Commission's assertion that this

[393] The Commission's implementation of this suggestion differs from the text proposed by the States. The Commission does not adopt the States' suggestion, with respect to the fact of filing and the waiting period, that, in order to prevent disclosure, the parties be required to affirmatively check a box and provide a basis for keeping the information confidential.

information is readily available to the filing person and that identifying these systems would impose minimal burden. One association of antitrust practitioners noted that because there is no limitation on the requirement, large or diffuse organizations may have hundreds of communications systems that would require identification but are unknown or unused by the filing person's employees who are involved in preparing the HSR filing. One commenter also flagged the inevitable complications caused by, for example, special IT systems, legacy IT systems, and individual employees who do not follow corporate IT policies. According to another, the process of gathering this information often requires the expertise of counsel and entails interviews of key employees as well as a careful review of company practices and policies. As a result, this commenter stated that the burdens associated with the additional requirements would fall more harshly on small companies that are not equipped to navigate the regulatory process. In addition, comments also objected that the information requested would not assist the Agencies in determining whether to issue a Second Request. They noted that the identification of these systems is best reserved for the transactions that are investigated as is the Commission's current practice when issuing Second Requests.

After carefully considering these comments, and as part of its overall effort to reduce burden on filing parties, the Commission does not adopt this proposal. The Commission notes, however, that the Agencies have taken steps to update their guidance related to obligations to preserve ephemeral messages and similar communications systems, and have provided language in the Model Second Request to reflect document production and retention obligations for these communication systems.[394] Based on this guidance, companies that take steps to preserve information related to these communications systems may reduce the likelihood that they will face consequences for non-compliance with a Second Request.

L. Certification

Each HSR Filing is accompanied by a notarized certification, signed by the person preparing or supervising the preparation of the filing. The person signing the certification attests to the veracity of the information submitted in the filing. The Commission proposed amending this certification to require filers to affirm that they have taken the steps necessary to prevent the destruction of documents and information relevant to the transaction. The Commission also proposed adding language to the Instructions to remind filers that criminal statutes prohibit practices that impede or frustrate functions of government agencies, such as submitting false information. This proposal would require most HSR filers to establish new document retention policies or revise existing policies prior to filing. As explained in the NPRM, the deletion of information or documents that could be called for in a Second Request could lead to a loss of information critical to the Agency's ability to conduct an in-depth investigation.

The Commission received approximately ten comments on this proposal. Some commenters noted that the proposed rule would expand document preservation beyond current law, which obligates parties to preserve documents and information related to an ongoing or anticipated government investigation [395] or if they have a reasonable anticipation of litigation.[396] Commenters noted that very few filers have an obligation to preserve information about the transaction since they are not yet under investigation and do not have a reasonable anticipation of litigation.

Commenters also described the burden, particularly the cost, associated with document preservation obligations. Several commenters explained that litigation holds are expensive and difficult to design and implement, especially concerning the breadth of documents and information that would be subject to a hold. One commenter noted that a document hold does not simply encompass the suspension of auto-delete policies, can be difficult and expensive to implement with precision, and typically extends to individuals, databases, communication systems, and materials beyond the scope of the transaction. Another pointed out that data is expensive to store and that filers would be required to retain documents that cover large components of their day-to-day operations. According to one commenter, at the time of filing, the notifying party may not know enough about what issues will be of interest to the Agencies to identify a set of custodians who are likely to have information related to the proposed transaction.

After carefully considering the comments, the Commission has determined not to adopt this proposal. The Commission notes that, under current law, when litigation is reasonably foreseeable, parties have an obligation to preserve documents relating to the proposed transaction. This obligation could arise before or after HSR filing. In addition, it is a Federal crime for any person to knowingly alter, destroy, mutilate, conceal, cover up, falsify, or make a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence an ongoing or anticipated Federal investigation.[397]

The Commission also received a few comments on the addition of language reminding the filer of potential criminal liability under other Federal statutes that prohibit various deceptive practices aimed at frustrating or impeding the legitimate functions of government departments or agencies. Commenters raised general concerns about how this language could alter how filers prepared their notification. One commenter stated that when read together with the requirement to preserve documents, the reminder of criminal penalties would prevent filers from instituting a tailored legal hold. Another stated that it seems to suggest that filers should fully expect a harsh and punitive response to filing errors. Commenters primarily noted that the added language merely restated existing law. Given that the proposed certification on criminal liability does not increase the burden or cost of filing and may have a benefit of putting some unaware filers on notice of possible criminal penalties, the Commission adopts this proposal as a simple restatement of existing penalties.

[394] *See* Press Release, U.S. Dep't of Justice, ''Justice Department and FTC Update Guidance that Reinforces Parties' Preservation Obligations for Collaboration Tools and Ephemeral Messaging'' (Jan. 26, 2024), *https://www.justice.gov/opa/pr/justice-department-and-ftc-update-guidance-reinforces-parties-preservation-obligations. See also* Fed. Trade Comm'n, ''Slack, Google Chats, and other Collaborative Messaging Platforms Have Always Been and Will Continue to be Subject to Document Requests,'' Fed. Trade Comm'n Competition Matters blog (Jan. 26, 2024), *https://www.ftc.gov/enforcement/competition-matters/2024/01/slack-google-chats-other-collaborative-messaging-platforms-have-always-been-will-continue-be-subject.*

[395] Federal law provides serious criminal penalties, including up to twenty years imprisonment, for any person who knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence an ongoing or anticipated Federal investigation. *See, e.g.,* 18 U.S.C. 1519.

[396] *Zubulake* v. *UBS Warburg LLC,* 220 FRD. 212, 218 (S.D.N.Y. 2003) (holding that once a party reasonably anticipates litigation, it must suspend its routine document retention/destruction policy and put in place a litigation hold to ensure the preservation of relevant documents).

[397] *See* 18 U.S.C. 1519.

M. Affidavit

As discussed in section V.D., the Commission proposed requiring filings for transactions without definitive agreements to include a term sheet or draft agreement that describes with specificity the scope of the transaction that would be consummated. In conjunction with that proposal, the Commission also proposed that parties making such filings attest in their affidavit that a term sheet or draft agreement that describes with specificity the scope of the transaction that will be consummated has been submitted with the executed letter of intent or agreement in principle.

As described above, the Commission modified the proposal and has made a conforming change to this section of the Instructions as part of the final rule.

VII. Severability

In the NPRM, the Commission noted that § 803.90 contains a separability (or severability) provision such that, if any provision of the Rules (including the Form) or the application of any such provision to any person or circumstance is held invalid, the other provisions of the Rules and their application to other persons or circumstances shall be unaffected.

The Commission did not propose any changes to the severability provision in § 803.90 and does not adopt any changes. However, as it did in the NPRM, the Commission confirms its intent that, if a court were to invalidate any provision, any part of any provision, or any application of the final rule, the remainder of the final rule would remain in effect to the greatest extent possible. The Commission's general view is that each substantive requirement of the final rule is severable from each of the others. The Agencies need the information requested by the final rule for the reasons discussed above. Each requirement in the final rule serves an important, related, but distinct purpose and provides a distinct benefit separate from, and in addition to, the benefit provided by other requirements. However, if a court finds that certain provisions are invalid, the following analysis applies.

The Commission notes that some reporting requirements are contingent upon filers reporting overlapping products or services in (1) the Overlap Description; (2) the Supply Relationships Description; and (3) the same NAICS codes. The severability of these reporting requirements are as follows:

Officers and Directors

If product or service overlaps are identified in the Overlap Description or Supply Relationships Description, the final rule requires the acquiring person to list officers and directors (or in the case of unincorporated entities, individuals exercising similar functions), and those who have served in the position within the past three months for each entity within the acquiring person responsible for the development, marketing, or sale of products or services that are identified as overlaps and who have also served in these roles with the target. The Commission does not view this requirement as severable from the Overlap or Supply Relationships Descriptions. However, the Commission's view is that the two other reporting requirements regarding Officers and Directors are severable and would remain if the Overlap or Supply Relationships Descriptions are held invalid. These are the requirements to (1) list all individuals likely to serve as, nominate, or appoint an officer or director of the acquiring entity (and the accompanying requirements); and (2) for each officer and director identified, list all other entities operating in commercial activities in the same NAICS codes reported by the target for which the individual currently serves as an officer or director. The Agencies need the information in the first requirement for the reasons discussed above in sections II.B.1. and VI.D.3.c., and this first requirement would not be affected by invalidation of the Overlap or Supply Relationships Descriptions. With respect to the second requirement, the Commission has long required reporting of NAICS code information, and the reporting of NAICS code information stands independent of, and can operate separately from, the Overlap or Supply Relationships Descriptions. The changes the Commission has finalized here are modest and do not significantly alter the existing requirement to report certain NAICS code information. Accordingly, the Commission believes that the requirement to report certain officer and director information in any identified NAICS code overlap would stand even if either (1) the Overlap or Supply Relationships Descriptions were held invalid, or (2) any of the final rule's changes regarding NAICS code reporting were invalidated.

Prior Acquisitions

Filers (both acquired and acquiring persons) are required to report certain information regarding prior acquisitions that (1) derived revenue in an identified NAICS code overlap or (2) provided or produced an overlap product or service as described in the Overlap Description. If the Overlap Description is invalidated, the Commission does not view the second part of the Prior Acquisitions reporting requirement as severable from that reporting requirement. However, the first requirement regarding derived revenue in an identified NAICS code overlap would remain in place, for the same reasons discussed previously in connection with the severability of the Officers and Directors requirement.

Defense or Intelligence Contracts

Filers are required to identify (1) proposals submitted to the U.S. Department of Defense or any member of the U.S. intelligence community, and (2) awarded procurement contracts with the U.S. Department of Defense or any member of the U.S. intelligence community, valued at $100 million or more, that (A) are or will be the source of revenues in any identified NAICS code overlap or (B) involve or will involve an overlapping product or service identified in the Overlap Description or the Supply Relationships Description. If the Overlap or Supply Relationships Descriptions are invalidated, the Commission does not view the portion of the Defense or Intelligence Contracts reporting requirement referring to the Overlap or the Supply Relationships Descriptions as severable from those reporting requirements. However, the portion requiring the reporting of certain information in any identified NAICS code overlap would remain in place, for the same reasons discussed previously in connection with the severability of the Officers and Directors requirement.

Annual Reports and Audit Reports for Acquiring Entities

The final rule requires the acquiring entities whose revenues contribute to a NAICS code overlap or any overlap identified in the Overlap Description to provide the most recent annual report or audit report and CIK number if annual reports are filed with the SEC. If the Overlap Description is invalidated, the Commission does not view the portion of the Annual Reports and Audit Reports requirement referring to the Overlap Description as severable from the requirement to provide an Overlap Description. However, the portion requiring annual reports or audit reports relating to NAICS code overlap would stand, for the same reasons discussed previously in connection with the

severability of the Officers and Directors requirement.

Author Information for Business Documents

For Business Documents, if (1) a NAICS code overlap has been identified, (2) an overlap within the Overlap Description has been identified, or (3) a supply relationship within the Supply Relationships Description has been identified, filers must provide certain information about the author of the documents. If the Overlap or Supply Relationships Descriptions are invalidated, the Commission does not view the portions of the Author Information requirement referring to those descriptions as severable from the Overlap and Supply Relationships Descriptions requirements. However, the portion requiring the reporting of author information if a NAICS ode overlap has been identified would stand, for the same reasons discussed previously in connection with the severability of the Officers and Directors requirement.

The Commission views all remaining provisions, parts of provisions, and applications of the final rule not specifically identified as non-severable above to be severable. These reporting requirements would have been adopted individually regardless of whether the other reporting requirements were adopted and could function effectively without the other provisions. If a reviewing court were to stay or invalidate any reporting requirement (or part or application thereof) not identified as non-severable above, the Commission states its intent to have adopted the remainder of the final rule.

VIII. Paperwork Reduction Act

On June 29, 2023, the Commission published its intention to submit the proposed rule and the associated Supporting Statement to OMB for review under the Paperwork Reduction Act of 1995 (''PRA''), 44 U.S.C. 3501 *et seq.*[398] The Commission emphasized that some of the proposed changes were intended to reduce the burden of filing[399] and that other proposed changes offered clarifications to the current rules and were unlikely to change the burden on filers.[400] Further, the Commission highlighted proposed changes that would require a filer to collect and report information kept in the filer's ordinary course of business records, minimizing the burden of new collection requirements.[401] The Commission noted that many of the proposed changes would increase the burden on all filers;[402] the Commission also noted that some of the proposed changes would significantly increase the burden on only certain filers.[403]

In conducting the PRA analysis for the proposed rule, in order to estimate the projected change in burden due to the proposed changes and to provide a baseline for public comment, PNO staff consulted current Agency staff attorneys who had previously prepared HSR filings for clients while in private practice. These experienced attorneys provided estimates of how many hours the proposed changes would require, depending on the complexity of the filing at issue. To estimate an average number of additional hours, the Commission conservatively assumed that 45% of HSR filings would be highly complex and 55% would be less complex. The Commission next multiplied the average estimate of additional hours per filing (107 hours) by the 7,096 non-index HSR filings that the Commission projected it would receive in FY 2023.[404] Finally, the Commission multiplied the total hours by an estimate of the hourly rate for executive and attorney compensation ($460/hour).

The Commission received numerous public comments referencing the NPRM's PRA burden analysis. One commenter supported the analysis, noting that the increase in the estimated time required to prepare an HSR filing is ''inconsequential,'' even ''trivial'' considering that these reporting requirements only apply to transactions valued at more than the reporting threshold. This commenter further asserted that it is appropriate to shift costs from the Agencies to the merging parties.

Some commenters, however, criticized the Commission's analysis for significantly underestimating the extent of the burden, and many raised concerns about the methodology employed by the Commission to calculate such burden. For instance, they raised concerns that the estimates are not based on empirical data or discussions with current practitioners; and that the Commission's methodology is non-verifiable, and thus not subject to empirical validation. They also argued that Agency staff's prior experience in preparing HSR filings is not relevant given the wholly different and new information requested under the proposed rule. One commenter called the Commission's approach biased and inaccurate, stating that there is no indication that Agency staff relied on any data when trying to create an estimate based on memories from past private practice. Additionally, several commenters also criticized the Commission's explanation of its PRA analysis. With respect to the survey of Agency staff, one commenter stated that the Commission failed to provide basic information, such as the number of staff surveyed, who these staff are, their level of experience in preparing HSR filings, when they last prepared HSR filings, and the results of the survey. Another commenter stated that it had no context for what the median might be for filings to better understand whether the low and high ends are outliers or the anticipated typical experience.

The Commission carefully reviewed the comments asserting that its analysis underestimated the extent of the cost and delay that would be imposed if the Commission adopted the proposed rule. The Commission was persuaded by commenters who asserted that the PRA analysis in the NPRM underestimated the time and expense associated with the proposed rule. To address commenters' concerns and recognizing the changes from the proposal discussed above in section II, the estimates are revised as reflected below.

As outlined in section I and discussed more fully in sections IV to VI above, the Commission has not adopted certain requirements in the proposed rule in an effort to reduce compliance costs, and has also modified other proposed requirements in a manner that reduces the burden in certain respects. Specifically, the Commission is not adopting proposals that would have required a timeline of key dates for closing the proposed transaction; organization charts; certain information about other interest holders; drafts of

[398] 88 FR 42178, 42207–08 (June 29, 2023).

[399] *Id.* at 42,207 (*e.g.,* the proposal to report NAICS codes in ranges rather than by specific dollar amount).

[400] *Id.* (*e.g.,* the proposal to eliminate references to paper and DVD filings).

[401] *Id.* (*e.g.,* the proposal to require the reporting of minority investors in additional entities related to the filed transaction).

[402] *Id.* (*e.g.,* the proposal to require narratives regarding transaction rationale).

[403] *Id.* (*e.g.,* filers whose businesses have existing horizontal, non-horizontal, or labor market overlaps or relationships).

[404] In January 2023, the Commission requested a three-year extension of its PRA clearance for information collection requirements related to the existing HSR rules, which was approved by OMB on February 23, 2023, through February 28, 2026 (OMB Control Number 3084–0005). *See* 88 FR 3413, 3414 (Jan. 19, 2023). At that time, FTC staff projected an average of 7,096 non-index filings per year for fiscal years 2023–2025. This estimate of 7,096 non-index filings was based on the fact that the FTC received 6,518 non-index filings in fiscal year 2022 and had experienced an average annual increase in filings of 4.3% in the pre-COVID fiscal years 2017–2019. Actual non-index filings in FY 2023 totaled 3,515. *See* Fed. Trade Comm'n & Dep't Just., Hart-Scott-Rodino Annual Report, Fiscal Year 2023 appendix A (FY 2023).

submitted documents; information about employees; information about board observers; geolocation information; prior acquisitions involving entities with less than $10 million in sales or revenues or consummated more than 5 years prior to filing; and information about steps taken to preserve documents or use of messaging systems. These items were frequently cited by commenters as unduly burdensome. While this information is relevant to the Agencies' premerger assessment, the Commission has determined it can forgo requiring this information at this time. The Commission also has modified, in some instances substantially, many other proposed information requirements, which will reduce the burden on filers to collect and report this information. As a result, the information requirements contained in the final rule are significantly less burdensome than those reflected in the proposed rule, and the costs imposed on filers are thus reduced as compared to the proposed rule.

Before finalizing the changes adopted in the final rule, the Commission undertook a new survey of Agency staff that responds to comments critiquing the estimate in the NPRM and implemented several improvements to its methodology, as explained below. The Commission believes that in light of these improvements, the estimates of the incremental costs associated with the final rule are reliable and consistent with survey techniques used by others to calculate the burden of filling out a form.[405]

The new survey included 15 current FTC and DOJ attorneys who have recent experience preparing HSR filings in private practice. The Commission asked each survey participant to estimate, based on their own experience with preparing HSR Filings, the incremental change in hours that would be required to respond to each of the new and updated items in the final rule. They were also asked to estimate how much time would be saved by no longer having to provide information for current requirements that are not included in the final rule. The survey participants were provided with (1) the current HSR Form and Instructions; (2) the HSR Form and Instructions for both acquiring and acquired persons for the final rule; (3) a spreadsheet listing each of the new, updated, and eliminated items for three categories of transactions; and (4) instructions regarding how to input their responses.

The survey participants provided estimates for the amount of time required to collect and submit information responsive to each of the new and updated items in the final rule, separately for acquiring and acquired persons, and separately for three types of HSR-reportable transactions that reflect varying levels of complexity and antitrust risk: (1) the new category of select 801.30 transactions; (2) transactions with no reportable competitive overlaps (*e.g.,* where an investment fund is buying or selling a portfolio company with no NAICS or competitive overlap or supply relationship); and (3) transactions where the parties report at least one NAICS code overlap or have an existing overlap or supply relationship (referred to below as ''overlap'' filings). They were asked to estimate the incremental change in costs of complying with each new and adjusted information requirement contained in the final rule in each of the categories and for each type of filer. Also, for each item, the survey participants were asked to indicate what percentage of the additional time required would be time spent by company personnel as compared to a law firm hired to prepare the HSR Filing or any third parties that would need to be hired to complete the HSR Form (*e.g.,* data vendors).

In generating their estimates, the survey participants were asked to consider all time spent to complete the HSR Form,[406] including time spent reviewing the HSR Instructions; generating and compiling the materials necessary for collection; acquiring, installing, and utilizing any necessary technology or systems; and completing and reviewing the collected information, among other tasks. They were also asked to consider whether filers would need to incur additional costs not necessarily measured in hours, *e.g.,* the costs associated with new IT investments, long-lived facilities or equipment, related one-time expenditures, and other non-labor expenditures, such as attorney training or general HSR resources.

The Commission took several steps to increase the reliability of its survey. First, to reduce sampling bias as much as possible, the Commission relied on Agency staff who have not been involved in this rulemaking and thus have no more familiarity with the changes to the HSR Form and Instructions than an attorney in private practice would have. As exclusion criteria, the Commission did not survey any staff from the FTC's Premerger Notification Office, nor any staff at either Agency who were part of the core team responsible for drafting the final rule.

Second, the survey participants were asked to provide details about their experience preparing HSR filings in private practice, both in terms of how many years they were in private practice and the number and types of transactions involved. Collectively, the survey participants had experience with each of the three types of HSR-reportable transactions described above. Based on the information provided, the survey participants with the most experience tended to generate a lower estimated number of hours than the average.

The Commission believes that, with these controls, the individuals who provided estimates for the PRA burden assessment had sufficient experience with the current HSR reporting requirements and enough understanding of the HSR Rules and practice to make their estimates of incremental costs reliable.

Based on the survey responses, the Commission finds that the average number of additional hours required to prepare an HSR filing with the changes outlined in the final rule is 68 hours, with an average low of 10 hours for select 801.30 transaction filings by the acquired person and an average high of 121 hours for filings from acquiring person in a transaction with overlaps or supply relationships. As noted, however, the estimate varies significantly based the type of filings, with filings that are more likely to raise antitrust risk requiring higher hours.

To calculate the average number of additional hours, the averages of the estimates provided by respondents were calculated separately for each change for both the acquiring and acquired person within each category of transaction. These averages were then summed by category of transaction and then divided by two to provide category-specific estimated averages for an individual filer to comply with all changes. The overall average estimate for an

[405] This same survey technique, asking experienced HSR practitioners to estimate the time required to comply with the new information requirements in addition to other costs, was used in the Kothari Report, discussed below.

[406] The Commission notes that parties to acquisitions, whether HSR-reportable or not, may hire antitrust counsel to assess whether the transaction would violate any of the antitrust laws. This is a different task from evaluating whether a transaction requires notification pursuant to the HSR Act, and if so, how to comply with the Form and Instructions. The final rule does not require any information from attorneys or any other advisors to assess the antitrust risk of the transaction. As a result, any cost related to the assessment of the potential for a substantive antitrust risk, rather than compliance with the information requirements of the Form and Instructions, are not costs attributable to the final rule and are not included in this PRA analysis.

individual filer was calculated as a weighted average of these category-specific estimates for an average filer, using as weights the Agencies' estimate of the fraction of filings that fall into each of the three categories. Specifically, the Commission estimates that 8 percent of filings will meet the definition of a select 801.30 transaction,[407] 45 percent will have a NAICS code overlap or an overlap or supply relationship identified in the Competition Descriptions section, and 47 percent of filings will have no overlaps or supply relationship.

One commenter commissioned a report (the Kothari Report, referenced in section III.C.2.) to estimate the additional monetary costs of the proposed rule and relied on a survey of company and private counsel to estimate the time required to comply with the new requirements of the proposed rule as compared to the current rules.[408] From the responses to this survey, the Kothari Report estimated that the proposed rule as published in the NPRM would have added 101.6 hours of internal personnel time and 140.3 hours of outside counsel time above the current requirements for a total incremental increase of 241.9 hours. Although this estimate is substantially higher than the estimate based on the Commission's new survey, the Kothari Report estimated costs for the proposed rule, and may have included costs related to advocacy about whether a transaction violates an antitrust law, rather than only costs related to collection and submission of information required by the Form and Instruction, as indicated by its inclusion of costs of economic experts. In contrast, the Commission has estimated the additional time attributable to the less burdensome requirements of the final rule and has included in its estimates only that time that is required to complete an HSR Filing that is fully compliant with the Act and the Rules. Given the significant modifications from the proposed rule to the final rule that lessen the estimated burden, the Commission finds the results of its new survey to be generally consistent with the survey relied on in the Kothari Report.

Several commenters also questioned the hourly rate that the Commission relied on to calculate the estimated cost of compliance. One commenter stated that the Commission's estimate of $460 per hour may underestimate the blended hourly rate applicable to most HSR filings, particularly given attorney billing rates and that such filings often require senior executive participation. Another noted that the rate is below the nationwide average hourly rate for M&A attorneys. Others objected to the lack of support for the previously assumed hourly wage and description of how the Commission calculated the assumed hourly wage. One commenter suggested that a more realistic average rate for outside counsel is $936 per hour; however, no law firm that submitted comments specified a different hourly rate that should be applied.

The Commission has carefully reviewed and considered the comments submitted regarding the hourly rate and has determined to apply a blended hourly rate of $583. To reach this number, the Commission consulted additional resources regarding the rates for outside counsel and in-house personnel. In an effort to make as few assumptions as possible, the Commission used current data from reliable, publicly available sources. Although the actual rates charged by HSR practitioners (and attorneys generally) are not typically publicly available (and no commenter provided actual rates), the Commission reviewed public media and industry reports to determine a range of approximate values that would realistically reflect the costs to prepare an HSR filing.

The ELM Solutions 2023 Real Rate Report published by Wolters Kluwer reports data regarding the 2023 hourly rates charged by corporate M&A attorneys.[409] According to the report, at firms with more than 1,000 lawyers, the nationwide mean rate charged by partners in 2023 was $1,254 per hour and the nationwide mean rate charged by associates in 2023 was $781 per hour. At firms with 501 to 1,000 lawyers, the nationwide mean rate charged by partners was $1,213 per hour and for associates it was $801 per hour. At firms with 201 to 500 lawyers, the nationwide mean rates were $786 per hour for partners and $519 per hour for associates.

The Commission notes that HSR filings are not typically prepared exclusively by M&A law firm partners or exclusively by M&A associate attorneys. As a result, relying on one mean rate or the other would be inappropriate. The WK 2023 Real Rate Report indicates that with regard to corporate M&A matters from 2020–2023 that resulted in 40–100 total billed hours, approximately 45% of the hours billed were at the partner hourly rate, and approximately 49% of the hours billed were at the associate hourly rate.[410] The report further notes that approximately 7% of the hours billed were at a lower paralegal hourly rate.[411]

The Commission further notes that HSR filings are not prepared exclusively by the largest law firms, nor is it necessary for filers to engage such counsel. To account for filings prepared by small to mid-sized firms, the Commission calculated blended rates for both partners and associates by weighting the nationwide mean rates for firms with more than 1,000 lawyers (67%) and firms with 201 to 500 lawyers (33%). Applying the billing percentages in the WK 2023 Real Rate Report to those blended rates, the Commission calculated a blended rate for outside counsel of approximately $878 per hour.

To generate an overall blended rate, the Commission also accounted for the cost of client time spent preparing the filing, which could include a range of employees depending on the type of business and may include in-house counsel. The Commission has factored in an hourly rate for in-house personnel of approximately $140 per hour, which reflects current wage data reported by the Bureau of Labor Statistics.[412] Additionally, the Commission believes that 60% of the time required to prepare

[407] Estimated based upon a review of HSR Filings from fiscal years 2018 through 2022.

[408] Comment of U.S. Chamber of Com., Doc. No. FTC–2023–0040–0684. The Kothari Report reflects the results of a survey of antitrust practitioners conducted by the Chamber of Commerce seeking input on the proposed rule as well as the Agencies' draft merger guidelines. *See* U.S. Chamber of Com., ''U.S. Chamber HSR/Merger Guides Practitioner Survey'' (Sept. 19, 2023), *https://www.uschamber.com/finance/antitrust/antitrust-experts-reject-ftc-doj-changes-to-merger-process*. The Kothari Report was prepared by Professor S.J. Kothari and is appended to its comment at 54–85.

[409] Wolters Kluwer's ELM Solutions, 2023 Real Rate Report (2023). *See also* Ctr. Ethics & L. Prof. at Geo. L. & Thomson Reuters Inst. 2024 Report on the State of the US Legal Market 11–12 (Jan. 8, 2024) (discussing rise in law firm worked rates over the past five years as well as the counterinfluence of billing realization practices); Andrew Maloney, ''Where Are Partner Billing Rates Surging the Most in Big Law?,'' Am. L. (May 24, 2023) (noting a 2023 median hourly rate for M&A partners of $955 per hour).

[410] Wolters Kluwer's ELM Solutions, *supra* note 410, at 214.

[411] Instead of separately estimating a paralegal hourly rate, the Commission conservatively estimated that the remaining 7% assigned to paralegals in the WK 2023 Real Rate Report would be work performed at the associate's hourly rate.

[412] This assumed hourly rate is based on the median wage for lawyers, which according to the Bureau of Labor Statistics was $70.08 in 2023. See *https://www.bls.gov/ooh/legal/lawyers.htm*. The Commission doubles this number to reflect the lost productivity of the worker. The Commission notes that a company's top executives may also participate in preparing or reviewing the filing; however, since the median wage for top executives was $49.92 in 2023, to be conservative the Commission values top executive time at the same rate as lawyer time. *See https://www.bls.gov/ooh/management/top-executives.htm*.

the HSR filing is time spent by outside counsel and 40% is time spent by the client. These percentages are supported by survey results from Agency staff and are also consistent with the survey results in the Kothari Report. By weighting the hourly rates for outside counsel and in-house personnel accordingly, the Commission calculates an overall blended rate of $583 per hour. This adjusted hourly rate generally reflects publicly available information; however, it does not reflect real-world factors that would likely drive down the overall cost of preparing an HSR filing under the final rule (*e.g.,* client-negotiated rates, discounts, write-offs, alternative fee agreements, and work shifted to paralegals and other support staff at substantially lower rates).

Multiple commenters cited to the Kothari Report as providing a better estimate of the additional costs of the proposed changes and concluding that the true cost of the proposed rule may be many times greater than the NPRM suggested. But the Commission has accounted for many of the same costs in its own estimates, such as the time required from outside counsel, in-house counsel, and business personnel. Much of the difference in estimates is attributable to the higher hourly rate applied to the required hours, which the Kothari Report suggests is more likely $936 per hour, and a category of ''other'' costs that is nearly one-third of the total projected costs.[413] These additional costs are attributable to ''other external costs'' that include economic consultants, investment bankers, and data vendors.

The Commission does not believe that there will be this level of additional costs outside of internal personnel and outside counsel. In particular, completing the new requirements contained in the final rule should not require the services of economic consultants or investment bankers. As described above, the Form and Instructions require information from the parties' own records. The Commission specifically is not seeking an analysis or post-hoc rationales developed by external parties. As for data vendors and similar services for the collection and production of the required information, in its new survey of Agency staff, the Commission asked the survey participants to indicate for each item the percentage of time that should be allocated to third parties that they did not otherwise attribute to time spent by outside counsel. Only a few of the survey participants indicated any need for third-party involvement—and even for those few, they estimated only a small percentage of time for a limited set of items (*e.g.,* for translations). As a result, there is no basis to further adjust the Commission's estimates to account for ''other'' external costs.

Commenters also objected that the Commission failed to consider the indirect costs to the economy that would result when parties are discouraged from pursuing clearly nonproblematic deals. The PRA does not require the Commission to consider potential indirect costs to the economy presented by the changes described in the proposed rule. Under the PRA, the term ''burden'' means time, effort, or financial resources expended by persons to generate, maintain, or provide information to or for a Federal agency, including the resources expended for (A) reviewing instructions; (B) acquiring, installing, and utilizing technology and systems; (C) adjusting the existing ways to comply with any previously applicable instructions and requirements; (D) searching data sources; (E) completing and reviewing the collection of information; and (F) transmitting, or otherwise disclosing the information.[414] Comments related to indirect costs attributable to the final rule are discussed in section III.C.

Despite these points of disagreement, the Commission notes that its estimate for the increase in the average number of hours required to prepare an HSR filing is generally consistent with the estimates put forth by commenters, including in the Kothari Report, which were based on the proposed rule but not the final rule. The Commission believes that the differences in projected total costs are mainly attributable to (1) the significant modifications that were made to the final rule as compared to the proposed rule; (2) the difference in the hourly rates ($583 versus $936); (3) a category of ''other'' costs that unduly increased total costs by one-third; and (4) use of projected filings for FY 2023 (7,096), which the Commission now replaces in its calculation with the actual number of filings for FY 2023 (3,515). The Commission's PRA assessment for the final rule addresses concerns raised by the commenters related to the methodology used in the NPRM.

Net Effect

The changes outlined in the final rule only affect non-index filings which, for FY 2023, totaled 3,515. As described above, the Commission estimates that the amendments to the HSR Rules and Notification and Report Form contained in the final rule could increase the time required to prepare responses for non-index filings, with an estimated average increase of 68 hours per filing. Thus, the annual estimated additional hours burden is 239,020 (3,515 non-index filings multiplied by 68 additional hours per filing). Applying the revised estimated hours, 239,020, to the updated hourly rate of $583 for executive and attorney compensation yields approximately $139.3 million in total additional annual costs for a year with that number of filings. The additional per filing cost is estimated at $39,644 (68 hours multiplied by $583 per hour). However, the Commission believes that this PRA cost estimate may overestimate the actual PRA burden. For a variety of reasons, costs for any particular transaction are likely to be different from these estimates. The final rule will result in higher costs for those transactions that present the most antitrust risk, and the PRA estimates do not take account of the substantial benefits to the Agencies, the parties, and third parties generated from a more efficient premerger review process that shifts some of the burden of information collection and reporting away from third parties to the merging parties and allows the Agencies to obtain critical business facts earlier in the initial waiting period, which in turn helps mitigate avoidable costs associated with Second Requests that might have been avoided or that were not tailored to areas of competitive concern due to insufficient information in the HSR Filing. In addition, the annual costs associated with the final rule will be directly related to the number of reportable transactions. See section III.C. Finally, any estimated additional hours burden is expected to decline over time as filers become more familiar with the HSR Form and Instructions.

The amendments are expected to impose either minimal or no additional capital or other non-labor costs, as businesses subject to the HSR Rules generally have or obtain necessary equipment for other business purposes.

[413] Comment of U.S. Chamber of Com., Doc. No. FTC–2023–0040–0684 at 74–75 (other costs estimated at $102,917, added to external costs of $234,259 for a total of $313,828, with other costs 33% of total).

[414] 44 U.S.C. 3502(2); *see also* 5 CFR 1320.3(b) (defining burden); U.S. General Services Administration & Office of Management and Budget, ''A Guide to the Paperwork Reduction Act: Estimating Burden,'' *https://pra.digital.gov/burden/*.

The Commission believes that the above requirements necessitate ongoing, regular training so that covered entities stay current and have a clear understanding of Federal mandates, but that this would be a small portion of and subsumed within the ordinary training that employees receive apart from that associated with the information collected under the HSR Rules and the corresponding Instructions.

Basis for OMB Assessment

Finally, one commenter stated that the proposed rule provides an insufficient basis for the Office of Management and Budget (OMB) to conduct the informed and accurate assessment required by the PRA. The OMB typically defers its substantive review until the final rule stage and did not provide substantive feedback on the NPRM. However, the Commission disagrees with the commenter and believes that it has provided a sufficient basis for OMB to conduct an informed and accurate PRA assessment. Based on comments it received, the Commission narrowed the information requirements in the final rule, conducted a new survey to estimate costs, and revised its PRA analysis accordingly. The Commission believes that its revised assessment provides a sufficient basis for OMB review under the PRA.

IX. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 through 612, requires that an agency conduct an initial and final regulatory analysis of the anticipated economic impact of the proposed amendments on ''small entities,'' unless the agency certifies that the regulatory action will not have a significant economic impact on a substantial number of small entities.[415] Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

The Commission finds that the final rule will not affect a substantial number of small entities, because small entities will be affected only when they are party to a transaction that exceeds the HSR Act thresholds, and less than 0.02% of the nation's small entities file premerger notifications in any given year. Furthermore, the economic impact on the very few small entities that are required to file is not significant, because smaller businesses generally have fewer employees, generate fewer documents related to a transaction, and are involved in less complex transactions, all of which will minimize their costs of complying with the final rule. Further, these costs will generally account for a small fraction (less than 0.5%) of the value of the transaction. This document serves as the required notice of this certification to the SBA's Chief Counsel for Advocacy.[416]

The Commission also certified in the NPRM that the changes in the proposed rule would not, if adopted, have a significant economic impact on a substantial number of small entities. Commenters objected to the Commission's reliance on this certification and stated that the Commission failed to use the proper definition of small business or to discuss the proposed rule's impact on them.[417] The Commission responds by providing an assessment of how many small businesses are subject to the reporting requirements of the HSR Act and therefore would be impacted by the final rule. The Commission also notes that the final rule does not change which entities (including which small entities) are required to submit HSR Filings.

Under the RFA, ''small entities'' are defined as small businesses, not-for-profit organizations that are independently owned and operated and not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.[418] The term ''small business'' has the same meaning as the term ''small business concern'' under section 3 of the Small Business Act, meaning that it must be independently owned and operated and not dominant in its field of operation.[419] The Small Business Act permits the Small Business Administration (SBA) to specify size standards by which a business may be determined to be a ''small business concern.''[420] The SBA publishes these standards at 13 CFR 121.201.

To determine whether a regulatory action will impact a ''substantial number'' of small entities, SBA Guidance encourages agencies to examine the number of small businesses affected by a given rule relative to the total number of small businesses in the regulated industry. The regulated industry may include the ''entire universe of small businesses'' where a rule's reach is economy wide.[421] That is the case here, as the HSR Rules apply broadly to the entire economy, and all persons involved in reportable transactions are required to file an HSR Form, irrespective of industry.

The SBA estimates that, as of March 2023, there were approximately 33.2 million small businesses in the United States.[422] As explained below, due to the filing thresholds Congress established in the HSR Act, the small businesses that would have to report a transaction under the HSR Act represent a tiny fraction of this number. Even under the counterfactual and extreme assumption that all of 6,288 HSR filings received in FY2022 were made by small businesses,[423] less than 0.02% (6,288 divided by 33.2 million) of all small businesses would need to file an HSR Form. Such a de minimis number of small businesses does not qualify as a ''substantial number'' of small entities under the SBA's Guidance.[424] In an abundance of caution, however, as detailed below, the Commission analyzed a randomized sample of the filings received in FY2022 and further estimates that the final rule will apply to less than 0.0007% of small businesses. Therefore, the final rule will

[415] 5 U.S.C. 605(b).

[416] *Id.*

[417] One commentor suggested that the increased information requirements will, on the margin, lead to less investment by private equity in small businesses. Such indirect effects are not the proper subject of RFA analyses. *See, e.g., Cement Kiln Recycling Coalition* v. *EPA,* 255 F.3d 855, 868 (D.C. Cir. 2001) (rejecting the contention that the RFA applies to small businesses indirectly affected by the regulation of other entities).

[418] 5 U.S.C. 601.

[419] *See id.* at 601(3) (cross-referencing 15 U.S.C. 632).

[420] 15 U.S.C. 632(a)(2)(A). The Commission does not expect that the final rule will impact other types of ''small entities'' (not-for-profit organizations that are independently owned and operated and not dominant in their fields and governmental jurisdictions with populations of less than 50,000). In the Agencies' experience, governmental jurisdictions are typically not parties to transactions that would be subject to the HSR Act. As a result, the Commission has focused its analysis on small businesses as defined by the SBA.

[421] U.S. Small Bus. Admin., Office of Advocacy, ''How to Comply with the Regulatory Flexibility Act'' 21 (Aug. 31, 2017), *https://advocacy.sba.gov/2017/08/31/a-guide-for-government-agencies-how-to-comply-with-the-regulatory-flexibility-act/* (''Depending on the rule, the substantiality of the number of small businesses affected should be determined on an industry-specific basis and/or on the number of small businesses overall. For example, the Internal Revenue Service, when changing the tax deposit rules, would examine the entire universe of small businesses to see how many would be affected.'').

[422] U.S. Small Bus. Admin., Office of Advocacy, ''Frequently Asked Questions'' (Mar. 2023), *https://advocacy.sba.gov/wp-content/uploads/2023/03/Frequently-Asked-Questions-About-Small-Business-March-2023-508c.pdf.*

[423] Federal Trade Commission, Hart-Scott-Rodino Annual Report Fiscal Year 2022, appendix A.

[424] U.S. Small Bus. Admin., Office of Advocacy, *supra* note 424, at 21 (''The interpretation of the term 'substantial number' is not likely to be five small firms in an industry with more than 1,000 small firms.'').

not apply to a substantial number of small businesses.

The SBA regulations define ''small business'' primarily based on firm revenue or total number of employees, depending on the industry.[425] For industries where the SBA uses revenue to define ''small business,'' the revenue thresholds vary from $2.25 million to $47 million. In other industries, the SBA definition of small is based upon the number of employees. These thresholds range from 100 to 1,500 employees. Finally, certain finance-related industries are defined as small if they have less than $850 million in assets. Each NAICS code has a corresponding SBA threshold to determine whether a business generating revenue in that code is ''small.'' [426] In addition to these thresholds, businesses must also be independently owned and operated and not dominant in their fields on a national basis and satisfy additional criteria to be considered ''small.'' [427] The calculation of the size of a business must also give present effect to agreements to mergers and acquisitions, including agreements in principle.[428]

To estimate how many small entities so defined might be required to make an HSR filing, the Commission analyzed a randomly selected, statistically significant 10% sample of the filings submitted in FY 2022. Of that sample, the Commission first eliminated filings made by individuals in their individual capacity, and not as the ultimate parent entity of a business, such as for filings resulting from executive compensation. Second, the Commission used NAICS code information and financials reported by the acquiring or acquired person to determine if they qualified as a small business by revenue or assets, as applicable. For NAICS codes with thresholds based upon the number of employees, the Commission used public information or documents submitted by the filing parties to determine if they qualified as a small business based on the number of employees. For transactions in which the acquiring person filed for control of the acquired entities, the Commission analyzed the acquiring person and acquired entities after giving effect to the change of control.[429] Additionally, because a small business must be independently owned and operated, all filings where an investment group was the ultimate parent entity of the acquiring or acquired person were coded as not small businesses. The Commission does not have information sufficient to determine whether other filers are independently owned and operated, but where the Commission lacked sufficient information to exclude a business on this basis, they were counted as a small business even if they may not truly qualify as one. As a result, the estimates below are likely over-inclusive; that is, it is likely that fewer filers were small than were coded as small in the sample.

Table 6: Estimated Number of Small Business HSR Filers in Fiscal Year 2022

Estimated # of	FY 2022 (Sample x 10)	As % of Small Businesses*	As % of M&A Parties**	As % of # of HSR Filings***
Small Buyers that May Remain Small After Consummation of the Transaction	40	0.00012%	0.13%	0.64%
Small Targets that May Remain Small After Consummation of the Transaction	180	0.00054%	0.57%	2.86%
Total # of Filers That May Remain Small After Consummation of the Transaction	220	0.00066%	0.70%	3.50%

* Small Businesses in 2022 = 33,200,000

** M&A Parties in 2022 = 31,468 (15,734 x 2)

*** Number of Filings FY2022 = 6,288

As shown above in Table 6,[430] the Commission estimates that in FY 2022, it received up to 220 filings from businesses that meet the definition of small (22 found in the 10% sample). Of these, approximately 180 (18 found in the 10% sample) were the targets of the transaction, and 40 (4 found in the 10% sample) were the buyers. As a result, the Commission estimates than less than 0.0007% of small businesses will be affected by the final rule.[431]

This is consistent with the structure of the HSR Act, which focuses on larger mergers, as defined by dollar value.[432] The framework of the Act established three tests that together serve to limit the applicability of the Act for small businesses: (1) the Commerce Test; (2) the Size of the Transaction Test; and (3) the Size of the Person Test.[433]

[425] 13 CFR 121.201.

[426] *Id.*

[427] 15 U.S.C. 632.

[428] 13 CFR 121.103(d)(1).

[429] The Commission notes that filers must attest (1) to their good faith intent to consummate a transaction, and (2) in all transactions to which 16 CFR 801.30 does not apply, that a contract, agreement in principle or letter of intent to merge or acquire has been executed. *See* 16 CFR 803.5.

[430] *See* Table 1 (showing 15,734 acquisitions in 2022).

[431] Though the SBA regulations give effect to agreements, including agreements in principle, when determining size, the Commission also analyzed whether the sample of filers might meet the thresholds if agreements resulting in a change of control were not considered. Here too, the Commission finds that the final rule does not affect a substantial number of small entities. It estimates that in FY2022 approximately 850 filers may have met the definition of small if the effect of agreements is not considered, representing less than 0.003% of small businesses in the United States, approximately 2.70% of the estimated number of M&A parties, and 13.52% of FY 2022 HSR filers.

[432] The Commission now provides this information to give context about the reach of the Act and does not rely upon any of the HSR reporting thresholds in this certification, since it has conducted an analysis of the filing parties using the SBA's definitions of small, as described above. Therefore, the Commission does not address comments related to the RFA analysis provided in the NPRM that drew different conclusions from the statutory thresholds.

[433] 15 U.S.C. 18a(a).

Table 7: Current HSR Form Filing Thresholds

	Size of Transaction (SOT) (as adjusted, as of March 6, 2024)		
	SOT ≤ $119.5 M	$119.5 M > SOT ≤ $478 M	SOT > $478 M
HSR Filing required?	No	No, unless the Size of Person Test is met.	Yes

The Commerce Test is met if either party is engaged in commerce or any activity affecting commerce.

Under the Size of the Transaction Test, no filing is required if the transaction is valued at $119.5 million [434] or less. Transactions valued between $119.5 million and $478 million only must be reported if the acquiring and acquired person also meet the Size of the Person Test. Transactions valued at more than $478 million are reportable regardless of the Size of the Person Test.

Where the Size of the Person Test applies, premerger notification is required only if (1) the acquiring person has total assets or annual net sales of $23.9 million (2024 adjusted value) and the acquired person has total assets or annual net sales of $239 million (2024 adjusted value); or (2) the acquiring person has total assets or annual net sales of $239 million (2024 adjusted value) and the acquired person has total assets (or, if it is ''engaged in manufacturing,'' annual net sales) of $23.9 million (2024 adjusted value). If these size thresholds are not met, no filing is required. For example, in 2024, if the size of a transaction were $475 million and the acquiring person had $1 billion in assets and revenue, but the acquired person was not engaged in manufacturing and had $220 million in revenue but only $20 million in assets, no filing would be required.

The final rule also will not have a significant economic impact on small entities that are required to file. An HSR filing is not an ongoing cost for small businesses. Instead, the costs are incurred only when a small business is a party to a reportable transaction. Therefore, the Commission does not expect that the costs of complying with the final rule will cause a significant impact on affected small businesses.

For the less than 0.0007% of American businesses that will remain small after engaging in an HSR reportable transaction, the impact will be minimal. Even in a case of a complex transaction between two small businesses where the size of the transaction was at the threshold (currently $119.5 million), the Commission estimates that the additional cost imposed by the final rule would be approximately 0.12% of the value of the transaction.[435] For the majority of transactions involving small businesses, actual costs are likely much lower and would represent an even smaller percentage of the proceeds from the transaction. For example, based upon the Commission's review of the sample of FY 2022 transactions, in some transactions involving a presumptively small business, the size of transaction value exceeded $1 billion, resulting in the additional cost of the final rule representing less than 0.015% of the transaction value for even a complex transaction.[436]

Finally, the Commission has no reason to believe that the final rule will have a significant economic impact on any entity, let alone entities that have assets or revenues substantial enough to meet the HSR Act's reporting thresholds but that nevertheless qualify as small businesses. As detailed in the final rule, the Commission estimates that the changes would result in approximately 10 to 121 additional hours per filing, depending on the complexity of the filing at issue. In the Commission's experience, smaller businesses have fewer lines of business and fewer employees, generate fewer documents related to a transaction and maintain fewer ordinary course documents, and are involved in less complex transactions, all of which will minimize their costs of responding to the document requests contained within the final rule, to the extent their compliance is even triggered under the HSR Act's thresholds.

Accordingly, the Commission hereby certifies that the final rule will not have a significant impact on a substantial number of small entities.

X. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs has designated this rule as a ''major rule,'' as defined by 5 U.S.C. 804(2).

List of Subjects

16 CFR Parts 801

Antitrust.

16 CFR Part 803

Antitrust, Fees, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, the Federal Trade Commission amends 16 CFR parts 801 and 803 as set forth below:

PART 801—COVERAGE RULES

■ 1. The authority citation for part 801 is revised as follows:

Authority: 15 U.S.C. 18a(d); 15 U.S.C. 18b.

■ 2. Amend § 801.1 by revising examples 1, 4, 5, and 6 in paragraph (d)(2) and by adding paragraph (r) to read as follows:

§ 801.1 Definitions

* * * * *

(d) * * *

(2) * * *

Examples: 1. ABC Investment Group has organized a number of investment partnerships. Each of the partnerships is its own ultimate parent, but ABC makes the investment decisions for all of the partnerships. One of the partnerships intends to make a reportable acquisition. For purposes of the Notification and Report Form, each of the other investment partnerships, and

[434] When Congress passed the HSR Act, it created minimum dollar thresholds for mandatory premerger reporting. In 2000, Congress amended the HSR Act to require an annual adjustment of these thresholds based on the change in gross national product. As a result, reportability under the Act changes from year to year as the statutory thresholds adjust. The most recent adjustment became effective March 6, 2024.

[435] Estimated cost for acquiring and acquired persons combined in transactions with overlaps using highest average cost (242 hours × $583) divided by the $119,500,000 threshold.

[436] Estimated cost for acquiring and acquired persons combined in transactions with overlaps using highest average cost (242 hours × $583) divided by $1,000,000,000.

ABC Investment Group itself, are associates of the partnership that is the acquiring person. In the Minority-Held Entity Overlaps section of the Notification and Report Form, the acquiring person will disclose any of its 5 percent or greater minority holdings that generate revenues in any of the same NAICS codes as the acquired entity(s) in the reportable transaction. In this same section, the acquiring person would also report any 5 percent or greater minority holdings of its associates in the acquired entity(s) and in any entities that generate revenues in any of the same NAICS codes as the acquired entity(s). In the Controlled Entity Geographic Overlaps section of the Notification and Report Form, the acquiring person will indicate whether there are any NAICS code overlaps between the acquired entity(s) in the reportable transaction, on the one hand, and the acquiring person and all of its associates, on the other.

* * * * *

4. CORP1 controls GP1 and GP2, the sole general partners of private equity funds LP1 and LP2 respectively. LP1 controls GP3, the sole general partner of MLP1, a newly formed master limited partnership which is its own ultimate parent entity. LP2 controls GP4, the sole general partner of MLP2, another master limited partnership that is its own ultimate parent entity and which owns and operates a natural gas pipeline. In addition, GP4 holds 25 percent of the voting securities of CORP2, which also owns and operates a natural gas pipeline.

MLP1 is acquiring 100 percent of the membership interests of LLC1, also the owner and operator of a natural gas pipeline. MLP2, CORP2 and LLC1 all derive revenues in the same NAICS code (Pipeline Transportation of Natural Gas). All of the entities under common investment management of CORP1, including GP4 and MLP2, are associates of MLP1, the acquiring person.

In the Controlled Entity Geographic Overlaps section of the Notification and Report Form, MLP1 would identify MLP2 as an associate that has an overlap in pipeline transportation of natural gas with LLC1, the acquired person. Because GP4 does not control CORP2 it would not be listed in this section, however, GP4 would be listed in the Minority-Held Entity Overlaps section of the Notification and Report Form as an associate that holds 25 percent of the voting securities of CORP2. In this example, even though there is no direct overlap between the acquiring person (MLP1) and the acquired person (LLC1), there is an overlap reported for an associate (MLP2) of the acquiring person in the Controlled Entity Geographic Overlaps section of the Notification and Report Form.

5. LLC is the investment manager for and ultimate parent entity of general partnerships GP1 and GP2. GP1 is the general partner of LP1, a limited partnership that holds 30 percent of the voting securities of CORP1. GP2 is the general partner of LP2, which holds 55 percent of the voting securities of CORP1. GP2 also directly holds 2 percent of the voting securities of CORP1. LP1 is acquiring 100 percent of the voting securities of CORP2. CORP1 and CORP2 both derive revenues in the same NAICS code (Industrial Gas Manufacturing).

All the entities under common investment management of the managing entity LLC, including GP1, GP2, LP2 and CORP1 are associates of LP1. In Minority-Held Entity Overlaps section of the Notification and Report Form, LP1 would report its own holding of 30 percent of the voting securities of CORP1. It would not report the 55 percent holding of LP2 in Minority-Held Entity Overlaps section of the Notification and Report Form because it is greater than 50 percent. It also would not report GP2's 2 percent holding because it is less than 5 percent. In the Controlled Entity Geographic Overlaps section, LP1 would identify both LP2 and CORP1 as associates that derive revenues in the same NAICS code as CORP2.

6. LLC is the investment manager for GP1 and GP2 which are the general partners of limited partnerships LP1 and LP2, respectively. LLC holds no equity interests in either general partnership but manages their investments and the investments of the limited partnerships by contract. LP1 is newly formed and its own ultimate parent entity. It plans to acquire 100 percent of the voting securities of CORP1, which derives revenues in the NAICS code for Consumer Lending. LP2 controls CORP2, which derives revenues in the same NAICS code. All of the entities under the common management of LLC, including LP2 and CORP2, are associates of LP1. For purposes of the Controlled Entity Geographic Overlaps section of the Notification and Report Form, LP1 would report LP2 and CORP2 as associates that derive revenues in the NAICS code that overlaps with CORP1. Even though the investment manager (LLC) holds no equity interest in GP1 or GP2, the contractual arrangement with them makes them associates of LP1 through common management.

* * * * *

(r)(1) *Foreign entity or government of concern.* The term *foreign entity or government of concern* means:

(i) An entity that is a foreign entity of concern as that term is defined in section 40207 of the Infrastructure Investment and Jobs Act (42 U.S.C. 18741(a)(5)); or

(ii) A government, or an agency thereof, of a foreign country that is a covered nation as that term is defined in section 40207 of the Infrastructure Investment and Jobs Act (42 U.S.C. 18741(a)(5)(C)).

(2) *Subsidy.* The term *subsidy* has the meaning given to the term in part IV of title VII of the Tariff Act of 1930 (19 U.S.C. 1677(5)(B)).

PART 803—TRANSMITTAL RULES

■ 3. The authority citation for part 803 is revised to read as follows:

Authority: 15 U.S.C. 18a(d); 15 U.S.C. 18b.

■ 4. Amend § 803.2 by:

■ a. Revising paragraph (a);

■ b. Removing paragraph (b) and the undesignated example following paragraph (b);

■ c. Redesignating paragraphs (c), (d), (e), and (f) as paragraphs (b), (c), (d), and (e), respectively; and

■ d. Revising newly redesignated paragraphs (b), (d), and (e). The revisions read as follows:

§ 803.2 Instructions applicable to Notification and Report Form.

(a)(1) The notification required by the act shall be filed by the preacquisition ultimate parent entity, or by any entity included within the person authorized by such preacquisition ultimate parent entity to file notification on its behalf. In the case of a natural person required by the act to file notification, such notification may be filed by his or her legal representative: *Provided however,* That notwithstanding §§ 801.1(c)(2) and 801.2 of this chapter, only one notification shall be filed by or on behalf of a natural person, spouse and minor children with respect to an acquisition as a result of which more than one such natural person will hold voting securities of the same issuer.

Example 1 to paragraph (a)(1). Jane Doe, her husband, and minor child collectively hold more than 50 percent of the shares of family corporation F. Therefore, Jane Doe (or her husband or minor child) is the ''ultimate parent entity'' of a ''person'' composed to herself (or her husband or minor child) and F; see § 801.1(a)(3), (b), and (c)(2) of of this chapter. If corporation F is to

acquire corporation X, under this paragraph only one notification is to be filed by Jane Doe, her husband, and minor child collectively.

(2) Persons that are both acquiring and acquired persons shall submit separate forms, one as the acquiring person and one as the acquired person, following the appropriate instructions for each.

(b) In response to the Revenue and Overlaps section of the Notification and Report Form, information need not be supplied with respect to assets or voting securities to be acquired, the acquisition of which is exempt from the requirements of the act.

* * * * *

(d) For annual reports and audit reports required by the Notification and Report Form, a person filing the notification may, instead of submitting a document, provide a cite to an operative internet address directly linking to the document, if the linked document is complete and payment is not required to access the document. If an internet address becomes inoperative during the waiting period, or the document is otherwise rendered inaccessible or incomplete, upon notification by the Commission or Assistant Attorney General, the parties must make the document available to the agencies by either referencing an operative internet address where the complete document may be accessed or by providing electronic copies to the agencies as provided in § 803.10(c)(1) by 5 p.m. Eastern Time on the next regular business day. Failure to make the document available, by the internet or by providing electronic copies, by 5 p.m. Eastern Time on the next regular business day, will result in notice of a deficient filing pursuant to § 803.10(c)(2).

(e) Filings must comply with all format requirements set forth at the Premerger Notification Office pages at *https://www.ftc.gov*. The use of any format not specified as acceptable, or any other failure to comply with the applicable format requirements, shall render the entire filing deficient within the meaning of § 803.10(c)(2).

■ 5. Amend § 803.5 by redesignating the paragraph (a)(1) heading as the paragraph (a) heading and republishing it and revising paragraphs (a)(1) introductory text, (a)(3), and (b) to read as follows:

§ 803.5 Affidavits required.

(a) *Section 801.30 acquisitions.* (1) For acquisitions to which § 801.30 of this chapter applies, the notification required by the act from each acquiring person shall contain an affidavit attesting that the issuer or unincorporated entity whose voting securities or non-corporate interests are to be acquired has received written notice delivered to an officer (or a person exercising similar functions in the case of an entity without officers) by email, certified or registered mail, wire, or hand delivery, at its principal executive offices, of:

* * * * *

(3) The affidavit required by this paragraph must have attached to it a copy of the written notice received by the acquired person pursuant to paragraph (a)(1) of this section.

(b) *Non-section 801.30 acquisitions.* For acquisitions to which § 801.30 of this chapter does not apply, the notification required by the act shall contain an affidavit attesting that a contract, agreement in principle, or letter of intent to merge or acquire has been executed, and further attesting to the good faith intention of the person filing notification to complete the transaction. If the executed agreement is not the definitive agreement, the affidavit must attest that a dated document that provides sufficient detail about the scope of the entire transaction that the parties intend to consummate has also been submitted.

■ 6. Revise § 803.8 to read as follows:

§ 803.8 Foreign language documents.

Documentary materials or information in a foreign language required to be submitted at the time of filing a Notification and Report Form and in response to a request for additional information or documentary material must be submitted with verbatim English language translations. All verbatim translations must be accurate and complete.

■ 7. Amend § 803.9 by revising paragraph (c) to read as follows:

§ 803.9 Filing fee.

* * * * *

(c) For a reportable transaction in which the acquiring entity has two ultimate parent entities, both ultimate parent entities are acquiring persons; however, if the responses for both ultimate parent entities would be the same for the NAICS Codes section of the Notification and Report Form, only one filing fee is required in connection with the transaction.

* * * * *

■ 8. Amend § 803.10 by revising paragraphs (c)(1)(i) and (ii) and redesignating the example following paragraph (c)(1)(ii) as Example 1 to paragraph (c)(1).

The revisions read as follows:

§ 803.10 Running of time.

* * * * *

(c) * * *

(1) * * *

(i) The date of receipt shall be the date of electronic submission if such date is not a Saturday, Sunday, a legal public holiday (as defined in 5 U.S.C. 6103(a)), or a legal public holiday's observed date, and the submission is completed by 5 p.m. Eastern Time. In the event electronic submission is unavailable, the FTC and DOJ may designate procedures for the submission of the filing. Notification of the alternate delivery procedures will normally be made through a press release and, if possible, on the *https://www.ftc.gov* website.

(ii) Delivery effected after 5 p.m. Eastern Time on a business day, or at any time on any day other than a business day, shall be deemed effected on the next following business day. If submission of all required filings is not effected on the same date, the date of receipt shall be the latest of the dates on which submission is effected.

* * * * *

■ 9. Amend § 803.12 by revising paragraph (c)(1)(iii) to read as follows:

§ 803.12 Withdraw and refile notification.

* * * * *

(c) * * *

(1) * * *

(iii) The resubmitted notification is recertified, and the submission, as it relates to Transaction-Specific Agreements, Transaction-Related Documents, and Subsidies from Foreign Entities of Concern sections of the Notification and Report Form, is updated to the date of the resubmission;

* * * * *

■ 10. Revise appendices A and B to part 803 to read as follows:

Appendix A to Part 803—*Notification and Report Form for Certain Mergers and Acquisitions*

BILLING CODE 6750–01–P

16 C.F.R. Part 803 – Appendix

Notification and Report Form for Certain Mergers and Acquisitions

Acquiring Person

FEE INFORMATION

Total Filing Fee: Select Filing Fee. **Paid By:** ☐ Acquiring Person ☐ Acquired Person ☐ Both

Name of Payer	Amount Paid	Check Number	EWT Institution & Confirmation Number

GENERAL INFORMATION

Post-Consummation Filing? ☐ Yes ☐ No
Cash Tender Offer? ☐ Yes ☐ No
Bankruptcy? ☐ Yes ☐ No

Do you request early termination of the waiting period? ☐ Yes ☐ No
(Grants of early termination are published in the Federal Register and on the FTC website.)

ULTIMATE PARENT ENTITY (UPE) INFORMATION

► UPE Details

Name: _____

Headquarters Address: _____ **Address Line 2:** _____

City: _____ **State:** _____ **Zip Code:** _____ **Country:** _____

Website: _____

Entity Type: The UPE of the acquiring person is a(n)?
☐ Corporation ☐ Unincorporated Entity ☐ Natural Person ☐ Other (Specify): _____

FILING MADE ON BEHALF OF THE UPE	Name and address of filing notification entity, if different than UPE (Name, Address, City, State, Zip Code, and Country)
☐ Not Applicable. ☐ This report is being filed on behalf of the ultimate parent entity by another entity within the same person authorized by it to file pursuant to § 803.2(a). ☐ This report is being filed on behalf of a foreign person pursuant to § 803.4.	

	PRIMARY HSR REPORT CONTACT	SECONDARY HSR REPORT CONTACT	SECOND REQUEST CONTACT
Name:			
Firm/Company:			
Address:			
City, State, Zip Code:			
Country:			
Telephone Number:			
E-Mail Address:			

Name of Acquiring Person UPE: **Date:**

UPE Annual Reports and Financial Information	
Central Index Key (CIK) Number	
Annual/Audit Report Document # or Link	
Date of Annual/Audit Report	

Does the person filing notification stipulate that the acquiring person meets the size of person test? See 15 U.S.C. § 18a(a).

☐ Yes, the lower size of person test ☐ Yes, the higher size of person test ☐ N/A

Minority Shareholders or Interest Holders ☐ None

Entity	Minority Holder & D/B/A Name	HQ Address	Percent Held

► **Acquiring Person Structure**

Entities Within the Acquiring Person

Company or Operating Business d/b/a Name(s):				
Entity Name	**City**	**State**	**Zip Code**	**Country**
Company or Operating Business d/b/a Name(s):				
Entity Name	**City**	**State**	**Zip Code**	**Country**
Company or Operating Business d/b/a Name(s):				
Entity Name	**City**	**State**	**Zip Code**	**Country**

Annual Reports and Audit Reports

Acquiring Entity or Overlapping Entity	Central Index Key (CIK) Number	Annual/Audit Report File Name or Link	Date of Annual/Audit Report

Name of Acquiring Person UPE:	Date:

► Additional Acquiring Person Information

OWNERSHIP STRUCTURE

Description of the ownership structure of the acquiring entity	
Document # of organizational chart for fund or MLP (or N/A)	

OFFICERS AND DIRECTORS

Name of Entity Within Acquiring Person	Name of Officer or Director	Title	List of Other Entities

TRANSACTION INFORMATION

► Parties

ACQUIRING UPE(S)	ACQUIRED UPE(S)
Name: Address: Address Line 2: City, State, Zip Code: Country: Website:	Name: Address: Address Line 2: City, State, Zip Code: Country: Website:
ACQUIRING ENTITY(IES) – *(Tab to add additional "Acquiring Entity" entries.)*	TARGET – *(Tab to add additional "Target" entries.)*
Name: Address: Address Line 2: City, State, Zip Code: Country: Website:	Name: Address: Address Line 2: City, State, Zip Code: Country: Website:

► Transaction Details Is this transaction subject to § 801.30? ☐ Yes, Specify Type(s) ☐ No

TRANSACTION TYPE

Check all that apply:

☐ Acquisition of voting securities
☐ Acquisition of non-corporate interests
☐ Acquisition of assets
☐ Merger (see § 801.2)
☐ Consolidation (see § 801.2)
☐ Formation of a joint venture, other corporation, or unincorporated entity (see §§ 801.40 and 801.50)
☐ Acquisition subject to § 801.31
☐ Secondary acquisition subject to § 801.4
☐ Acquisition subject to § 801.2(e)
☐ Other, specify _____

Name of Acquiring Person UPE: **Date:**

ACQUISITION DETAILS

Percentage of voting securities already held %	Percentage of non-corporate interests already held %		
Value of voting securities already held ($MM) $	Value of non-corporate interests already held ($MM) $		
Total percentage of voting securities to be held as a result of the acquisition %	Total percentage of non-corporate to be held as a result of the acquisition %		
Total value of voting securities to be held as a result of the acquisition ($MM) $	Total value of non-corporate securities to be held as a result of the acquisition ($MM) $	Total value of assets to be held as a result of the acquisition ($MM) $	**Aggregate total value ($MM)** **$ 0.00**

NOTIFICATION THRESHOLD

☐ $50 million (as adjusted) ☐ $100 million (as adjusted) ☐ $500 million (as adjusted) ☐ 25% ☐ 50% ☐ N/A

► Transaction Description

BUSINESS OF THE ACQUIRING PERSON	
BUSINESS OF THE TARGET	
NON-REPORTABLE UPE(S)	
TRANSACTION DESCRIPTION	

RELATED TRANSACTIONS

Does the transaction that is the subject of this filing have related filings? ☐ Yes ☐ No ☐ Unknown

If the transaction has related filings, indicate whether the related filing(s) (choose all that apply):

☐ Is a principal transaction that triggers one or more shareholder backside transactions
☐ Is a shareholder backside transaction
☐ Has more than one acquiring UPE
☐ Has more than one acquired UPE
☐ Has more than one reportable step
☐ Is a joint venture
☐ Is a consolidation
☐ Is an exchange of assets
☐ Has one or more filings in the alternative
☐ Other, explain:_____

Party Names or Transaction Numbers for Related Transactions:

► Transactions Subject to International Antitrust Notification

Has (or will) a non-U.S. antitrust or competition authority been (or be) notified of the transaction? ☐ No ☐ Yes (provide details below)

Jurisdiction	Date Notified

Name of Acquiring Person UPE:	Date:

► Additional Transaction Information

Transaction Rationale ☐ Not applicable, select 801.30 transaction	
Document Numbers Related to Transaction Rationale	
Document # for Transaction Diagram ☐ Not applicable, select 801.30 transaction	

► Joint Ventures

Complete only if acquisition is the formation of a joint venture corporation or unincorporated entity ☐ Not Applicable

Contributions to be Made	
Description of Consideration	
Description of The Business of the Joint Venture	

Joint Venture NAICS Codes

6-Digit Code	Code Description

► Business Documents

Transaction Related Documents

Privileged	Document #	Document Title	Estimated Date	Author/Title
☐				
☐				
☐				

Plans and Reports ☐ Not Applicable, Select 801.30 Transaction

Privileged	Document #	Document Title	Estimated Date	Author/Title
☐				
☐				
☐				

Privilege Log Document # _____

Name of Acquiring Person UPE:	Date:

► Agreements

TRANSACTION-SPECIFIC AGREEMENTS ☐ Not Applicable, 801.30 or Bankruptcy

Document #	Document Title

OTHER AGREEMENTS BETWEEN THE ACQUIRING PERSON AND TARGET

Does the acquiring person have (or within one year of filing, had) any agreements with the target?

☐ No ☐ Yes (provide details below)

Has Type of Agreement		Type
☐ Yes	☐ No	Agreement with non-compete or non-solicitation terms between the acquiring person and target
☐ Yes	☐ No	Lease
☐ Yes	☐ No	Licensing Agreement
☐ Yes	☐ No	Master Service Agreement
☐ Yes	☐ No	Operating Agreement
☐ Yes	☐ No	Supply Agreement
☐ Yes	☐ No	Other

COMPETITION DESCRIPTIONS

☐ Not Applicable, Select 801.30 Transaction

► Overlap Description

Briefly describe the acquiring person's principal categories of products or services.

List and briefly describe current and known planned products or services that compete (or could compete) with the target. (See Instructions)

Name of Acquiring Person UPE:	Date:

Competing Product or Service Details ☐ None

Product or Service:	**Sales ($):** **Categories of Customers:** **Top 10 Customers Overall:** **Top 10 Customers by Category:**
Product or Service:	**Sales ($):** **Categories of Customers:** **Top 10 Customers Overall:** **Top 10 Customers by Category:**
Product or Service:	**Sales ($):** **Categories of Customers:** **Top 10 Customers Overall:** **Top 10 Customers by Category:**

► Supply Relationships Description

RELATED SALES

List and briefly describe the acquiring person's products, services, or assets that are supplied to the target or a business that competes with the target. (See Instructions)

Product, Service, or Asset Details ☐ None

Product, Service, or Asset:	**Sales to Target ($):** **Sales to Target's Competitors ($):** **Top 10 Customers:** **Description of Supply or Licensing Agreement:**
Product, Service, or Asset:	**Sales to Target ($):** **Sales to Target's Competitors ($):** **Top 10 Customers:** **Description of Supply or Licensing Agreement:**
Product, Service, or Asset:	**Sales to Target ($):** **Sales to Target's Competitors ($):** **Top 10 Customers:** **Description of Supply or Licensing Agreement:**

Name of Acquiring Person UPE:	Date:

RELATED PURCHASES

List and briefly describe the products, services, or assets that are purchased by the acquiring person from the target or a business that competes with the target. (See Instructions)

Product, Service, or Asset Details ☐ None

Product, Service, or Asset:	**Purchases from Target ($):** **Purchases from Target's Competitors ($):** **Top 10 Suppliers:** **Description of Purchase or Licensing Agreement:**
Product, Service, or Asset:	**Purchases from Target ($):** **Purchases from Target's Competitors ($):** **Top 10 Suppliers:** **Description of Purchase or Licensing Agreement:**
Product, Service, or Asset:	**Purchases from Target ($):** **Purchases from Target's Competitors ($):** **Top 10 Suppliers:** **Description of Purchase or Licensing Agreement:**

REVENUE AND OVERLAPS

Does the acquiring person have US revenue? ☐ Yes ☐ No, explain: _____

► NAICS Codes

6-Digit Code	Code Description	Operating Business	Revenue Range				Overlap
			<$10MM	$10MM - $100MM	$100MM - $1B	>$1B	
							☐
							☐
							☐
							☐
							☐

► Controlled Entity Geographic Overlaps

STATE LEVEL REPORTING ☐ None

NAICS Code	Code Description	Operating Business and D/B/A Name(s)	Person or Associate?	States and Total Number

Name of Acquiring Person UPE: Date:

STREET LEVEL REPORTING ☐ None

NAICS Code and Description:					
Operating Business and D/B/A Name(s)	Person or Associate	State	County	ZIP Code	Street Address

NAICS Code and Description:					
Operating Business and D/B/A Name(s)	Person or Associate	State	County	ZIP Code	Street Address

NAICS Code and Description:					
Operating Business and D/B/A Name(s)	Person or Associate	State	County	Zip Code	Street Address

► Minority-Held Entity Overlaps

☐ None

Entity Held and D/B/A Name(s)	Percentage Held	Held By	Person or Associate?	NAICS Code or Industry Overlap with Target

► Prior Acquisitions

☐ None

Overlapping 6-Digit NAICS Code and Description or Overlap Product or Service Description	Acquired Entity and Former HQ Address	Transaction Type	Consummation Date

ADDITIONAL INFORMATION

► Subsidies from Foreign Entities or Governments of Concern

SUBSIDIES ☐ None ☐ Yes (provide details below)

Entity or Government	Description

Name of Acquiring Person UPE:	Date:

COUNTERVAILING DUTIES IMPOSED ☐ None ☐ Yes (provide details below)

Product	Duty Imposed	Jurisdiction

COUNTERVAILING DUTY INVESTIGATIONS ☐ None ☐ Yes (provide details below)

Product	Jurisdiction Conducting Investigation

► Defense or Intelligence Contracts

☐ None ☐ Not Applicable, Select 801.30 Transaction

Entity Within Acquiring Person	Contracting Office	Contracting Office ID	Award ID	NAICS Codes

► Voluntary Waivers

INTERNATIONAL COMPETITION AUTHORITIES (VOLUNTARY)

The acquiring person agrees to waive the disclosure exemption in the HSR Act for the following competition authorities: ☐ None

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

STATE ATTORNEYS GENERAL (VOLUNTARY)

The acquiring person agrees to waive the disclosure exemption in the HSR Act for the following states: ☐ None

State	Permit Disclosure of	
	Fact of Notification and Waiting Period	Information and Documents
	☐	☐
	☐	☐
	☐	☐

► End Notes

☐ None

Number	Note

Name of Acquiring Person UPE: **Date:**

CERTIFICATION

PENALTIES FOR FALSE STATEMENTS

Federal law provides criminal penalties, including up to twenty years imprisonment, for any person who knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence an ongoing or anticipated federal investigation (see, e.g., Section 1519 of Title 18, United States Code.). It is also a criminal offense to knowingly make a false statement in a federal investigation, obstruct a federal investigation, or conspire to obstruct justice or obstruct or impede the lawful functioning of the government (see, e.g., Sections 371, 1001, and 1505 of Title 18, United States Code).

CERTIFICATION

This NOTIFICATION AND REPORT FORM, together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Commission. Subject to the recognition that, where so indicated, reasonable estimates have been made because books and records do not provide the required data, the information is, to the best of my knowledge, true, correct, and complete in accordance with the statute and rules.

I acknowledge that the Commission or the Assistant Attorney General of the Antitrust Division of the Department of Justice may, prior to the expiration of the initial waiting period pursuant to 15 U.S.C. § 18a, require the submission of additional information or documentary material relevant to the proposed transaction.

Name (Please Print or Type)	**Title**
Signature	**Date**

☐ **Sworn under penalty of perjury**

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Signature	**Executed Date**

☐ **Notarized**

Subscribed and sworn to before me at the: Seal:

_____

City of: _____

State of: _____

This _____ day of _____ the year _____

Signature: _____

My commission expires: _____

Name of Acquiring Person UPE:	Date:

16 C.F.R. Part 803 – Appendix NOTIFICATION AND REPORT FORM FOR CERTAIN MERGERS AND ACQUISITIONS	Approved by OMB 3084-0005

THE INFORMATION REQUIRED TO BE SUPPLIED ON THESE ANSWER SHEETS IS SPECIFIED IN THE INSTRUCTIONS

THIS FORM IS REQUIRED BY LAW and must be filed separately by each person that, by reason of a merger, consolidation, or acquisition, is subject to § 7A of the Clayton Act, 15 U.S.C. § 18a, and rules promulgated thereunder (hereinafter referred to as "the rules" or by section number). The rules may be found at 16 CFR Parts 801-03. Failure to file this **Notification and Report Form**, and to observe the required waiting period before consummating the acquisition in accordance with the applicable provisions of 15 U.S.C. § 18a and the rules, subjects any "person," as defined in the rules, or any individuals responsible for noncompliance, to liability for a penalty for each day during which such person is in violation of 15 U.S.C. § 18a. The maximum daily civil penalty amount is listed in 16 C.F.R. § 1.98(a).

Pursuant to the Hart-Scott-Rodino Act, information and documentary material filed in or with this Form is confidential. It is exempt from disclosure under the Freedom of Information Act and may be made public only in an administrative or judicial proceeding, or disclosed to Congress or to a duly authorized committee or subcommittee of Congress.

DISCLOSURE NOTICE - Public reporting burden for this report is estimated at 105 hours per response, including time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this report, including suggestions for reducing this burden to:

Premerger Notification Office
Federal Trade Commission
400 7th St. SW
Washington, DC 20024

and

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

Under the **Paperwork Reduction Act**, as amended, 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. That number is 3084-0005, which also appears above.

Privacy Act Statement--Section 18a(a) of Title 15 of the U.S. Code authorizes the collection of this information. The primary use of information submitted on this Form is to determine whether the reported merger or acquisition may violate the antitrust laws. Taxpayer information is collected, used, and may be shared with other agencies and contractors for payment processing, debt collection and reporting purposes. Furnishing the information on the Form is voluntary. Consummation of an acquisition required to be reported by the statute cited above without having provided this information may, however, render a person liable to civil penalties up to the amount listed in 16 C.F.R. § 1.98(a) per day. We also may be unable to process the Form unless you provide all of the requested information.

This page may be omitted when submitting the Form.

16 C.F.R. Part 803 – Appendix

Notification and Report Form for Certain Mergers and Acquisitions

Acquired Person

FEE INFORMATION

Total Filing Fee: Select Filing Fee. **Paid By:** ☐ Acquiring Person ☐ Acquired Person ☐ Both

Name of Payer	Amount Paid	Check Number	EWT Institution & Confirmation Number

GENERAL INFORMATION

Post-Consummation Filing? ☐ Yes ☐ No
Cash Tender Offer? ☐ Yes ☐ No
Bankruptcy? ☐ Yes ☐ No

Do you request early termination of the waiting period? ☐ Yes ☐ No
(Grants of early termination are published in the Federal Register and on the FTC website.)

ULTIMATE PARENT ENTITY (UPE) INFORMATION

► UPE Details

Name: _____

Headquarters Address: _____ **Address Line 2:** _____

City: _____ **State:** _____ **Zip Code:** _____ **Country:** _____

Website: _____

Entity Type: The UPE of the acquired person is a(n)?
☐ Corporation ☐ Unincorporated Entity ☐ Natural Person ☐ Other (Specify): _____

FILING MADE ON BEHALF OF THE UPE	Name and address of filing notification entity, if different than UPE (Name, Address, City, State, Zip Code, and Country)
☐ Not Applicable. ☐ This report is being filed on behalf of the ultimate parent entity by another entity within the same person authorized by it to file pursuant to § 803.2(a). ☐ This report is being filed on behalf of a foreign person pursuant to § 803.4.	

	PRIMARY HSR REPORT CONTACT	SECONDARY HSR REPORT CONTACT	SECOND REQUEST CONTACT
Name:			
Firm/Company:			
Address:			
City, State, Zip Code:			
Country:			
Telephone Number:			
E-Mail Address:			

Name of Acquired Person UPE:	Date:

UPE Annual Reports and Financial Information	
Central Index Key (CIK) Number	
Annual/Audit Report Document # or Link	
Date of Annual/Audit Report	

Does the person filing notification stipulate that the acquired person meets the size of person test? See 15 U.S.C. § 18a(a).

☐ Yes, the lower size of person test ☐ Yes, the higher size of person test ☐ N/A

Minority Shareholders or Interest Holders ☐ None

Entity	Minority Holder & D/B/A Name	HQ Address	Percent Held

► Acquired Entity Structure

Entities Within the Acquired Entity(ies)

Company or Operating Business d/b/a Name(s):				
Entity Name	City	State	Zip Code	Country
Company or Operating Business d/b/a Name(s):				
Entity Name	City	State	Zip Code	Country
Company or Operating Business d/b/a Name(s):				
Entity Name	City	State	Zip Code	Country

Annual Reports and Audit Reports

Acquired Entity	Central Index Key (CIK) Number	Annual/Audit Report File Name or Link	Date of Annual/Audit Report

Name of Acquired Person UPE: **Date:**

TRANSACTION INFORMATION

► Parties

ACQUIRING UPE(s)	ACQUIRED UPE(s)
Name: **Address:** **Address Line 2:** **City, State, Zip Code:** **Country:** **Website:**	**Name:** **Address:** **Address Line 2:** **City, State, Zip Code:** **Country:** **Website:**
ACQUIRING ENTITY(IES) – *(Tab to add additional "Acquiring Entity" entries.)*	**TARGET(S)** – *(Tab to add additional "Target" entries.)*
Name: **Address:** **Address Line 2:** **City, State, Zip Code:** **Country:** **Website:**	**Name:** **Address:** **Address Line 2:** **City, State, Zip Code:** **Country:** **Website:**

► Transaction Details

Is this transaction subject to § 801.30? ☐ Yes, Specify Type(s) _____ ☐ No

TRANSACTION TYPE

Check all that apply:

☐ Acquisition of voting securities
☐ Acquisition of non-corporate interests
☐ Acquisition of assets
☐ Merger (see § 801.2)
☐ Consolidation (see § 801.2)
☐ Acquisition subject to § 801.31
☐ Secondary acquisition subject to § 801.4
☐ Acquisition subject to § 801.2(e)
☐ Other, specify _____

ACQUISITION DETAILS

Percentage of voting securities already held %	Percentage of non-corporate interests already held %		
Value of voting securities already held ($MM) $	Value of non-corporate interests already held ($MM) $		
Total percentage of voting securities to be held as a result of the acquisition %	Total percentage of non-corporate to be held as a result of the acquisition %		
Total value of voting securities to be held as a result of the acquisition ($MM) $	Total value of non-corporate securities to be held as a result of the acquisition ($MM) $	Total value of assets to be held as a result of the acquisition ($MM) $	**Aggregate total value ($MM)** **$ 0.00**

Name of Acquired Person UPE: **Date:**

► Transaction Description

Business of the Target	
Non-Reportable UPE(s)	
Transaction Description	

Related Transactions

Does the transaction that is the subject of this filing have related filings? ☐ Yes ☐ No ☐ Unknown

If the transaction has related filings, indicate whether the related filing(s) (choose all that apply):

☐ Is a principal transaction that triggers one or more shareholder backside transactions
☐ Is a shareholder backside transaction
☐ Has more than one acquiring UPE
☐ Has more than one acquired UPE
☐ Has more than one reportable step
☐ Is a joint venture
☐ Is a consolidation
☐ Is an exchange of assets
☐ Has one or more filings in the alternative
☐ Other, explain:_____

Party Names or Transaction Numbers for Related Transactions:

► Additional Transaction Information

Transaction Rationale ☐ Not applicable, select 801.30 transaction	
Document Numbers Related to Transaction Rationale	

► Business Documents

Transaction Related Documents

Privileged	Document #	Document Title	Estimated Date	Author/Title
☐				
☐				
☐				

Plans and Reports ☐ Not Applicable, Select 801.30 Transaction

Privileged	Document #	Document Title	Estimated Date	Author/Title
☐				
☐				
☐				

Privilege Log Document # _____

Name of Acquired Person UPE: **Date:**

► **Agreements**

TRANSACTION-SPECIFIC AGREEMENTS ☐ Not Applicable, 801.30 or Bankruptcy

Document #	Document Title

COMPETITION DESCRIPTIONS

☐ Not Applicable, Select 801.30 Transaction

► **Overlap Description**

Briefly describe the target's principal categories of products or services.

List and briefly describe current and known planned products or services that compete (or could compete) with the acquiring person. (See Instructions)

Name of Acquired Person UPE:	Date:

Competing Product or Service ☐ None

Product or Service:	**Sales ($):** **Categories of Customers:** **Top 10 Customers Overall:** **Top 10 Customers by Category:**
Product or Service:	**Sales ($):** **Categories of Customers:** **Top 10 Customers Overall:** **Top 10 Customers by Category:**
Product or Service:	**Sales ($):** **Categories of Customers:** **Top 10 Customers Overall:** **Top 10 Customers by Category:**

► Supply Relationships Description

RELATED SALES

List and briefly describe the target's products, services, or assets that are supplied to the acquiring person or a business that competes with acquiring person. (See Instructions)

Product, Service, or Asset Details ☐ None

Product, Service, or Asset:	**Sales to Target ($):** **Sales to Target's Competitors ($):** **Top 10 Customers:** **Description of Supply or Licensing Agreement:**
Product, Service, or Asset:	**Sales to Acquiring Person ($):** **Sales to Acquiring Person's Competitors ($):** **Top 10 Customers:** **Description of Supply or Licensing Agreement:**
Product, Service, or Asset:	**Sales to Acquiring Person ($):** **Sales to Acquiring Person's Competitors ($):** **Top 10 Customers:** **Description of Supply or Licensing Agreement:**

Name of Acquired Person UPE:	Date:

RELATED PURCHASES

List and briefly describe the products, services, or assets that are purchased by the target from the acquiring person or a business that competes with the acquiring person. (See Instructions)

Product, Service, or Asset Details ☐ None

Product, Service, or Asset:	**Purchases from Acquiring Person ($):** **Purchases from Acquiring Person's Competitors ($):** **Top 10 Suppliers:** **Description of Purchase or Licensing Agreement:**
Product, Service, or Asset:	**Purchases from Acquiring Person ($):** **Purchases from Acquiring Person's Competitors ($):** **Top 10 Suppliers:** **Description of Purchase or Licensing Agreement:**
Product, Service, or Asset:	**Purchases from Acquiring Person ($):** **Purchases from Acquiring Person's Competitors ($):** **Top 10 Suppliers:** **Description of Purchase or Licensing Agreement:**

REVENUE AND OVERLAPS

Does the target have US revenue? ☐ Yes ☐ No, explain: _____

► NAICS Codes

6-Digit Code	Code Description	Operating Business	Revenue Range				Overlap
			<$10MM	$10MM - $100MM	$100MM - $1B	>$1B	
							☐
							☐
							☐
							☐
							☐

► Controlled Entity Geographic Overlaps

STATE LEVEL REPORTING ☐ None

NAICS Code	Code Description	Operating Business and D/B/A Name(s)	States and Total Number

Name of Acquired Person UPE: Date:

STREET LEVEL REPORTING ☐ None

NAICS Code and Description:				
Operating Business and D/B/A Name(s)	State	County	ZIP Code	Street Address

NAICS Code and Description:				
Operating Business and D/B/A Name(s)	State	County	ZIP Code	Street Address

NAICS Code and Description:				
Operating Business and D/B/A Name(s)	State	County	ZIP Code	Street Address

► Minority-Held Entity Overlaps

☐ None

Entity Held and D/B/A Name(s)	Percentage Held	Held By	NAICS Code or Industry Overlap with Acquiring Person

► Prior Acquisitions

☐ None

Overlapping 6-Digit NAICS Code and Description or Overlap Product or Service Description	Acquired Entity and Former HQ Address	Transaction Type	Consummation Date

ADDITIONAL INFORMATION

► Subsidies from Foreign Entities or Governments of Concern

SUBSIDIES ☐ None ☐ Yes (provide details below)

Entity or Government	Description

Name of Acquired Person UPE: **Date:**

COUNTERVAILING DUTIES IMPOSED ☐ None ☐ Yes (provide details below)

Product	Duty Imposed	Jurisdiction

COUNTERVAILING DUTY INVESTIGATIONS ☐ None ☐ Yes (provide details below)

Product	Jurisdiction Conducting Investigation

► Defense or Intelligence Contracts

☐ None ☐ Not Applicable, Select 801.30 Transaction

Entity Within Target	DOD/IC Contracting Office	Contracting Office ID	Award ID	NAICS Codes

► Voluntary Waivers

INTERNATIONAL COMPETITION AUTHORITIES (VOLUNTARY)

The acquired person agrees to waive the disclosure exemption in the HSR Act for the following competition authorities: ☐ None

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____

STATE ATTORNEYS GENERAL (VOLUNTARY)

The acquired person agrees to waive the disclosure exemption in the HSR Act for the following states: ☐ None

State	Permit Disclosure of	
	Fact of Notification and Waiting Period	Information and Documents
	☐	☐
	☐	☐
	☐	☐

► End Notes

☐ None

Number	Note

Name of Acquired Person UPE: **Date:**

CERTIFICATION

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Name (Please Print or Type)	**Title**
Signature	**Date**

☐ **Sworn under penalty of perjury**

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Signature	**Executed Date**

☐ **Notarized**

Subscribed and sworn to before me at the: Seal:

_____

City of: _____

State of: _____

This _____ day of _____ the year _____

Signature: _____

My commission expires: _____

Name of Acquired Person UPE:	Date:

16 C.F.R. Part 803 – Appendix NOTIFICATION AND REPORT FORM FOR CERTAIN MERGERS AND ACQUISITIONS	Approved by OMB 3084-0005

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Premerger Notification Office
Federal Trade Commission
400 7th St. SW
Washington, DC 20024

and

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, DC 20503

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Privacy Act Statement--Section 18a(a) of Title 15 of the U.S. Code authorizes the collection of this information. The primary use of information submitted on this Form is to determine whether the reported merger or acquisition may violate the antitrust laws. Taxpayer information is collected, used, and may be shared with other agencies and contractors for payment processing, debt collection and reporting purposes. Furnishing the information on the Form is voluntary. Consummation of an acquisition required to be reported by the statute cited above without having provided this information may, however, render a person liable to civil penalties up to the amount listed in 16 C.F.R. § 1.98(a) per day. We also may be unable to process the Form unless you provide all of the requested information.

This page may be omitted when submitting the Form.

Appendix B to Part 803—Instructions to the Notification and Report Form for Certain Mergers and Acquisitions

Antitrust Improvements Act
Notification for Certain Mergers and Acquisitions

Acquiring Person Instructions

GENERAL INSTRUCTIONS AND INFORMATION

These instructions specify the information that must be submitted pursuant to § 803.1(a) of the premerger notification rules, 16 CFR Parts 801-803 ("the Rules"). Submitted materials must be provided to the Federal Trade Commission ("FTC") and to the Antitrust Division of the Department of Justice ("DOJ") (together, "the Agencies").

► Information

The central office for information and assistance concerning the Rules is:

Premerger Notification Office
Federal Trade Commission
400 7th Street, S.W.
Washington, D.C. 20024
Phone: (202) 326-3100
E-mail: HSRhelp@ftc.gov for Rules questions
Premerger@ftc.gov for filing information

Copies of these Instructions, the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("the Act"), the Rules, FTC final rules (including their Statements of Basis and Purpose) published in the Federal Register, as well as information to assist in submitting the required information are available at the FTC's Premerger Notification Office ("PNO") website.

► Definitions and Explanation of Terms

Unless otherwise indicated, the definitions provided in the Rules apply to these Instructions.

Dollar Values
All financial information should be expressed in millions of dollars rounded to the nearest hundred thousand.

Fee Information
The filing fee is based on the aggregate total value of assets, voting securities, and controlling non-corporate interests to be held as a result of the acquisition. Filing fee tiers are adjusted annually pursuant to 15 U.S.C. § 18a note, based on the change in gross national product, in accordance with 15 U.S.C. § 19(a)(5). Filing fees increase annually by the percentage increase, if any, in the consumer price index ("CPI") over the CPI for the fiscal year ending September 30, 2022, pursuant to 15 U.S.C. § 18a note. For current fee information, see the PNO website.

North American Industry Classification System (NAICS) Data
When reporting information by 6-digit NAICS code, refer to the North American Industry Classification System - United States, 2022, published by the Executive Office of the President, Office of Management and Budget, available at https://www.census.gov/naics/. This website also provides guidance in choosing the proper code(s).

Notification Thresholds
Notification thresholds are adjusted annually based on the change in gross national product, in accordance with 15 U.S.C. § 19(a)(5). See § 801.1(h). The current threshold values can be found at Current Thresholds.

Person Filing and Filing Person
The terms "person filing" or "filing person" mean the ultimate parent entity ("UPE"). See § 801.1(a)(3). The terms are used herein interchangeably.

Select 801.30 Transaction
A transaction to which § 801.30 applies **and** where (1) the acquisition would not confer control, (2) there is no agreement (or contemplated agreement) between any entity within the acquiring person and any entity within the acquired person governing any aspect of the transaction, and (3) the acquiring person does not have, and will not obtain, the right to serve as, appoint, veto, or approve board members, or members of any similar body, of any entity within the acquired person or the general partner or management company of any entity within the acquired person. Executive compensation transactions also qualify as select 801.30 transactions.

Supervisory Deal Team Lead
The individual who has primary responsibility for supervising the strategic assessment of the deal, and who would not otherwise qualify as a director or officer.

Target
The target includes all entities and assets to be acquired by the acquiring person from the acquired person in the reported transaction.

Year
All references to "year" refer to calendar year. If data are not available on a calendar year basis, supply the requested data for the fiscal year reporting period that most nearly corresponds to the calendar year specified. References to "most recent year" mean the most recently completed calendar or fiscal year for which the requested information is available.

► Filing

If the UPE is both an acquiring and acquired person, separate filings must be submitted, one as the acquiring person and one as the acquired person, following the appropriate instructions for each. See § 803.2(a)(2).

Filings should be submitted electronically consistent with the instructions on the PNO website. If the electronic submission platform is unavailable, the Agencies may announce sites for delivery through the media and, if possible, at the PNO website.

► Responses

Documents, including the Form, should be produced as (1) a searchable PDF from which text can be copied or (2) an Excel file.

For Business Documents (see below), check the box to indicate whether any part of the document is privileged and then provide the document number, title, and estimated date. If the acquiring person has identified (1) a NAICS overlap, (2) an overlap within the Overlap Description, or (3) a supply relationship within the Supply Relationships Description, also provide the following:

1. Author(s) (and job title(s)) for documents created by the acquiring person; or
2. Recipient(s) or supervisor(s) (and job title(s)) of documents created by third parties as part of an engagement with the acquiring person.

If a group of people prepared the document, list all the authors and their titles, identifying the principal authors. Alternatively, it is acceptable to indicate that the document was prepared under the supervision of the lead author and to provide the name and title of that author. Similarly, if the acquiring person engaged a third party to prepare a document, provide the name of the third party, and the name, title, and company name for the individual within the acquiring person who supervised the creation of the document, or for whom the document was prepared. For materials received from a third party that was not engaged by the acquiring person, only the name of the third party is required.

If the acquiring person submits documents in addition to what is required, such documents should be identified as "Voluntary". See § 803.1(b).

Submit only one copy of identical responsive documents.

► Privilege

See § 803.3(d). For privileged documents, the filing person must also provide the following in a log:

1. The privilege type (redacted or withheld);
2. The privilege claim;
3. Addressee(s) and all recipients, with company name and title, of the original and any copies;
4. Subject matter;
5. Document's present location; and
6. Who has control over it.

If a privileged document was circulated to a group, such as the board or an investment committee, the name of the group is sufficient, but the filing person should be prepared to disclose the names and titles/positions of the individual group members, if requested.

If the claim of privilege is based on advice from inside and/or outside counsel, the name of the inside and/or outside counsel providing the advice (and the law firm, if applicable) must be provided. If several lawyers participated in providing advice, identifying lead counsel is sufficient. In identifying who controls a document, the name of the law firm is sufficient.

► Translations

Materials or information in a language other than English must be translated into English, with the English translation attached to the original version. See § 803.8.

► Non-Compliance

If unable to answer any item fully, provide such information as is available and a statement of reasons for non-compliance as required by § 803.3. If exact answers to any item cannot be given, enter best estimates and indicate the source or basis of such estimates. Add an endnote with the notation "est." to any item where data are estimated.

► Limited Response

Information need not be supplied regarding assets, voting securities, or non-corporate interests currently being acquired when their acquisition is exempt under the Act or Rules. See § 803.2(c).

FEE INFORMATION

Total Expected Filing Fee
Indicate the value of the total required fee for the transaction.

Parties Paying the Fee
Indicate which filing person(s) is paying the filing fee and, if applicable, whether the fee is being paid by multiple entities. For each entity within the acquiring person paying a portion of the fee, provide the name of the payer, the amount paid, the payment method, and the Electronic Wire Transfer (EWT) confirmation number or check number.

Note on Paying by EWT
In order for the FTC to track payment, the payer must provide information required by the Fedwire Instructions to the financial institution initiating the EWT. A template of the Fedwire Instructions is available at the PNO website on the Filing Fee Information page.

Note on Paying by Check
The FTC strongly discourages check payments because handling a physical check will create a delay in processing the Form. However, if an EWT cannot be arranged, the FTC will accept a check, sent to Financial Operations. Cashiers' or certified checks are preferred. Make the check payable to the Federal Trade Commission and deliver to:

Federal Trade Commission
Financial Operations Division
600 Pennsylvania Ave, Drop H-790
Washington, DC 20580

Please note that the waiting period may be delayed until the fee has been confirmed.

GENERAL INFORMATION

Special Filing Types
Indicate whether the filing is a post-consummation filing, or whether the transaction is a cash tender offer or bankruptcy that is subject to Section 363(b) of the Bankruptcy Code (11 U.S.C. § 363).

Early Termination
Indicate whether the acquiring person requests early termination of the waiting period. Notification of each grant of early termination will be published in the Federal Register, as required by 15 U.S.C. § 18a(b)(2), and on the PNO website. Note that if either person in any transaction requests early termination, it may be granted and published.

ULTIMATE PARENT ENTITY (UPE) INFORMATION

► UPE Details

Name
Provide the name, headquarters address, and website (if one exists) of the person filing notification. The name of the person filing is the name of the UPE of the acquiring person. See § 801.1(a)(3).

Entity Type
Specify whether the UPE is a corporation, unincorporated entity, natural person, or other entity type (specify). See § 801.1.

Filing Made on Behalf of the UPE
If the filing is being made on behalf of the UPE by another entity within the acquiring person authorized by the UPE to file the notification on its behalf pursuant to § 803.2(a) or filed pursuant to § 803.4 on behalf of a foreign person, provide the name and mailing address of the entity filing the notification on behalf of the UPE.

Contact Information
Provide the name, firm/company name, address, telephone number, and e-mail address of two individuals (primary and secondary) to contact regarding the filing. See § 803.20(b)(2)(ii).

Additionally, provide the name, firm/company name, address, telephone number, and e-mail address of an individual located in the United States designated for the limited purpose of receiving notice of the issuance of a request for additional information or documentary material. See § 803.20(b)(2).

UPE Annual Reports and Financial Information

- **Central Index Key**
  If the UPE of the acquiring person files annual reports (Form 10-K or Form 20-F) with the United States Securities and Exchange Commission (SEC), provide the Central Index Key (CIK) number.

- **Annual Reports and Audit Reports**
  Provide the most recent annual reports and/or annual audit reports (or, if audited is unavailable, unaudited) of the UPE of the acquiring person.

  Natural person UPEs should not provide personal balance sheets or tax returns. Natural person UPEs should leave this section blank and instead provide the most recent reports for the highest-level entity(ies) that controls the acquiring entity under "UPE Structure."

  The person filing notification may incorporate a document responsive to this item by reference to an internet address directly linking to the document. See § 803.2(e).

- **Date of Report(s)**
  Provide the date of the most recent annual report(s) and/or audit reports (or, if audited is unavailable, unaudited) of the UPE of the acquiring person.

- **Size of Person**
  If applicable, indicate whether the person filing notification stipulates that the acquiring person meets either the higher or lower size of person test. See 15 U.S.C. § 18a(a), § 801.11.

Minority Shareholders or Interest Holders
This section requires the acquiring person to report the name, headquarters mailing address, and approximate percentage held by certain minority holders of (1) the acquiring entity, (2) any entity directly or indirectly controlled by the acquiring entity, (3) any entity that directly or indirectly controls the acquiring entity, and (4) any entity within the acquiring person that has been or will be created in contemplation of, or for the purposes of, effectuating the transaction (each a "covered entity").

If a covered entity is not a limited partnership, provide the required information for each individual or entity that currently holds, or will hold as a result of the transaction, 5% or more but less than 50% of the voting securities or non-corporate interests of any covered entity, starting with the UPE.

If a covered entity is a limited partnership, provide the required information for its (a) general partner, regardless of the percentage it holds, and (b) limited partners that (i) currently hold, or will hold as a result of the transaction, 5% or more but less than 50% of the non-corporate interests of the covered entity, and (ii) have or will have the right to serve as, nominate, appoint, veto, or approve board members, or individuals with similar responsibilities, of any covered entity, or of the general partner or management company of a covered entity.

If a minority holder is related to a master limited partnership, fund, investment group, or similar entity that does business under a common name, the d/b/a or "street name" of such group should also be listed, if known to the acquiring person.

If the identity of minority investors or percentages to be held of a covered entity is not finalized at the time of filing, provide good faith estimates and explain in an endnote.

► Acquiring Person Structure

Entities Within the Acquiring Person
List the name, city, state, zip code, and country of all U.S. entities, and all foreign entities that have sales in or into the United States, that are included within the acquiring person. Entities with total assets of less than $10 million may be omitted. Alternatively, the acquiring person may report all entities within it. The acquiring person must also list all names under which the entities do business (e.g., d/b/a names).

The list of entities should be organized by operating company or operating business ("top-level entity"), if applicable. Filings for select 801.30 transactions need not include d/b/a names and the list of entities can be organized as kept in the ordinary course of business.

Annual Reports and Audit Reports
For the acquiring entity(ies) and any entity controlled by the acquiring person whose revenues contribute to a NAICS overlap or any overlap identified in the Overlap Description, provide the CIK number(s) if annual reports (Form 10-K or Form 20-F) are filed with the SEC, and the most recent annual or audit report(s).

Natural person UPEs must also provide the most recent annual report or audit report and CIK number for the highest-level entity that controls the acquiring entity.

► Additional Acquiring Person Information

Ownership Structure
Describe the ownership structure of the acquiring entity.

For transactions where a fund or master limited partnership is the UPE, provide any existing organizational chart that shows the relationship of any entities that are affiliates or associates. If such an organizational chart does not exist, there is no requirement to create one.

Officers and Directors
For all entities within the acquiring person responsible for the development, marketing, or sale of products or services that are identified as overlaps within the Overlap Description or as supply relationships within the Supply Relationships Description:

- List all current officers and directors (or in the case of unincorporated entities, individuals exercising similar functions) and those who have served in one of these positions within the three months before filing that also serve as an officer or director of another entity that derives revenue in the same NAICS codes reported by the target. For each, provide the name of all such entities. If NAICS codes are unavailable, list all such entities that have operations in the same industry, based on the knowledge or belief of the acquiring person or the identified individual.

For the acquiring entity, entities the acquiring entity directly or indirectly controls, entities that directly or indirectly control the acquiring entity, and entities within the acquiring person that have been or will be created as a result of or as contemplated by the transaction:

- List all current officers and directors (or in the case of unincorporated entities, individuals exercising similar functions) as well as those who are likely to serve in one of these positions that also serve as an officer or director of another entity that derives revenue in the same NAICS codes reported by the target. For each, provide the name of all such entities. If NAICS codes are unavailable, list all such entities that have operations in the same industry, based on the knowledge or belief of the acquiring person or the identified individual. If the identities of the prospective officers or directors are unknown, briefly describe in an endnote who will have the authority to select them.

No filer is required to disclose any individual's role as an officer, director, or member of any non-profit entity organized for a religious or political purpose, even if that entity carries on substantial commerce. Organize the response by entity and include entities that are not yet created but are expected to be created as a result of or as contemplated by the transaction.

TRANSACTION INFORMATION

► Parties

List the name and mailing address of each acquiring and acquired person and each acquiring and acquired entity. Do not list entities controlled by an acquired entity.

Acquiring UPE
Provide the name, headquarters address, and website of the acquiring person.

Acquiring Entity(ies)
If an entity other than the acquiring UPE is making the acquisition, provide the name, mailing address, and website of that entity.

Acquired UPE
Provide the name, headquarters address, and website of the acquired person.

Target(s)
If the assets, voting securities, or non-corporate interests of an entity other than the acquired UPE are being acquired, provide the name, mailing address, and website of that entity.

► Transaction Details

801.30 Transaction
Indicate whether the transaction is subject to § 801.30 and if so, what type(s), including select 801.30.

Transaction Type
Indicate whether the transaction is any of the following (select all that apply):

- Acquisition of voting securities;
- Acquisition of non-corporate interests;
- Acquisition of assets;
- Merger (see § 801.2);
- Consolidation (see § 801.2);
- Formation of a joint venture, other corporation, or unincorporated entity (see §§ 801.40 and 801.50);
- Acquisition subject to § 801.31;
- Secondary acquisition subject to § 801.4;
- Acquisition subject to § 801.2(e); or
- Other (specify)

Acquisition Details
Provide the requested information for the value and percentage of assets, voting securities, and non-corporate interests to be acquired. If a combination of assets, voting securities, and/or non-corporate interests is being acquired and allocation is not possible, note such information in an endnote.

For determining the percentage of voting securities, evaluate total voting power per § 801.12. For determining the percentage of non-corporate interests, evaluate the economic interests per § 801.1(b)(1)(ii).

To complete this item:

- State the percentage of voting securities already held by the acquiring person. See § 801.12.
- State the value of voting securities already held by the acquiring person. See § 801.10.
- State the total percentage of voting securities to be held by the acquiring person as a result of the acquisition. See § 801.12.
- State the total value of voting securities to be held by the acquiring person as a result of the acquisition. See § 801.10.
- State the percentage of non-corporate interests already held by the acquiring person. See § 801.1(b)(1)(ii).
- State the value of non-corporate interests already held by the acquiring person. See § 801.10.
- State the total percentage of non-corporate interests to be held by the acquiring person as a result of the acquisition. See §§ 801.10 and 801.1(b)(1)(ii).
- State the total value of non-corporate interests to be held by the acquiring person as a result of the acquisition. See § 801.10.
- State the total value of assets to be held by the acquiring person as a result of the acquisition. See § 801.10.
- State the aggregate total value of assets, voting securities, and non-corporate interests of the acquired person to be held by the acquiring person as a result of the acquisition. See §§ 801.10, 801.12, 801.13 and 801.14.

Notification Threshold
This item should only be completed when voting securities are being acquired. If more than voting securities are being acquired, respond to this item only regarding voting securities. Indicate the highest applicable threshold for which notification is being filed. See § 801.1(h).

- $50 million (as adjusted);
- $100 million (as adjusted);
- $500 million (as adjusted);
- 25% (if the value of voting securities to be held is greater than $1 billion, as adjusted);
- 50%; or
- N/A.

Note that the 50% notification threshold is the highest threshold and should be used for any acquisition of 50% or more of the voting securities of an issuer, regardless of the value of the voting securities. For instance, an acquisition of 100% of the voting securities of an issuer valued in excess of $500 million (as adjusted) would cross the 50% notification threshold, not the $500 million (as adjusted) threshold.

► Transaction Description

Business of the Acquiring Person
Describe the business operation(s) of the acquiring person.

Business of the Target
Describe the business operation(s) being acquired. If assets, describe the assets and whether they comprise an operating business.

Non-Reportable UPE(s)
Provide the names of any UPE that does not have a reporting obligation.

Transaction Description
Briefly describe the transaction, indicating whether assets, voting securities, or non-corporate interests (or some combination) are being acquired. Indicate what consideration will be received by each person and the scheduled consummation date of the transaction. Also identify any special circumstances that apply to the filing, such as whether part of the transaction is exempt under one of the exemptions found in Part 802.

If any attached transaction documents use code names to refer to the parties, provide an index identifying the code names.

Related Transactions
If the transaction that is the subject of this filing has related filings, indicate whether the related filing(s) (choose all that apply):

- Is a principal transaction that triggers one or more shareholder backside transactions;
- Is a shareholder backside transaction;
- Has more than one acquiring UPE;
- Has more than one acquired UPE;
- Has more than one reportable step;
- Is a joint venture;
- Is a consolidation;
- Is an exchange of assets;
- Has one or more filings in the alternative; or
- Has other circumstances that require more than one filing and if so, explain.

Provide all additional details regarding the related filings(s), including party names and transaction numbers, necessary to identify and connect all related filings.

► Transactions Subject to International Antitrust Notification

Indicate whether, to the knowledge or belief of the filing person at the time of filing, a non-U.S. antitrust or competition authority has been or will be notified of the transaction.

If yes, list the name of each such authority. Identify, to the knowledge or belief of the filing person at the time of filing, any jurisdiction where (1) a merger notification has been filed, (2) a merger notification is being prepared for filing, or (3) the parties have a good faith belief that a merger notification will be made, along with the dates of the filing or planned filing.

► Additional Transaction Information

Transaction Rationale

Except for select 801.30 transactions, identify and explain each strategic rationale for the transaction discussed or contemplated by the filing person or any of its officers, directors, or employees. If the rationale of acquiring entity is different from the UPE, submit an explanation for each. Identify each document produced in the filing that confirms or discusses the stated rationale(s). If documents produced in the filing are referenced, identify the specific page(s) that discusses the stated rationale(s).

Transaction Diagram

Except for select 801.30 transactions, submit a diagram of the transaction, if one exists. If such a diagram does not exist, there is no requirement to create one.

► Joint Ventures

Complete only if the acquisition is the formation of a joint venture corporation or unincorporated entity. See §§ 801.40 and 801.50.

Contributions

List the contributions that each person forming the joint venture corporation or unincorporated entity has agreed to make, specifying when each contribution is to be made and the value of the contribution as agreed by the contributors.

Consideration

Describe fully the consideration that each person forming the joint venture corporation or unincorporated entity will receive in exchange for its contribution(s).

Business Description

Describe generally the business in which the joint venture corporation or unincorporated entity will engage, including its principal types of products or activities, and the geographic areas in which it will do business.

NAICS Codes

Identify each 6-digit NAICS industry code in which the joint venture corporation or unincorporated entity will derive dollar revenues.

► Business Documents

Transaction-Related Documents

- **Competition Documents**
  Provide all studies, surveys, analyses, and reports prepared by or for any officer(s), director(s), or supervisory deal team lead for the purpose of evaluating or analyzing the acquisition with respect to market shares, competition, competitors, markets, potential for sales growth, or expansion into product or geographic markets. For unincorporated entities, provide such documents prepared by or for individuals exercising similar functions as officers and directors, as well as the supervisory deal team lead.

- **Confidential Information Memoranda**
  Provide all confidential information memoranda prepared by or for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) of the UPE of the acquiring or of the acquiring entity(s) that specifically relate to the sale of the target. If no such confidential information memorandum exists, submit any document(s) given to any officer(s) or director(s) of the acquiring person meant to serve the function of a confidential information memorandum. This does not include ordinary course documents and/or financial data shared in the course of due diligence, except to the extent that such materials served the purpose of a confidential information memorandum when no such confidential information memorandum exists. Documents responsive to this item are limited to those produced within one year before the date of filing.

- **Third-Party Studies, Surveys, Analyses, and Reports**
  Provide all studies, surveys, analyses and reports prepared by investment bankers, consultants, or other third-party advisors ("third-party advisors") for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) of the UPE of the acquiring person or of the acquiring entity(s) for the purpose of evaluating or analyzing market shares, competition, competitors, markets, potential for sales growth or expansion into product or geographic markets that specifically relate to the sale of the target. This item requires only materials developed by third party advisors during an engagement or for the purpose of seeking an engagement. Documents responsive to this item are limited to those produced within one year before the date of filing.

- **Synergies and Efficiencies**
  Provide all studies, surveys, analyses, and reports evaluating or analyzing synergies, and/or efficiencies prepared by or for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) for the purpose of evaluating or analyzing the acquisition. Financial models without stated assumptions need not be provided.

Plans and Reports
Except for select 801.30 transactions, provide all regularly prepared plans and reports that were provided to the Chief Executive Officer (CEO) of the acquiring entity or any entity that it controls or is controlled by that analyze market shares, competition, competitors, or markets pertaining to any product or service of the acquiring person also produced, sold, or known to be under development by the target, as identified in the Overlap Description. Documents responsive to this item are limited to those prepared or modified within one year of the date of filing.

Except for select 801.30 transactions, provide all plans and reports that were provided to the Board of Directors of the acquiring entity or any entity that it controls or is controlled by that analyze market shares, competition, competitors, or markets pertaining to any product or service of the acquiring person also produced, sold, or known to be under development by the target, as identified in the Overlap Description. Documents responsive to this item are limited to those prepared or modified within one year of the date of filing.

► Agreements

Transaction-Specific Agreements
Furnish copies of all documents that constitute the agreement(s) related to the transaction, including, but not limited to, exhibits, schedules, side letters, agreements not to compete or solicit, and other agreements negotiated in conjunction with the transaction that the parties intend to consummate, and excluding clean team agreements.

Documents that constitute the agreement(s) (e.g., Agreement and Plan of Merger, Letter of Intent, Purchase and Sale Agreement, Asset Purchase Agreement, Stock/Securities Purchase Agreement) must be executed, while supporting agreements, such as employment agreements and agreements not to compete may be provided in draft form if that is the most recent version.

If the executed agreement is not the definitive agreement, submit a dated document that provides sufficient detail about the scope of the entire transaction that the parties intend to consummate, such as an agreement in principle, or term sheet, or the most recent draft agreement. See § 803.5. Such document should include information regarding some combination of the following terms: the identity of the parties; the structure of the transaction; the scope of what is being acquired; calculation of the purchase price; an estimated closing timeline; employee retention policies, including with respect to key personnel; post-closing governance; and transaction expenses or other material terms.

Note that transactions subject to § 801.30 and bankruptcies under 11 U.S.C. § 363(b) do not require an executed agreement. For bankruptcies, provide the order from the bankruptcy court.

Other Agreements Between the Acquiring Person and Target
Indicate whether the acquiring person has, or had within one year of filing, any contractual agreement(s) with the target. If so, indicate which type(s). If an agreement has terms that apply to more than one category, indicate each category that applies.

COMPETITION DESCRIPTIONS

This section is not applicable to select 801.30 transactions.

► Overlap Description

Briefly describe each of the principal categories of products and services (as reflected in documents created in the ordinary course of business) of the acquiring person.

In addition, list and briefly describe each of the current or known planned products or services of the acquiring person that competes with (or could compete with) a current or known planned product or service of the target, based on documents created in the ordinary course of business. Current or known planned products or services include those that the acquiring person or target researches, develops, manufactures, produces, sells, offers, provides, supplies, or distributes. Known planned products or services may be limited to those referenced in any submitted Business Document and should reflect the acquiring person's existing knowledge of the target's business. The acquiring and acquired person should not exchange information for the purpose of answering this item.

For each such product or service listed, provide:

1. The sales (in dollars) for the most recent year. For those products or services not generating revenue or whose performance is not measured by revenue in the ordinary course of business, provide projected revenue, estimates of the volume of products to be sold, time spent using the service, or any other metric by which the acquiring person measures performance (e.g., daily users, new signups).

2. A description of all categories of customers of the acquiring person that purchase or use the product or service (e.g., retailer, distributor, broker, government, military, educational, national account, local account, commercial, residential, or institutional). If no customers have yet used the product or service, provide the date that development of the product or service began; a description of the current stage in development, including any testing and regulatory approvals and any planned improvements or modifications; the date that development (including testing and regulatory approvals) was or will be completed; and the date that the product or service is expected to be sold or otherwise commercially launched.

3. The top 10 customers in the most recent year (as measured in dollars), and the top 10 customers for each customer category identified.

► Supply Relationships Description

Related Sales

List and briefly describe each product, service, or asset (including data) that the acquiring person has sold, licensed, or otherwise supplied, and which represented at least $10 million in revenue (including internal transfers) in the most recent year (1) to the target, or (2) to any other business that, to the acquiring person's knowledge or belief, uses the acquiring person's product, service, or asset to compete with the target's products or services, or as an input for a product or service that competes or is intended to compete with the target's products or services. Responses to this item should reflect the acquiring person's existing knowledge of the target's business; the acquiring and acquired person should not exchange information for the purpose of answering this item.

For each product, service, or asset listed, for the most recent year, provide:

1. The sales (in dollars) to (1) the target and (2) any other business that, to the acquiring person's knowledge or belief, uses the acquiring person's product, service, or asset to compete with the target's products or services, or as an input for a product or service that competes or is intended to compete with the target's products or services.

2. The top 10 customers (as measured in dollars) of the acquiring person that use the acquiring person's product, service, or asset to compete with the target's products or services, or as an input for a product or service that competes or is intended to compete with the target's products or services. For each such customer, describe the acquiring person's supply or licensing agreement (or other comparable terms of supply).

Related Purchases

List and briefly describe each product, service, or asset (including data) that the acquiring person incorporates as an input into any product or service and that the acquiring person has purchased, licensed, or otherwise obtained, and which represented at least $10 million in revenue (including internal transfers), in the most recent year (1) from the target or (2) from any other business that, to the acquiring person's knowledge or belief, competes with the target to provide a substantially similar product, service, or asset. Responses to this item should reflect the acquired person's existing knowledge of the acquiring person's business; the acquiring and acquired person should not exchange information for the purpose of answering this item.

For each product, service, or asset listed, for the most recent year, provide:

1. The purchased amount (in dollars) for (1) the target and (2) any other business that, to the acquiring person's knowledge or belief, competes with the target to provide a substantially similar product, service, or asset.

2. The top 10 suppliers (as measured in dollars) for the associated input product, service, or asset, and a description of the acquiring person's purchase or licensing agreement (or other comparable terms of purchase).

REVENUES AND OVERLAPS

► NAICS Codes

This item requests information regarding the industry categories for the acquiring person's products and services that derived revenue in the most recent year.

No Revenue
If there is no revenue to report, explain why.

NAICS Codes Describing U.S. Operations with Estimates of Revenue
Identify all 6-digit NAICS industry codes that describe the U.S. operations of the acquiring person, inclusive of all entities included within the acquiring person at the time the filing is made.

Responses must be organized by NAICS code in ascending order. For each code, provide the name of the operating business(es) that derive(s) revenue in that code and the estimated revenue range: less than $10 million; $10 million or more but less than $100 million; $100 million or more but less than $1 billion; or $1 billion or more.

Identify each 6-digit NAICS industry code in which both the acquiring person and target derive revenue by checking the overlap box.

For products and services that derived revenue in the most recent year in a non-manufacturing NAICS code, if the revenue is estimated at less than one million dollars, that code may be omitted so long as the code does not overlap with a code in which the target derived revenue from U.S. operations.

► Controlled Entity Geographic Overlaps

If, to the knowledge or belief of the person filing notification, the acquiring person, or any associate of the acquiring person (see § 801.1(d)(2)), derived any amount of dollar revenues in the most recent year from operations:

1. In industries within any 6-digit NAICS industry code in which the target also derived any amount of dollar revenues in the most recent year; or
2. In which a joint venture corporation or unincorporated entity will derive dollar revenues;

then for each such 6-digit NAICS industry code follow the instructions below for this section.

Note that if the target is a joint venture, the only overlaps that should be reported are those between the assets to be held by the joint venture and any assets of the acquiring person or its associates not contributed to the joint venture.

NAICS Overlaps of Controlled Entities
List each overlapping NAICS code and description. For each, list the name of each operating business within the acquiring person or associate of the acquiring person that has U.S. operations in the same NAICS code as the target and the name(s) under which the operating business does business, whether the listed entity is controlled by the acquiring person or an associate of the acquiring person, and provide the appropriate Geographic Market Information, based upon the NAICS code. Organize responses by NAICS code in ascending order.

Geographic Market Information
For each identified overlapping NAICS code, provide geographic information, as described below. Use the 2-digit postal codes for states and territories and provide the total number of states and territories at the end of the response.

Except in the case of those NAICS industries in the sectors, subsectors, and codes that require street-address level reporting, the person filing notification may respond with the word "national" if business is conducted in all 50 states.

- **State-Level Reporting**
  - Manufacturing Industries
    For each 6-digit NAICS code within the industry sector, subsector, or code listed below, list the states in which, to the knowledge or belief of the person filing the notification, the products in that 6-digit NAICS industry code produced by the acquiring person or associate of the acquiring person are sold without a significant change in their form (whether they are sold by the acquiring person or associate of the acquiring person or by others to whom such products have been sold or resold).

    31** through 33**** Manufacturing**, *except:*

3115**	Dairy Product Manufacturing
311611	Animal (except Poultry) Slaughtering
311613	Rendering and Meat Byproduct Processing
311615	Poultry Processing
31181*	Bread and Bakery Product Manufacturing
321***	Wood Product Manufacturing
32221*	Paperboard Container Manufacturing
324***	Petroleum and Coal Products Manufacturing
3251**	Basic Chemical Manufacturing

325521 Plastics Materials and Resin Manufacturing
3271** Clay Product and Refractory Manufacturing
3272** Glass and Glass Product Manufacturing
3273** Cement and Concrete Product Manufacturing

- Wholesale Trade
  For each 6-digit NAICS code within the industry sector, subsector, or code listed below, list the states or, if desired, portions thereof in which the customers of the acquiring person or associate of the acquiring person are located.

42** **Wholesale Trade**, *except*:
42331* Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers
42333* Roofing, Siding, and Insulation Material Merchant Wholesalers
42344* Other Commercial Equipment Merchant Wholesalers
42345* Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers
42346* Ophthalmic Goods Merchant Wholesalers
42349* Other Professional Equipment and Supplies Merchant Wholesalers
4239** Miscellaneous Durable Goods Merchant Wholesalers
4241** Paper and Paper Product Merchant Wholesalers
4242** Drug and Druggists' Sundries Merchant Wholesalers
42441* General Line Grocery Merchant Wholesalers
42442* Packaged Frozen Food Merchant Wholesalers
42451* Grain and Field Bean Merchant Wholesalers
42452* Livestock Merchant Wholesalers
4247** Petroleum and Petroleum Products Merchant Wholesalers
4248** Beer, Wine, and Distilled Alcoholic Beverage Merchant Wholesalers
42491* Farm Supplies Merchant Wholesalers
42495* Paint, Varnish, and Supplies Merchant Wholesalers

- Insurance Carriers
  For the 6-digit NAICS code within the industry subsector listed below, list the state(s) in which the acquiring person or associate of the acquiring person is licensed to write insurance.

5241** **Insurance Carriers**

- Other NAICS Sectors
  For each 6-digit NAICS code within the industry sector, subsector, or code listed below, list the states or, if desired, portions thereof in which the acquiring person or associate of the acquiring person conducts such operations.

11** **Agriculture, Forestry, Fishing, and Hunting**, *except*:
113*** Forestry and Logging

21** **Mining, Quarrying, and Oil and Gas Extraction**, *except:*
2123** Nonmetallic Mineral Mining and Quarrying

2213** **Water, Sewage, and Other Systems**

23** **Construction**

44912* **Home Furnishing Retailers**
4492** **Electronics and Appliance Retailers**

48** and 49**** Transportation and Warehousing**, *except*:
493*** Warehousing and Storage

51** **Information**, *except*:
512*** Motion Picture and Sound Recording Industries

5222** **Nondepository Credit Intermediation**
523*** **Securities, Commodity Contracts, and Other Financial Investments and Related Activities**
5242** **Agencies, Brokerages, and Other Insurance Related Activities**
525*** **Funds, Trusts, and Other Financial Vehicles**

531* Real Estate**
533* Lessors of Nonfinancial Intangible Assets (Except Copyrighted Works)**

54** Professional, Scientific and Technical Services**, *except*:
54138* Testing Laboratories and Services
54194* Veterinary Services

55** Management of Companies and Enterprises**

561* Administrative and Support Services**

61** Educational Services**

71** Arts, Entertainment, and Recreation**, *except*:
7132** Gambling Industries
71394* Fitness and Recreational Sports Centers

7212 RV (Recreational Vehicle) Parks and Recreational Camps**
7213 Rooming and Boarding Houses, Dormitories, and Workers' Camps**
8114 Personal and Household Goods Repair and Maintenance**
813* Religious, Grantmaking, Civic, Professional, and Similar Organizations**
814* Private Households**

- **Street-Level Reporting**
  For each 6-digit NAICS code within the industry sector, subsector, or code listed below, provide the street address, arranged by state, zip code, county and city or town of each establishment from which dollar revenues were derived (either directly by the acquiring person or associate of the acquiring person or by a franchisee) in the most recent year.

113* Forestry and Logging**
2123 Nonmetallic Mineral Mining and Quarrying**

22** Utilities**, *except*:
2213** Water, Sewage and Other Systems

3115 Dairy Product Manufacturing**
311611 Animal (except Poultry) Slaughtering
311613 Rendering and Meat Byproduct Processing
311615 Poultry Processing
31181* Bread and Bakery Product Manufacturing
321* Wood Product Manufacturing**
32221* Paperboard Container Manufacturing
324* Petroleum and Coal Products Manufacturing**
3251 Basic Chemical Manufacturing**
325521 Plastics Materials and Resin Manufacturing
3271 Clay Product and Refractory Manufacturing**
3272 Glass and Glass Product Manufacturing**
3273 Cement and Concrete Product Manufacturing**
42331* Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers
42333* Roofing, Siding, and Insulation Material Merchant Wholesalers
42344* Other Commercial Equipment Merchant Wholesalers
42345* Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers
42346* Ophthalmic Goods Merchant Wholesalers
42349* Other Professional Equipment and Supplies Merchant Wholesalers
4239 Miscellaneous Durable Goods Merchant Wholesalers**
4241 Paper and Paper Product Merchant Wholesalers**
4242 Drug and Druggists' Sundries Merchant Wholesalers**
42441* General Line Grocery Merchant Wholesalers
42442* Packaged Frozen Food Merchant Wholesalers
42451* Grain and Field Bean Merchant Wholesalers
42452* Livestock Merchant Wholesalers

4247** **Petroleum and Petroleum Products Merchant Wholesalers**
4248** **Beer, Wine, and Distilled Alcoholic Beverage Merchant Wholesalers**
42491* **Farm Supplies Merchant Wholesalers**
42495* **Paint, Varnish, and Supplies Merchant Wholesalers**

44** and 45**** Retail Trade**, *except:*
44912* Home Furnishings Retailers
4492** Electronics and Appliance Retailers

493*** **Warehousing and Storage**
512*** **Motion Picture and Sound Recording Industries**
521*** **Monetary Authorities-Central Bank**
5221** **Depository Credit Intermediation**
5223** **Activities Related to Credit Intermediation**
532*** **Rental and Leasing Services**
54138* **Testing Laboratories and Services**
54194* **Veterinary Services**
562*** **Waste Management and Remediation Services**
62**** **Health Care and Social Assistance**
7132** **Gambling Industries**
71394* **Fitness and Recreational Sports Centers**

72**** **Accommodation and Food Services**, *except:*
7212** RV (Recreational Vehicle) Parks and Recreational Camps
7213** Rooming and Boarding Houses, Dormitories, and Workers' Camps

811*** **Repair and Maintenance**, except
8114** Personal and Household Goods Repair and Maintenance

812*** **Personal and Laundry Services**

► Minority-Held Entity Overlaps

This section requires the disclosure of holdings of the acquiring person and its associates (see § 801.1(d)(2)) of 5% or more but less than 50% of certain entities that derive dollar revenues in any 6-digit NAICS code reported by the target. If NAICS codes are unavailable, holdings in entities that have operations in the same industry as the target, based on the knowledge or belief of the filing person, should be listed. Holdings in those entities that have total assets of less than $10 million may be omitted.

Minority Holdings of Acquiring Person and Its Associates
If the acquiring person holds 5% or more but less than 50% of the voting securities of any issuer or non-corporate interests of any unincorporated entity that derived dollar revenues in the most recent year from operations in industries within any 6-digit NAICS code(s) reported by the target, list the name of such entity and d/b/a names (if known), the percentage held, the entity within the acquiring person that holds the minority interests, and the overlapping 6-digit NAICS code(s) or industry(ies).

Additionally, based on the knowledge or belief of the acquiring person, for each associate of the acquiring person holding:
1. 5% or more but less than 50% of the voting securities or non-corporate interests of an acquired entity; and/or
2. 5% or more but less than 50% of the voting securities of any issuer or non-corporate interests of any unincorporated entity that derived dollar revenues in the most recent year from operations in industries within any 6-digit NAICS industry code in which the target also derived dollar revenues in the most recent year,

list the name of such entity and d/b/a names (if known), percentage held, the associate of the acquiring person that holds the minority interests, and the overlapping 6-digit NAICS code(s) or industry(ies).

Responses should be organized alphabetically by the name of the entity in which minority interests are held.
The acquiring person may rely on its regularly prepared financials that list its investments, and those of its associates that list their investments, provided the financials are no more than three months old.

► Prior Acquisitions

This item pertains only to prior acquisitions of U.S. entities or assets and foreign entities or assets with sales in or into the U.S. by the acquiring person that in the most recent year (1) derived revenue in an identified 6-digit NAICS industry code overlap, **or** (2) provided or produced a competitive overlap product or service as described in the Overlap Description.

For each such overlap, list all acquisitions of entities or assets deriving dollar revenues in an overlapping 6-digit NAICS industry code or overlapping product or service made by the acquiring person in the five years prior to the date of the instant filing, even if the transaction was non-reportable. List only acquisitions of 50% or more of the voting securities of an issuer, 50% or more of non-corporate interests of an unincorporated entity, or all or substantially all the assets of an operating business if the entity or business had annual net sales or total assets greater than $10 million in the year prior to the acquisition and any acquisitions of assets that did not constitute all or substantially all of an operating business valued at or above the statutory size-of-transaction test at the time of their acquisition.

For each such acquisition, supply:

1. the overlapping 6-digit NAICS code(s) (by number and description) identified above in which the acquired entity or assets derived dollar revenues, or the competitive overlap product(s) or service(s) in the Overlap Description;
2. the name of the entity from which the assets, voting securities, or non-corporate interests were acquired;
3. the headquarters address of that entity prior to the acquisition;
4. whether assets, voting securities, or non-corporate interests were acquired; and
5. the consummation date of the acquisition.

ADDITIONAL INFORMATION

► Subsidies from Foreign Entities or Governments of Concern

Indicate whether, to the knowledge or belief of the filing person, within the two years prior to filing, the acquiring person has received any subsidy (or a commitment to provide a subsidy in the future) from any foreign entity or government of concern (see § 801.1(r)). If yes, list each entity or government from which such subsidy was received (or which has made the commitment) and provide a brief description of the subsidy.

Indicate whether, for products the acquiring person produced in whole or in part in a country that is a covered nation under 42 U.S.C. § 18741(a)(5)(C), any product is subject to countervailing duties imposed by any jurisdiction. If yes, list each product, the countervailing duty imposed, and the jurisdiction that imposed the duty.

Indicate whether, to the knowledge or belief of the filing person, for products the acquiring person produced in whole or in part in a country that is a covered nation under 42 U.S.C. § 18741(a)(5)(C), any product is the subject of a current investigation for countervailing duties in any jurisdiction. If yes, list each product and the jurisdiction conducting the investigation.

► Defense or Intelligence Contracts

Except for select 801.30 transactions, identify (1) pending requests for proposals from the U.S. Department of Defense or any member of the U.S. intelligence community, as defined by 10 U.S.C. § 101(a)(6) or 50 U.S.C. § 3003(4) for which the acquiring person has submitted a proposal and (2) awarded procurement contracts with the U.S. Department of Defense or any member of the U.S. intelligence community, as defined by 10 U.S.C. § 101(a)(6) or 50 U.S.C. § 3003(4) valued at $100 million or more if such pending requests for proposals or such awarded procurement contracts (a) are or will be the source of revenues in any identified 6-digit NAICS industry code overlap; or (b) involve or will involve an overlap product or service as described in the Overlap Description or the Supply Relationships Description. Limit the response to the acquiring entity and any entity within the acquiring person that directly or indirectly controls the acquiring entity. Include (1) the name of the entity within the filing person (2) the contracting office, as defined by 48 C.F.R. § 2.101(b); (3) the Contracting Office ID; (4) the Award ID; and (5) the NAICS code(s), if any, listed in the System for Award Management database. Do not include classified information but note that responsive information was withheld on that basis.

► Voluntary Waivers

- **HSR Confidentiality Waiver for International Competition Authorities (VOLUNTARY)**
  Indicate whether the acquiring person agrees to waive the disclosure exemption contained in the Act, 15 U.S.C. § 18a(h), to permit the DOJ and FTC to disclose to non-U.S. competition authority/authorities listed by the filing person (1) the fact that a notification was filed, (2) the waiting period associated with the notification, and (3) information and documents filed with the notification. This waiver will not cover materials provided in response to a request for additional information issued pursuant to 15 U.S.C. § 18a(e) and does not preclude the acquiring person from providing a full waiver as provided for under FTC and DOJ practice as reflected in the Model Waiver. The acquiring person should list the jurisdictions to which the waiver applies. This item is voluntary.

- **HSR Confidentiality Waiver for State Attorneys General (VOLUNTARY)**
  Indicate whether the acquiring person agrees to waive any part of the disclosure exemption contained in the Act, 15 U.S.C. § 18a(h). If yes, list the applicable State Attorneys General and whether the acquiring person permits the DOJ and FTC to disclose (1) the fact that a notification was filed and the waiting period associated with the notification, (2) information and documents filed with the notification, or (3) both (1) and (2). This waiver will not cover materials provided in response to a request for additional information

issued pursuant to 15 U.S.C. § 18a(e) and does not preclude the acquiring person from providing a full waiver as provided for under FTC and DOJ practice as reflected in the Model Waiver. The acquiring person should list the jurisdictions to which the waiver applies. This item is voluntary.

CERTIFICATION

See § 803.6 for requirements.

The certification must be notarized or use the language found in 28 U.S.C. § 1746 relating to unsworn declarations under penalty of perjury. The Form includes the following language:

Penalties for False Statements
Federal law provides criminal penalties, including up to twenty years imprisonment, for any person who knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence an ongoing or anticipated federal investigation (see, e.g., Section 1519 of Title 18, United States Code.). It is also a criminal offense to knowingly make a false statement in a federal investigation, obstruct a federal investigation, or conspire to obstruct justice or obstruct or impede the lawful functioning of the government (see, e.g., Sections 371, 1001, and 1505 of Title 18, United States Code).

CERTIFICATION
This NOTIFICATION AND REPORT FORM, together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Commission. Subject to the recognition that, where so indicated, reasonable estimates have been made because books and records do not provide the required data, the information is, to the best of my knowledge, true, correct, and complete in accordance with the statute and rules.

I acknowledge that the Commission or the Assistant Attorney General of the Antitrust Division of the Department of Justice may, prior to the expiration of the initial waiting period pursuant to 15 U.S.C. § 18a, require the submission of additional information or documentary material relevant to the proposed transaction.

AFFIDAVITS

Affidavit(s) required by § 803.5 must be notarized or use the language found in 28 U.S.C. § 1746 relating to unsworn declarations under penalty of perjury. If an entity is filing on behalf of the acquiring person, the affidavit must still attest to the good faith intent of the UPE.

In non-§ 801.30 transactions, the affidavit(s) (submitted by both persons filing) must attest that an agreement to merge or acquire has been executed, and if the executed agreement is not the definitive agreement, that a dated document that provides sufficient detail about the scope of the entire transaction that the parties intend to consummate has been submitted. The affidavit(s) must further attest to the good faith intention of the person filing notification to complete the transaction. See § 803.5(b).

In § 801.30 transactions, the affidavit (submitted only by the acquiring person) must attest:

1. That the issuer whose voting securities or the unincorporated entity whose non-corporate interests are to be acquired has received notice, as described below, from the acquiring person;
2. In the case of a tender offer, that the intention to make the tender offer has been publicly announced; and
3. The good faith intention of the person filing notification to complete the transaction.

Acquiring persons in § 801.30 transactions are also required to submit a copy of the notice received by the acquired person pursuant to § 803.5(a)(3) along with the filing. This notice must include:

1. The identity of the acquiring person and the fact that the acquiring person intends to acquire voting securities of the issuer or non-corporate interests of the unincorporated entity;
2. The specific notification threshold that the acquiring person intends to meet or exceed in an acquisition of voting securities;
3. The fact that the acquisition may be subject to the Act, and that the acquiring person will file notification under the Act;
4. The anticipated date of receipt of such notification by the Agencies; and
5. The fact that the person within which the issuer or unincorporated entity is included may be required to file notification under the Act. See § 803.5(a).

PRIVACY ACT STATEMENT

Section 18a(a) of Title 15 of the U.S. Code authorizes the collection of this information. The primary use of information submitted on this Form is to determine whether the reported merger or acquisition may violate the antitrust laws. Taxpayer information is collected, used, and may be shared with other agencies and contractors for payment processing, debt collection and reporting purposes. Furnishing the information on the Form is voluntary. Consummation of an acquisition required to be reported by the statute cited above without having provided this information may, however, render a person liable to civil penalties up to the amount listed in 16 C.F.R. §1.98(a) per day.

We also may be unable to process the Form unless you provide all of the requested information.

DISCLOSURE NOTICE

Public reporting burden for this report is estimated to average 105 hours per response, including time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this report, including suggestions for reducing this burden to:

Premerger Notification Office
Federal Trade Commission
400 7th Street, S.W.
Washington, D.C. 20024

and

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

Under the Paperwork Reduction Act, as amended, 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 operative OMB control number, 3084-0005, appears within the Notification and Report Form and these Instructions.

Antitrust Improvements Act
Notification for Certain Mergers and Acquisitions

Acquired Person Instructions

GENERAL INSTRUCTIONS AND INFORMATION

These instructions specify the information that must be submitted pursuant to § 803.1(a) of the premerger notification rules, 16 CFR Parts 801-803 ("the Rules"). Submitted materials must be provided to the Federal Trade Commission ("FTC") and to the Antitrust Division of the Department of Justice ("DOJ") (together, "the Agencies").

► Information

The central office for information and assistance concerning the Rules is:

Premerger Notification Office
Federal Trade Commission
400 7th Street, S.W.
Washington, D.C. 20024
Phone: (202) 326-3100
E-mail: HSRhelp@ftc.gov for Rules questions
Premerger@ftc.gov for filing information

Copies of these Instructions, the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("the Act"), the Rules, FTC final rules (including their Statements of Basis and Purpose) published in the Federal Register, as well as information to assist in submitting the required information are available at the FTC's Premerger Notification Office ("PNO") website.

► Definitions and Explanation of Terms

Unless otherwise indicated, the definitions provided in the Rules apply to these Instructions.

Dollar Values
All financial information should be expressed in millions of dollars rounded to the nearest hundred thousand.

Fee Information
The filing fee is based on the aggregate total value of assets, voting securities, and controlling non-corporate interests to be held as a result of the acquisition. Filing fee tiers are adjusted annually pursuant to 15 U.S.C. § 18a note, based on the change in gross national product, in accordance with 15 U.S.C. § 19(a)(5). Filing fees increase annually by the percentage increase, if any, in the consumer price index ("CPI") over the CPI for the fiscal year ending September 30, 2022, pursuant to 15 U.S.C. § 18a note. For current fee information, see the PNO website.

North American Industry Classification System (NAICS) Data
When reporting information by 6-digit NAICS code, refer to the North American Industry Classification System - United States, 2022, published by the Executive Office of the President, Office of Management and Budget, available at https://www.census.gov/naics/. This website also provides guidance in choosing the proper code(s).

Notification Thresholds
Notification thresholds are adjusted annually based on the change in gross national product, in accordance with 15 U.S.C. § 19(a)(5). See § 801.1(h). The current threshold values can be found at Current Thresholds.

Person Filing and Filing Person
The terms "person filing" or "filing person" mean the ultimate parent entity ("UPE"). See § 801.1(a)(3). The terms are used herein interchangeably.

Select 801.30 Transaction
A transaction to which § 801.30 applies **and** where (1) the acquisition would not confer control, (2) there is no agreement (or contemplated agreement) between any entity within the acquiring person and any entity within the acquired person governing any aspect of the transaction, and (3) the acquiring person does not have, and will not obtain, the right to serve as, appoint, veto, or approve board members, or members of any similar body, of any entity within the acquired person or the general partner or management company of any entity within the acquired person. Executive compensation transactions also qualify as select 801.30 transactions.

Supervisory Deal Team Lead
The individual who has primary responsibility for supervising the strategic assessment of the deal, and who would not otherwise qualify as a director or officer.

Target
The target includes all entities and assets to be acquired by the acquiring person from the acquired person in the reported transaction.

Year
All references to "year" refer to calendar year. If data are not available on a calendar year basis, supply the requested data for the fiscal year reporting period that most nearly corresponds to the calendar year specified. References to "most recent year" mean the most recently completed calendar or fiscal year for which the requested information is available.

► Filing

If the UPE is both an acquiring and acquired person, separate filings must be submitted, one as the acquiring person and one as the acquired person, following the appropriate instructions for each. See § 803.2(a)(2).

Filings should be submitted electronically consistent with the instructions on the PNO website. If the electronic submission platform is unavailable, the Agencies may announce sites for delivery through the media and, if possible, at the PNO website.

► Responses

Documents, including the Form, should be produced as (1) a searchable PDF format from which text can be copied or (2) an Excel file.

For Business Documents (see below), check the box to indicate whether any part of the document is privileged and then provide the document number, title, and estimated date. If the acquired person has identified (1) a NAICS overlap, (2) an overlap within the Overlap Description, or (3) a supply relationship within the Supply Relationships Description, also provide the following:

1. Author(s) (and job title(s)) for documents created by the acquired person; or
2. Recipient(s) or supervisor(s) (and job title(s)) of documents created by third parties as part of an engagement with the acquired person.

If a group of people prepared the document, list all the authors and their titles, identifying the principal authors. Alternatively, it is acceptable to indicate that the document was prepared under the supervision of the lead author and to provide the name and title of that author. Similarly, if the acquired person engaged a third party to prepare a document, provide the name of the third party, and the name, title, and company name for the individual within the acquired person who supervised the creation of the document, or for whom the document was prepared. For materials received from a third party that was not engaged by the acquired person, only the name of the third party is required.

If the acquired person submits documents in addition to what is required, such documents should be identified as "Voluntary". See § 803.1(b).

Submit only one copy of identical responsive documents.

► Privilege

See § 803.3(d). For privileged documents, the filing person must also provide the following in a log:

1. The privilege type (redacted or withheld);
2. The privilege claim;
3. Addressee(s) and all recipients, with company name and title, of the original and any copies;
4. Subject matter;
5. Document's present location; and
6. Who has control over it.

If a privileged document was circulated to a group, such as the board or an investment committee, the name of the group is sufficient, but the filing person should be prepared to disclose the names and titles/positions of the individual group members, if requested.

If the claim of privilege is based on advice from inside and/or outside counsel, the name of the inside and/or outside counsel providing the advice (and the law firm, if applicable) must be provided. If several lawyers participated in providing advice, identifying lead counsel is sufficient. In identifying who controls a document, the name of the law firm is sufficient.

► Translations

Materials or information in a language other than English must be translated into English, with the English translation attached to the original version. See § 803.8.

► Non-Compliance

If unable to answer any item fully, provide such information as is available and a statement of reasons for non-compliance as required by § 803.3. If exact answers to any item cannot be given, enter best estimates and indicate the source or basis of such estimates. Add an endnote with the notation "est." to any item where data are estimated.

► Limited Response

Information need not be supplied regarding assets, voting securities, or non-corporate interests currently being acquired when their acquisition is exempt under the Act or Rules. See § 803.2(c).

FEE INFORMATION

Total Expected Filing Fee
Indicate the value of the total required fee for the transaction.

Parties Paying the Fee
Indicate which filing person(s) is paying the filing fee and, if applicable, whether the fee is being paid by multiple entities. For each entity within the acquired person paying a portion of the fee, provide the name of the payer, the amount paid, the payment method, and the Electronic Wire Transfer (EWT) confirmation number or check number.

Note on Paying by EWT
In order for the FTC to track payment, the payer must provide information required by the Fedwire Instructions to the financial institution initiating the EWT. A template of the Fedwire Instructions is available at the PNO website on the Filing Fee Information page.

Note on Paying by Check
The FTC strongly discourages check payments because handling a physical check will create a delay in processing the Form. However, if an EWT cannot be arranged, the FTC will accept a check, sent to Financial Operations. Cashiers' or certified checks are preferred. Make the check payable to the Federal Trade Commission and deliver to:

Federal Trade Commission
Financial Operations Division
600 Pennsylvania Ave, Drop H-790
Washington, DC 20580

Please note that the waiting period may be delayed until the fee has been confirmed.

GENERAL INFORMATION

Special Filing Types
Indicate whether the filing is a post-consummation filing, or whether the transaction is a cash tender offer or bankruptcy that is subject to Section 363(b) of the Bankruptcy Code (11 U.S.C. § 363).

Early Termination
Indicate whether the acquired person requests early termination of the waiting period. Notification of each grant of early termination will be published in the Federal Register, as required by 15 U.S.C. § 18a(b)(2), and on the PNO website. Note that if either person in any transaction requests early termination, it may be granted and published.

ULTIMATE PARENT ENTITY (UPE) INFORMATION

► UPE Details

Name
Provide the name, headquarters address, and website (if one exists) of the person filing notification. The name of the person filing is the name of the UPE of the acquired person. See § 801.1(a)(3).

Entity Type
Specify whether the UPE is a corporation, unincorporated entity, natural person, or other entity type (specify). See § 801.1.

Filing Made on Behalf of the UPE
If the filing is being made on behalf of the UPE by another entity within the acquired person authorized by the UPE to file the notification on its behalf pursuant to § 803.2(a) or filed pursuant to § 803.4 on behalf of a foreign person, provide the name and mailing address of the entity filing the notification on behalf of the UPE.

Contact Information
Provide the name, firm/company name, address, telephone number, and e-mail address of two individuals (primary and secondary) to contact regarding the filing. See § 803.20(b)(2)(ii).

Additionally, provide the name, firm/company name, address, telephone number, and e-mail address of an individual located in the United States designated for the limited purpose of receiving notice of the issuance of a request for additional information or documentary material. See § 803.20(b)(2).

UPE Annual Reports and Financial Information

- **Central Index Key**
  If the UPE of the acquired person files annual reports (Form 10-K or Form 20-F) with the United States Securities and Exchange Commission (SEC), provide the Central Index Key (CIK) number.

- **Annual Reports and Audit Reports**
  Provide the most recent annual reports and/or annual audit reports (or, if audited is unavailable, unaudited) of the UPE of the acquired person.

  Natural person UPEs should not provide personal balance sheets or tax returns. Natural person UPEs should leave this section blank and instead provide the most recent reports for the highest-level entity(ies) that controls the target under "UPE Structure."

  The person filing notification may incorporate a document responsive to this item by reference to an internet address directly linking to the document. See § 803.2(e).

- **Date of Report(s)**
  Provide the date of the most recent annual report(s) and/or audit reports (or, if audited is unavailable, unaudited) of the UPE of the acquired person.

- **Size of Person**
  If applicable, indicate whether the person filing notification stipulates that the acquired person meets either the higher or lower size of person test. See 15 U.S.C. § 18a(a), § 801.11.

Minority Shareholders or Interest Holders
This section requires the acquired person to report the name, headquarters mailing address, and approximate percentage held by certain minority holders of (1) the acquired entity and (2) any entity directly or indirectly controlled by the acquired entity, but only if such minority holder will continue to hold an interest (whether voting securities or non-corporate interests) in such entity(ies) or will acquire an interest in any entity within the acquiring person as a result of the transaction.

If the acquired entity or an entity directly or indirectly controlled by the acquired entity is not a limited partnership, provide the required information for each individual or entity that currently holds 5% or more but less than 50% of the voting securities or non-corporate interests of any such entity, starting with the acquired entity.

If the acquired entity or an entity directly or indirectly controlled by the acquired entity is a limited partnership, provide the required information for its (a) its general partner, regardless of the percentage it holds, and (b) its limited partners that (i) currently hold 5% or more

but less than 50% of the non-corporate interests of such limited partnership and (ii) have or will have the right to serve as, nominate, appoint, veto, or approve board members, or individuals with similar responsibilities, of (1) the acquiring entity, (2) any entity directly or indirectly controlled by the acquiring entity, (3) any entity that directly or indirectly controls the acquiring entity, and (4) any entity within the acquiring person that has been or will be created in contemplation of, or for the purposes of, effectuating the transaction (each a "covered entity"), or of the general partner or management company of a covered entity.

► Acquired Entity Structure

If the acquisition includes only assets that do not comprise substantially all the assets of an operating business, the acquired person should not complete the questions in this section. Otherwise, the acquired person must complete these questions for the portion of the transaction related to the voting securities, non-corporate interests, and assets that comprise substantially all the assets of an operating business.

Acquired Entity(ies)
List the name, city, state, zip code, and country of the acquired entity(ies) and all U.S. entities, and all foreign entities that have sales in or into the United States that are included within the acquired entity. Entities with total assets of less than $10 million may be omitted. Alternatively, the acquired entity may report all entities within it. Also list all names under which the entities do business (e.g., d/b/a names).

The list of entities should be organized by operating company or operating business ("top-level entity"), if applicable. Filings for select 801.30 transactions need not include d/b/a names and the list of entities can be organized as kept in the ordinary course of business.

Annual Reports and Audit Reports
Provide the CIK number(s), if the acquired entity(ies) file(s) annual reports (Form 10-K or Form 20-F) with the SEC, and the most recent annual or audit report(s) of the acquired entity(ies).

Natural person UPEs must also provide the most recent annual report or audit report and CIK number for the highest-level entity that controls the acquired entity.

TRANSACTION INFORMATION

► Parties

List the name and mailing address of each acquiring and acquired person and each acquiring and acquired entity. Do not list entities controlled by an acquired entity.

Acquiring UPE
Provide the name, headquarters address, and website of the acquiring person.

Acquiring Entity(ies)
If an entity other than the acquiring UPE is making the acquisition, provide the name, mailing address, and website of that entity.

Acquired UPE
Provide the name, headquarters address, and website of the acquired person.

Target(s)
If the assets, voting securities, or non-corporate interests of an entity other than the acquired UPE are being acquired, provide the name, mailing address, and website of that entity.

► Transaction Details

801.30 Transaction
Indicate whether the transaction is subject to § 801.30 and if so, what type(s), including select 801.30.

Transaction Type
Indicate whether the transaction is any of the following (select all that apply):

- Acquisition of voting securities;
- Acquisition of non-corporate interests;
- Acquisition of assets;
- Merger (see § 801.2);
- Consolidation (see § 801.2);

- Formation of a joint venture, other corporation, or unincorporated entity (see §§ 801.40 and 801.50);
- Acquisition subject to § 801.31;
- Secondary acquisition subject to § 801.4;
- Acquisition subject to § 801.2(e); or
- Other (specify)

Acquisition Details
Provide the requested information for the value and percentage of assets, voting securities, and non-corporate interests to be acquired. If a combination of assets, voting securities, and/or non-corporate interests is being acquired and allocation is not possible, note such information in an endnote.

For determining the percentage of voting securities, evaluate total voting power per § 801.12. For determining the percentage of non-corporate interests, evaluate the economic interests per § 801.1(b)(1)(ii).

To complete this item:
- State the percentage of voting securities already held by the acquiring person. See § 801.12.
- State the value of voting securities already held by the acquiring person. See § 801.10.
- State the total percentage of voting securities to be held by the acquiring person as a result of the acquisition. See § 801.12.
- State the total value of voting securities to be held by the acquiring person as a result of the acquisition. See § 801.10.
- State the percentage of non-corporate interests already held by the acquiring person. See § 801.1(b)(1)(ii).
- State the value of non-corporate interests already held by the acquiring person. See § 801.10.
- State the total percentage of non-corporate interests to be held by the acquiring person as a result of the acquisition. See §§ 801.10 and 801.1(b)(1)(ii).
- State the total value of non-corporate interests to be held by the acquiring person as a result of the acquisition. See § 801.10.
- State the total value of assets to be held by the acquiring person as a result of the acquisition. See § 801.10.
- State the aggregate total value of assets, voting securities, and non-corporate interests of the acquired person to be held by the acquiring person as a result of the acquisition. See §§ 801.10, 801.12, 801.13 and 801.14.

► Transaction Description

Business of the Target
Describe the business operation(s) being acquired. If assets, describe the assets and whether they comprise an operating business.

Non-Reportable UPE(s)
Provide the names of any UPE that does not have a reporting obligation.

Transaction Description
Briefly describe the transaction, indicating whether assets, voting securities, or non-corporate interests (or some combination) are being acquired. Indicate what consideration will be received by each person and the scheduled consummation date of the transaction. Also identify any special circumstances that apply to the filing, such as whether part of the transaction is exempt under one of the exemptions found in Part 802.

If any attached transaction documents use code names to refer to the parties, provide an index identifying the code names.

Related Transactions
If the transaction that is the subject of this filing has related filings, indicate whether the related filing(s) (choose all that apply):
- Is a principal transaction that triggers one or more shareholder backside transactions;
- Is a shareholder backside transaction;
- Has more than one acquiring UPE;
- Has more than one acquired UPE;
- Has more than one reportable step;
- Is a joint venture;
- Is a consolidation;
- Is an exchange of assets;
- Has one or more filings in the alternative; or
- Has other circumstances that require more than one filing and if so, explain.

Provide all additional details regarding the related filings(s), including party names and transaction numbers, necessary to identify and connect all related filings.

► Additional Transaction Information

Transaction Rationale

Except for select 801.30 transactions, identify and explain each strategic rationale for the transaction discussed or contemplated by the filing person or any of its officers, directors, or employees. If the rationale of the target is different from the UPE, submit an explanation for each. Identify each document produced in the filing that confirms or discusses the stated rationale(s). If documents produced in the filing are referenced, identify the specific page(s) that discusses the stated rationale(s).

► Business Documents

Transaction-Related Documents

- **Competition Documents**
  Provide all studies, surveys, analyses, and reports prepared by or for any officer(s), director(s), or supervisory deal team lead for the purpose of evaluating or analyzing the acquisition with respect to market shares, competition, competitors, markets, potential for sales growth, or expansion into product or geographic markets. For unincorporated entities, provide such documents prepared by or for individuals exercising similar functions as officers and directors, as well as the supervisory deal team lead.

- **Confidential Information Memoranda**
  Provide all confidential information memoranda prepared by or for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) of the UPE of the acquired person or of the target that specifically relate to the sale of the target. If no such confidential information memorandum exists, submit any document(s) given to any officer(s) or director(s) of the acquiring person meant to serve the function of a confidential information memorandum. This does not include ordinary course documents and/or financial data shared in the course of due diligence, except to the extent that such materials served the purpose of a confidential information memorandum when no such confidential information memorandum exists.
  Documents responsive to this item are limited to those produced within one year before the date of filing.

- **Third-Party Studies, Surveys, Analyses, and Reports**
  Provide all studies, surveys, analyses and reports prepared by investment bankers, consultants, or other third-party advisors ("third-party advisors") for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) of the UPE of the acquired person or of the target for the purpose of evaluating or analyzing market shares, competition, competitors, markets, potential for sales growth or expansion into product or geographic markets that specifically relate to the sale of the target. This item requires only materials developed by third party advisors during an engagement or for the purpose of seeking an engagement. Documents responsive to this item are limited to those produced within one year before the date of filing.

- **Synergies and Efficiencies**
  Provide all studies, surveys, analyses, and reports evaluating or analyzing synergies, and/or efficiencies prepared by or for any officer(s) or director(s) (or, in the case of unincorporated entities, individuals exercising similar functions) for the purpose of evaluating or analyzing the acquisition. Financial models without stated assumptions need not be provided.

Plans and Reports

Except for select 801.30 transactions, provide all regularly prepared plans and reports that were provided to the Chief Executive Officer (CEO) of the target or any entity that it controls or is controlled by that analyze market shares, competition, competitors, or markets pertaining to any product or service of the target also produced, sold, or known to be under development by the acquiring person, as identified in the Overlap Description. Documents responsive to this item are limited to those prepared or modified within one year of the date of filing.

Except for select 801.30 transactions, provide all plans and reports that were provided to the Board of Directors of the target or any entity that it controls or is controlled by that analyze market shares, competition, competitors, or markets pertaining to any product or service of the target also produced, sold, or known to be under development by the acquiring person, as identified in the Overlap Description. Documents responsive to this item are limited to those prepared or modified within one year of the date of filing.

► Agreements

Transaction-Specific Agreements

Furnish copies of all documents that constitute the agreement(s) related to the transaction, including, but not limited to, exhibits, schedules, side letters, agreements not to compete or solicit, and other agreements negotiated in conjunction with the transaction that the parties intend to consummate, and excluding clean team agreements.

Documents that constitute the agreement(s) (e.g., Agreement and Plan of Merger, Letter of Intent, Purchase and Sale Agreement, Asset Purchase Agreement, Stock/Securities Purchase Agreement) must be executed, while supporting agreements, such as employment agreements and agreements not to compete may be provided in draft form if that is the most recent version.

If the executed agreement is not the definitive agreement, submit a dated document that provides sufficient detail about the scope of the entire transaction that the parties intend to consummate, such as an agreement in principle, or term sheet, or the most recent draft agreement. See § 803.5. Such document should include information regarding some combination of the following terms: the identity of the parties; the structure of the transaction; the scope of what is being acquired; calculation of the purchase price; an estimated closing timeline; employee retention policies, including with respect to key personnel; post-closing governance; and transaction expenses or other material terms.

Note that transactions subject to § 801.30 and bankruptcies under 11 U.S.C. § 363(b) do not require an executed agreement. For bankruptcies, provide the order from the bankruptcy court.

COMPETITION DESCRIPTIONS

This section is not applicable to select 801.30 transactions.

► Overlap Description

Briefly describe each of the principal categories of products and services (as reflected in documents created in the ordinary course of business) of the target.

In addition, list and briefly describe each of the current or known planned products or services of the target that competes with (or could compete with) a current or known planned product or service of the acquiring person, based on documents created in the ordinary course of business. Current or known planned products or services include those that the acquiring person or target researches, develops, manufactures, produces, sells, offers, provides, supplies, or distributes. Known planned products or services may be limited to those referenced in any submitted Business Document and should reflect the acquired person's existing knowledge of the acquiring person's business. The acquiring and acquired person should not exchange information for the purpose of answering this item.

For each such product or service listed, provide:

1. The sales (in dollars) for the most recent year. For those products or services not generating revenue or whose performance is not measured by revenue in the ordinary course of business, provide projected revenue, estimates of the volume of products to be sold, time spent using the service, or any other metric by which the target measures performance (e.g., daily users, new signups).
2. A description of all categories of customers of the target that purchase or use the product or service (e.g., retailer, distributor, broker, government, military, educational, national account, local account, commercial, residential, or institutional). If no customers have yet used the product or service, provide the date that development of the product or service began; a description of the current stage in development, including any testing and regulatory approvals and any planned improvements or modifications; the date that development (including testing and regulatory approvals) was or will be completed; and the date that the product or service is expected to be sold or otherwise commercially launched.
3. The top 10 customers in the most recent year (as measured in dollars), and the top 10 customers for each customer category identified.

► Supply Relationships Description

Related Sales

List and briefly describe each product, service, or asset (including data) that the target has sold, licensed, or otherwise supplied, and which represented at least $10 million in revenue (including internal transfers) in the most recent year (1) to the acquiring person, or (2) to any other business that, to the acquired person's knowledge or belief, uses the target's product, service, or asset to compete with the acquiring person's products or services, or as an input for a product or service that competes or is intended to compete with the acquiring person's products or services. Responses to this item should reflect the acquired person's existing knowledge of the acquiring person's business; the acquiring and acquired person should not exchange information for the purpose of answering this item.

For each product, service, or asset listed, for the most recent year, provide:

1. The sales (in dollars) to (1) the acquiring person and (2) any other business that, to the acquired person's knowledge or belief, uses the target's product, service, or asset to compete with the acquiring person's products or services, or as an input for a product or service that competes or is intended to compete with the acquiring person's products or services.

2. The top 10 customers (as measured in dollars) of the target that use the target's product, service, or asset to compete with the acquiring person's products or services, or as an input for a product or service that competes or is intended to compete with the acquiring person's products or services. For each such customer, describe the target's supply or licensing agreement (or other comparable terms of supply).

Related Purchases
List and briefly describe each product, service, or asset (including data) that the target incorporates as an input into any product or service and that the target has purchased, licensed, or otherwise obtained and which represented at least $10 million in revenue (including internal transfers), in the most recent year (1) from the acquiring person or (2) from any other business that, to the acquired person's knowledge or belief, competes with acquiring person to provide a substantially similar product, service, or asset. Responses to this item should reflect the acquired person's existing knowledge of the acquiring person's business; the acquiring and acquired person should not exchange information for the purpose of answering this item.

For each product, service, or asset listed, for the most recent year, provide:

1. The purchased amount (in dollars) for (1) the acquiring person and (2) any other business that, to the acquired person's knowledge or belief, competes with the acquiring person to provide a substantially similar product, service, or asset.
2. The top 10 suppliers (as measured in dollars) for the associated input product, service, or asset, and a description of the target's purchase or licensing agreement (or other comparable terms of purchase).

REVENUES AND OVERLAPS

► NAICS Codes

This item requests information regarding the industry categories for the target's products and services that derived revenue in the most recent year.

No Revenue
If there is no revenue to report, explain why.

NAICS Codes Describing U.S. Operations with Estimates of Revenue
Identify all 6-digit NAICS industry codes that describe the U.S. operations of the target, inclusive of all entities and assets anticipated to be included within the target at the time the transaction will be consummated.

Responses must be organized by NAICS code in ascending order. For each code, provide the name of the operating business(es) that derive(s) revenue in that code and the estimated revenue range: less than $10 million; $10 million or more but less than $100 million; $100 million or more, but less than $1 billion; or $1 billion or more.

Identify each 6-digit NAICS industry code in which both the acquiring person and target derive revenue by checking the overlap box.

For products and services that derived revenue in the most recent year in a non-manufacturing NAICS code, if the revenue is estimated at less than one million dollars, that code may be omitted so long as the code does not overlap with a code in which the acquiring person derived revenue from U.S. operations.

► Controlled Entity Geographic Overlaps

If, to the knowledge or belief of the person filing notification, the target, derived any amount of dollar revenues in the most recent year from operations in industries within any 6-digit NAICS industry code in which the acquiring person also derived any amount of dollar revenues in the most recent year, then for each such 6-digit NAICS industry code follow the instructions below for this section.

NAICS Overlaps of Controlled Entities
List each overlapping NAICS code and description. For each, list the name of each operating business within the target that has U.S. operations in the same NAICS code as the acquiring person and the name(s) under which the operating business does business, and provide the appropriate Geographic Market Information, based upon the NAICS code. Organize responses by NAICS code in ascending order.

Geographic Market Information
For each identified overlapping NAICS code, provide geographic information, as described below. Use the 2-digit postal codes for states and territories and provide the total number of states and territories at the end of the response.

Except in the case of those NAICS industries in the sectors, subsectors, and codes that require street-address level reporting, the person filing notification may respond with the word "national" if business is conducted in all 50 states.

- **State-Level Reporting**
  - Manufacturing Industries
    For each 6-digit NAICS code within the industry sector, subsector, or code listed below, list the states in which, to the knowledge or belief of the person filing the notification, the products in that 6-digit NAICS industry code produced by the target are sold without a significant change in their form (whether they are sold by the target or by others to whom such products have been sold or resold).

    31** through 33**** Manufacturing**, *except*:
    3115** Dairy Product Manufacturing
    311611 Animal (except Poultry) Slaughtering
    311613 Rendering and Meat Byproduct Processing
    311615 Poultry Processing
    31181* Bread and Bakery Product Manufacturing
    321*** Wood Product Manufacturing
    32221* Paperboard Container Manufacturing
    324*** Petroleum and Coal Products Manufacturing
    3251** Basic Chemical Manufacturing
    325521 Plastics Materials and Resin Manufacturing
    3271** Clay Product and Refractory Manufacturing
    3272** Glass and Glass Product Manufacturing
    3273** Cement and Concrete Product Manufacturing

  - Wholesale Trade
    For each 6-digit NAICS code within the industry sector, subsector, or code listed below, list the states or, if desired, portions thereof in which the customers of target are located.

    42** **Wholesale Trade**, *except*:
    42331* Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers
    42333* Roofing, Siding, and Insulation Material Merchant Wholesalers
    42344* Other Commercial Equipment Merchant Wholesalers
    42345* Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers
    42346* Ophthalmic Goods Merchant Wholesalers
    42349* Other Professional Equipment and Supplies Merchant Wholesalers
    4239** Miscellaneous Durable Goods Merchant Wholesalers
    4241** Paper and Paper Product Merchant Wholesalers
    4242** Drug and Druggists' Sundries Merchant Wholesalers
    42441* General Line Grocery Merchant Wholesalers
    42442* Packaged Frozen Food Merchant Wholesalers
    42451* Grain and Field Bean Merchant Wholesalers
    42452* Livestock Merchant Wholesalers
    4247** Petroleum and Petroleum Products Merchant Wholesalers
    4248** Beer, Wine, and Distilled Alcoholic Beverage Merchant Wholesalers
    42491* Farm Supplies Merchant Wholesalers
    42495* Paint, Varnish, and Supplies Merchant Wholesalers

  - Insurance Carriers
    For the 6-digit NAICS code within the industry subsector listed below, list the state(s) in which the target is licensed to write insurance.

    5241** **Insurance Carriers**

  - Other NAICS Sectors
    For each 6-digit NAICS code within the industry sector, subsector, or code listed below, list the states or, if desired, portions thereof in which the target conducts such operations.

    11** **Agriculture, Forestry, Fishing, and Hunting**, *except*:
    113*** Forestry and Logging

21** **Mining, Quarrying, and Oil and Gas Extraction**, *except:*
2123** Nonmetallic Mineral Mining and Quarrying

2213** **Water, Sewage, and Other Systems**

23** **Construction**

44912* **Home Furnishing Retailers**
4492** **Electronics and Appliance Retailers**

48** and 49**** Transportation and Warehousing**, *except:*
493*** Warehousing and Storage

51** **Information**, *except:*
512*** Motion Picture and Sound Recording Industries

5222** **Nondepository Credit Intermediation**
523*** **Securities, Commodity Contracts, and Other Financial Investments and Related Activities**
5242** **Agencies, Brokerages, and Other Insurance Related Activities**
525*** **Funds, Trusts, and Other Financial Vehicles**
531*** **Real Estate**
533*** **Lessors of Nonfinancial Intangible Assets (Except Copyrighted Works)**

54** **Professional, Scientific and Technical Services**, *except:*
54138* Testing Laboratories and Services
54194* Veterinary Services

55** **Management of Companies and Enterprises**

561*** **Administrative and Support Services**

61** **Educational Services**

71** **Arts, Entertainment, and Recreation**, *except:*
7132** Gambling Industries
71394* Fitness and Recreational Sports Centers

7212** **RV (Recreational Vehicle) Parks and Recreational Camps**
7213** **Rooming and Boarding Houses, Dormitories, and Workers' Camps**
8114** **Personal and Household Goods Repair and Maintenance**
813*** **Religious, Grantmaking, Civic, Professional, and Similar Organizations**
814*** **Private Households**

- **Street-Level Reporting**
  For each 6-digit NAICS code within the industry sector, subsector, or code listed below, provide the street address, arranged by state, zip code, county, and city or town, of each establishment from which dollar revenues were derived (either directly by the target or by a franchisee) in the most recent year.

113*** **Forestry and Logging**
2123** **Nonmetallic Mineral Mining and Quarrying**

22** **Utilities**, *except:*
2213** Water, Sewage and Other Systems

3115** **Dairy Product Manufacturing**
311611 **Animal (except Poultry) Slaughtering**
311613 **Rendering and Meat Byproduct Processing**
311615 **Poultry Processing**
31181* **Bread and Bakery Product Manufacturing**

321* Wood Product Manufacturing**
32221* Paperboard Container Manufacturing
324* Petroleum and Coal Products Manufacturing**
3251 Basic Chemical Manufacturing**
325521 Plastics Materials and Resin Manufacturing
3271 Clay Product and Refractory Manufacturing**
3272 Glass and Glass Product Manufacturing**
3273 Cement and Concrete Product Manufacturing**
42331* Lumber, Plywood, Millwork, and Wood Panel Merchant Wholesalers
42333* Roofing, Siding, and Insulation Material Merchant Wholesalers
42344* Other Commercial Equipment Merchant Wholesalers
42345* Medical, Dental, and Hospital Equipment and Supplies Merchant Wholesalers
42346* Ophthalmic Goods Merchant Wholesalers
42349* Other Professional Equipment and Supplies Merchant Wholesalers
4239 Miscellaneous Durable Goods Merchant Wholesalers**
4241 Paper and Paper Product Merchant Wholesalers**
4242 Drug and Druggists' Sundries Merchant Wholesalers**
42441* General Line Grocery Merchant Wholesalers
42442* Packaged Frozen Food Merchant Wholesalers
42451* Grain and Field Bean Merchant Wholesalers
42452* Livestock Merchant Wholesalers
4247 Petroleum and Petroleum Products Merchant Wholesalers**
4248 Beer, Wine, and Distilled Alcoholic Beverage Merchant Wholesalers**
42491* Farm Supplies Merchant Wholesalers
42495* Paint, Varnish, and Supplies Merchant Wholesalers

44** and 45**** Retail Trade**, *except:*
44912* Home Furnishings Retailers
4492** Electronics and Appliance Retailers

493* Warehousing and Storage**
512* Motion Picture and Sound Recording Industries**
521* Monetary Authorities-Central Bank**
5221 Depository Credit Intermediation**
5223 Activities Related to Credit Intermediation**
532* Rental and Leasing Services**
54138* Testing Laboratories and Services
54194* Veterinary Services
562* Waste Management and Remediation Services**
62** Health Care and Social Assistance**
7132 Gambling Industries**
71394* Fitness and Recreational Sports Centers

72** Accommodation and Food Services**, *except:*
7212** RV (Recreational Vehicle) Parks and Recreational Camps
7213** Rooming and Boarding Houses, Dormitories, and Workers' Camps

811* Repair and Maintenance**, except
8114** Personal and Household Goods Repair and Maintenance

812* Personal and Laundry Services**

► Minority-Held Entity Overlaps

This section requires the disclosure of holdings of the target of 5% or more but less than 50% of certain entities that derive dollar revenues in any 6-digit NAICS code reported by the acquiring person. If NAICS codes are unavailable, holdings in entities that have operations in the same industry as the acquiring person, based on the knowledge or belief of the filing person, should be listed. Holdings in those entities that have total assets of less than $10 million may be omitted.

Minority Holdings of the Target
If the target holds 5% or more but less than 50% of the voting securities of any issuer or non-corporate interests of any unincorporated entity that derived dollar revenues in the most recent year from operations in industries within any 6-digit NAICS code(s) reported by the acquiring person, list the name of such entity and d/b/a names (if known), the percentage held, the entity within the target that holds the minority interests, and the overlapping 6-digit NAICS code(s) or industry(ies).

Responses should be organized alphabetically by the name of the entity in which minority interests are held.

► Prior Acquisitions

This item should be completed for the target and pertains only to prior acquisitions of U.S. entities or assets and foreign entities or assets with sales in or into the U.S. that in the most recent year (1) derived revenue in an identified 6-digit NAICS industry code overlap, or (2) provided or produced a competitive overlap product or service as described in the Overlap Description.

For each such overlap, list all acquisitions of entities or assets deriving dollar revenues in an overlapping 6-digit NAICS industry code or overlapping product or service made by the target in the five years prior to the date of the instant filing, even if the transaction was non-reportable. List only acquisitions of 50% or more of the voting securities of an issuer, 50% or more of non-corporate interests of an unincorporated entity, or all or substantially all the assets of an operating business if the entity or business had annual net sales or total assets greater than $10 million in the year prior to the acquisition and any acquisitions of assets that did not constitute all or substantially all of an operating business valued at or above the statutory size-of-transaction test at the time of their acquisition.

For each such acquisition, supply:

1. the overlapping 6-digit NAICS code(s) (by number and description) identified above in which the acquired entity or assets derived dollar revenues, or the competitive overlap product(s) or service(s) in the Overlap Description;
2. the name of the entity from which the assets, voting securities, or non-corporate interests were acquired;
3. the headquarters address of that entity prior to the acquisition;
4. whether assets, voting securities, or non-corporate interests were acquired; and
5. the consummation date of the acquisition.

ADDITIONAL INFORMATION

► Subsidies from Foreign Entities or Governments of Concern

Indicate whether, to the knowledge or belief of the filing person, within the two years prior to filing, the acquired person has received any subsidy (or a commitment to provide a subsidy in the future) from any foreign entity or government of concern (see § 801.1(r)). If yes, list each entity or government from which such subsidy was received (or which has made the commitment) and provide a brief description of the subsidy.

Indicate whether, for products the acquired person produced in whole or in part in a country that is a covered nation under 42 U.S.C. § 18741(a)(5)(C), any product is subject to countervailing duties imposed by any jurisdiction. If yes, list each product, the countervailing duty imposed, and the jurisdiction that imposed the duty.

Indicate whether, to the knowledge or belief of the filing person, for products the acquired person produced in whole or in part in a country that is a covered nation under 42 U.S.C. § 18741(a)(5)(C), any product is the subject of a current investigation for countervailing duties in any jurisdiction. If yes, list each product and the jurisdiction conducting the investigation.

► Defense or Intelligence Contracts

Except for select 801.30 transactions, identify (1) pending requests for proposals from the U.S. Department of Defense or any member of the U.S. intelligence community, as defined by 10 U.S.C. § 101(a)(6) or 50 U.S.C. § 3003(4) for which the target has submitted a proposal and (2) awarded procurement contracts with the U.S. Department of Defense or any member of the U.S. intelligence community, as defined by 10 U.S.C. § 101(a)(6) or 50 U.S.C. § 3003(4); valued at $100 million or more if such pending requests for proposals or such awarded procurement contracts (a) are or will be the source of revenues in any identified 6-digit NAICS industry code overlap; or (b) involve or will involve an overlap product or service as described in the Overlap Description or the Supply Relationships Description. Limit the response to the target. Include (1) the name of the entity within the filing person; (2) the contracting office, as defined by 48 C.F.R. § 2.101(b); (3) the Contracting Office ID; (4) the Award ID; and (5) the NAICS code(s), if any, listed in the System for Award Management database. Do not include classified information but note that responsive information was withheld on that basis.

► Voluntary Waivers

- **HSR Confidentiality Waiver for International Competition Authorities (VOLUNTARY)**
  Indicate whether the acquired person agrees to waive the disclosure exemption contained in the Act, 15 U.S.C. § 18a(h), to permit the DOJ and FTC to disclose to non-U.S. competition authority/authorities listed by the filing person (1) the fact that a notification was filed, (2) the waiting period associated with the notification, and (3) information and documents filed with the notification. This waiver will not cover materials provided in response to a request for additional information issued pursuant to 15 U.S.C. § 18a(e) and does not preclude the acquired person from providing a full waiver as provided for under FTC and DOJ practice as reflected in the Model Waiver. The acquired person should list the jurisdictions to which the waiver applies. This item is voluntary.

- **HSR Confidentiality Waiver for State Attorneys General (VOLUNTARY)**
  Indicate whether the acquired person agrees to waive any part of the disclosure exemption contained in the Act, 15 U.S.C. § 18a(h). If yes, list the applicable State Attorneys General and whether the acquired person permits the DOJ and FTC to disclose (1) the fact that a notification was filed and the waiting period associated with the notification, (2) information and documents filed with the notification, or (3) both (1) and (2). This waiver will not cover materials provided in response to a request for additional information issued pursuant to 15 U.S.C. § 18a(e) and does not preclude the acquired person from providing a full waiver as provided for under FTC and DOJ practice as reflected in the Model Waiver. The acquired person should list the jurisdictions to which the waiver applies. This item is voluntary.

CERTIFICATION

See § 803.6 for requirements.

The certification must be notarized or use the language found in 28 U.S.C. § 1746 relating to unsworn declarations under penalty of perjury. The Form includes the following language:

Penalties for False Statements
Federal law provides criminal penalties, including up to twenty years imprisonment, for any person who knowingly alters, destroys, mutilates, conceals, covers up, falsifies, or makes a false entry in any record, document, or tangible object with the intent to impede, obstruct, or influence an ongoing or anticipated federal investigation (see, e.g., Section 1519 of Title 18, United States Code.). It is also a criminal offense to knowingly make a false statement in a federal investigation, obstruct a federal investigation, or conspire to obstruct justice or obstruct or impede the lawful functioning of the government (see, e.g., Sections 371, 1001, and 1505 of Title 18, United States Code).

CERTIFICATION
This NOTIFICATION AND REPORT FORM, together with any and all appendices and attachments thereto, was prepared and assembled under my supervision in accordance with instructions issued by the Commission. Subject to the recognition that, where so indicated, reasonable estimates have been made because books and records do not provide the required data, the information is, to the best of my knowledge, true, correct, and complete in accordance with the statute and rules.

I acknowledge that the Commission or the Assistant Attorney General of the Antitrust Division of the Department of Justice may, prior to the expiration of the initial waiting period pursuant to 15 U.S.C. § 18a, require the submission of additional information or documentary material relevant to the proposed transaction.

AFFIDAVITS

Affidavit(s) required by § 803.5 must be notarized or use the language found in 28 U.S.C. § 1746 relating to unsworn declarations under penalty of perjury. If an entity is filing on behalf of the acquired person, the affidavit must still attest to the good faith intent of the UPE.

In non-§ 801.30 transactions, the affidavit(s) (submitted by both persons filing) must attest that an agreement to merge or acquire has been executed, and if the executed agreement is not the definitive agreement, that a dated document that provides sufficient detail about the scope of the entire transaction that the parties intend to consummate has been submitted. The affidavit(s) must further attest to the good faith intention of the person filing notification to complete the transaction. See § 803.5(b).

In § 801.30 transactions, the acquired person is not required to submit an affidavit.

PRIVACY ACT STATEMENT

Section 18a(a) of Title 15 of the U.S. Code authorizes the collection of this information. The primary use of information submitted on this Form is to determine whether the reported merger or acquisition may violate the antitrust laws. Taxpayer information is collected, used, and may be shared with other agencies and contractors for payment processing, debt collection and reporting purposes. Furnishing the information on the Form is voluntary. Consummation of an acquisition required to be reported by the statute cited above without having provided this information may, however, render a person liable to civil penalties up to the amount listed in 16 C.F.R. §1.98(a) per day.

We also may be unable to process the Form unless you provide all of the requested information.

DISCLOSURE NOTICE

Public reporting burden for this report is estimated to average 105 hours per response, including time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this report, including suggestions for reducing this burden to:

Premerger Notification Office
Federal Trade Commission
400 7th Street, S.W.
Washington, D.C. 20024

and

Office of Information and Regulatory Affairs
Office of Management and Budget
Washington, D.C. 20503

Under the Paperwork Reduction Act, as amended, 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 operative OMB control number, 3084-0005, appears within the Notification and Report Form and these Instructions.

BILLING CODE 6750–01–C

By the direction of the Commission.

April J. Tabor,

Secretary.

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

Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro Bedoya

The Federal Trade Commission, with the collaboration and concurrence of the Assistant Attorney General of the Department of Justice's Antitrust Division, has voted unanimously to issue a Final Rule to amend the Hart-Scott-Rodino (''HSR'') Form and Instructions. This marks the first time in 46 years that the agencies have undertaken a top-to-bottom review of the form (''HSR Form'') that businesses must fill out when pursuing an acquisition that must be notified in accordance with the HSR Act.[1] Alongside this Final Rule, the

[1] Press Release, Fed. Trade Comm'n, FTC Finalizes Changes to Premerger Notification Form (Oct. 10, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/10/ftc-finalizes-changes-premerger-notification-form.*

Commission voted to submit to Congress its FY2023 Annual Report regarding the Federal Trade Commission and Department of Justice's administration of the HSR Act. This Annual Report highlights the agencies' work investigating and challenging illegal mergers.[2]

Much has changed in the 48 years since the HSR Act was passed. Changes in the economy, corporate structure, and investment strategies have reshaped how businesses compete in today's marketplace. The number of transactions reported to the agencies surged during fiscal years 2021 and 2022 and remains high.[3] And deal valuations have soared. In FY2019, only 13.3% of transactions reported to the agencies exceeded $1 billion.[4] Those high-value transactions now represent nearly a quarter (24%) of all transactions that come before the agencies.[5] Transactions have also become increasingly complex in both structure and potential competitive impact.[6]

The HSR Form, meanwhile, has largely stayed the same. Against the backdrop of vast changes in the structure of business associations and corporate transactions, the information currently collected by the HSR Form is insufficient for our teams to determine, in the initial 30 days provided by the HSR Act, whether a proposed deal may violate the antitrust laws and hence warrant an in-depth investigation. The antitrust agencies are put in the position of expending significant time and effort to develop even a basic understanding of key facts. They must often rely on information provided in third-party interviews that can be challenging to obtain in 30 days. Much of the key information, moreover, is known only to the firms proposing the merger, such as the breadth of their business operations, including any existing relationship with the other party, the deal rationale, and the structure of each relevant entity. Seeking this information on a voluntary basis can leave critical gaps that allow unlawful deals to go undetected.

By reflecting modern day commercial realities, the HSR Form updates in the Final Rule will provide the antitrust agencies with information that is more probative as to whether a proposed deal risks violating the antitrust laws. Several aspects of the Final Rule bear particular mention:

• *Shed light on complex and opaque entities, including private equity and minority holders.* The existing HSR Form did not require information about the entities between the ultimate parent entity and the acquiring entity. Nor did it allow the agencies to determine whether the acquiring person may have competitively relevant premerger entanglements with the target's industry or whether minority holders have significant rights to direct the acquiring entity's actions. To close this gap, the Final Rule requires parties to provide information about the entities and individuals involved in the deal that will have the ability to influence decision-making post-merger.

• *Report vertical and other non-horizontal relationships.* The existing HSR Form failed to provide agencies with meaningful information about non-horizontal relationships. After a decades-long focus primarily on mergers between direct competitors, the antitrust agencies in recent years have reinvigorated merger enforcement against non-horizontal deals that violate the antitrust laws. Since 2021, the FTC has brought six enforcement actions against mergers involving a vertical combination—more than the total number of vertical cases pursued in the last decade overall.[7] The FTC's efforts have already resulted in the government's first litigated victory against a vertical merger in over 50 years.[8] As we continue building on this work, ensuring that the agencies receive information on non-horizontal components of deals is vital. Accordingly, the Final Rule requires filers to report supply relationships to reveal whether the transaction may undermine competition, including through limiting rivals' access to key products or services they need to compete. The Final Rule also contains new document requirements that are intended to reveal any existing or future non-horizontal business relationships that could give rise to competitive risks.

• *Reveal areas of future competition and emerging rivals.* As section 7 instructs us to arrest anticompetitive tendencies in their incipiency, the agencies must scrutinize acquisitions that may eliminate emerging rivals or threaten competition in lines of products that are still in development.[9] The existing HSR form has been particularly ill-suited to this task, as it gives no insight into merging parties' ongoing product development efforts or pipeline projects that could implicate future areas of competition. The Final Rule fixes this problem by requesting key information about products and services under development that are not yet generating revenues. In recent years the FTC pursued an enforcement action involving a pipeline product still in early-stage development, as well as successfully litigated a case involving the market for research and development.[10] The new HSR Form will further bolster these efforts.

• *Identify a greater range of prior acquisitions.* Another notable trend has been the rise of serial acquirers, firms that engage in numerous strategic acquisitions in the same industry and sometimes ''roll up'' many small competitors in the same or adjacent

[2] Press Release, Fed. Trade Comm'n, FTC, DOJ Issue Fiscal Year 2023 Hart-Scott-Rodino Notification Report and Announce Corrected Fiscal Year 2022 Report (Oct. 10, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/10/ftc-doj-issue-fiscal-year-2023-hsr-report-and-announce-corrected-2022-report.* On July 1, 2024, the Commission and DOJ Antitrust Division submitted to Congress a summary of this Report.

[3] Fed. Trade Comm'n & Dept. of Justice, Hart-Scott-Rodino Annual Report Fiscal Year 2023 (2024) [hereinafter *FY23 Report*] at 20.

[4] Fed. Trade Comm'n & Dept. of Justice, Hart-Scott-Rodino Annual Report Fiscal Year 2019 (2020) at Ex. A, Table I, *https://www.ftc.gov/system/files/documents/reports/federal-trade-commission-bureau-competition-department-justice-antitrust-division-hart-scott-rodino/p110014hsrannualreportfy2019.pdf.*

[5] FY2023 Report at Ex. A, Table I.

[6] *See* Remarks by Chair Lina M. Khan, Private Capital, Public Impact Workshop on Private Equity in Healthcare (March 5, 2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/2024.03.05-chair-khan-remarks-at-the-private-capital-public-impact-workshop-on-private-equity-in-healthcare.pdf*; Statement of Chair Lina M. Khan Joined by Comm'r Rebecca Kelly Slaughter & Comm'r Alvaro Bedoya in the Matter of EQT Corporation (Aug. 16, 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/statement-chair-lina-m-khan-joined-commissioner-rebecca-kelly-slaughter-commissioner-alvaro-m-bedoya-4.*

[7] *Illumina, Inc.* v. *FTC,* 88 F.4th 1036 (5th Cir. 2023); *FTC* v. *IQVIA et al,* 710 F.Supp.3d 329 (S.D.N.Y. 2024); *FTC* v. *Tempur Sealy Intern'l, Inc.,* 4:24–cv–02508 (S.D. Tex. July 2, 2024); *In re Lockheed Martin Corp.,* Docket No. 9405 (2022), *https://www.ftc.gov/legal-library/browse/cases-proceedings/211-0052-lockheedaerojet-matter* (alleging that the merger would enable missile systems manufacturer to use control over missile propulsion systems to harm rival defense prime contractors) (transaction abandoned); *In re Nvidia Corp.,* Docket No. 9404 (2021), *https://www.ftc.gov/legal-library/browse/cases-proceedings/2110015-nvidiaarm-matter* (alleging that the merger would give chip manufacturer the ability and incentive to use control over microprocessor design technology to undermine competitors) (transaction abandoned); *In re Intercontinental Exchange, Inc. & Black Knight, Inc.,* Docket No. 9413, *https://www.ftc.gov/legal-library/browse/cases-proceedings/221-0142-intercontinental-exchange-incblack-knight-inc-matter* (2023).

[8] *Illumina, Inc.,* 88 F.4th 1036.

[9] *See Illumina, Inc.* v. *FTC,* 88 F.4th 1036, 1049–51 (2023) (stating that antitrust markets are not limited to products that exist but may include those that are anticipated or expected or encompass research, development and commercialization of products in development); *FTC* v. *PPG Indus., Inc.,* 798 F.2d 1500, 1504 (D.C. Cir. 1986) (noting that merging firms competed in evolving high technology market at the request-for-proposal stage of product development).

[10] *In re Sanofi/Maze Therapeutics,* Docket No. 9422 (2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/2310091-sanofimaze-therapeutics-inc-matter; Illumina, Inc.,* 88 F.4th 1036.

markets. This strategy can consolidate a market through a series of smaller deals that fly below the radar of antitrust enforcers. Private equity firms and other investors have deployed roll-up strategies across a range of industries, from healthcare to housing—with potentially major ramifications for the public.[11] Indeed, the FTC's lawsuit against U.S. Anesthesia Partners charges the entity with acquiring over a dozen anesthesiology providers across Texas in the span of eight years, a reduction in competition that cost consumers and businesses tens of millions of dollars.[12] The Commission's investigations into acquisitions of veterinary clinics have also revealed roll-up plays.[13] To understand whether a proposed transaction is part of an anticompetitive roll-up scheme, the agencies need insight into what prior acquisitions the entity has made within the same lines of business. While the existing Form required some reporting of these acquisitions, the Final Rule provides a more complete picture of the merging parties' overarching acquisition strategies by requiring that both entities provide information on certain prior acquisitions that closed within the previous five years.

The notice of proposed rulemaking included a requirement that would have aided the agencies' assessment of whether the proposed deal would risk threatening competition in labor markets. This proposal fit within a wider effort at the agencies to correct for antitrust enforcers' decades-long neglect of promoting fair competition in labor markets. As Commissioner Bedoya rightly notes, when antitrust enforcers did pay attention to workers, it usually involved weaponizing antitrust against them.[14] This disposition had no basis in the law—and, as Commissioner Bedoya notes, directly contravenes the goals Congress sought to advance in passing the antitrust laws. No antitrust law gives primacy to some market participants over others or states that some are entitled to greater protection from unlawful monopolization or mergers; to the contrary, the Clayton Act prohibits mergers that may substantially lessen competition ''in any line of commerce.'' [15] I am pleased that in recent years the FTC has reoriented towards a more faithful application of the law, including—for the first time in our 110-year history—through challenging a transaction on the grounds that it risks undermining competition in labor markets.[16]

While the Final Rule pares back some of the labor market requirements, I believe that the information required by other provisions of the Final Rule will position the agencies to identify transactions that threaten competition in labor markets. In particular, the newly-mandated information on overlap and supply relationship descriptions, as well as new high-level business and transaction-related documents, will enable the agencies to identify whether a proposed deal risks undermining competition for workers. And partnerships with the National Labor Relations Board and the Department of Labor will allow the FTC to continue deepening its expertise in how competition works in labor markets.[17]

The FTC also announced today that, following the Final Rule coming into effect, we will lift the categorical suspension on early termination of filings made under the HSR Act. When the antitrust agencies grant early termination, merging parties can consummate their deal without waiting for the full 30-day period ordinarily required under the law. The Commission initially suspended early termination due to a historic volume of filings amidst the COVID–19 pandemic.[18] But a revisiting of the FTC's early termination policy was overdue. Data reveal that permissively granting early termination led to the consummation of some deals that resulted in significant harm.[19] Moreover, the law makes clear that the granting of early termination is purely a discretionary function.[20] Merging

[11] *See, e.g.,* Richard M. Scheffler et al., Am. Antitrust Inst., Soaring Private Equity Investment in the Healthcare Sector: Consolidation Accelerated, Competition Undermined, and Patients at Risk 8–16 (2021), *https://publichealth.berkeley.edu/wp-content/uploads/2021/05/Private-Equity-I-Healthcare-Report-FINAL.pdf*; Atul Gupta, et al., *Does Private Equity Investment in Healthcare Benefit Patients? Evidence from Nursing Homes* (Becker Friedman Inst., Working Paper No. 2021–20, 2021), *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3537612*. The Commission recently hosted a public workshop to discuss the growing body of economic research examining the role of private equity investment in health care markets. Fed. Trade Comm'n, Private Capital, Public Impact: An FTC Workshop on Private Equity in Health Care (Mar. 5, 2024), *https://www.ftc.gov/news-events/events/2024/03/private-capital-public-impact-ftc-workshop-private-equity-health-care*.

[12] Complaint, *FTC* v. *U.S. Anesthesia Partners, Inc., et al.,* No. 4:23–cv–03560 (S.D. Tex. Sept. 21, 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/2010031-us-anesthesia-partners-inc-ftc-v*.

[13] *In re JAB Consumer Partners, et al.,* Docket Nos. C–4766 & C–4770 (2022), *https://www.ftc.gov/legal-library/browse/cases-proceedings/2110140-jab-consumer-partnersnational-veterinary-associatessage-veterinary-partners-matter*.

[14] Statement of Comm'r Alvaro M. Bedoya Joined by Comm'r Rebecca Kelly Slaughter & Chair Lina M. Khan in the Matter of Amendments to the Premerger Notification and Report Form and Instructions and the Hart-Scott-Rodino Rule (Oct. 10, 2024).

[15] 15 U.S.C. 18. See also, Statement of Comm'r Alvaro M. Bedoya, *id.*

[16] Press Release, Fed. Trade Comm'n, FTC Challenges Kroger's Acquisition of Albertsons (Feb. 26, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/02/ftc-challenges-krogers-acquisition-albertsons*; *see also,* Statement of Comm'r Rebecca Kelly Slaughter & Chair Lina M. Khan Regarding *FTC and State of Rhode Island* v. *Lifespan Corporation and Care New England Health System* (Feb. 17, 2022), *https://www.ftc.gov/system/files/ftc_gov/pdf/public_statement_of_commr_slaughter_chair_khan_re_lifespan-cne_redacted.pdf*.

[17] Press Release, Fed. Trade Comm'n, FTC, Department of Labor Partner to Protect Workers from Anticompetitive, Unfair, and Deceptive Practices (Sept. 21, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/09/ftc-department-labor-partner-protect-workers-anticompetitive-unfair-deceptive-practices*, Press Release, Fed. Trade Comm'n, FTC, National Labor Relations Board Forge New Partnership to Protect Workers from Anticompetitive, Unfair, and Deceptive Practices (July 19, 2022), *https://www.ftc.gov/news-events/news/press-releases/2022/07/federal-trade-commission-national-labor-relations-board-forge-new-partnership-protect-workers*.

[18] Press Release, Fed. Trade Comm'n, FTC, DOJ Temporarily Suspend Discretionary Practice of Early Termination,'' Federal Trade Commission (Feb. 4, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/02/ftc-doj-temporarily-suspend-discretionary-practice-early-termination*.

[19] *See* Premerger Notification; Reporting and Waiting Period Requirements, 16 CFR parts 801, 803 (2024) at 17 (The consequences of inadequate detection are revealed in a recent analysis of hospital mergers that were reported to the Agencies for premerger review co-authored by two economists from the Commission's Bureau of Economics. Keith Brand et al., ''In the Shadow of Antitrust Enforcement: Price Effects of Hospital Mergers from 2009–2016,'' 66 J. L. Econ. 639 (2023). The paper examined a set of consummated hospital mergers and measured the effect of each merger on prices. The study concluded that mergers not reportable under the HSR Act did not result in larger price increases than reportable mergers. In contrast, the authors found different outcomes among mergers that were subject to premerger review based on how much review the transaction received. Of the mergers reported to the Agencies, the largest average percentage price increase occurred for those mergers that received early termination of the initial waiting period. This suggests that the HSR Filings failed to provide sufficient information to trigger additional investigations that could have blocked these harmful mergers before they were consummated; instead, the filings resulted in early termination of the waiting period. While the study was not designed to test the impact of this rulemaking, the study supports the Commission's belief that there are information deficiencies with the current HSR Rules that prevent the Agencies from identifying mergers that may violate the antitrust laws.'').

[20] Both the Clayton Act and the HSR Act provide for an exception to the waiting period by empowering the FTC and DOJ to grant early terminations ''in their discretion.''16 CFR 803.11(c) (HSR Act: ''The Federal Trade Commission and the Assistant Attorney General may, in their discretion, terminate a waiting period upon the written request of any person filing notification or . . . sua sponte.''); 15 U.S.C.A. 18a(2) (Clayton Act: ''The Federal Trade Commission and the Assistant Attorney General may, in individual cases, terminate the waiting period specified in paragraph (1) and allow any person to proceed with any acquisition subject to this section, and promptly shall cause to be published in the **Federal Register**

parties are not entitled to early termination, and I question the wisdom of using agency resources on a discretionary function while resource constraints impede our ability to fully execute on our mandatory functions. Because the Final Rule will provide the agencies with additional information necessary to probe the competitive risk that a transaction may pose, we will be better positioned to determine the right set of policies and procedures around early termination, including which subset of deals may receive it and under what circumstances.

The new HSR Form marks a generational upgrade that will sharpen the antitrust agencies' investigations and allow us to more effectively protect against mergers that may substantially lessen competition or tend to create a monopoly. But it is not the only part of the HSR regime that requires upgrading. As I've noted in past years, the HSR Act must be modernized for today's economy.[21] In particular, the statutory timelines laid out in the HSR Act have not kept pace with the surge in deal volume, the complexity of transactions, and the increased burden associated with proving in court a violation of section 7. The HSR Act gives the agencies 30 days to determine whether a deal warrants close investigation, and then another 30 days after parties certify they have ''substantially complied'' with the inquiry. These timelines were set in an era when document productions were measured in the number of boxes and not the number of terabytes—and when lawmakers expected the agencies would receive around 150 merger notifications per year, rather than 150 notifications per month (as the agencies now routinely receive).[22] While the new HSR Form will bolster the antitrust agencies' ability to adequately screen proposed deals during the initial waiting period, Congress should revisit HSR and appropriately extend these timelines to match today's realities.[23]

Faithfully discharging the Commission's statutory obligations also requires adequate funding. The HSR Annual Report summarizes the agencies' merger enforcement work over FY2023.[24] During that period the FTC's work resulted in challenges to 15 transactions that risked threatening competition.[25] Ten of these challenges resulted in parties abandoning the transactions, nearly double the average annual number of abandonments from the preceding 10 years. Our efforts to keep building on this efficacy, however, will run into major resource constraints. The FTC's enacted budget for fiscal year 2024 represented a one percent reduction from the previous year. Alongside a statutorily mandated five percent pay raise and higher non-pay costs resulting from inflation, the result of this reduction has been significantly fewer resources to support the FTC's mission. While our teams work diligently to faithfully enforce the antitrust laws, resource constraints have meant the FTC has been forced to make difficult triage decisions and forgo meritorious investigations—likely resulting in the public bearing the cost of illegal mergers. Additional resources would better equip the Commission to fully pursue its mandate and protect the public.

Finally, the FTC today is launching a new online portal so that members of the public can directly submit comments on mergers that may threaten competition.[26] This portal is part of the FTC's broader work to ensure we are opening our doors to hear from people across the country on issues of public concern.[27] Whether the antitrust agencies do or do not take action against a merger can be of enormous consequence—determining how much people pay for essential goods and services, how much workers earn on a job, whether independent businesses can keep serving their communities, whether an entrepreneur can bring a breakthrough innovation to market, and whether our supply chains are brittle or resilient. Ensuring the antitrust agencies are positioned to make these high-stakes decision with a full understanding of what may follow from a merger is vital. Well-resourced businesses know how best to inform the agencies' investigations, but one shouldn't need to hire a lawyer to provide public enforcers with relevant information on a merger. This new portal will allow the FTC to systematize the regular gathering of public input on mergers and continue broadening the types of expertise and experience that inform our work.

The Final Rule, HSR Report, and new merger portal reflect tremendous work by teams across the FTC, in particular from the Premerger Notification Office, the Office of Policy and Coordination, and the Office of Policy Planning, as well as from throughout the Bureau of

a notice that neither intends to take any action within such period with respect to such acquisition.'').

[21] Statement of Chair Lina M. Khan Joined by Commissioner Rebecca Kelly Slaughter and Commissioner Alvaro M. Bedoya Regarding the FY2022 HSR Annual Report to Congress (Dec. 21, 2023), *https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/statement-chair-lina-m-khan-joined-commissioner-rebecca-kelly-slaughter-commissioner-alvaro-m-bedoya-5*.

[22] *See id.*

[23] Presently, FTC staff are routinely at the mercy of merging parties granting extensions of the statutory deadline so that staff has the necessary time to review the transaction. But it should not be merging parties that get to determine the amount of time FTC staff has to review mergers and do the work required by law.

[24] Commissioners Holyoak and Ferguson dissent from the issuance of the HSR Annual Report. In particular, Commissioner Holyoak disagrees with the longstanding practice to count abandonments and deals where parties were not required to make an HSR filing. Dissenting Statement of Commissioner Melissa Holyoak, Hart-Scott-Rodino Annual Report, Fiscal Year 2023 (Oct. 10, 2024) at 2. For over a decade, the Report has been clear that it includes certain non-HSR reportable matters. FY23 Report at n.28 (''The cases listed in this section were not necessarily reportable under the premerger notification program. Given the confidentiality of information obtained pursuant to the Act, it would be inappropriate to identify the cases initiated under the program except in those instances in which that information has already been disclosed.''); *see also Fed. Trade Comm'n, FY 2010 Hart Scott Rodino Annual Report* (2011) at n.18. A proposed merger may be anticompetitive even if it falls below the threshold that would require an HSR filing. As a result, FTC staff may raise concerns regarding certain transactions even where such a filing has not been made. Those matters are part of the FTC's merger enforcement work and including them faithfully represents the Commission's work to Congress. The HSR Annual Report also states plainly that it references certain deals where ''the transaction was abandoned or restructured as a result of antitrust concerns raised during the investigation,'' *id.* at 2, and Commissioner Holyoak does not identify any inconsistency or explain any insufficiency in how the numbers are tabulated here versus how the Commission has historically done so. Commissioner Ferguson notes in his dissent that the precise timing of HSR reports is not mandated by Congress and has varied in past years, but neglects to mention that timing under prior administrations also varied significantly. Dissenting Statement of Commissioner Andrew N. Ferguson Regarding the FY2023 HSR Annual Report to Congress (Oct. 10, 2024) at 1–2. *See, e.g.,* Fed. Trade Comm'n, Annual Competition Reports (last visited Oct. 9. 2024), *https://www.ftc.gov/policy/reports/annual-competition-reports* (for example, the FY19 Annual HSR Report was released in July of 2020, the FY18 Annual HSR Report was released Sept 2019, the FY17 Annual HSR Report was released Apr. 11, 2018, the FY16 Annual HSR Report was released Oct. 4, 2017. Strangely, Commissioner Ferguson also suggests that the decision to issue this year's report in October is part of some political scheme related to giving the Democratic ticket an advantage in the forthcoming presidential election. I am unaware of any reports, research, or evidence suggesting that the HSR Report has any bearing on voting patterns or electoral outcomes.

[25] One transaction challenged in FY2023 remains in litigation.

[26] *See* Press Release, Fed. Trade Comm'n, FTC Finalizes Changes to Premerger Notification Form (Oct. 10, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/10/ftc-finalizes-changes-premerger-notification-form*.

[27] When the FTC in recent years has invited public input, we have received thousands—and sometimes tens of thousands—of comments, including on issues relating to merger enforcement. *See, e.g.,* Public Docket FTC–2023–0043, Draft Merger Guidelines for Public Comment, *Regulations.gov* (Jul. 19, 2023); Public Docket FTC–2024–0028, FTC and DOJ Seek Info on Serial Acquisitions, Roll-Up Strategies Across U.S. Economy, *Regulations.gov* (May 23, 2024).

Competition, the Office of General Counsel, and the Bureau of Economics. I am grateful to this team for their diligent efforts, as well as to the FTC's partners at DOJ for their collaboration, and to my fellow Commissioners for their thoughtful engagement.

Statement of Commissioner Alvaro M. Bedoya Joined by Chair Lina M. Khan and Commissioner Rebecca Kelly Slaughter

My colleagues Commissioners Ferguson and Holyoak write at some length in support of the Commission's decision not to adopt, at this time, a set of proposed requests for employment information (''the labor screen'') that was included in the original notice of proposed rulemaking.[1] Rather than litigating the merits of the labor screen, I write to respond to one of the ideas underlying my colleagues' arguments against it.

The Sherman Act was passed in 1890; the Clayton Act and the Federal Trade Commission Acts were passed in 1914, creating this Commission and empowering it to enforce this newly expanded set of antitrust laws.[2] Yet it was only in 2021 that a Federal antitrust enforcer first stopped a merger because of its impact on competition in the labor market.[3]

My colleagues cite the absence of such merger challenges as a key reason for dropping the labor screen. Both stress the extensive efforts the antitrust agencies have expended to identify such mergers.[4] They argue that, if enforcers have been working for years to identify mergers that harm competition in labor markets and have not brought more challenges, how can we justify requesting additional data to identify those mergers? In fact, Commissioner Holyoak seems to imply that labor monopsony is rare, going so far as to say that the labor screen ''was a solution in search of a nonexistent problem.'' [5]

History tells a different story. While my colleagues suggest that the absence of labor-based merger challenges exists ''not for a lack of trying,'' [6] a review of the first hundred years of that history finds dreadfully little trying. Indeed, most of the history of antitrust enforcement has been marked by a clear aversion to protecting labor market competition. This arguably has only been reversed in the last decade.

The historical record reveals several reasons for the lack of labor-based merger challenges, none of which suggest that labor monopsony is rare. The first would be early antitrust enforcers' overt hostility to labor organizing specifically and labor organizations more generally—a position that put them in sharp opposition to the legislators who created American antitrust law.

From the first Senate debates over passage of the law that would come to bear his name, Senator John Sherman made clear he was concerned with combinations of companies that could unilaterally set the price of labor. In denouncing the ''trust,'' he explained that:

> ''The sole object of such a combination is to make competition impossible. It can control the market, raise or lower prices, as will best promote its selfish interests. . . It dictates the terms to transportation companies, it commands the price of labor without fear of strikes, for in its field it allows no competitors. Such a combination is more dangerous than any heretofore invented. . .'' [7]

He wasn't the only legislator who was concerned with labor. The debates in 1890 as well as 1914 were defined by an overriding concern that the laws being considered would be misused to stop labor organizing. Thus, the Sherman Act was amended not once but twice to avoid such a result, ultimately being rewritten nearly in its entirety; sections 6 and 20 of the Clayton Act were enacted for the same reason 24 years later.[8]

Early antitrust enforcers ignored this legislative intent, as did the courts hearing challenges brought under the laws. Prosecutors instead turned the Sherman Act into what Professor Hovenkamp termed a ''savage weapon'' against labor, [9] using it to break the strikes of longshoremen in New Orleans and hungry Pullman Palace Car workers in Illinois.[10] The labor protections in the Clayton Act arguably fared worse. Despite the law's clear prohibition against the use of antitrust laws against labor organizing, courts in the 1920s used it to stop 2,100 strikes.[11]

In short, for the first four decades of their existence, the antitrust laws were used as a cudgel against organized labor, not a tool to detect and block mergers that risked harming labor markets. While the law was there to allow for a challenge to a merger based on its impact on labor market competition,[12] the idea that the DOJ or FTC of that era would try to block such mergers finds no basis in reality.

In his treatise exploring the absence of antitrust enforcement targeted at labor markets, Professor Posner presents two other reasons for the lack of labor-based merger challenges, both of which post-date the heyday of the labor injunction in the first half of the 20th century.[13] He argues that, starting in the 1960s, legal scholars began to prevail upon law enforcers to target antitrust enforcement on conduct and combinations that raised the prices on products and services sold to the public—that is, ''consumer welfare.'' More interestingly, he explains that until very recently, most economists assumed labor markets were more or less competitive, and labor market power—the power of employers to set wages below a competitive level—was thus not an important problem for society.[14]

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[1] Premerger Notification; Reporting and Waiting Period Requirements, 88 FR 42178, 42197 (June 29, 2023) (to be codified at 16 CFR pts. 801, 803).

[2] 15 U.S.C. 1–38; 15 U.S.C. 12–27; 15 U.S.C. 41–58.

[3] *United States* v. *Bertelsmann SE & Co. KGaA,* 646 F. Supp. 3d 1, 1 (D.D.C. 2022).

[4] Statement of Commissioner Melissa Holyoak, *Final Premerger Notification Form and the Hart-Scott-Rodino Rules,* at 9; Concurring Statement of Commissioner Andrew N. Ferguson, *In the Matter of Amendments to the Premerger Notification and Report Form and Instructions and the Hart-Scott-Rodino Rule,* at 11.

[5] Statement of Commissioner Melissa Holyoak, *Final Premerger Notification Form and the Hart-Scott-Rodino Rules,* at 9.

[6] *Id.; see also* Concurring Statement of Commissioner Andrew N. Ferguson, *In the Matter of Amendments to the Premerger Notification and Report Form and Instructions and the Hart-Scott-Rodino Rule,* at 11 (''It is not for a lack of effort.'').

[7] 21 Cong. Rec. 2457 (Mar. 21, 1890) (remarks of Sen. John Sherman of Ohio).

[8] *See* Alvaro M. Bedoya & Bryce Tuttle, ''*Aiming at Dollars, Not Men*'': *Recovering the Congressional Intent Behind the Labor Exemption to Antitrust Law,*'' 85 Antitrust L.J. 805, 809–812 (2024).

[9] Herbert Hovenkamp, *Labor Conspiracies in American Law,* 1880–1930, 66 Tex. L. Rev. 919, 928 (1988).

[10] *See* Bedoya & Tuttle, *supra* note 8, at 811–812; *see also U.S.* v. *Workingmen's Amalgamated Council of New Orleans,* 54 F. 994, 996 (E.D. La. 1893); Melvin I. Urofsky, *Pullman Strike,* Encyc. Britannica (Sept. 2, 2022), *https://www.britannica.com/event/Pullman-Strike.*

[11] *See* William E. Forbath, *Law and the Shaping of the American Labor Movement* 158 (1991).

[12] In 1926, in line with Senator Sherman's intent, the Supreme Court held that antitrust law could be used affirmatively to protect competition in labor markets, allowing a group of sailors to sue shipowners for wage-fixing. *Anderson* v. *Shipowners Ass'n of the Pac. Coast,* 272 U.S. 359, 365 (1926).

[13] *See generally* Eric A. Posner, *How Antitrust Failed Workers* (2021).

[14] *See id* at 4. Professor Posner cites a popular economics textbook from 2005 which declared that ''[m]ost labor economists believe there are few monopsonized labor markets in the United States.'' *Id. citing* Dennis W. Carlton & Jeffrey M. Perloff, *Modern Industrial Organization* 108 (2005). *See also* David Card, *Who Set Your Wage?* American Economic Review at 1075 (2022) (''the time has come to recognize that many—or even most—firms have some wage-setting power. Such a shift was made with respect to firm's price-setting power many decades ago[. . .] In the past few years we may have reached a tipping point for a similar transition in labor economics, driven by the combination of new (or at least post-1930) theoretical perspectives, newly available data sources, and accumulating evidence on several

That understanding of labor markets has begun to unravel. New research suggests that the fewer companies in a community competing for workers, the lower the wages.[15] Research also suggests that mergers, specifically, help companies keep wages low.[16] This appears to be a common problem in American society. Professor Posner found it plausible that in many labor markets, workers receive thousands of dollars less than the competitive rate.[17] Two years ago, the Treasury Department estimated that as a result of current employer market concentration as well as how time consuming it is to find, interview for, and accept a job, Americans likely lose out on the equivalent of eight weeks of pay every year. In other words, in a perfectly competitive labor market—in a world where we can easily switch jobs to one of any number of firms, most of us would be about two to four paychecks richer.[18] Few people may know about ''labor monopsony,'' but anyone on a budget knows what they'd do with that money.

In short, my colleagues seem to say that labor monopsony is not a problem even though we've only just started to look for that problem. Then, they wave away tools to help find that problem because we haven't found it yet.[19]

All of this said, a key barrier to any merger challenge, including labor-based challenges, is a lack of time. The changes voted out today will help FTC staff quickly find and focus on the mergers that hurt competition in any market, including labor markets. For this and many other reasons, I am proud to support them.

different fronts.''); *id.* at 1086 (''By insisting that 'markets set wages,' labor economists ceded the field, and had very little to say about questions like the design of online labor markets, or the effects of no-solicitation or no-poaching agreements—other than that they should not matter[. . .] One of the most exciting developments in the field today is the evidence of labor economists taking questions about wage setting seriously[. . .] I also expect this work to lead to some rethinking on policies such as minimum wages, the regulation of trade unions, and anti-Trust'').

[15] See, *e.g.,* Efraim Benmelech, et al., *Strong Employers and Weak Employees: How Does Employer Concentration Affect Wages,* 57. J. of Hum. Res. S200, S203 (Supplement) (2022).

[16] See Elena Prager & Matt Schmitt, *Employer Consolidation and Wages: Evidence from Hospitals,* 111 Am. Econ. Rev. 397, 397 (2021); Benmelech, supra note 3, at S200 (''instrumenting concentration with merger activity shows that increased concentration decreases wages''); David Arnold, *Mergers and Acquisitions, Local Labor Market Concentration, and Worker Outcomes* (unpublished) (Oct. 29, 2021) (''M&As that increase local labor market concentration have negative impacts on worker earnings with the largest impacts in already concentrated markets.''), *available at https://sites.google.com/site/davidhallarnold/research.*

[17] *See* Posner, *supra* note 13, at 28.

[18] The report's review of academic studies ''places the decrease in wages at roughly 20 percent relative to the level in a fully competitive market.'' This is a middle estimate from an estimated range of $0.15 to $0.25 cents of lost wages on every dollar. The ''eight weeks of pay'' figure applies the lower bound of that estimate ($0.15, or 15%) to 52 weeks of pay. *See* U.S. Dep't of Treasury, *The State of Labor Market Competition,* at ii (2022) (''20 percent''); *id.* at 24–25 (''15–25 cents on the dollar'').

[19] Commissioner Holyoak states that ''[t]he agencies have never made a standalone labor challenge to an acquisition,'' and Commissioner Ferguson states that the agencies have never made a challenge ''based on labor market theories that could have been identified by the proposed requirements.'' Statement of Commissioner Melissa Holyoak, *Final Premerger Notification Form and the Hart-Scott-Rodino Rules,* at 9–10; Concurring Statement of Commissioner Andrew N. Ferguson, *In the Matter of Amendments to the Premerger Notification and Report Form and Instructions and the Hart-Scott-Rodino Rule,* at 11. I evaluate this new era quite differently. In 2021, our colleagues at the Antitrust Division successfully blocked a proposed merger between two of the nation's largest book publishers based on a labor theory that the elimination of competition between the merging publishers likely would have negatively impacted the advances paid to authors for their work. *See United States* v. *Bertelsmann SE & Co. KGaA,* 646 F. Supp. 3d 1 (D.D.C. 2022). What's more, in addition to Commission staff's challenge of the Kroger/Albertson's merger in part on a labor theory, FTC staff just last month submitted a comment urging the Indiana Department of Health to deny an application that seeks to combine Union Hospital and Terre Haute Regional Hospital, in part because, in staff's view, the proposed merger would likely depress wage growth for hospital employees and exacerbate challenges with recruiting and retaining healthcare professionals. *See* Complaint, *FTC* v. *Kroger Co., and Albertsons Co.,* (D. Or. Feb. 26, 2024); Federal Trade Commission Staff Submission to Indiana Health Department Regarding the Certificate of Public Advantage Application of Union Health and Terra Haute Regional Hospital at 54–63 (Sept. 5, 2024). The Commission unanimously authorized staff to file the comment. Press Release, Fed. Trade Comm'n, *FTC Staff Opposes Proposed Indiana Hospital Merger* (Sept. 5, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/09/ftc-staff-opposes-proposed-indiana-hospital-merger.* Additionally, in 2018, under Republican leadership, the Commission alleged that Grifols S.A.'s proposed acquisition of Biotest U.S. Corporation would likely have enabled the combined firm to decrease fees paid to blood plasma donors and required Grifols to divest certain assets as a condition of the acquisition. *See* Complaint, *In the Matter of Grifols S.A. and Grifols Shared Services North America, Inc.* (Aug. 1, 2018). Finally, I note that prior to my arrival at the Commission, Chair Khan and Commissioner Slaughter sounded the alarm on labor concerns in the abandoned merger between Lifespan Corporation and Care New England Health System stating that, in addition to allegations contained in staff's complaint, they would have also supported an allegation on labor grounds. See Concurring Statement of Comm'r Rebecca Kelly Slaughter and Chair Lina M. Khan Regarding *FTC and State of Rhode Island* v. *Lifespan Corporation and Care New England Health System*, Fed. Trade Comm'n (Feb. 17, 2022), *https://www.ftc.gov/system/files/ftc_gov/pdf/public_statement_of_commr_slaughter_chair_khan_re_lifespancne_redacted.pdf.*

Statement of Commissioner Melissa Holyoak

I. Introduction

The Commission issued its notice of proposed rulemaking for the Premerger Notification, Reporting and Waiting Period Requirements which implements the Hart-Scott-Rodino Antitrust Improvements Act (''NPRM'') on June 29, 2023.[1] The contents of the NPRM were harrowing and generated (justifiably) substantial outcry from many commentors. Many of the contemplated filing requirements, if implemented, would have been beyond the Commission's legal authority, arbitrary and capricious, unjustifiably burdensome, and just plain bad policy.[2]

The Commission worked together on the monumental task of modifying the NPRM into the Final Rule,[3] ensuring the Final Rule does not suffer from the many legitimate criticisms raised by the commentors. The Final Rule modifies many provisions in the NPRM while taking great care to avoid unduly burdening merging parties or chilling the many procompetitive transactions that happen each year. To be clear, this Final Rule does not align exactly with my preferences. But I have worked to curb the excesses of the NPRM in meaningful ways that would not have happened absent my support. These significant modifications resulted in a Final Rule that is not only consistent with the agencies' statutory grant of authority but will also close certain informational gaps that affect the agencies' ability to conduct effective premerger screening.

Commissioner Ferguson, in section III of his statement, describes in detail the

[1] Premerger Notification; Reporting and Waiting Period Requirements, 88 FR 42178 (proposed Jun. 29, 2023) (to be codified at 16 CFR parts 801 and 803) (hereinafter NPRM).

[2] Out of the gate, the NPRM made broad assertions about increasing concentration as a justification for the unprecedented and wide-sweeping proposed changes. NPRM, *supra* note 1, at 42179. The concentration literature upon which it relied, *id.* at 42179 n.7, however, has been heavily criticized and debunked. *See, e.g.,* Chad Syverson, *Macroeconomics and Market Power: Context, Implications, and Open Questions,* 33 J. Econ. Perspectives 23 (2019); Carl Shapiro, *Antitrust in a Time of Populism,* 61 Int'l J. Indus. Org. 714 (2018); Gregory J. Werden & Luke M. Froeb, *Don't Panic: A Guide to Claims of Increasing Concentration*, Antitrust Magazine, Fall 2018. Most notably, the literature cited by the NPRM does not use well-defined antitrust markets in its assessment or conclusions. Further, even if increasing concentration had been a reality, it only has a limited role in analyzing competitive effects. *See infra* note 57.

[3] Fed. Trade Comm'n, Premerger Notification; Reporting and Waiting Period Requirements, Final Rule (Oct. 3, 2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/p110014hsrfinalrule.pdf* (hereinafter Final Rule).

benefits of certain provisions that the Commission included in the Final Rule. These provisions that he describes fill information gaps in the agencies' current ability to fulfill their missions under the HSR Act. I agree with Commissioner's Fergusson's assessments and applaud the Commission's efforts to include these new requests in the Final Rule.

Simultaneous with today's issuance of the Final Rule, the Commission has also announced that it will lift its suspension of early termination when the Final Rule takes full effect. The suspension itself has been in place for more than three-and-a-half years, even though the suspension was supposed to be ''temporary'' and ''brief.'' [4] I have been baffled by this unjustified delay and disappointed that it took the promulgation of this Final Rule to lift the suspension of early termination. One of the virtues of the Final Rule is that certain provisions will allow staff to more quickly identify which mergers should receive early termination, a significant benefit to both staff and merging parties. So I guess late is better than never.

For the remainder of my statement, I write to demonstrate the dramatic differences between this Final Rule and the proposed rule set forth in the NPRM, and also to elaborate on some of the changes, in addition to lifting the early termination suspension, that drove my decision to vote in favor of the Final Rule. My overview of the Final Rule is not a substitute to the text of the Final Rule or the analysis in the Statement of Basis and Purpose (''SBP''),[5] both of which should be consulted by all filers.

Of the twenty-nine primary proposals in the NPRM, ten were rejected entirely, including, among others, the request for labor information, the obligation to produce draft transaction documents, and the requirements to create organizational charts. Of the remaining nineteen proposals, the Final Rule includes just two without modification; we have made meaningful changes to the other seventeen requirements.

TABLE 1—REJECTED PROPOSALS

NPRM provision	Results in final rule
Labor Market/Employee Information	Proposal rejected.
Drafts of Transaction-Related Documents	Proposal rejected.
Organizational Chart of Authors and Recipients	Proposal rejected.
Other Types of Interest Holders that May Exert Influence	Proposal rejected.
Expand Current 4(d)(iii) to Include Financial Projections to Synergies and Efficiencies	Proposal rejected.
Deal Timeline	Proposal rejected.
Provision of Geolocation Information	Proposal rejected.
Identification of Messaging Systems	Proposal rejected.
Litigation Hold Certification Language	Proposal rejected.
Identification of F/K/A Names	Proposal rejected.

For example, the prior acquisition proposal that called for ten years of prior acquisitions without any size threshold was reversed in the Final Rule to request only five years of acquisitions, and reinstated the $10 million threshold—returning to the time period adopted in 1987 [6] and dollar threshold that had existed since the original rules in 1978.[7] The NPRM proposal that would have required the filers to identify and produce all agreements between the merging parties has been modified significantly in the Final Rule to simply require the filers to check boxes to indicate whether they have a few types of agreements between them—nothing has to be produced or described. The Final Rule similarly modifies the NPRM's overlap and supply ''narratives'' to require only ''brief'' descriptions instead. And, among other revisions, the Final Rule's overlap and supply descriptions requirement makes clear that antitrust analysis is not required.

Further, many of the modifications exempt ''Select 801.30 Transactions'' from having to report certain information required by the Final Rule. Select 801.30 Transactions are acquisitions of third parties' voting securities where the acquirer does not gain control, no agreements between the acquiring and acquired person govern the transaction, and the acquiror does not have the ability to appoint or serve on a board.[8] The Final Rule likewise exempts transactions where there is no horizontal overlap or supply relationship from certain information requirements, and sets a *de minimis* threshold to exclude the requirement to describe supply relationships where the sale or purchase of the product, service, or asset represents less than $10 million in revenue in the most recent year. Table 2 highlights some of the main modifications that have been made in the Final Rule (again, this list is not exhaustive and does not substitute for the text of the Final Rule).

[4] Press Release, Fed. Trade Comm'n, FTC, DOJ Temporarily Suspend Discretionary Practice of Early Termination (Feb. 4, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/02/ftc-doj-temporarily-suspend-discretionary-practice-early-termination.*

[5] Fed. Trade Comm'n, 16 CFR parts 801 and 803, Premerger Notification; Reporting and Waiting Period Requirements, Statement of Basis and Purpose (Oct. 3, 2024) (hereinafter SBP).

[6] 52 FR 7066 at 7078 (Mar. 6, 1987) (''[The Commission] believes that this change can be made without harming the agencies' ability to conduct a thorough antitrust review since an account of the acquiring person's acquisitions over the past five years will give adequate notice of possible trends toward concentration.'').

[7] 43 FR 33450 at 33534 (July 31, 1978) (''The item permits the omission of prior transactions that did not involve the acquisition of more than 50 percent of the voting securities or assets of a person with preacquisition sales or assets of $10 million, since smaller acquisitions are likely to be less significant from an antitrust standpoint.''). Unlike prior iterations of the rules, the Final Rule does require the acquired entity to also identify prior acquisitions and clarified that an acquisition of ''all or substantially all'' of the assets of a business must be reported.

[8] The Final Rule defines Select 801.30 Transactions as ''[a] transaction to which § 801.30 applies and where (1) the acquisition would not confer control, (2) there is no agreement (or contemplated agreement) between any entity within the acquiring person and any entity within the acquired person governing any aspect of the transaction, and (3) the acquiring person does not have, and will not obtain, the right to serve as, appoint, veto, or approve board members, or members of any similar body, of any entity within the acquired person or the general partner or management company of any entity within the acquired person. Executive compensation transactions also qualify as select 801.30 transactions.'' 16 CFR part 803, appendix B at 1.

TABLE 2—SELECT MODIFIED NPRM PROPOSALS

NPRM provision	Select modification in final rule
Prior Acquisitions [9]	Among others, retain the five-year lookback and $10 million sales/assets threshold that existed in prior iterations of the HSR rules.
Other Agreements Between the Parties [10]	Among others, filers are not required to produce or describe agreements between the parties; instead, they must only, via checkbox, identify types of agreements between them, if any.
Officers, Directors, and Board Observers [11]	Among others, (1) exclude reporting on board observers; (2) limit to acquiring person only; (4) limit to officers/directors of entities in overlap industries as described by the text of the Final Rule.
4(c) Documents by/for Supervisory Deal Team Lead(s) [12]	Limit to only apply to *one* individual (*not* the plural ''leads'' like in the NPRM) supervisory deal team lead, as defined in the text of the Final Rule.
Supply Relationships [13]	Among others, (1) require only ''brief'' descriptions rather than a narrative; (2) exclude ''Select 801.30 Transactions''; (3) impose a *de minimis* threshold and (4) limit descriptions to a business assessment rather than an antitrust analysis (*see* SBP).
Overlap Products and Services [14]	Among others, (1) require only ''brief'' descriptions rather than a narrative; (2) exclude ''Select 801.30 Transactions''; and (3) limit description to a business assessment rather than an antitrust analysis (*see* SBP).
Ordinary Course Documents (Periodic Plans and Reports) [15]	Among others, limit to exclude ''Select 801.30 Transactions'' and limited to only require documents provided to Chief Executive Officers.
Identification of Limited Partners [16]	Among others, limit disclosure requirements for limited partners who do not have management rights.
Description of Entity Structures and Organizational Chart for Funds and MLPs [17].	Among others, eliminate requirement to create an organizational chart.
Transaction Diagram [18]	Among others, exclude ''Select 801.30 Transactions'' and only necessary if diagrams previously existed (*i.e.,* no need to create diagrams).
Mandatory Identification of Foreign Jurisdiction Reporting by Both Parties [19].	Limit to acquiring person.
Requiring a draft agreement or term sheet and transaction specific agreements for filings on non-definitive agreements [20].	Clarify scope and provide more details about the information required.
Transaction Rationale [21]	Among others, exclude ''Select 801.30 Transactions.''
Voluntary Waivers for State AGs and International Enforcers [22]	Allow filers to voluntarily check two separate boxes that would permit certain disclosures.
Defense or Intelligence Contracts [23]	Among others, limit to contracts generating $100 million or more of revenue and only if there is an Overlap or Supply Relationship.
Document Log Requirements [24]	Among others, limit requirement to identify authors to certain and limited circumstances.
Adjustments to NAICS revenue reporting [25]	Modified to limit scope.

Notably, only two of the main proposals in the NPRM were adopted without modification: the requirements to translate foreign-language documents and to report subsidies from foreign entities of concern, which was mandated by the Merger Filing Fee Modernization Act of 2022.[26] All other proposals were rejected or significantly modified. Taken together, the dramatic revisions to the proposed rule set forth in the NPRM result in a Final Rule that I can support. The decisions made to scale back the proposed requirements in the NPRM will limit burden, aligns the Final Rule with the Commission's legal authority under the HSR Act, and is tailored to address information gaps that have hampered the agencies' premerger review.[27]

Sections II through IV of my statement explain why three proposals in the NPRM were especially problematic to me, and why their elimination or substantial revision was critical to my vote on this Final Rule: (II) Labor Market/Employee Information, (III) Drafts of Transaction-Related Documents, and (IV) Ten Years of Prior Acquisitions Without any Size Thresholds. To be clear, by focusing on these three proposals I do not mean to diminish the importance of the other changes reflected in the Final Rule. Each of the many revisions that scaled back the proposed requirements in the NPRM contributed to my vote to issue the Final Rule. Finally, I discuss in section V some additional considerations that led me to support the Final Rule, including important limitations in the Final Rule that ensure

[9] *See* Final Rule, *supra* note 3, Acquiring Person Instructions, at 14–15.

[10] *See id.* at 9.

[11] *See id.* at 5.

[12] *See id.* at 1.

[13] *See id.* at 10.

[14] *See id.* at 9–10.

[15] *See id.* at 9.

[16] *See id.* at 4–5.

[17] *See id.* at 5.

[18] *See id.* at 8.

[19] *Compare id.* at 7 (requiring disclosure for acquiring person) with Final Rule, *supra* note 3, Acquired Person Instructions (not requiring disclosure of transactions subject to international antitrust notification).

[20] *See* Final Rule, *supra* note 3, Acquiring Person Instructions, at 9.

[21] *See id.* at 8.

[22] *See id.* at 15–16.

[23] *See id.* at 15.

[24] *See id.* at 2.

[25] *See id.* at 10–11.

[26] *See* 15 U.S.C. 18b (requiring the Commission to promulgate a rule requiring HSR filings to include information on subsidies received from certain foreign governments or entities that are identified as foreign entities of concern); Consolidated Appropriations Act, 2023, Public Law 117–328 (2023) (reflecting the appropriations bill that included the Merger Filing Fee Modernization Act of 2022).

[27] The incremental burden estimated in the NPRM decreased from 107 hours to only 68 hours in the Final Rule, a result that was critical to my decision. NPRM, *supra* note 1, at 42208 (reporting 107 incremental hours); SBP, *supra* note 3, at section VIII, 386 of 406 (reporting 68 incremental hours).

the Final Rule will not result in fishing expeditions.

Before proceeding, I want to discuss the Commission's authority to issue today's Final Rule, an issue that is critical to me as a Commissioner.[28] The HSR Act obligates the Commission, ''with the concurrence of the Assistant Attorney General,'' to issue rules that require information to be submitted in HSR filings that will ''be in such form and contain such documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable the Federal Trade Commission and the Assistant Attorney General to determine whether such acquisition may, if consummated, violate the antitrust laws.'' [29] While this mandate affords some discretion to the Commission, this discretion is not unbounded. Critically, Congress did not give the Commission authority to promulgate rules to gather information generally, or to merely heap burden upon merging parties in an effort to dissuade acquisitions. Rather, the Act explains that the purpose of HSR filings, and the rules determining the content of filings, is for the agencies ''to determine whether such acquisition may, if consummated, violate the antitrust laws.'' [30] Many proposals in the NPRM—including the three discussed below—have been rejected or substantially modified to ensure the Final Rule includes only new requirements that are consistent with the text and structure of the HSR Act.

II. Labor Market Information

The NPRM contained many problematic proposals. Chief among them was its proposal to collect information from filers about labor markets.[31] As proposed, filers would report three different types of information related to labor:

- ''Largest Employee Classifications[:] Provide the aggregate number of employees . . . for each of the five largest occupational categories'' based upon 6-digit SOC classifications; [32]
- ''Geographic Market Information for Each Overlapping Employee Classification[:] Indicate the five largest 6-digit SOC codes in which both parties . . . employ workers [and also provide] each ERS commuting zone in which both parties employ workers with the 6-digit classification and provide the aggregate number of classified employees in each ERS commuting zone; and'' [33]
- ''Worker and Workplace Safety Information[:] Identify any penalties or findings issued against the filing person by the U.S. Department of Labor's Wage and Hour Division (WHD), the National Labor Relations Board (NLRB), or the Occupational Safety and Health Administration (OSHA) in the last five years and/or any pending WHD, NLRB, or OSHA matters.'' [34]

All three of these requirements (''Labor Proposal'') were completely rejected in the Final Rule. Chair Khan asserts in her statement that ''the Final Rule pares back some of the labor market requirements.'' [35] Despite this confusing statement, the text of the Final Rule makes clear that all (not ''some'') of the labor requirements have been fully removed (not ''pare[d] back''). And for good reason. Despite repeated and extensive efforts to make harm in labor markets a standard component of merger enforcement, no evidence exists to justify including the Labor Proposal in the Final Rule. Accordingly, the Labor Proposal was rightfully excluded from the Final Rule and, absent new evidence, has no place in any future rulemaking that the Commission may contemplate.

To be sure, a merger may theoretically create anticompetitive effects in a relevant labor market.[36] A post-merger entity might, for example, be able to lower wages for workers when the merger eliminates a critical employment option for workers. Such a scenario is more likely when the merger involves specialized workers who may have fewer comparable alternatives than less skilled workers.[37] Theory aside, the Labor Proposal would have asked for information generally unhelpful for determining whether an acquisition violates the antitrust laws.

First, the ''worker and workplace safety information'' would have provided no measurable benefit to the agency in its initial determination of whether the proposed merger violates the antitrust laws. To support burdening all filers with providing this information, the NPRM asserted that ''[i]f a firm has a history of labor law violations, it may be indicative of a concentrated labor market where workers do not have the ability to easily find another job.'' [38] No evidence, empirical or otherwise, was presented to support this assertion. And I am not aware of any supportive literature and have never seen a court opinion that suggests such evidence indicates competitive harm from a merger under section 7 of the Clayton Act (or any other antitrust violation under the Sherman Act or otherwise). Instead, this proposal seems like an overt way to harass firms with any workplace failure under the guise of an antitrust investigation. As the Supreme Court observed, ''[e]ven an act of pure malice by one business competitor against another does not, without more, state a claim under the [F]ederal antitrust laws; those laws do not create a [F]ederal law of unfair competition or 'purport to afford remedies for all torts committed by or against persons engaged in interstate commerce.' '' [39] We simply do not have authority under the HSR Act to require filers to submit information about workplace safety.

Second, the proposed request for Standard Occupational Classification (''SOC'') codes would have been of—at most—limited value because SOC codes by themselves are not sufficient to define a relevant labor market for antitrust purposes.[40] Phrased differently, they are not tethered to the hypothetical monopolist test which has been applied by the agencies and courts in various iterations of the merger guidelines for decades.[41] Depending on the merger, SOC codes may be too broad

[28] *See, e.g.,* Dissenting Statement of Commissioner Melissa Holyoak, Joined by Commissioner Andrew N. Ferguson, *In the Matter of the Non-Compete Clause Rule,* Matter Number P201200 (June 28, 2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/2024-6-28-commissioner-holyoak-nc.pdf.*

[29] 15 U.S.C. 18a(d).

[30] *Id.* (emphasis added).

[31] NPRM, *supra* note 1, at 42197.

[32] *Id.* at 42215. SOC codes are ''Standard Occupational Classification'' codes used by the Bureau of Labor Statistics of the Department of Labor. *See id.* at 42210.

[33] *Id.* at 42215.

[34] *Id.* Filers also had to provide, ''[f]or each identified penalty or finding . . . (1) the decision or issuance date, (2) the case number, (3) the JD number (for NLRB only), and (4) a description of the penalty and/or finding.'' *Id.*

[35] Statement of Chair Lina M. Khan, Regarding The Final Premerger Notification Form and the Hart-Scott-Rodino Rules, Commission File No. P239300, and Regarding the FY2023 HSR Annual Report to Congress Commission File No. P859910 at 5–6 (Oct. 3, 2024) (hereinafter Statement of Chair Khan).

[36] Ioana Marinescu & Herbert J. Hovenkamp, *Anticompetitive Mergers in Labor Markets,* 94 Ind. L.J. 1031, 1032 (2019).

[37] *Id.* at 1038.

[38] NPRM, *supra* note 1, at 42198.

[39] *Brooke Grp. Ltd.* v. *Brown & Williamson Tobacco Corp.,* 509 U.S. 209, 225 (1993) (quoting *Hunt* v. *Crumboch,* 325 U.S. 821, 826 (1945)); *cf. Rambus Inc.* v. *FTC,* 522 F.3d 456, 464 (D.C. Cir. 2008) (''Deceptive conduct—like any other kind—must have an anticompetitive effect in order to form the basis of a monopolization claim. 'Even an act of pure malice by one business competitor against another does not, without more, state a claim under the [F]ederal antitrust laws,' without proof of 'a dangerous probability that [the defendant] would monopolize a particular market.' '' (alteration in original) (quoting *Brooke Grp.,* 509 U.S. at 225)).

[40] *See Comment of U.S. Chamber of Com.,* Doc. No. FTC–2023–0040–0684 at 34 (hereinafter *U.S. Chamber Comment*) (''The data sought by the proposed rules defines labor markets imprecisely at best.'').

[41] *See Fed. Trade Comm'n* v. *Advoc. Health Care Network,* 841 F.3d 460, 468–70 (7th Cir. 2016) (using the hypothetical monopolist test to inform market definition); *Fed. Trade Comm'n* v. *Hackensack Meridian Health, Inc.,* 30 F.4th 160, 167 (3d Cir. 2022) (similar).

to accurately assess labor competition,[42] limiting their predictive value for assessing competitive harm. The NPRM itself appeared to acknowledge the limited value of SOC codes: ''[t]he use of [SOC] codes as a screening tool is not intended to endorse their use for any other purpose, such as defining a relevant labor market.'' [43] In fact, just a few examples demonstrate the limited value SOC codes would provide to the Commission:

Attorneys working across diverse areas of expertise are broken down into attorneys (23–1011 Lawyers) and . . . well, attorneys, although there is a separate category for Judges, Magistrate Judges, and Magistrates (23–1023), who are likely lawyers, too. To paraphrase Shakespeare (or a character in ''Henry VI, Part 2''), let's kill all the widgets.

To the best of my recollection, the agencies tend to slice the professional salami a little thinner than that when hiring staff.

Physicians fare a little better, although 10 categories of specialist physicians, plus ''family medicine physicians'' and ''physicians, all other'' leave out some specialties (like, say, surgery and ophthalmology) and make no room for subspecialties, which might be of interest if you're hiring a cardiothoracic surgeon to do a quad bypass or an orthopedic surgeon to do a hip replacement (or both, but you care which surgeon does which procedure).[44]

Third, the agencies have not relied upon the Economic Research Service (''ERS'') commuting zones to allege a relevant labor market,[45] and based upon this limited experience, they cannot be considered sufficiently applicable to require all filers to provide the ERS data proposed by the NPRM. Further, the NPRM proposal on ERS commuting zones relied upon data from 2000—yes, 24-year-old data—even though more recent iterations are available.[46] And newer data confirm that the older data fail to reflect current market realities, including the widespread transition to telework.[47] Given that there is no evidence that forcing all filers to provide the proposed labor market information would assist the agencies in determining whether the filed-for acquisition violates the antitrust laws, the Commission lacks authority to request the information under the HSR Act.

Even if one were to assume that the agencies had the authority to request the proposed labor market information, it was nonetheless properly excluded from the Final Rule because it was a solution in search of a nonexistent problem. The agencies have never brought a standalone labor challenge to an acquisition.[48] And this is not for lack of trying. Officials at the Commission,[49] Department of Justice,[50] and State enforcers [51] have stated their desire to focus on harms to the labor market, especially in mergers, since at least 2018, but the expended resources so far have been to no avail.

Granted, the Commission has included tagalong labor claims in addition to traditional theories of harm.[52] And, in a press release, the Commission has taken credit for protecting against harms in the labor market even though the actual complaint being announced by the press release did not allege harm in a labor market.[53] But these few and obscure outliers do not justify the widespread proposal to include labor market information in the Final Rule, especially information (*e.g.,* SOC codes) that has never been used in any of the agencies' filings (litigated or otherwise).

Moreover, the NPRM did not identify any economics literature that justified the request for labor information.[54] As explained by Albrecht *et al.:*

[D]espite growing interest in the use of antitrust law to address labor monopsony, such efforts are not supported by empirical and theoretical foundations sufficient to bear the weight of these galvanized efforts . . . .

Empirical data concerning the magnitude and impact of labor monopsonies is

[42] *E.g.,* Jose Azar et al., *Concentration in US Labor Markets: Evidence from Online Vacancy Data,* 66 Labor Econ. 101886, 5 (2020). (''[T]he 6-digit SOC is too broad of a market according to the [small significant non-transitory reduction in wage test].'').

[43] NPRM, *supra* note 1, at 42197; *see Comment of International Center for Law & Economics,* Doc. No. FTC–2023–0040–698 at 15 (''Given the systematic misfit between the proposed 'Labor Markets' section and any actual labor markets, given the agencies lack of experience in analyzing the local labor-market effects of proposed mergers, and given the hard questions of when or under what conditions such labor-market effects might be both material and unlikely to covary with product-market effects, we suggest that the screening utility of the new information remains unclear.'').

[44] Daniel J. Gilman, *Antitrust at the Agencies Roundup: Kill all the Widgets Edition,* Truth on the Market (Aug. 4, 2023), *https://truthonthemarket.com/2023/08/04/antitrust-at-the-agencies-roundup-kill-all-the-widgets-edition/* (ellipses in original).

[45] The Commission did not use SOC codes or ERS commuting zones in their complaint allegations that reference concerns in labor markets in its recent litigations. *See* Compl., *In re Tapestry, Inc., & Capri Holdings Ltd.,* No. 9429 (F.T.C. Apr. 22, 2024); *see* Compl., *In re The Kroger Co. & Albertsons Cos., Inc.,* No. D–9428 (F.T.C. Feb. 26, 2024). And the DOJ did not rely upon ERS commuting zones in *United States* v. *Bertelsmann SE & Co. KGaA See* Compl., *United States* v. *Bertelsmann SE & Co. KGaA,* 646 F. Supp. 3d 1 (D.D.C. 2022); see also *infra* note 48 (explaining why *Bertelsmann* is not properly considered a case about harm in a labor market, but rather a monopsony input case).

[46] *Comment of Wachtell, Lipton, Rosen & Katz,* Doc. No. FTC–2023–0040–0670 at 8.

[47] *Id.*

[48] Some have considered *United States* v. *Bertelsmann SE & Co. KGaA,* 646 F. Supp. 3d 1, 1 (D.D.C. 2022) to be a labor-market case. I disagree. On balance, this was more of a traditional monopsony input case. *Id.* The primary concern was whether there would be sufficient outlets for best-selling books. *Id.* I am also unaware of merger challenges by private parties where the plaintiffs alleged harm in a labor market. *See* Suresh Naidu et al., *Antitrust Remedies for Labor Market Power,* 132 Harv. L. Rev. 536, 571 (2018) (''[W]e [have not] found a reported case in which a court found that a merger resulted in illegal labor market concentration.''). The Commission, as reflected in the SBP, also classifies *Bertelsmann* as an input monopsony case. SBP, *supra* note 5, at section II.B.2, 32 of 406.

[49] *See* Testimony of Fed. Trade Comm'n Chair Joseph Simons, US Congress, *Oversight of the Enforcement of the Antitrust Laws,* Senate Judiciary Committee, 2018, available at *https://www.judiciary.senate.gov/meetings/10/03/2018/oversight-of-the-enforcement-of-the-antitrust-laws* (staff instructed to ''look for potential effects on the labor market with every merger they review'').

[50] Assistant Attorney General Makan Delrahim, Remarks at the Public Workshop on Competition in Labor Markets 3 (Sept. 23, 2019), *https://www.justice.gov/opa/speech/assistant-attorney-general-makan-delrahim-delivers-remarks-public-workshop-competition* (''With respect to mergers, the Division also has challenged transactions where the merged firm would likely have the ability to depress reimbursement rates to physicians, including the Anthem/Cigna merger challenge.''); *Counsel to the Assistant Attorney General of the Antitrust Division Doha Mekki Testifies Before House Judiciary Committee on Antitrust and Economic Opportunity: Competition in Labor Markets* (Oct. 29, 2019), available at *https://www.justice.gov/opa/speech/counsel-assistant-attorney-general-antitrust-division-doha-mekki-testifies-house* (''[L]abor competition issues are a high priority for Assistant Attorney General Delrahim and for the Antitrust Division. We have devoted significant resources to enforcement and advocacy in this area recently.''); *id.* (''The Division has also been busy developing and implementing screens to help agency staff detect mergers that are likely to create or enhance monopsony power in labor markets. Over the last 18 months, the Division has developed important new specifications for Second Requests and Civil Investigative Demands to determine whether a transaction will create or enhance labor monopsony. Moreover, the Division has leveraged improved search and review technology to identify labor competition concerns in merger and non-merger investigations.'').

[51] Testimony of Rahul Rao before Subcommittee on Antitrust, Commercial and Administrative Law of the Committee on the Judiciary, U.S. Hours of Rep. (Oct. 29, 2019), available at *https://www.govinfo.gov/content/pkg/CHRG-116hhrg45126/html/CHRG-116hhrg45126.htm.* (''Labor is an input, and it is a critical input. It's one that directly affects people's lives in that, when there's a monopoly power, the effect is increase in prices for consumers. When there is monopsony power of a dominant buyer, it decreases wages for workers.'').

[52] *See* Compl., *In re The Kroger Company and Albertsons Companies, Inc.,* No. D–9428 (F.T.C. Feb. 26, 2024).

[53] *See* Press Release, Fed. Trade Comm'n, *FTC Moves to Block Tempur Sealy's Acquisition of Mattress Firm* (Jul. 2, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-moves-block-tempur-sealys-acquisition-mattress-firm* (stating that ''[t]his deal isn't about creating efficiencies; it's about crippling the competition, which . . . could lead to layoffs for good paying American manufacturing jobs in nearly a dozen States,'' even though nothing in the complaint suggests any harm in the labor markets); *see also* Compl. *In re* Tapestry, Inc., and Capri Holdings Limited, No. 9429 (F.T.C. Apr. 22, 2024) (discussing labor issues but not alleging violations of the law based upon harm in labor markets).

[54] *See* NPRM, *supra* note 1, at 42197–98.

inconsistent. Evidence on the extent of labor-market power is mixed, with studies reaching divergent conclusions depending on the data, methodology, and markets analyzed.[55]

The NPRM also asserted that alleged increases in concentration justified its proposals, including its proposal for labor information.[56] While concentration levels may have a role in antitrust enforcement (*e.g.,* merger presumptions), general and imprecise observations of increased concentration are a slender reed upon which to base such a significant expansion of HSR authority.[57] These limitations also apply in the labor context. ''Many factors other than concentration can affect wages, such as differences in firm productivity, local labor-market conditions (*e.g.,* urban vs. rural), and institutional factors like unionization rates.'' [58] Further, as explained by Berry *et al.:*

> A main difficulty in [the monopsony power literature] is that most of the existing studies of monopsony and wages follow the structure-conduct-performance paradigm; that is, they argue that greater concentration of employers can be applied to labor markets and then proceed to estimate regressions of wages on measures of concentration. [S]tudies like this may provide some interesting descriptions of concentration and wages but are not ultimately informative about whether monopsony power has grown and is depressing wages.[59]

In short, the economic literature does not provide any conclusive evidence on the viability or likelihood of merger harms in labor markets that would justify the NPRM's proposals regarding labor information.

Finally, the Commission's HSR rulemaking authority does not extend to heaping burdens upon merging parties as a fishing expedition in the hopes of developing new merger enforcement theories. Instead, if labor market concerns exist, then the Commission should conduct merger retrospectives or utilize its 6(b) authority to investigate the issue. The Commission has done neither, and it cannot rely on the need for general information gathering as a basis for demanding that all merging parties provide this information.

And no doubt, the NPRM's proposal would have come with a substantial and unjustifiable burden upon filers and also the agencies. First, firms do not typically maintain SOC codes in the ordinary course of business.[60] Investing in the expertise to generate and report the codes would have required substantial resources.[61] And smaller businesses who make filings infrequently will be particularly disadvantaged compared to frequent filers. Second, the agencies' staff would have borne the burden of this additional information. Staff have limited experience working with SOC codes, and utilizing the data would have required aid from already extremely overtaxed economist staffers. But shifting resources has an opportunity cost, particularly when Congress has flatlined our budget, significantly limiting staff's capacity to take on new work.[62] Thus it is unclear how the Commission would have found resources to utilize the information. This substantial, unjustified burden to filers and the agencies made it impossible for me to support any rule that included the Labor Proposal.

As a final comment on the Labor Proposal, I recognize that excising it from the Final Rule may not have been the desired outcome for some of my colleagues on the Commission.[63] I

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[55] Brian C. Albrecht et al., Labor Monopsony and Antitrust Enforcement: A Cautionary Tale, ICLE White Paper No. 2024–05–01 at 1 (2024); *see also* Suresh Naidu et al., *Antitrust Remedies for Labor Market Power,* 132 Harv. L. Rev. 536 (2018) (''[W]e have not found a reported case in which a court found that a merger resulted in illegal labor market concentration.''). I also note that a variety of articles sometimes cited to support increased antitrust scrutiny in labor markets fail to justify imposing a request for labor information in HSR filings—nor does the literature necessarily support broader enforcement of antitrust laws in labor markets. *See* Anna Stansbury & Lawrence H. Summers, ''The Declining Worker Power Hypothesis: An Explanation for the Recent Evolution of the American Economy'' at 1 (Nat'l Bureau of Econ. Rsch., Working Paper No. 27193, 2020), *https://www.nber.org/papers/w27193* (identifying decreased ability to unionize, *not* monopsony power, as the source of declining labor share of income); David Berger et al., *Labor Market Power,* 112 Am. Econ. Rev. 1147 (2022) (at 1 in SSRN version) (''[We] conclude that changes in labor market concentration are unlikely to have contributed to the declining labor share in the United States.''); Chen Yeh at al., *Monopsony in the US Labor Market,* 112 Am. Econ. Rev. 2099, 2099 (2022) (''[T]he growing gap between worker pay and productivity might be more about technological change than about employers' bargaining power—a very different issue than the monopsony problem that antitrust law could (potentially) address.''); *id.* (''[T]he correlation between markdowns and employment concentration is quite modest, both cross-sectionally (across local labor markets) and in the aggregate over time.''); *id.* at 2125 (''[A]t least within manufacturing—cross-sectional and temporal variation in local employment concentration may not necessarily reflect variation in employer market power as measured by markdowns.''); David Arnold, *Mergers and Acquisitions, Local Labor Market Concentration, and Worker Outcomes* at 2 (Oct. 29, 2021) (''The evidence . . . does not support the conclusion that lack of antitrust scrutiny for labor markets has been a major contributor to labor market trends such as the falling labor share or stagnant wage growth. Most mergers do not generate large shifts in concentration and I find no evidence that the number of anticompetitive mergers in labor markets has been increasing over time.''); Elena Prager & Matt Schmitt, *Employer Consolidation and Wages: Evidence from Hospitals,* 111 Am. Econ. Rev. 397, 397 (2021) (''For unskilled workers, we do not find evidence of differences in wage growth post-merger, irrespective of the change in employer concentration induced by the merger.'').

[56] NPRM, *supra* note 1, at 42179 (''This concentration may reflect decreased competition, which can result in higher prices for consumers, decreased innovation, reduction in output, and *lower wages for workers.*'' (emphasis added))

[57] *See* Carl Shapiro, *Protecting Competition in the American Economy: Merger Control, Tech Titans, Labor Markets,* 33 J. Econ. Persp. 69, 75–76 (2019) (increased concentration ''does not prove that competition in that market has declined.''); Carl Shapiro, *Antitrust in a Time of Populism,* 61 Int'l J. Indus. Org. 714, 722–23 (2018) (''Sheer size and market power are just not the same thing.''); Dennis W. Carlton & Jeffrey M. Perloff, Modern Industrial Organization 268 (4th ed. 2005) (''[P]erhaps the most significant criticism is that concentration itself is determined by the economic conditions of the industry and hence is not an industry characteristic that can be used to explain pricing or other conduct.''); Timothy J. Muris, *Improving the Economic Foundations of Competition Policy,* 12 Geo. Mason L. Rev. 1, 10 (2003) (''The [structural] paradigm was overturned because its empirical support evaporated.''); Fiona Scott Morton, *Modern U.S. Antitrust Theory and Evidence Amid Rising Concerns of Market Power and Its Effects,* Wash. Ctr. for Equitable Growth at 24 (May 29, 2019) (''[I]t is widely understood that either vigorous competition could cause concentration to increase or increased concentration could reduce competition.''); Cristina Caffarra & Serge Moresi, *Issues and Significance Beyond U.S. Enforcement,* Mlex Magazine, Apr.–June 2010, at 41, 42–43 (''Most economists would agree that market shares and the HHI often are poor indicators of market power.''); Herbert Hovenkamp, *The Looming Crisis in Antitrust Economics,* 101 Boston Univ. L. Rev. 489 (2021) (''The pursuit of business concentration or bigness for its own sake will injure consumers far more than it benefits small business, the intended beneficiaries.''); Timothy F. Bresnahan & Peter C. Reiss, *Entry and Competition in Concentrated Markets,* 99 J. Pol. Econ. 977, 978 (1991) (''[O]nce a market has between three and five firms, the next entrant has little effect on competitive conduct . . . . These data show that prices fall when the second and third firms enter and then level off.''); Albrecht et al, *supra* note 55 at 17 n.76 (providing additional supporting citations).

[58] Albrecht et al., *supra* note 55 at 17.

[59] *Id.* at 18 (quoting Steven Berry, Martin Gaynor, & Fiona Scott Morton, *Do Increasing Markups Matter? Lessons from Empirical Industrial Organization,* 33 J. Econ. Persp. 44, 57 (2019)).

[60] *See, e.g., Comment of Wachtell, Lipton, Rosen & Katz,* Doc. No. FTC–2023–0040–0670 at 8.

[61] Comment of *American Bar Association's Antitrust Law Section,* Doc. No. FTC–2023–0040–0723 at 10–12.

[62] Given current budgetary constraints at the Commission and reduced hiring, this is unlikely to change either. Fed. Trade Comm'n, *FTC Appropriation and Full-Time Equivalent (FTE) History,* available at *https://www.ftc.gov/about-ftc/bureaus-offices/office-executive-director/financial-management-office/ftc-appropriation* (demonstrating that the FTC budget went down from 2023 to 2024); Caroline Nihill, *FTC Modernization, Enforcement Efforts Jeopardized by Cuts, Officials Say,* FedScoop (Jul. 10, 2024) (''Commissioner Rebecca Slaughter noted that proposed fiscal year 2025 budget cuts would result in the agency passing 'up important investigations and enforcement matters' in addition to considering furloughs and workforce reductions.''); *see also* Statement of Chair Khan, *supra* note 35, at 5–6.

[63] *See* Statement of Chair Khan, *supra* note 35, at 3–4; *see generally* Statement of Commissioner Alvaro M. Bedoya, Joined by Chair Lina M. Khan and Commissioner Rebecca Kelly Slaughter,

nonetheless commend them for agreeing to this unanimous outcome, and I am equally pleased that the Chair rescinded the most recent Memorandum of Understanding Related to Antitrust Review of Labor Issues in Merger Investigations.[64] These efforts reflect an evolution in thinking by the Commission toward evidence over rhetoric.[65]

III. Drafts of Transaction-Related Documents

Historically, filers have not been required to provide drafts of transaction-related documents with their filings.[66] The production and review of drafts typically occurs during a full-phase investigation, usually after the reviewing agency issues a second request.[67] The NPRM proposed abandoning this practice and requiring that drafts of responsive documents be produced as well.[68] The NPRM explained that requiring the production of drafts would allow staff to have ''documents that reflect pre-transaction assessments of business realities, as opposed to 'sanitized' versions.''[69] Many commentors on the NPRM opposed this requirement.[70] The Commission ultimately rejected this proposal, which was critical to my vote.

Simply put, the likely burden of producing drafts would have outweighed any perceived benefit. Depending upon the practice of the individuals drafting the documents, and how many people are involved in preparing different sections of the documents, there may be ''dozens or even hundreds of iterative drafts.''[71] No question, filings would be much larger under the proposal.[72] Forensic collections, that is a full collection of an individual's emails or documents, are incredibly burdensome. They not only require resources from a technical team to collect the materials; they also require time from the individual businesspeople and then, in most cases, counsel, to review the collected materials, identify responsive documents, conduct privilege reviews, prepare more expansive privilege logs, and prepare the documents for production. The status quo for HSR filings, where generally only final versions are produced, typically does not require a forensic collection. But if all drafts became a requirement for all transactions, then forensic collections, with all their costs, would become standard practice for almost all HSR filings.[73] The use of online collaborative workspaces further complicates the issue—and adds burden—because when multiple parties simultaneously revise the same document, it becomes difficult to know which versions constitute drafts.[74]

To defend the proposal, the NPRM argued drafts are more likely to contain a ''smoking gun.''[75] As evidence to support this claim, the NPRM observed the drafts produced during a second request have more salacious content.[76] But receiving all drafts amounts to building a haystack around a needle. Even if some drafts contain some interesting content, that content does not support the NPRM's proposed expansive production obligations for two reasons. First, earlier drafts of transaction documents sometimes contain information that may not have been finalized, may occasionally reflect incorrect assumptions, and in some situations may be based on iterations of the transaction that were not part of the final, executed agreement.[77] Not every change to a draft document is nefarious. Many of the drafts, compared to the final version, would consist of minor or inconsequential edits, excessive repetition, or incomplete thoughts that will require much effort for staff to review.[78] The dramatic increase in the number of documents associated with each filing would have been sufficiently onerous that staff would be simply unable to scrutinize the differences among drafts as they triage dozens of filings each week.

Second, for each of the alleged ''smoking gun'' drafts identified in a second request by staff, other information contained in the HSR filings already prompted the staff to issue a second request. Phrased differently, the agencies already had enough information, without the drafts, to decide to issue a second request in each of those cases. And beyond bald assertions, the NPRM did not provide any evidence demonstrating the drafts would have made a difference in the decision whether to issue a second request.

In summary, the extensive burden resulting from the production and review by staff of drafts would have outweighed any benefits of the requirement. I struggle to imagine any circumstance in which all draft documents would become a ''necessary and appropriate'' input for the agencies' initial review of proposed mergers, and therefore believe the inclusion of this requirement in any future revision would exceed the Commission's rulemaking authority. I would not have supported a Final Rule that required drafts and am heartened by the removal of this provision.

IV. Prior Acquisitions

The NPRM proposed radical changes to the prior acquisition request in the 2011 Rule. The proposed changes included: (1) expanding the lookback period for reporting prior acquisitions from five years to ten years; (2) eliminating the prior *de minimis* exception that required reporting only for prior acquisitions that ''had annual net sales or total assets greater than $10 million''; (3) requiring the acquired entity to also report prior acquisitions; and (4) requiring that acquisitions of substantially all of the assets of a business be treated the same as acquisitions of securities or non-corporate interests.[79] My vote was conditioned on the Commission eliminating the first two of these proposed changes. I write to explain why I believe it was proper to remove those requirements from the Final Rule

Regarding Amendments to the Hart-Scott-Rodino Rules and Premerger Notification Form and Instructions (Oct. 10, 2024).

[64] Press Release, Fed. Trade Comm'n, FTC, DOJ Partner with Labor Agencies to Enhance Antitrust Review of Labor Issues in Merger Investigations (Aug. 28, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/08/ftc-doj-partner-labor-agencies-enhance-antitrust-review-labor-issues-merger-investigations* (discussing Chair Khan's unilateral decision to enter a memorandum of understanding with the Department of Labor, National Labor Relations Board, and the Department of Justice); Press Release, Fed. Trade Comm'n, Statement on Memorandum of Understanding Related to Antitrust Review of Labor Issues in Merger Investigations (Sep. 27, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/09/statement-memorandum-understanding-related-antitrust-review-labor-issues-merger-investigations* (rescinding the same memorandum of understanding).

[65] Chair Khan and Commissioner Bedoya each write to express continued support for the now jettisoned Labor Proposal. I respect their enthusiasm for the idea. But between the decision to reject the Labor Proposal and rescind the memorandum of understanding, the public should rely more on revealed versus expressed preferences.

[66] NPRM, *supra* note 1, at 42194. One exception has been when a draft was sent to the board of directors. *Id.*

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] *See, e.g., U.S. Chamber Comment, supra* note 40, at 21–22.

[71] Comment of Foley & Lardner LLP, Doc. No. FTC–2023–0040–0653 at 11 (hereinafter *Foley Comment*).

[72] *Id.* (''The proposed instruction could potentially increase the size of at least some HSR filings by a factor of ten or twenty.'').

[73] *U.S. Chamber Comment, supra* note 40, at 21–22.

[74] *Id.*

[75] NPRM, *supra* note 1, at 42194.

[76] *Id.*

[77] *See Comment of Wachtell, Lipton, Rosen & Katz,* Doc. No. FTC–2023–0040–0670 at 11–12; *Foley Comment, supra* note 71, at 11–13.

[78] *Id.* at 12.

[79] NPRM, *supra* note 1, at 42203.

and why the Commission should not revisit these proposals in future revisions to the HSR rules.

Prior acquisitions may, in limited circumstances, be relevant to analyzing the filed-for transaction, but consideration of these prior transactions comes with risk of government overreach. A prior acquisition may be relevant to analyzing a filed-for transaction when the competitive effects of the prior acquisition have not yet manifested. For example, if a firm acquired a rival and integration was ongoing or existing contractual terms prevent the effects of the merger from being fully realized, a prior acquisition may help the agencies better understand the dynamics and competitive effects of the filed-for transaction. Once firms have completed integration, realized efficiencies, and implemented any strategies they plan to orchestrate, prior acquisitions provide almost no value [80] to the agencies as they assess the competitive conditions surrounding the filed-for transaction because at that juncture, the condition of the current market will reflect the effects of past transactions.[81]

For the last thirty-seven years, the Commission has determined that five years of prior acquisitions, with a threshold based upon the sales and assets of the entity that was acquired, was justifiable.[82] I do not seek to relitigate thirty-seven years of precedent. The question is whether the rulemaking record contained sufficient evidence to justify the request to reach ten years of prior acquisitions without any size threshold. I conclude that it did not.

The HSR Act limits the information that can be required under the Commission's HSR Rules to ''documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable the Federal Trade Commission and the Assistant Attorney General to determine whether such acquisition may, if consummated, violate the antitrust laws.'' [83] Based upon this text, HSR Rules can seek only the information the agencies need to screen for potential violations of the antitrust laws arising from consummation of the filed-for transaction.[84]

Since 1987, the Commission has required only five years of prior acquisitions.[85] Despite the Commission making no efforts to change this rule for thirty-seven years, the NPRM contended that it needed the additional five years of prior acquisitions ''because the current five-year requirement for prior acquisitions is often insufficient to meaningfully identify patterns of serial acquisitions or a trend toward concentration or vertical integration.'' [86] Further, the NPRM alleged that ''changes to the economy and the varied acquisition strategies of filing parties'' justified ''a more detailed consideration of how numerous past acquisitions, including those in related sectors, affect the competitive landscape of the current transaction under review.'' [87] The Supreme Court has explained that when an agency ''depart[s] from a prior policy,'' ''the agency must show that there are good reasons for the new policy.'' [88] And ''a more detailed justification'' is required when an agency's ''new policy rests upon factual findings that contradict those which underlay its prior policy.'' [89] Beyond bald and conclusory assertions, however, neither the NPRM nor the rulemaking record presented ''good reasons'' that justified the production of ten years of prior acquisitions, let alone ''a more detailed justification'' that is required in this circumstance.[90]

Insofar as the NPRM's proposal required the production of information in order to investigate past transactions—*i.e.,* not the filed-for transaction—under theories of serial acquisitions or otherwise,[91] the Commission lacks the authority to gather that information via an HSR filing. Because neither the NPRM nor the rulemaking record provided evidence that ten years would be relevant to analyzing the effects of the filed-for transaction, the NPRM's proposal did nothing more than attempt an end-run around the HSR Act's reportability requirements.[92] Congress already specified which transactions must be reported to the agencies, and the Commission cannot gather information that does not help the agencies analyze the filed-for transaction.[93] Sensibly, the Final Rule does not adopt the proposed changes to the lookback period. In the SBP for the Final Rule, the Commission explains that the information required for prior acquisitions is limited to what the agencies need to analyze the anticompetitive effects of the filed-for transaction.[94]

The proposed removal of the $10 million threshold also suffered deficiencies. The $10 million threshold has been the threshold for prior acquisitions since the original HSR

[80] As one exception, the agencies have considered the ability to realize efficiencies in past transactions as evidence of the likelihood of achieving efficiencies in the current transaction. But even that information becomes stale and loses probative value at some point.

[81] Dan O'Brien, *The 2023 Merger Guidelines: A Giant Leap in the Wrong Direction,* Consumer Technology Association (Jun. 2024) (''[T]he acquisition history is irrelevant to the current merger except to the extent it provides information about the current merger's likely competitive effects.''); *see also Brown Shoe Co.* v. *United States,* 370 U.S. 294, 332 (1962) (''[T]he statute prohibits a given merger only if the effect of that merger may be substantially to lessen competition.'').

[82] NPRM, *supra* note 1, at 42203.

[83] 15 U.S.C. 18a(d)(1).

[84] *Id.*

[85] Premerger Notification; Reporting and Waiting Period Requirements, 50 FR 38742, 38769 (Sep. 24, 1985) (to be codified at 16 CFR parts 801, 802, and 803).

[86] NPRM, *supra* note 1, at 42203.

[87] *Id.*

[88] *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 515 (2009) (Scalia, J.).

[89] *Id.; see also id.* at 537 (Kennedy, J., concurring) (''Where there is a policy change the record may be much more developed because the agency based its prior policy on factual findings. In that instance, an agency's decision to change course may be arbitrary and capricious if the agency ignores or countermands its earlier factual findings without reasoned explanation for doing so. An agency cannot simply disregard contrary or inconvenient factual determinations that it made in the past, any more than it can ignore inconvenient facts when it writes on a blank slate.'').

[90] *Id.* at 515. In 1987, when the Commission adopted the rule that required filers to report five years of prior acquisitions, it explained that ''[t]he Commission believes that this change can be made without adversely affecting the agencies' ability to conduct a thorough antitrust review. The Commission believes than an accurate account of the acquiring person's acquisitions over the past five years will adequately put it on notice of possible trends toward concentration in the affected industry.'' Premerger Notification; Reporting and Waiting Period Requirements, 50 FR 38742, 38769 (Sep. 24, 1985) (to be codified at 16 CFR parts 801, 802, and 803). The simple conclusory statements in the NPRM do not qualify as ''a more detailed justification,'' which is necessary here because the Commission now contradicts its previous factual finding that five years was adequate for review.

[91] *See* NPRM, *supra* note 1, at 42203.

[92] The HSR Act identifies which transactions must be reported—*i.e.,* filed—based upon three tests: the commerce test, size of transaction test, and the size of person test. 15 U.S.C. 18a(a); *see also* Fed. Trade Comm'n, *Steps for Determining Whether an HSR Filing is Required* (last visited Oct. 4, 2024), *https://www.ftc.gov/enforcement/premerger-notification-program/hsr-resources/steps-determining-whether-hsr-filing.*

[93] Under the Administrative Procedure Act, a court reviewing an agency rule can declare it ''unlawful and set aside agency actions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.'' 5 U.S.C. 706 (Under the Administrative Procedure Act, a court reviewing an agency rule can deem it ''unlawful and set aside agency actions found to be . . . in excess of statutory jurisdiction, authority, or limitations, or short of statutory right''). ''[N]o matter how important, conspicuous, and controversial the issue, . . . an administrative agency's power to regulate in the public interest must always be grounded in a valid grant of authority from Congress.'' *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 161 (2000).

[94] *See* SBP, *supra* note 5, at section II.B.5, 61 of 406 (explaining focus is on reportable transaction).

Rules in 1978.[95] But the NPRM disregarded this forty-six-year history where the threshold, despite inflation, has been the same. To justify abandoning the threshold, the NPRM pointed to ''the Commission's technology acquisition study [that] revealed that between 39.3% and 47.9% of transactions were for target entities that were less than five years old at the time of their acquisition.'' [96] It then stated, without citation, ''[g]iven the relative nascency of these acquired companies, the Commission believes that excluding prior acquisitions of firms that have not yet had the chance to achieve $10 million in net sales or assets does not provide a comprehensive picture of each filer's acquisition strategy.'' [97] Nothing cited by the NPRM suggests that just because an acquisition target is less than five years old, that its sales will be below $10 million. Moreover, nothing in the NPRM explained why the age of targets in ''technology acquisitions'' would be relevant to the whole economy, and yet the proposed rule would have applied universally. Indeed, neither the NPRM nor the rulemaking record presented evidence to justify this dramatic expansion, and without evidence, there is no justification to impose such a requirement on filers.

The NPRM's proposal to double the time period and to remove the $10 million threshold would have added substantial burden to filing parties. The NPRM appeared content with the burden because it provided an expanded ability to analyze non-reportable prior acquisitions, including under theories of serial acquisitions.[98] But as explained, this benefit contravenes the Commission's rulemaking authority. Because the Final Rule must be limited to the Commission's authority, the focus must also be limited to how it assists the agencies' assessment of the filed-for transaction during the initial waiting period. As explained above, the NPRM's prior acquisition expansion would have provided almost nothing that would help the agencies to assess filed-for transactions.

V. Additional Considerations

The changes implemented by the Final Rule request information to analyze only the filed-for transaction. The changes are not to authorize the agencies to engage in general fishing expeditions to analyze non-reportable transactions or other allegedly problematic conduct divorced from the effects of the filed-for transaction. The same could not be said for some of the proposals in the NPRM, and those concerns have been rectified in the Final Rule. I understand potential filers may be skeptical that the information gathered in HSR filings may be collected with an eye toward other purposes. In the Final Rule, each of these provisions is now modified to collect only information that is necessary and appropriate to analyze the filed-for transaction.[99]

The Final Rule requires filers to produce new information about officers and directors within the ''stack'' of companies. The ultimate rule differs substantially from the NPRM's proposal.[100] Among the key changes, the request only applies to acquiring persons; filers no longer have to provide information about board observers; and the request is limited to only those entities who generate revenue in the same NAICS codes as the target. This information, like all the information requested by the Final Rule, is designed to help staff better analyze the filed-for transaction. The SBP provides a detailed description of why this requested information helps obtain that goal.[101] The purpose of this revision is not a general fishing expedition; it is to illuminate complicated and overlapping management structures that may impact the competitive effects of the filed-for transaction.

The additional information about minority shareholders and limited partners has also raised concern. The Final Rule again reflects key changes to the proposals in the NPRM. In particular, the final version eliminates the requirement to create an organization chart and eliminates the requirement to disclose limited partners that do not also have management rights. The complicated nature of this request, especially as included in the NPRM, raised confusion and concern of the Commission's purpose for this request. The SBP goes to great lengths to describe—and illustrate via helpful diagrams—why this information will be important to analyzing the filed-for transactions. The purpose is not to pursue or launch general investigations into theories of harm based upon fringe concepts such as common ownership.[102] Nor do I believe it would be possible to construct such theories based upon the information required by the Final Rule. My vote in support of the Final Rule reflects my understanding and belief this information will help the agencies to more quickly understand the competitive dynamics of a filed-for transaction, and nothing more.

VI. Conclusion

The Final Rule has been scaled back dramatically from the NPRM. And rightly so. I voted in favor of the Final Rule because of the revisions and outright removal of certain proposals in the NPRM. As modified, I believe the Final Rule is consistent with that statutory grant of authority and will help staff analyze the filed-for transaction and protect consumers without unduly burdening the filing parties.

On a going forward basis, the Commission can and should carefully scrutinize the effect of the Final Rule on our enforcement efforts and on the burden it imposes upon filing parties and the agencies' staff. A thoughtful retrospective will allow the Commission to modify the Final Rule, if necessary, in a principled and evidence-based fashion.

Concurring Statement of Commissioner Andrew N. Ferguson

Today, the Commission updates the Hart-Scott-Rodino Act (''HSR'' or ''the Act'')[1] notification form requirements. It concurrently announces that, after an over three-and-a-half-year wait, it will lift its categorical ''temporary suspension'' of early terminations once the Final Rule goes into effect.[2] Unlike

[95] Premerger Notification; Reporting and Waiting Period Requirements, 43 FR 33450 at 33534 (July 31, 1978).

[96] NPRM, *supra* note 1, at 42203.

[97] *Id.*

[98] The NPRM sought to right the wrongs of the so-called 40 years of failed antitrust enforcement. *See* Exec. Order No. 14,036, Executive Order on Promoting Competition in the American Economy; *see* NPRM, *supra* note 1, at 42203.

[99] To be clear, if a filing demonstrates anticompetitive conduct, such as price fixing, it can prompt another investigation.

[100] *See* app. A.

[101] SBP, *supra* note 5, at section VI.D.3.c., 241–254 of 406.

[102] *See, e.g.,* Einer Elhauge, *Horizontal Shareholding,* 129 Harv. L.R. 1267 (2016). Though beyond the scope of this statement, I do note that no court has endorsed such a theory of harm and it has faced scrutiny in the literature. *See* Matthew Backus, Christopher Conlon & Michael Sinkinson, *The Common Ownership Hypothesis: Theory and Evidence,* Brookings Econ Studies (Jan. 2019), *https://www.brookings.edu/wp-content/uploads/2019/02/ES_20190205_Common-Ownership.pdf*; Keith Glovers & Douglas H. Ginsburg, *Common Sense About Common Ownership,* 2018 Concurrences Rev. 28 (Fall 2018); Thomas A. Lambert & Michael E. Sykuta, *Calm Down About Common Ownership, Regulation (F*all 2018).

[1] 15 U.S.C. 18a.

[2] Press Release, FTC, FTC, DOJ Temporarily Suspend Discretionary Practice of Early Termination (Feb. 4, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/02/ftc-doj-*

Continued

the Commission's recent, doomed effort to ban noncompete agreements,[3] Congress undoubtedly gave us authority to promulgate rules governing HSR notification requirements.[4]

The notice of proposed rulemaking (''NPRM'') that launched today's rulemaking would have abused that authority by imposing onerous, unlawful requirements that could not have survived judicial review.[5] But the NPRM also proposed some important, lawful updates to the HSR instructions. Mergers have become increasingly complex since we first adopted an HSR rule nearly five decades ago. The current HSR instructions do not adequately address forms of business association that were rare in 1978. And long experience implementing HSR has taught the Commission which information is most important to fulfilling Congress's mandate to conduct premerger review. The current HSR instructions did not always ensure that the Commission and the Antitrust Division (together, the ''Antitrust Agencies'') had the information they needed to fulfill Congress's intention.

The NPRM, however, was a nonstarter. My colleagues and I engaged in intense negotiations to separate the lawful wheat from the lawless chaff. Today's Final Rule,[6] and the lifting of the early-termination ban, are the culmination of those negotiations. Were I the lone decision maker, the rule I would have written would be different from today's Final Rule. But it is a lawful improvement over the status quo. And although not required for the Final Rule's lawfulness, the Commission wisely accompanies the Final Rule with a lifting of the ban on early termination. I therefore concur in its promulgation.

I. Congress passed HSR in 1976, adding section 7A to the Clayton Antitrust Act of 1914.[7] It requires merging firms to notify the Antitrust Agencies before consummating large mergers, and forbids them from consummating the merger until some period after notifying the Antitrust Agencies. The purpose of this premerger notify-and-wait requirement was to give the Antitrust Agencies the opportunity to investigate mergers and sue to block them. Premerger review dispenses with ''interminable post-consummation divestiture trials . . . [and] advance[s] the legitimate interests of the business community in planning and predictability, by making it more likely that Clayton Act cases will be resolved in a timely and effective fashion.'' [8]

Obviously, the Antitrust Agencies need information about the proposed transactions to review them. Congress therefore provided that firms seeking to merge must ''file notification pursuant to rules under subsection (d)(1)'' of the Act.[9] Subsection (d), titled ''Commission rules,'' in turn commands the Commission to, ''by rule,'' ''require that [a merging party's] notification . . . contain such documentary material and information relevant to a proposed acquisition as is necessary and appropriate to enable the [Antitrust Agencies] to determine whether such acquisition may, if consummated, violate the antitrust laws.'' [10] The Commission may also ''prescribe such other rules as may be necessary and appropriate to carry out the purposes of this section.'' [11] ''Taken together, these statutory provisions give the FTC . . . great discretion . . . to promulgate rules to facilitate Government identification of mergers and acquisitions likely to violate [F]ederal antitrust laws before the mergers and acquisitions are consummated.'' [12]

The Commission has regularly deployed the rulemaking power Congress conferred on it in the Act. The Commission published its first final HSR rule two years after Congress passed the Act.[13] In the intervening decades, the Commission has made dozens of changes to the HSR form and instructions.[14] Some changes expanded the scope of information requested.[15] Others narrowed it.[16] Only one faced judicial review. In 2013, an industry association challenged a Commission rulemaking that required parties to file HSR notifications when they transferred most, but not all, of their pharmaceutical patent rights. The D.C. Circuit held that the rule was a proper exercise of the Commission's rulemaking authority and reflected reasoned decision-making.[17] The revised HSR rule survived and took effect, as have many HSR form changes beforehand and afterwards.

II. The Administrative Procedure Act (''APA'')[18] governs our HSR rulemakings.[19] ''The APA 'sets forth the procedures by which [F]ederal agencies are accountable to the public and their actions are reviewed by courts.' '' [20] First, the Rule must be promulgated in ''observance of procedure required by law.'' [21] For a rule like the Final Rule, section 4 of the APA[22] is the ''procedure required by law,'' and it ''prescribes a three-step procedure.'' [23] ''First, the agency must issue a 'general notice of proposed rulemaking,' ordinarily by publication in the **Federal Register**.'' [24] We published the NPRM for the Final Rule on June 29, 2023.[25] ''Second, if 'notice is required,' the agency must give 'interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments.' '' [26] We received approximately 721 comments during the 90-day comment period.[27] ''Third, when

temporarily-suspend-discretionary-practice-early-termination.

[3] See Dissenting Statement of Comm'r Andrew N. Ferguson, Joined by Comm'r Melissa Holyoak, In the Matter of the Non-Compete Clause Rule, Matter No. P201200 (June 28, 2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-noncompete-dissent.pdf*; *Ryan LLC* v. *FTC,* No. 3:24–CV–00986–E, 2024 WL 3879954 (N.D. Tex. Aug. 20, 2024) (vacating the Commission's Non-Compete Rule).

[4] See *Pharm. Rsch. & Mfrs. of Am.* v. *FTC,* 790 F.3d 198, 208 (D.C. Cir. 2015) (hereinafter ''*PhRMA*'') (''There is no doubt that the Commission's action was taken pursuant to express delegations of authority. The Act grants the FTC the authority to act by rulemaking.'' (citing 15 U.S.C. 18a)).

[5] FTC, Notice of Proposed Rulemaking, Premerger Notification; Reporting and Waiting Period Requirements, 88 FR 42178 (June 29, 2023) (hereinafter ''NPRM'').

[6] FTC, Premerger Notification; Reporting and Waiting Period Requirements, Final Rule (Oct. 10, 2024) (hereinafter ''Final Rule''), *https://www.ftc.gov/system/files/ftc_gov/pdf/p110014hsrfinalrule.pdf.*

[7] 15 U.S.C. 18a(a); see also *PhRMA,* 790 F.3d at 199.

[8] H.R. Rep. No. 94–1373, at 11 (1976).

[9] 15 U.S.C. 18a(a).

[10] 15 U.S.C. 18a(d)(1). If the initial notification reveals a potential competitive problem, the Antitrust Agencies may seek additional information, which delays the proposed transaction until the merging parties have complied. See 15 U.S.C. 18a(e).

[11] 15 U.S.C. 18a(d)(2).

[12] *PhRMA,* 790 F.3d at 205.

[13] See 43 FR 33450 (July 31, 1978) (publishing final rules for premerger notification).

[14] See FTC, 16 CFR parts 801 and 803, Premerger Notification; Reporting and Waiting Period Requirements, Statement of Basis and Purpose, 107, n.248 (Oct. 10, 2024) (hereinafter ''SBP''), *https://www.ftc.gov/system/files/ftc_gov/pdf/p110014hsrfinalrule.pdf.*

[15] E.g., 76 FR 42471 (July 19, 2011) (adding Items 4(d), 6(c)(ii) and 7(d) to capture additional information).

[16] E.g., 70 FR 73369 (Dec. 12, 2005) (amending Form and Instructions to reduce the burden of complying with Items 4(a) and (b)).

[17] *PhRMA,* 790 F.3d at, 209–12.

[18] 5 U.S.C. 551 *et seq.*

[19] *PhRMA,* 790 F.3d at 209.

[20] *Dep't of Homeland Security* v. *Regents of the Univ. of Cal.,* 591 U.S. 1, 16 (2020) (quoting *Franklin* v. *Massachusetts,* 505 U.S. 788, 796 (1992)).

[21] 5 U.S.C. 706(2)(D).

[22] *Id.* section 553.

[23] *Perez* v. *Mortgage Bankers Ass'n,* 572 U.S. 92, 96 (2015).

[24] *Ibid.* (quoting 5 U.S.C. 553(b) (cleaned up)).

[25] NPRM, *supra* note 5.

[26] *Perez,* 572 U.S. at 96 (quoting 5 U.S.C. 553(c) (cleaned up)).

[27] SBP, *supra* note 14, at 6, n.4; Press Release, FTC, FTC and DOJ Extend Public Comment Period by 30 Days on Proposed Changes to HSR Form (Aug. 4, 2023), *https://www.ftc.gov/news-events/news/press-releases/2023/08/ftc-doj-extend-public-*

the agency promulgates the final rule, it must include in the rule's text a 'concise general statement of its basis and purpose.' '' [28] With today's Final Rule the Commission includes a statement of basis and purpose that thoroughly explains its reasoning for each of the changes contained in the Final Rule. The Commission has therefore satisfied the APA's procedural requirements.[29]

APA section 10's standard of judicial review also imposes substantive limits on the exercise of our authority under HSR. The APA requires courts to ''hold unlawful and set aside agency action'' that is ''arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law''; ''contrary to constitutional right, power, privilege, or immunity''; or ''in excess of statutory jurisdiction, authority, or limitations, or short of statutory right.'' [30] The APA standard generally requires an agency to show two things. First, that it has a lawful grant of authority from Congress to issue the rule [31]—that is, that Congress enacted a statute conferring on the agency power to issue the rule,[32] and that the statute is consistent with the Constitution.[33] Second, that the agency has exercised that grant of authority in a lawful way.[34]

To be sure, the Commission recently has been all too happy to issue rules without valid grants of authority from Congress.[35] But today's Final Rule is plainly authorized by a valid grant of authority from Congress. HSR commands the Commission to issue rules governing the form and contents of premerger-notification filings as it determines are ''necessary and appropriate to enable [the Antitrust Agencies] to determine whether'' mergers ''may, if consummated, violate the antitrust laws.'' [36] Congress further authorized us to ''prescribe such other rules as may be necessary and appropriate to carry out the purposes of'' the Act.[37] The text of HSR therefore unambiguously commands the agency to issue rules of the type we today issue.[38] And I am not aware of any serious arguments that this grant of discretion to prescribe the procedures by which firms notify the Commission of a pending merger—distinct from the power to adjudicate merger challenges[39]—violates the Constitution. We therefore have statutory and constitutional authority to issue the Final Rule.[40]

The question, then, is whether the Commission has lawfully exercised the power Congress unambiguously conferred on it. As a general matter, an agency lawfully exercises power conferred on it by ''engag[ing] in reasoned decisionmaking,'' which requires that the ''agency['s] action . . . rest[ ] 'on a consideration of the relevant factors.' '' [41] We must ''examine the relevant data and articulate a satisfactory explanation for [our] action including a 'rational connection between the facts found and the choice made.' '' [42] This ''standard is deferential'' to the agency's policy choices, so long as ''the agency has acted within a zone of reasonableness and . . . reasonably considered the relevant issues and reasonably explained the decision.'' [43]

Importantly, this standard does not change because we are amending an existing rule. The APA does not require that ''agency action representing a policy change must be justified by reasons more substantial than those required to adopt a policy in the first instance.'' [44] ''The statute makes no distinction . . . between initial agency action and subsequent agency action undoing or revising that action.'' [45] When an agency revises an existing regulation, reasoned decision-making ''would ordinarily demand that it display awareness that it *is* changing its position,'' and it must show ''that there

comment-period-30-days-proposed-changes-hsr-form.

[28] *Perez,* 572 U.S. at 96 (quoting 5 U.S.C. 553(c) (cleaned up)).

[29] See *Little Sisters of the Poor Saints Peter & Paul Home* v. *Pennsylvania,* 591 U.S. 657, 685–86 (2020) (explaining that an agency satisfies the procedural requirements of the APA so long as it complies with the ''objective criteria'' of notice, opportunity to comment, and a concise general statement of basis and purpose).

[30] 5 U.S.C. 706(2)(A), (B), (C).

[31] *NFIB* v. *Dep't of Labor,* 595 U.S. 109, 117 (2022) (per curiam) (''Administrative agencies are creatures of statute. They accordingly possess only the authority that Congress has provided.'').

[32] *FEC* v. *Cruz,* 596 U.S. 289, 301 (2022) (''An agency, after all, 'literally has no power to act' . . . unless and until Congress authorizes it to do so by statute.'' (quoting *La. Pub. Serv. Comm'n* v. *FCC,* 476 U.S. 355, 374 (1986))).

[33] *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 161 (2000) (''[N]o matter how important, conspicuous, and controversial the issue, and regardless of how likely the public is to hold the Executive Branch politically accountable, an administrative agency's power to regulate in the public interest must always be grounded in a *valid* grant of authority from Congress.'' (cleaned up) (emphasis added)).

[34] *Allentown Mack Sales & Serv., Inc.* v. *NLRB,* 522 U.S. 359, 374 (1998) (''Not only must an agency's decreed result be within the scope of its lawful authority, but the process by which it reaches that result must be logical and rational.'').

[35] See *Ryan LLC* v. *FTC,* No. 3:24–CV–00986–E, 2024 WL 3879954 (N.D. Tex. Aug. 20, 2024) (vacating the Commission's Non-Compete Rule).

[36] 15 U.S.C. 18a(d)(1).

[37] *Id.* section 18a(d)(2)(C).

[38] *PhRMA,* 790 F.3d at 208 (''There is no doubt that the Commission's action was taken pursuant to express delegations of authority.'').

[39] See, *e.g.,* Compl. ¶¶ 45, 55–59, 72–76, *The Kroger Co.* v. *FTC,* No. 1:24–cv–438 (S.D. Ohio Aug. 19, 2024), ECF No. 1 (challenging constitutionality of FTC administrative proceedings as a violation of Article III of the Constitution).

[40] When the judiciary last reviewed one of our HSR rules, it deferred to our interpretation of various undefined terms of the Act under the doctrine announced in *Chevron U.S.A. Inc.* v. *Nat. Res. Def. Council, Inc.,* 467 U.S. 837 (1983). See *PhRMA,* 790 F.3d at 204 (''[W]e apply the familiar *Chevron* framework . . .''). The Supreme Court has since overruled *Chevron,* correctly interpreting the APA to require the judiciary to resolve statutory ambiguities without deferring to administrative agencies' views on how to resolve those ambiguities. See *Loper Bright Enter.* v. *Raimondo,* 144 S. Ct. 2244, 2261 (2024) (''On the contrary, by directing courts to 'interpret constitutional and statutory provisions' without differentiating between the two, [the APA] makes clear that agency interpretations of statutes—like agency interpretations of the Constitution—are *not* entitled to deference. Under the APA, it thus remains the responsibility of the court to decide whether the law means what the agency says.'' (cleaned up)). The Court in *Loper Bright* held, however, that ''[i]n a case involving an agency, . . . the statute's meaning may well be that the agency is authorized to exercise a degree of discretion.'' *Id.* at 2263. The Court gave as examples statutes that delegate ''to an agency the authority to give meaning to a particular statutory term,'' and ''[o]thers'' that ''empower an agency to 'fill up the details' of a statutory scheme, or to regulate subject to the limits imposed by a particular term or phrase that 'leave the agencies with flexibility,' such as 'appropriate' or 'reasonable.' '' *Ibid.* (quoting *Wayman* v. *Southard,* 23 U.S. (10 Wheat.) 1, 43 (1825), and *Michigan* v. *EPA,* 576 U.S. 743, 752 (2015)). HSR expressly authorizes the Commission to promulgate rules ''defin[ing] the terms used in'' the Act, and to issue all rules that are ''necessary and appropriate to carry[ing] out the purposes of'' the Act. 15 U.S.C. 18a(d)(2)(A), (C); see also *id.* 18a(d)(1) (authorizing the Commission to issue rules that are ''necessary and appropriate to enable the [Antitrust Agencies] to determine whether such acquisition may, if consummated, violate the antitrust laws''). HSR thus appears to be the sort of discretion-conferring statute that the *Loper Bright* Court suggested may require some modicum of judicial deference to agency decision making. My vote in favor of the Final Rule, however, does not depend on the Commission receiving any judicial deference. I conclude that the Final Rule properly interprets and implements HSR.

[41] *Michigan,* 576 U.S. at 750 (quoting *Motor Vehicle Mfrs. Ass'n of U.S.* v. *State Farm Mut. Automobile Ins. Co.,* 463 U.S. 29, 43 (1983)); see also *Dep't of Homeland Sec.* v. *Regents of the Univ. of Cal.,* 591 U.S. 1, 16 (2020) (The APA ''requires agencies to engage in reasoned decision-making, and directs that agency actions be set aside if they are arbitrary and capricious.'' (cleaned up)).

[42] *State Farm,* 463 U.S. at 43 (quoting *Burlington Truck Lines* v. *United States,* 371 U.S. 156, 246 (1962)).

[43] *FCC* v. *Prometheus Radio Project,* 592 U.S. 414, 423 (2021); see also *Dep't of Commerce* v. *New York,* 588 U.S. 752, 773 (2019) (Courts ''may not substitute [their] judgment for that of the [agency], but instead must confine [them]selves to ensuring that [the agency] remained within the bounds of reasoned decisionmaking.'' (cleaned up)); *Garland* v. *Ming Dai,* 593 U.S. 357, 369 (2021) (''[A] reviewing court must 'uphold' even 'a decision of less than ideal clarity if the agency's path may reasonably be discerned.''' (quoting *Bowman Transp., Inc.* v. *Arkansas-Best Freight Sys., Inc.,* 419 U.S. 281, 286 (1974)).

[44] *FCC* v. *Fox Television Stations, Inc.,* 556 U.S. 502, 514 (2009) (Scalia, J.).

[45] *Id.* at 515.

are good reasons for the new policy.'' [46] But the APA does not require that the agency show that ''the reasons for the new policy are *better* than the reasons for the old one; it suffices that the new policy is permissible under the statute, that there are good reasons for it, and that the agency *believes* it to be better, which the conscious change of course adequately indicates.'' [47]

The Final Rule is not perfect, nor is it the rule I would have written if the decision were mine alone. But I believe that it addresses important shortcomings in the current HSR rule, and that it is ''necessary and appropriate'' to enable the Antitrust Agencies to determine whether proposed mergers may violate the antitrust laws.[48]

III. I turn now to the specific provisions of the Final Rule to address whether they are ''necessary and appropriate'' to executing the premerger-review provisions of HSR.[49]

A. The Final Rule requires the disclosure of some information not currently required by the old HSR rule. That information is ''necessary and appropriate'' to the execution of our premerger-review mandate under the Act, and the burdens the disclosure requirements impose on merging firms are justified by the requirements of effective premerger review.

Mergers and acquisitions have become increasingly complex since 1978. The Antitrust Agencies review a large number of deals involving corporate structures that were rare when we adopted our first HSR rule. For example, twenty years ago, only ten percent of acquiring firms were funds or limited partnerships; now, that figure is close to forty percent.[50] Such firms may be shell companies that disclose little public information about their holdings or operations, and, in many cases, have no other assets. But these deals can still present competitive problems through the acquiring person's relationships with other entities. Minority investors, including limited partners, might pull the strings for the acquiring person. And those minority investors might also control entities that compete with the transaction target, creating potential antitrust concerns.[51] The current rule does not require disclosure of investors in entities between the parent company and the acquiring person, nor does it require disclosure of any limited partners, even if they have management rights for the acquiring person. The Final Rule addresses this shortcoming. It requires disclosure of investors that own at least a five percent share in certain entities related to the acquiring person; if those entities are limited partnerships, filers must disclose limited partners that have certain management rights, such as a board seat. But unlike the NPRM, the Final Rule sensibly does not require disclosure of limited partner investors without any management rights.[52] The Final Rule's minority investor disclosures are a reasonable way to address what the Antitrust Agencies fairly determined was a shortcoming of the previous rule, and are necessary and appropriate to determining the competitive effects of a transaction involving limited partnerships or complex corporate structures.[53]

The Final Rule also requires merging firms to disclose information about their potential vertical relationships—that is, whether the two merging firms currently interact with each other at different levels of the supply chain.[54] HSR rules long required disclosure of information about vertical relationships, but a 2001 amendment to the HSR rules removed that requirement.[55] Since 2001, however, the Antitrust Agencies under the leadership of both parties have increased their scrutiny of, and rate of enforcement actions against, vertical mergers. During the Trump Administration, the Antitrust Division litigated the first vertical merger challenge in decades.[56] The Antitrust Agencies released the 2020 Vertical Merger Guidelines, the first major revision to agency guidance on vertical mergers since 1984.[57] The Commission released its 2020 Commentary on Vertical Merger Enforcement, which demonstrated the breadth of Commission investigations and consent agreements involving vertical transactions.[58] And the Commission investigated Illumina's proposed acquisition of Grail, which ultimately led to a successful 2023 Fifth Circuit opinion that effectively blocked the vertical transaction.[59] These efforts continue today. I recently joined a unanimous Commission vote authorizing a complaint to challenge a vertical merger between America's leading mattress supplier and its leading mattress retailer.[60]

Since 2001, however, the Antitrust Agencies have had to rely on limited acquisition-related documents and publicly available information to identify potential vertical-competition concerns. Not every competitive issue shows up in transaction documents or is apparent to Commission staff without experience in the industry. As a result, some anticompetitive transactions have likely slipped through the cracks. The Final Rule will also provide the Antitrust Agencies with other information that they can use to quickly identify (or rule out) potential vertical-competition problems. The new Supply Relationships Description requires filers to identify whether they supply, or are supplied by, the other merging party or its competitors.[61] The buyer must also now indicate whether it has certain types of existing contracts with the seller.[62] This information is ''necessary and appropriate'' to carrying out Congress's command that the Antitrust Agencies review mergers—including vertical mergers—to determine whether they violate the antitrust laws.[63]

The Final Rule requires the disclosure of additional information that will facilitate effective premerger review. Filers must now provide some regularly prepared plans and reports that analyze market shares or competition.[64] Such information, particularly market-share

[46] *Ibid.*

[47] *Ibid* (emphasis in original).

[48] 15 U.S.C. 18a(d)(1).

[49] 15 U.S.C. 18a(d)(1).

[50] See SBP, *supra* note 5, at 25.

[51] See *id.* at 225–27 (''some limited partnerships function as aggregation vehicles that allow private equity or other investor groups to direct the strategic business decisions of the portfolio companies in which they invest.'').

[52] See FTC, 16 CFR part 803—appendix B, Notification for Certain Mergers and Acquisitions: Acquiring Person Instructions, 4–5 (Oct. 10, 2024) (hereinafter ''Acquiring Person Instructions''); SBP at 226–27.

[53] See SBP at 28–31; 15 U.S.C. 18a(d)(1).

[54] FTC, 16 CFR part 803—appendix A, Notification and Report Form for Certain Mergers and Acquisitions: Acquiring Person, 6–7 (Oct. 10, 2024) (hereinafter ''Acquiring Person Form'') (requesting ''other agreements between the acquiring person and target'' and the ''supply relationship description'').

[55] See SBP at 327 (describing past requests for information on vendor-vendee relationships); 66 FR 8680 (Feb. 1, 2001) (HSR rule amendment removing that request).

[56] See *United States* v. *AT&T Inc.,* 310 F. Supp. 3d 161, 193–94 (D.D.C. 2018) (''the Antitrust Division apparently has not tried a vertical merger case to decision in four decades''), *aff'd* 916 F.3d 1029 (D.C. Cir. 2019).

[57] Press Release, FTC, FTC and DOJ Issue Antitrust Guidelines for Evaluating Vertical Mergers (June 30, 2020), *https://www.ftc.gov/news-events/news/press-releases/2020/06/ftc-doj-issue-antitrust-guidelines-evaluating-vertical-mergers.*

[58] Press Release, FTC, FTC Issues Commentary on Vertical Merger Enforcement (Dec. 22, 2020), *https://www.ftc.gov/news-events/news/press-releases/2020/12/ftc-issues-commentary-vertical-merger-enforcement.*

[59] *Illumina, Inc.* v. *FTC,* 88 F.4th 1036 (5th Cir. 2023).

[60] Press Release, FTC, FTC Moves to Block Tempur Sealy's Acquisition of Mattress Firm, (July 2, 2024), *https://www.ftc.gov/news-events/news/press-releases/2024/07/ftc-moves-block-tempur-sealys-acquisition-mattress-firm.*

[61] See Acquiring Person Instructions at 10.

[62] See Acquiring Person Form at 6.

[63] 15 U.S.C. 18a(d)(1).

[64] See Acquiring Person Instructions at 9.

data, often is not available publicly, nor does it always appear in transaction documents. But market-share data are critical to antitrust enforcement. The Supreme Court many decades ago concluded that mergers of competitors constituting thirty percent or more of the relevant market presumptively violate the Clayton Act.[65] And one of the leading metrics for assessing the competitive effects of a transaction is the Herfindahl-Hirschman Index (HHI),[66] which uses market shares to assess the level of concentration in the relevant market, and the change in concentration that the merger would create.[67] Market-share data therefore are not only ''necessary and appropriate to . . . determin[ing] whether [an] acquisition may, if consummated, violate the antitrust laws.'' [68] They are vital to our enforcement mandate. Requiring the provision of these data also promotes efficiency. If the market shares of the two firms are small, the Antitrust Agencies may swiftly conclude that little further investigation is needed—and, thanks to the concurrent lifting of the unfortunate ban on early termination, may also facilitate the grant of early termination in appropriate cases once the Final Rule becomes effective. And the cost of compliance is modest; parties must collect only documents provided, within the past year, to individuals already subject to other document requests.

In addition, the Overlap Description will require filers to identify whether they compete with the other merging party.[69] Under the current form, parties identify overlaps only through Census Bureau NAICS revenue codes.[70] These codes can be painfully vague or overinclusive, particularly for new sectors. For example, NAICS code 518210 covers ''companies that provide computing infrastructure, data processing, web hosting, and related services'' such as ''data entry services, cloud storage services and cryptocurrency mining.'' [71] Despite a NAICS overlap, many firms within this broad category undoubtedly do not compete. Many other NAICS codes present similar concerns, flagging overlaps where none truly exist. Misleading or overbroad NAICS code overlaps may lead to unnecessary investigations. The Overlap Description will mitigate this problem by permitting filers to explain misleading NAICS code overlaps up front.[72]

Improving the type of information the Commission receives in an HSR notification is likely to improve the merger-review process for many merging parties. If Commission staff believes that a proposed merger merits investigation beyond the initial HSR filing and publicly available information, it must formally open an investigation and obtain clearance for that investigation from the Antitrust Division. Most such investigations show that the transaction poses little risk of competitive harm and are closed without a second request for additional information.[73] Once the investigation is begun, however, the Antitrust Agencies can fall victim to bureaucratic inertia. We, like all law-enforcement agencies, have limited resources. Commencing an investigation and obtaining clearance eats up some of those resources. Commission leadership may therefore resist recommendations to close an investigation quickly even if the early stages of the investigation demonstrate that the merger presents no competitive concerns. Additionally, even investigations that do not lead to a second request can still involve significant cost and delay for merging parties.[74] The information required by the Final Rule will mitigate the risk of false positives. It can reveal that a merger presents no competitive threat at all, and the Commission can avoid crawling down rabbit holes in unnecessary investigations.

Third parties will benefit, too. Commission staff regularly requests voluntary interviews with the merging parties' customers, suppliers, and competitors following an HSR filing. These third parties often cooperate, at the cost of their senior executives' time and legal fees paid to outside lawyers. As these third parties explain the industry and competitive landscape, the lack of any competitive issues can quickly become apparent. By providing the Antitrust Agencies with greater information upfront, the Final Rule can remove the need to burden third parties with such fruitless engagement.

B. The Final Rule must be considered in light of another decision the Commission announces today: the lifting of the suspension on early termination. ''Early termination'' describes the Commission practice of informing merging parties that the Commission is terminating its investigation into the merger before the conclusion of the statutory waiting period, thereby freeing them to consummate the merger immediately. The benefits of early termination are obvious. It reduces financing costs associated with the delay inherent in premerger review, and it allows companies and consumers to realize the benefits of procompetitive mergers more quickly.

Until 2021, Commission staff routinely granted early termination of the initial HSR review period for acquisitions that obviously presented no competitive issues.[75] In February 2021, however, the then-Acting Chairwoman announced a ''temporary suspension'' of early termination due to ''the confluence of an historically unprecedented volume of filings during a leadership transition amid a pandemic.'' [76] The Antitrust Agencies announced that they ''anticipate[d] the suspension [to] be brief.'' [77]

The ''confluence'' has been over for some time. The pandemic long ago subsided. We have had a permanent Chair since June 2021. And merger filings have slowed to about half the

[65] See *United States* v. *Phila. Nat'l Bank,* 374 U.S. 321, 363–65 (1963) (''Without attempting to specify the smallest market share which would still be considered to threaten undue concentration, we are clear that 30% presents that threat.'').

[66] *ProMedica Health Sys., Inc.* v. *FTC,* 749 F.3d 559, 568 (6th Cir. 2014) (''Agencies typically use the Herfindahl-Hirschman Index (HHI) to measure market concentration.'').

[67] See *FTC* v. *H.J. Heinz Co.,* 246 F.3d 708, 716 (D.C. Cir. 2001) (''Sufficiently large HHI figures establish the FTC's prima facie case that a merger is anti-competitive.'').

[68] 15 U.S.C. 18a(d)(1).

[69] See Acquiring Person Form at 6.

[70] See SBP at 301. Federal statistical agencies use the North American Industry Classification System to classify businesses. See *id.* at 147, n.296 (citing U.S. Census Bureau, North American Industry Classification System (rev. Sept. 10, 2024), *https://www.census.gov/naics/*).

[71] *Id.* at 300.

[72] See *id.* at 301.

[73] In Fiscal Year 2023, the Commission received clearance to investigate 124 transactions but only issued second requests for additional information for 26 transactions. See FTC and DOJ, HSR Annual Report Fiscal Year 2023, at Exhibit A, Table 1, *https://www.ftc.gov/policy/reports/annual-competition-reports.*

[74] *See* SBP at 89 (''[A]n average of 73 transactions each year . . . were delayed by an additional 30 days and filers were burdened by having to submit additional materials on a voluntary basis even though the investigation did not lead to the issuance of Second Requests. These delays impose costs on the parties and the Agencies, as well as third parties contacted during the extended initial review period.'').

[75] *See id.* at 16, n.22, 95; *see also* Statement of Comm'r Noah J. Phillips and Comm'r Christine S. Wilson Regarding the Commission's Indefinite Suspension of Early Terminations, at 2 (Feb. 4, 2021), *https://www.ftc.gov/legal-library/browse/cases-proceedings/public-statements/statement-commissioners-noah-joshua-phillips-christine-s-wilson-regarding-commissions-indefinite.*

[76] Press Release, FTC, FTC, DOJ Temporarily Suspend Discretionary Practice of Early Termination (Feb. 4, 2021), *https://www.ftc.gov/news-events/news/press-releases/2021/02/ftc-doj-temporarily-suspend-discretionary-practice-early-termination.*

[77] *Ibid.*

number we saw in 2021 and 2022.[78] Nevertheless, the ''temporary suspension'' persisted. The Final Rule recognizes that this persistence is no longer tenable: ''if the Agencies can determine from review of an HSR Filing that a transaction does not present [competitive concerns], the Agencies can more quickly and confidently determine that the transaction does not require a more in-depth review and may proceed to consummation.'' [79]

Indeed, maintaining the ban would have been absurd in light of the Final Rule's explicit recognition that many transactions pose no competitive risks. Specifically, the Final Rule takes a tailored approach to identify and reduce compliance costs for transactions with lower risks of harm. The Final Rule creates a new category—''select 801.30 transactions''—for acquisitions that almost never present competitive concerns, such as executive compensation agreements. For these deals, filers are excused from many new requirements, including descriptions and some document requests.[80] The Final Rule also recognizes when enough is enough. It tailors the burdens of acquiring and acquired persons, rather than requiring both sides of a transaction to provide the same information. Accordingly, it significantly pares back the requests for acquired persons.[81] Finally, the Final Rule also employs a conditional-request format—a series of if/then queries—to omit certain requirements for acquisitions that do not involve an overlap or vertical relationship.[82] Again, the burden is reduced commensurate with the lower risk of harm.

I am pleased that today the Commission announces that it will lift the categorical ban on early termination and restore this important feature of the merger-review process once the Final Rule becomes effective. It should have happened earlier. I have objected before to the majority's tendency to use our HSR authority to accomplish political objectives.[83] An indefinite ban on early termination was just more of the same. Maintaining the ban after the Final Rule's effective date would have undermined the efficiencies that justify the new information that the Final Rule requires. I am glad it is gone.

IV. The Final Rule must stand on its own feet. An arbitrary-and-capricious rule is not lawful merely because it is better than a bad NPRM. And the NPRM with which the Commission launched today's Final Rule was about as bad as it gets. It was indefensible bureaucratic overreach and could not have survived judicial review. It drew no distinctions between merger filings that presented little risk of competitive harm—such as executive compensation agreements—and those that raised potentially serious concerns. Instead, the NPRM applied the same blunderbuss approach to every filing. To make matters worse, the NPRM proposed a deluge of new onerous requirements the benefits of which could never have justified the burdens imposed on merging parties. In fact, several would have added little or no value to the Antitrust Agencies at all during their brief window to identify transactions that warrant further investigation. Had today's Final Rule been identical to the NPRM, I would not have voted for it.

Although today's Final Rule is a logical outgrowth of the NPRM,[84] it dramatically curtails the NPRM's wild overreach. That curtailment unsurprisingly followed the arrival of Republican Commissioners. A Final Rule identical to the NPRM would have been little more than a procedural auxiliary to the majority's general suspicion of mergers and acquisitions.[85] I would not have voted for it. The changes adopted after the arrival of Republicans to the Commission, however, rescued the Final Rule from the NPRM's lawlessness. The Final Rule, unlike the NPRM, is a reasoned decision about what is ''necessary and appropriate'' to carrying out Congress's premerger-review mandate. It also reasonably addresses shortcomings in the old HSR rule. It therefore satisfies the requirements of both the HSR and APA. None of this was true about the NPRM.

Although the Final Rule's lawfulness does not turn on how much better it is than the NPRM, the changes from the unlawful NPRM demonstrate that the Final Rule is in fact the product of reasoned decision-making, which required us to respond to valid objections about the NPRM's many problems.[86] The most important climbdown from the NPRM is the abandonment of the proposed Labor Markets section.[87] This section would have forced merging parties to classify their employees by job category codes from the U.S. Bureau of Labor Statistics,[88] even though few companies use such codes in the ordinary course of business. And it would have required filers to classify their employees by the U.S. Department of Agriculture's ERS commuting zones, even though companies do not use them in the ordinary course of business and these zones have not been updated since 2000 and are unreliable. The new burden would have been massive, and commenters understandably objected vociferously.[89]

Beyond the major burden and methodological problems, the NPRM's

[78] *See* FTC and DOJ, HSR Annual Report Fiscal Year 2023, at Appendix A (showing 7,002, 6,288 and 3,515 HSR filings for 2021, 2022, and 2023, respectively), *https://www.ftc.gov/policy/reports/annual-competition-reports.*

[79] SBP at 16.

[80] *See id.* at 150–51.

[81] *See id.* at 152.

[82] *See id.* at 152–54.

[83] *See* Dissenting Statement of Comm'r Andrew N. Ferguson, *In the Matter of Chevron Corp. and Hess Corp.,* FTC Matter No. 2410008, at 6 (Sept. 30, 2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/chevron-hess-ferguson-statement_0930.pdf;* Joint Dissenting Statement of Comm'r Melissa Holyoak and Comm'r Andrew N. Ferguson, *In re ExxonMobil Corp.,* FTC Matter No. 2410004 (May 1, 2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/2410004exxonpioneermh-afstmt.pdf.*

[84] *Mock* v. *Garland,* 75 F.4th 563, 583 (5th Cir. 2023) (''After the required NPRM is published in the **Federal Register**, with either the terms or substance of the proposed rule or a description of the subjects and issues involved, the final rule the agency adopts must be a logical outgrowth of the rule proposed.'' (cleaned up)); *Env't Integrity Project* v. *EPA,* 425 F.3d 992, 996 (D.C. Cir. 2005) (''Given the strictures of notice-and-comment rulemaking, an agency's proposed rule and its final rule may differ only insofar as the latter is a 'logical outgrowth' of the former.''); see also *Long Island Care at Home, Ltd.* v. *Coke,* 551 U.S. 158, 160 (2007) (''The Courts of Appeals have generally interpreted this to mean that the final rule the agency adopts must be a logical outgrowth of the rule proposed.'' (cleaned up)).

[85] See *infra* pp. 11–14; Statement of Comm'r Melissa Holyoak, Final Premerger Notification Form and the Hart-Scott-Rodino Rules, File No. P239300, at 7–19 (Oct. 10, 2024).

[86] See, *e.g., Perez,* 575 U.S. at 96 (''An agency must consider and respond to significant comments received during the period for public comment.''); *Chamber of Commerce of the U.S.* v. *SEC,* 85 F.4th 760, 774 (5th Cir. 2023) (An agency must ''consider all relevant factors raised by the public comments and provide a response to significant points within. Comments the agency must respond to include those that can be thought to challenge a fundamental premise underlying the proposed agency decision or include points that if true and adopted would require a change in an agency's proposed rule.'' (cleaned up)); *Bloomberg L.P.* v. *SEC,* 45 F.4th 462, 476–77 (D.C. Cir. 2022) (''[A]n agency must respond to comments that can be thought to challenge a fundamental premise underlying the proposed agency decision. Indeed, the requirement that agency action not be arbitrary or capricious includes a requirement that the agency adequately explain its result and respond to relevant and significant public comments. In sum, an agency's response to public comments must be sufficient to enable the courts to see what major issues of policy were ventilated and why the agency reacted to them as it did.'' (cleaned up)).

[87] For a fulsome accounting of the economic and legal errors that infected the Labor Markets instruction, see Statement of Comm'r Melissa Holyoak, Final Premerger Notification Form and the Hart-Scott-Rodino Rules, File No. P239300, at 7–13 (Oct. 10, 2024).

[88] NPRM, 88 FR at 42197.

[89] *See, e.g.,* Comment of A.B.A. Antitrust L. Sec., Doc. No. FTC–2023–0040–0723 at 10–12; Comment of Wachtell, Lipton, Rosen & Katz, Doc. No. FTC–2023–0040–0670 at 6–10; Comment of Dechert LLP, FTC–2023–0040–0659 at 3–5.

Labor Markets instructions were a clear abuse of Congress's mandate that the Commission require only information ''necessary and appropriate'' to identify transactions that ''violate the antitrust laws.'' [90] In the nearly half century since Congress passed HSR, the Antitrust Agencies have never successfully challenged any transactions based on labor market theories that could have been identified by the proposed requirements.[91] Until recently, the Antitrust Agencies had never even tried.[92] It is not for a lack of effort. For years, the Commission and Antitrust Division looked for viable labor market theories when investigating transactions that present other competition concerns. The lack of any success lays bare that the Commission never could have justified the immense cost of requiring every single filer to provide extensive labor-related information. Fortunately, my colleagues on the Commission agreed to jettison the Labor Markets section that likely would have doomed the Final Rule.[93]

The Final Rule also eliminates the NPRM's requirement that merging parties provide all drafts of transaction-related ''document[s] that were sent to an officer, director, or supervisory deal team lead(s).'' [94] Commenters rightly pointed out that this requirement would have imposed an undue burden on merging parties,[95] with the American Bar Association noting that this provision could have forced filers to use e-discovery tools to capture every draft.[96] The cost of this information demand is high. But the value to the Antitrust Agencies would have been low. Commission staff would have struggled to comb through a dozen versions of the same document. And insofar as the goal was to catch merging parties giving honest appraisals about the anticompetitive effects of mergers, I doubt demanding drafts would have succeeded. Knowing that such drafts would have to be produced, parties would just create methods to avoid exposing their honest thoughts in documents that are guaranteed to wind up in the hands of enforcers. Demanding drafts of documents in every transaction would have likely increased the expense of merging—of great benefit to antitrust lawyers—without giving the Antitrust Agencies the sort of ''hot docs'' for which they were hoping. The Final Rule appropriately eliminated this requirement for every transaction. The Commission can obtain drafts under the only circumstances it would ever need them—when it opens investigations into those few mergers that the HSR filings reveal present a genuine risk of anticompetitive effects.

Similarly, the Final Rule curtailed several of the NPRM's other burdensome requirements for merging parties to produce documents. It revises the definition of ''supervisory deal team lead'' to limit it to a single individual, eliminating the need to review multiple employees' files to fulfill this request for transaction-related documents.[97] The Final Rule also removes the NPRM's demand for ordinary course plans and reports that were shared with senior executives but not the CEO. Commenters rightfully noted that this would have forced filers to search the files of additional custodians, greatly increasing the burden on merging parties.[98] Instead, the Final Rule limits the request to certain plans and reports directly provided to the CEO or board of directors.[99] Lastly, the Final Rule no longer forces merging parties to produce all agreements between them. The NPRM's requirement to produce every single agreement between the parties would have been burdensome and expensive, but likely would have shed little light on the potential competitive effects of the merger. Some agreements between merging parties might shed light on competitive effects, but the vast majority would tell us nothing. The Final Rule acknowledges this mismatch of costs and benefits, and instead requires parties to note only whether they have particular types of agreements.[100]

The Final Rule makes many additional changes to the abusive NPRM. It makes clear that filers do not need to disclose any individual's role in a ''non-profit entity organized for a religious or political purpose.'' [101] This exception is important. Requiring a Catholic hospital, for example, to disclose its membership rolls merely because it wishes to make a reportable acquisition, without regard to the competitive effects of that acquisition, would raise serious First Amendment concerns.[102] The Final Rule also creates

[90] 15 U.S.C. 18a(d)(1).

[91] The NPRM identified two successful merger challenges with purported labor theories. See NPRM, 88 FR at 42197, n.47. The first, the Antitrust Division's challenge to Penguin Random House's acquisition of Simon & Schuster, did not involve harm to employees of the merging firms. Instead, the alleged harm was in the market for ''publishing rights to anticipated top-selling books.'' *United States* v. *Bertelsmann SE & Co. KGaA,* 646 F. Supp. 3d 1, 12 (D.D.C. 2022). The second, the Commission's challenge to Lifespan Corporation's acquisition of Care New England, did not include a labor market count in the complaint. See Compl., *In the Matter of Lifespan Corp. and Care New England Health Sys.,* FTC Matter No. 2110031 (Feb. 17, 2022). Commissioner Bedoya identifies another purported merger challenge based on a labor theory, specifically ''decrease[d] fees paid to blood plasma donors.'' Statement of Comm'r Alvaro M. Bedoya, In the Matter of Amendments to the Premerger Notification and Report Form and Instructions and the Hart-Scott-Rodino Rule, File No. P239300, at n.20 (Oct. 10, 2024) (''Statement of Comm'r Bedoya''). But, like the Antitrust Division's *Bertelsmann* challenge, the complaint did not allege harm to the merging parties' employees and therefore could not have been identified by the NPRM's proposed demands for employee information. See Compl., *In the Matter of Grifols S.A. and Grifols Shared Services North America, Inc.,* FTC Matter No. 1810081 (Aug. 1, 2018).

[92] Given the pendency of litigation within the Commission's administrative tribunal, I withhold comment on the strength of the Commission's labor market theory in its challenge to The Kroger Company's acquisition of Albertsons Companies, Inc.

[93] Commissioner Bedoya defends the NPRM's Labor Markets section, reasoning that because the antitrust laws apply to the labor markets, the Commission should screen every single merger subject to HSR for potential labor-competition problems. Statement of Comm'r Bedoya, *supra* n.89, at 2, 4. I do not disagree that the antitrust laws apply to labor markets. But that fact would not have made lawful a rule that was identical to the NPRM. Under ordinary principles of administrative law, the Commission would have to ''examine the relevant data and articulate a satisfactory explanation for its action, including a rational connection between the facts found and the choices made.'' *State Farm,* 463 U.S. at 43 (cleaned up). That means the Commission would need enough evidence of labor-competition problems in mergers to establish that the labor-markets instruction's onerous costs were reasonable. The evidence marshalled by Commissioner Bedoya—a couple papers and a book—comes nowhere near to clearing that bar. Statement of Comm'r Bedoya at 3. The majority made the same mistake in the Noncompete Rule by relying on sparse social-science research to justify massive regulatory burdens. See Dissenting Statement of Comm'r Andrew N. Ferguson, Joined by Comm'r Melissa Holyoak, In the Matter of the Non-Compete Clause Rule, Matter No. P201200, at 37–45 (June 28, 2024), *https://www.ftc.gov/system/files/ftc_gov/pdf/ferguson-noncompete-dissent.pdf* (''The handful of academic papers cited in the Final Rule cannot justify its incredible reach and relying on them to prohibit noncompete agreements categorically is a clear error of judgment.'' (cleaned up)); *Ryan LLC* v. *FTC,* No. 3:24–CV–00986–E, 2024 WL 3879954, at *13–14 (N.D. Tex. Aug. 20, 2024) (finding the Noncompete Rule arbitrary and capricious because ''[t]he record does not support the Rule.''). Making that mistake here would have been a ''clear error of judgment'' requiring vacatur under the APA. *Huawei Technologies USA, Inc.* v. *FCC,* 2 F.4th 421, 434 (5th Cir. 2021) (cleaned up).

[94] NPRM, 88 FR at 42214.

[95] SBP at 270–71.

[96] Comment of A.B.A. Antitrust L. Sec., Doc. No. FTC–2023–0040–0723 at 15–16.

[97] *See* SBP at 203–05.

[98] E.g., Comment of U.S. Chamber of Com., Doc. No. FTC–2023–0040–0684 at 22, 24.

[99] *See id.* at 274–77.

[100] *See id.* at 291–93.

[101] *See* Acquiring Person Instructions at 5.

[102] *See, e.g., Americans for Prosperity Found.* v. *Bonta,* 594 U.S. 595, 606 (2021) (''This Court has 'long understood as implicit in the right to engage in activities protected by the First Amendment a corresponding right to associate with others.' Protected association furthers 'a wide variety of political, social, economic, educational, religious, and cultural ends,' and 'is especially important in preserving political and cultural diversity and in shielding dissident expression from suppression by

Continued

de minimis exclusions, which remove the need for filers to note tiny prior acquisitions, supply relationships, and defense contracts that could not plausibly move the competitive needle.[103] The Final Rule shortens lookback periods for many requests, including prior acquisitions, which limits the burdens associated with digging through dated company records.[104] It removes demands for filers to create some new documents, such as deal timelines and organization charts.[105] And the Final Rule includes other important, burden-reducing changes from the indefensible NPRM, all of which help tailor the Final Rule to only those things that are necessary and appropriate to carry out the requirements of HSR.[106]

I still would prefer a deeper cut. For example, I would not have included the transaction rationale requirement.[107] Our requests for transaction-related documents already cover the same ground, in the parties' own words. I expect most transaction rationales will be heavily lawyered essays designed to ensure that the rationale matches these transaction documents. Indeed, I cannot imagine any lawyer worth his or her salt ever permitting the rationale to depart meaningfully from other parts of the notification. I therefore doubt that the rationales will provide any valuable information that we could not glean elsewhere. Perhaps in some cases parties may use the transaction rationale to explain why a merger that appears suspect at first blush presents no competitive problems. But on the whole, I doubt the transaction rationale will benefit the Antitrust Agencies in the mine run of cases, and I would not impose the burden on every filer.

This example highlights an important consideration the Commission must bear in mind for the future. If post-promulgation experience teaches us that some parts of the rule are not working well, we can and should get rid of them in subsequent rulemakings. We have done that in the past.[108] If, for example, my prediction about the value of the transaction rationale proves correct, we can and should jettison it. The same is true of all provisions of the Final Rule. Although we have satisfied the APA's requirement that the Final Rule be the product of reasoned decision making about what is necessary and appropriate to carry the Act into execution, experience almost certainly will reveal that the Final Rule can be improved. The Commission should abandon whatever parts of the Final Rule do not work.

Considered as a whole, however, the additional information sought in the Final Rule is ''necessary and appropriate'' for the Antitrust Agencies to identify transactions that may violate the antitrust laws.[109] Its benefits are many, and, by comparison, the added burdens are reasonable.

Because the Final Rule represents the Commission's reasoned decision about what is necessary and appropriate to carry into execution the requirements of HSR, and because I believe it lawfully addresses shortcomings in the current HSR rule, I concur in its promulgation.

[FR Doc. 2024–25024 Filed 11–8–24; 8:45 am]

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the majority.' '' (quoting *Roberts* v. *U.S. Jaycees,* 468 U.S. 609, 622 (1984)); *id.* at 608 (forbidding mandatory disclosure of donor rolls unless the disclosure requirement is narrowly tailored to vindicate an important government interest); *NAACP* v. *Alabama ex rel. Patterson,* 357 U.S. 449, 462–63 (1958) (holding that mandatory disclosure of membership rolls without a sufficient justification violates the First Amendment).

[103] *See* SBP at 153–54.

[104] *See id.* at 151–52.

[105] *See id.* at 6, 293–95.

[106] *See id.* at 6–8, 147–56.

[107] *See* SBP at 253–56.

[108] E.g., 70 FR 73369 (Dec. 12, 2005) (amending Form and Instructions to reduce the burden of complying with Items 4(a) and (b)); SBP at 107, n.248 (summarizing numerous changes to HSR Rule since 1978).

[109] 15 U.S.C. 18a(d)(1).

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Part IV

Environmental Protection Agency

40 CFR Part 745

Reconsideration of the Dust-Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 745

[EPA–HQ–OPPT–2023–0231; FRL–8524–02–OCSPP]

RIN 2070–AK91

Reconsideration of the Dust-Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: As part of EPA's high-priority efforts to reduce childhood lead exposure, and in accordance with a U.S. Court of Appeals for the Ninth Circuit 2021 opinion, EPA is finalizing its proposal to lower the dust-lead hazard standards to any reportable level as analyzed by a laboratory recognized by EPA's National Lead Laboratory Accreditation Program (NLLAP). EPA's lead-based paint (LBP) regulations do not compel property owners or occupants to evaluate their property for LBP hazards or to take control actions, but if a LBP activity such as an abatement is performed, then EPA's regulations set requirements for doing so. EPA is also finalizing changes to lower the post-abatement dust-lead clearance levels to 5 micrograms per square foot (μg/ft^2), 40 μg/ft^2, and 100 μg/ft^2 for floors, window sills and troughs respectively, the current levels in New York City. Due to feedback from public comments, EPA is also finalizing changes to the nomenclature to adopt the terms dust-lead reportable levels (DLRL) and dust-lead action levels (DLAL). Given the decoupling of the action levels from the reportable levels, EPA is finalizing revisions to the definition of abatement so that the recommendation for action based on dust-lead applies when dust-lead loadings are at or above the action levels, rather than the hazard standards, as has been the case historically. The dust-lead hazard standards will be described as DLRL moving forward (*i.e.,* after publication of this final rule) and the dust-lead clearance levels will be described as DLAL. Additionally, EPA is finalizing several other amendments, including revising the definition of target housing to conform with the statute.

DATES: This final rule is effective January 13, 2025. The incorporation by reference of certain material listed in this rule is approved by the Director of the **Federal Register** as of January 13, 2025.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPPT–2023–0231, is available online at *https://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in-person, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT:

For technical information: Claire Brisse, Existing Chemicals Risk Management Division (7404M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–9004; email address: *brisse.claire@epa.gov.*

For general information on lead: The National Lead Information Center, 422 South Clinton Avenue, Rochester, NY 14620; telephone number: (800) 424–LEAD [5323]; online form: *https://www.epa.gov/lead/forms/lead-hotline-national-lead-information-center.*

For general information on TSCA: The TSCA Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554–1404; email address: *TSCA-Hotline@epa.gov.*

For hearing- or speech-impaired assistance: Persons may reach the telephone numbers for the contacts through TTY by calling the toll-free Federal Communications Commission's Telecommunications Relay Service at 711.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you conduct LBP activities in accordance with 40 CFR 745.227; if you operate a training program required to be accredited under 40 CFR 745.225; if you are a firm or individual who must be certified to conduct LBP activities or renovations in accordance with 40 CFR 745.226; or if you own, manage, and/or conduct abatement, rehabilitations or maintenance activities in most pre-1978 housing that is covered by a Federal housing assistance program in accordance with 24 CFR part 35. You may also be impacted by this rule if you administer the LBP activities program in States, territories, or Tribes that are authorized by EPA to operate their own lead abatement programs (40 CFR part 745, subpart Q) (see Unit V.A. for more information). You may also be affected by this action if you operate a laboratory that is recognized by EPA's National Lead Laboratory Accreditation Program in accordance with 40 CFR 745.90, 745.223, 745.227, and 745.327. You may also be affected by this action, in accordance with 40 CFR 745.107 and 24 CFR 35.88, as the seller or lessor of target housing, which is most pre-1978 housing. See 40 CFR 745.103 and 24 CFR 35.86. You may also be affected by this action if you are a resident of target housing, even if you would not be subject to the requirements of this action. Due to the change in the definition of ''target housing,'' you may also be affected if you are a firm or individual who must be certified to perform renovations in target housing or child-occupied facilities (COFs) in accordance with 40 CFR part 745, subpart E.

The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Affected entities may include:

- Building construction (NAICS code 236) (*e.g.,* single-family housing construction, multi-family housing construction, residential remodelers).
- Specialty trade contractors (NAICS code 238) (*e.g.,* plumbing, heating, and air-conditioning contractors, painting, and wall covering contractors, electrical contractors, finish carpentry contractors, drywall and insulation contractors, siding contractors, tile and terrazzo contractors, glass, and glazing contractors).
- Real estate (NAICS code 531) (*e.g.,* lessors of residential buildings and dwellings, residential property managers, and property owners, as well as those property owners that receive assistance through Federal housing programs).
- Child day care services (NAICS code 624410).
- Elementary and secondary schools (NAICS code 611110) (*e.g.,* elementary schools with kindergarten classrooms).
- Other technical and trade schools (NAICS code 611519) (*e.g.,* training providers).
- Engineering services (NAICS code 541330) and building inspection services (NAICS code 541350) (*e.g.,* dust sampling technicians).
- Lead abatement professionals (NAICS code 562910) (*e.g.,* firms and supervisors engaged in LBP activities).
- Testing laboratories (NAICS code 541380) (*e.g.,* those laboratories that analyze dust wipe samples for lead).
- Federal agencies that own residential property (NAICS codes 92511, 92811).

If you have questions regarding the applicability of this action to a particular entity, consult the regulations

or contact the technical information person listed in the **FOR FURTHER INFORMATION CONTACT** section.

B. What is the Agency's authority for taking this action?

EPA is finalizing this rule under the authority of sections 401, 402, 403, 404, and 406 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601 *et seq.,* as amended by Title X of the Housing and Community Development Act of 1992 (also known as the Residential Lead-Based Paint Hazard Reduction Act of 1992 or ''Title X'') (Pub. L. 102–550) (Ref. 1) and section 237(c) of Title II of Division K of the Consolidated Appropriations Act, 2017 (Pub. L. 115–31, 131 Stat. 789), as well as sections 1004 and 1018 of Title X (42 U.S.C. 4851b, 4852d), as amended by section 237(b) of Title II of Division K of the Consolidated Appropriations Act, 2017.

TSCA section 403 (15 U.S.C. 2683) mandates EPA to identify LBP hazards for purposes of administering Title X and TSCA Title IV. Under TSCA section 401, LBP hazards are defined as conditions of LBP and lead-contaminated dust and soil that ''would result in adverse human health effects,'' (15 U.S.C. 2681(10)) and lead-contaminated dust is defined as ''surface dust in residential dwellings'' that contains lead in excess of levels determined ''to pose a threat of adverse health effects . . .'' (15 U.S.C. 2681(11)). EPA has referred to the dust-lead portion of the LBP hazards as the dust-lead hazard standards. As explained in Unit IV.A. of this final rule, going forward EPA is also describing these as the dust-lead reportable levels in order to better connote their purpose under the revisions. In this document, EPA has endeavored to use the term dust-lead hazard standards or DLHS to describe the standards in place prior to this final rule and the term dust-lead reportable levels or DLRL to describe the standards in place going forward.

TSCA section 402 (15 U.S.C. 2682) directs EPA to regulate LBP activities, which include risk assessments, inspections, and abatements. TSCA section 401 (15 U.S.C. 2681) defines abatements as ''measures designed to permanently eliminate lead-based paint hazards'' and the term includes ''all . . . cleanup . . . and post[-]abatement clearance testing activities'' (15 U.S.C. 2681(1)). EPA has referred to the dust-lead level to be achieved after the post-abatement clearance activities as the dust-lead clearance levels. As explained in Unit IV.A. of this final rule, going forward EPA is also describing these as the dust-lead action levels in order to better connote their purpose under the revisions. In this document, EPA has endeavored to use the term dust-lead clearance level or DLCL to describe the standards in place prior to this final rule and the term dust-lead action levels or DLAL to describe the standards in place going forward.

EPA's statutory authority for setting the hazard standards is laid out differently in Title X and TSCA Title IV than its authority for regulating clearance activities. In contrast to the grant of authority for setting hazard standards, EPA is directed, in promulgating the LBP activities regulations (including the DLAL), to ''tak[e] into account reliability, effectiveness, and safety'' (15 U.S.C. 2682(a)(1)).

Pertaining to the other amendments presented in Unit IV.G. of this preamble, TSCA section 406 (15 U.S.C. 2686) requires EPA, in consultation with the Secretary of the U.S. Department of Housing and Urban Development (HUD) and with the Secretary of the U.S. Department of Health and Human Services (HHS) to ''publish, and from time to time revise, a lead hazard information pamphlet to be used in connection with this subchapter and section 4852d of title 42.'' TSCA section 406 (15 U.S.C. 2686) also requires EPA's regulations to require any person performing for compensation a renovation of target housing to provide the pamphlet to the owner and occupant prior to commencing the renovation. Additionally, section 1018 of Title X (42 U.S.C. 4852d) mandates that the Lead Warning Statement to be provided in contracts for the purchase or sale of target housing include, among other language, the following text: ''. . . The seller of any interest in residential real property is required to provide the buyer with any information on lead-based paint hazards from risk assessments or inspections in the seller's possession and notify the buyer of any known lead-based paint hazards.'' TSCA section 401 (15 U.S.C. 2681(17)) and section 1004 of Title X (42 U.S.C. 4851b), as amended by section 237(b) and (c) of Title II of Division K of the Consolidated Appropriations Act, 2017 (Pub. L. 115–31, 131 Stat. 789), define target housing as ''any housing constructed prior to 1978, except housing for the elderly or persons with disabilities or any 0-bedroom dwelling (unless any child who is less than 6 years of age resides or is expected to reside in such housing) . . .'' In this context, ''housing for the elderly'' refers to retirement communities or similar types of housing reserved for households composed of one or more persons 62 years of age or more at the time of initial occupancy (40 CFR 745.103). Note that HUD's Lead Safe Housing Rule (LSHR) caveats its definition of ''housing for the elderly'' at 24 CFR 35.110 to rely on an age other than 62 years ''if recognized as elderly by a specific Federal housing assistance program.''

C. What action is the Agency taking?

In 2019, EPA promulgated a final rule to lower the DLHS to 10 μg/ft² for floors and 100 μg/ft² for window sills (the 2019 Final Rule) (Ref. 2). In 2021, EPA promulgated a final rule to lower the DLCL to 10 μg/ft² for floors and 100 μg/ft² for window sills (the 2021 Final Rule) (Ref. 3). The 2019 Final Rule and the 2021 Final Rule continued a long-standing practice of setting the same levels for the DLHS and the DLCL and basing those levels in part on consideration of factors such as laboratory capacity and capabilities. On August 1, 2023, EPA proposed revisions in keeping with an opinion issued by the U.S. Court of Appeals for the Ninth Circuit (the Court) in 2021 (described in Unit I.D.) that instructed EPA to consider only health factors when setting the DLHS (described as DLRL moving forward) and that EPA must continue to consider non-health factors (*e.g.,* laboratory capabilities/capacity, and achievability after an abatement) when setting the DLCL (described as DLAL moving forward). Note that due to feedback from public comments, EPA is finalizing the previously mentioned changes to the nomenclature, from DLHS to dust-lead reportable level and from DLCL to dust-lead action level (see Unit IV.A., for more discussion on this terminology change).

EPA is finalizing the proposed changes to the DLRL from 10 μg/ft² for floors and 100 μg/ft² for window sills, as established in the 2019 Final Rule, to any reportable level of dust-lead analyzed by a NLLAP-recognized laboratory. The DLRL is not a static level set by EPA but rather the numerically reportable level as analyzed by a NLLAP-recognized laboratory. The approach represents a shift in the LBP activities program to a more inclusive DLRL, which will identify dust-lead hazards in the context of TSCA Title IV as any reportable level of dust-lead in target housing and child-occupied facilities and will not distinguish based on health risks posed. Additional discussion on DLRL can be found in Unit IV.B.

Additionally, EPA is finalizing a reduction of 50% or more in the values set by the 2021 Final Rule to the proposed alternative DLAL, from 10 μg/ft² to 5 μg/ft² for dust-lead for floors,

from 100 μg/ft² to 40 μg/ft² dust-lead for window sills and from 400 μg/ft² to 100 μg/ft² dust-lead for window troughs. The reportable level for floors and window sills will not be the same as the action level for floors and window sills (*i.e.,* the standards will be decoupled), acknowledging the different statutory direction that Congress provided EPA with respect to each. As a result, EPA is also finalizing the proposed amendment to the LBP activities regulations' definition of abatement to be any measure or set of measures designed to eliminate LBP hazards, in the case of dust-lead hazards, to a level below the final DLAL; thus modifying the trigger so that the *recommendation for action applies when dust-lead loadings are at or above the dust-lead action levels,* rather than the hazard standards (described as dust-lead reportable levels moving forward), as has been the case historically. Note that EPA's LBP regulations do not automatically compel property owners or occupants to evaluate their property for LBP hazards or to take control actions, but if a LBP activity such as an abatement is performed, then EPA's regulations set requirements that must be met while doing so. EPA is also finalizing a requirement to include an additional statement in the final abatement reports that States that LBP hazards (particularly dust-lead hazards) remain after an abatement if post-abatement testing has found that reportable levels remain below the action levels. See Unit IV.E., and Unit IV.F. for additional information on these programmatic changes.

EPA is also finalizing several other amendments to 40 CFR part 745, subparts E (Residential Property Renovation), F (Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards Upon Sale or Lease of Residential Property), and L (Lead-Based Paint Activities), including: conforming changes to the definition of ''target housing;'' conforming the age requirements throughout the LBP regulations to under six years old; requiring that application payments, applications, and notices be submitted electronically; updating the Disclosure Rule warning statement (Ref. 4); correcting an incorrect reference to the lead-hazard control pamphlet; deleting obsolete regulatory text where language is out of date or no longer applicable; and adding incorporations by reference of two voluntary consensus standards already included in a relevant definition.

D. Why is the Agency taking this action?

Lead exposure has the potential to impact individuals of all ages, but it is especially harmful to young children because the developing brain can be particularly sensitive to environmental contaminants (Refs. 5 and 6). Because of this, reducing childhood lead exposure is a priority for both EPA and the Federal government. In December 2018, the President's Task Force on Environmental Health Risks and Safety Risks to Children released the *Federal Action Plan to Reduce Childhood Lead Exposures and Associated Health Impacts* (Federal Lead Action Plan) (Ref. 7) to enhance the Federal government's efforts to identify and reduce lead exposure while ensuring children impacted by such exposure are getting the support and care they need to prevent or mitigate any associated health effects. The Federal Lead Action Plan is helping Federal agencies to work strategically and collaboratively to reduce exposure to lead and improve children's health. On October 27, 2022, EPA released the *Strategy to Reduce Lead Exposures and Disparities in U.S. Communities* (EPA Lead Strategy). The EPA Lead Strategy lays out Agency and governmentwide approaches to strengthen public health protections, address legacy lead contamination for communities with the greatest exposures and promote environmental justice. It describes how the Agency will utilize the full suite of EPA authorities, expertise, and resources to continue to reduce lead exposure. This final rule, which revises the DLRL and the DLAL, among other regulatory changes, is an action that EPA committed to undertake in the EPA Lead Strategy (Ref. 8).

In 2019, EPA re-evaluated the DLHS (described as DLRL moving forward) (Ref. 2). Based on that evaluation, the final rule revised the DLHS from 40 μg/ft² and 250 μg/ft² to 10 μg/ft² and 100 μg/ft² for floors and window sills, respectively. However, public health advocates filed a lawsuit in the U.S. Court of Appeals for the Ninth Circuit seeking judicial review of the 2019 Final Rule as insufficiently protective. On May 14, 2021, the Court issued its opinion on the 2019 Final Rule. The Court held that ''the 2019 Rule lowers the lead hazard level but not to a level sufficient to protect health as Congress has directed, because the EPA has looked to factors in addition to health.'' *A Cmty. Voice* v. *U.S. Env't Prot. Agency,* 997 F.3d 983, 992 (9th Cir. 2021). The remedy the Court granted was a remand without vacatur of the lowered standard, and the Court instructed EPA to consider only health factors when setting the DLHS (Ref. 9). The 2023 Proposed Rule was issued to reconsider the DLHS and DLCL in light of the 2021 Court Opinion, which directed EPA to ''reconsider the DLHS . . . [and] the dust-lead clearance levels . . . in the same proceeding'' and affirmed that EPA must consider non-health factors when setting the DLCL (described as DLAL moving forward). *A Cmty. Voice,* 997 F.3d at 995. This 2021 Court Opinion led EPA to undertake a major shift from its approach in the 2019 and 2021 final rules to the LBP activities program because the Court found that EPA did not have the authority, when setting the DLHS, to consider non-health factors. Consistent with the 2021 Court Opinion and based on the Agency's careful review of the public comments received on the proposal, EPA is finalizing the DLRL in this rulemaking as proposed, based on only health considerations, as well as finalizing the proposed alternative DLAL, based on a variety of factors. See Unit IV. for more information on the final revisions to the DLRL and DLAL.

E. What are the estimated incremental impacts of this action?

EPA has prepared an Economic Analysis (EA), which is available in the docket, of the potential incremental impacts associated with this rulemaking (Ref. 10). The analysis focused specifically on the subset of target housing and child-occupied facilities affected by this rule. Although the DLHS and DLCL do not compel specific actions under the LBP Activities Rule to address identified LBP hazards, the DLHS and DLCL are directly cross-referenced in certain requirements mandated by HUD in the housing subject to HUD's LSHR. As such, the analysis estimates incremental costs and benefits for two categories of events: (1) where dust-wipe testing occurs to comply with HUD's Lead-Safe Housing Rule; and (2) where dust wipe testing occurs in response to blood lead testing that detects a blood lead level (BLL) above State or Federal action levels. The following is a brief outline of the estimated incremental impacts of this rulemaking.

1. Benefits

This rule will result in reduced exposure to lead, yielding benefits to residents of pre-1978 housing from avoided adverse health effects. Using a 2% discount rate, the annualized benefits of improved cognitive function in children (quantified using the effect of avoided IQ decreases on lifetime earnings) are estimated to be $831 million to $3.1 billion per year; the

annualized benefits of reduced cases of attention deficit hyperactivity disorder (ADHD) in children are estimated to be $129 million to $274 million per year; and the annualized benefits of reduced cases of cardiovascular mortality in adults are estimated to be $614 million to $6.9 billion per year. The total annualized quantified benefits for all health endpoints are estimated to range from $1.6 billion to $10.3 billion per year. EPA also analyzed the effect of mothers' exposures to lead on the risk of low birthweight in their infants, but the analysis found that the resulting changes in infant birthweight could not be monetized using EPA's cost-of-illness approach. Nevertheless, the increases in birth weights from this rule, however small, may still reduce initial birth-related costs and hospitalization costs incurred by mothers.

These benefits calculations are sensitive to the range in the estimated number of lead hazard reduction events triggered by children with tested BLLs above State action thresholds or the Centers for Disease Control and Prevention (CDC) blood lead reference value (BLRV) of 3.5 micrograms per deciliter (μg/dL). The wide range is driven largely by uncertainty about the BLLs at which action might be taken, since in many States the action level is currently higher than the Federal blood lead reference value. The benefit estimates are also sensitive to the concentration response function used to estimate the number of reduced cases of premature cardiovascular mortality in adults, and the assumed rate of soil and dust ingestion by adults. EPA undertook a rigorous process to identify concentration response functions to quantify benefits. This included reviewing all available studies which could be used to develop quantitative relationships between changes in lead exposure and/or changes in blood lead levels and changes in health endpoints. EPA evaluated the studies for quality and potential biases. EPA then developed a separate report for each health endpoint. In addition to the quality review findings, each report provides quantitative estimates, based on the identified functions, of potential changes in the health endpoint and was reviewed by EPA experts and/or externally peer reviewed. For the analysis of this final rule EPA has relied on concentration response functions for four quantified health endpoints that have been extensively reviewed by the agency and in the case of reductions in IQ losses, low birth weight and cardiovascular disease premature mortality, externally peer reviewed. Also, the approach used for IQ has been used in multiple prior rulemakings and undergone SAB review. EPA will consider updates to the benefits estimation methodologies and peer review as appropriate and as new information becomes available in the future.

Additionally, there may be benefits that are unquantified. These additional benefits might include avoided adverse health effects, including reduced post-natal growth, delayed puberty, and decreased kidney function in children, cancer, and impacts on reproductive function and outcomes in adults.

2. Costs

This rule is estimated to result in quantified costs of $207 million to $348 million per year. These costs are expected to accrue to landlords, owners and operators of child-occupied facilities, residential remodelers, and abatement firms. Real estate agents and brokers may incur negligible costs related to the target housing definition amendment. The cost calculations are highly sensitive to the range in the estimated number of lead hazard reduction events triggered by children with higher BLLs. In the events affected by this rule, incremental costs can be incurred for specialized cleaning used to reduce dust-lead loadings (*i.e.,* quantity of lead per unit of surface area) to below the action levels. In some instances, floors will also be sealed, overlaid, or replaced, or window sills will be sealed or repainted. Additional costs may result from the retesting of dust-lead levels. Additional potential impacts to HUD programs and their beneficiaries are discussed in Unit V.

3. Small Entity Impacts

This rule will directly impact approximately 18,000 small businesses of which 85% to 86% have cost impacts less than 1% of revenues, 12% to 13% have impacts between 1% and 3%, and 2% have impacts greater than 3% of revenues. These small entities include landlords, owners and operators of child-occupied facilities, residential remodelers, abatement firms, and real estate agents and brokers.

4. Environmental Justice

EPA is finalizing this rulemaking under TSCA Title IV, as explained in Unit I.B. This rule would address lead exposure, as discussed throughout this preamble. EPA prepared an Economic Analysis for this rulemaking that assessed whether there are disproportionate effects to communities from lead exposure. EPA identified an existing concern: children living in communities with environmental justice concerns have significantly higher BLLs than other children (Ref. 11). This rule addresses health concerns for all affected communities, including those identified with environmental justice concerns. As identified in EPA's Economic Analysis, the rule is expected to affect housing units receiving Federal assistance under HUD's LSHR and housing units with a child with a BLL above the Federal BLRV, or above a State, or local blood lead action level. Because, in general, only lower income households are eligible to receive Federal housing assistance, the occupants of housing subject to the LSHR (and thus benefitting from the regulation) are considered an overburdened community. Additional details on any identified disproportionate impacts to communities with environmental justice concerns are contained in Unit IX.J. of this preamble and Section 8.6 of the Economic Analysis.

5. Children's Environmental Health

Consistent with Executive Order 13045, EPA evaluated the health and safety effects of this action on children. Children are disproportionately impacted by lead exposure. Children can have greater exposures than adults because they crawl on floors and often put their hands and other objects (that can have lead from dust on them) into their mouths and are more susceptible than adults to adverse health effects associated with lead exposure due to their rapid anatomical growth and physiological differences in lead uptake and metabolism. This rule protects children from these disproportionate environmental health risks.

This action is also subject to EPA's Policy on Children's Health (*https://www.epa.gov/children/childrens-health-policy-and-plan*) because the rule has considerations for human health and early life exposures. Accordingly, EPA has evaluated the environmental health or safety effects of dust-lead exposure on children. The results of this evaluation are contained in the EA and the Technical Support Document (TSD), where the health impacts of lead exposure on children are discussed more fully (Refs. 10 and 12). The documents referenced in this unit are available in the public docket for this action.

A primary purpose of this rule is to reduce exposure to dust-lead hazards in target housing where children reside and in child-occupied facilities. EPA's analysis indicates that there will be approximately 178,000 to 326,000 children under age six per year affected

by the rule, and 83,000 to 158,000 children between the ages of six and fifteen per year (Ref. 10). Using a 2% discount rate, the total annualized quantified benefits for children's health endpoints (improved cognitive function and reduced cases of ADHD) are estimated to range from $960 million to $3.4 billion per year.

6. Effects on State, Local, and Tribal Governments

EPA has concluded that this action has federalism implications because of the potential effects on certain public housing authorities. These compliance costs result from application of EPA's standards in HUD's LSHR. While some HUD funding for LBP projects exists, the Federal government may not provide the funds necessary to pay the entirety of the costs. As described in Section 8.8 of the EA (Ref. 10), the costs to public housing authorities that include State, local, and Tribal governments—estimated at $27 million per year—cover additional lead hazard reduction activities, cleaning, and dust-lead testing to ensure that public housing units are in compliance with the LSHR. State and local governments may provide additional funding to pay for some of these costs. EPA also estimates annual compliance costs of approximately $850,000 per year to public school districts that operate a child-occupied facility built before 1978. Additionally, States that have authorized LBP activities programs must demonstrate that they meet any new requirements imposed by this rulemaking and are at least as protective as the levels at 40 CFR 745.65 and 40 CFR 745.227. However, authorized States are under no obligation to continue to administer the LBP activities program, and if they do not wish to adopt the new DLRL and DLAL they can relinquish their authorization. In the absence of a State authorization, EPA will administer these requirements. EPA provides a federalism summary impact statement, which is found in Unit IX.E.

This action contains a Federal mandate under the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538, that may result in expenditures of $183 million or more in 2023 dollars ($100 million or more in 1995 dollars, adjusted for inflation) for State, local, and Tribal governments, in the aggregate, or the private sector in any one year. Accordingly, EPA has prepared a written statement as required under section 202 of UMRA, which is summarized in Unit IX.D. and included in the public docket (Ref. 13). This action is not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that exceed the inflation-adjusted cost significance threshold or uniquely affect small governments.

This action will not have substantial direct effects (as specified in Executive Order 13175) on one or more federally recognized Indian Tribes. This action neither creates an obligation for Tribes to administer LBP activities programs nor alters EPA's authority to administer these programs.

Additionally, this rule would not have any significant or unique effects on small governments. See Unit IX. for more information on the executive orders.

II. Background

A. Health Effects of Lead

Lead exposure has the potential to impact individuals of all ages, but it is especially harmful to young children because the developing brain can be particularly sensitive to environmental contaminants (Refs. 5, 6, 14). Ingestion of lead-contaminated dust is a major contributor to BLLs in children, particularly to those who reside in homes built prior to 1978 (Refs. 13 and 15). Throughout early childhood, floor dust contamination is a source of lead exposure with the potential to affect children's BLLs (Ref. 16). Infants, toddlers, and other young children are more highly exposed to lead through dust on floors and other surfaces at home and in child care facilities than older children and adults because they crawl on floors and often put their hands and other objects that can have lead from dust on them into their mouths. This is the main pathway of exposure to lead for young children (Ref. 5).

Lead exposure in young children can cause neurocognitive decrements, such as reduction in intelligence as measured by IQ. Depending on the exposure and other factors, the effect may persist into adolescence and adulthood (Refs. 5, 6 and 16). In children, lead exposure can also cause adverse developmental, neurobehavioral, hematological, and immunological effects (Refs. 5, 6, and 14). In adults, lead exposure can cause adverse cardiovascular, hematological, renal, neurocognitive, psychopathological, immunological, and reproductive effects (Refs. 5, 6, and 14). Lead is also classified as ''reasonably anticipated'' to be a human carcinogen by the National Toxicology Program (NTP) (Ref. 17) and EPA has concluded that lead exposure has a ''likely causal'' relationship with carcinogenesis (Ref. 5). In addition to the risk of harmful effects posed to the mother, lead can be transferred to the fetus during pregnancy with increased risk of adverse effects on the developing fetus (Refs. 5 and 14). Given young children's disproportionate exposure to dust-lead in target housing, this rulemaking principally considers their exposure and associated adverse health effects, although dust-lead exposure and adverse health effects in adolescents and adults are also considered when estimating the rule's benefits (Ref. 10).

Currently available scientific information informs EPA's understanding of the relationships between exposures to dust-lead, BLLs, and adverse human health effects. These relationships are summarized in the Integrated Science Assessment (ISA) for Lead, finalized in January 2024 (known as the 2024 Lead ISA) (Ref. 5), and the Agency for Toxic Substances and Disease Registry (ATSDR) Toxicological Profile for Lead, which was released by the Department of Health and Human Services in August 2020 (''ATSDR Tox Profile for Lead'') (Ref. 6). The 2024 Lead ISA is a synthesis and evaluation of scientific information on the health and environmental effects of lead, including cognitive function decrements in children (Ref. 5). The 2024 Lead ISA, as well as NIEHS' 2012 NTP monograph on lead, summarize the scientific evidence regarding potential health effects associated with low-level lead exposure and also note uncertainties in the data (Refs. 5 and 14). Based on the epidemiological studies and the evidence available, EPA stated in the 2024 ISA that blood-lead-associated effects on children's cognition as measured by IQ were observed in groups of children with mean BLLs as low as 2 μg/dL, and further that that ''the collective body of epidemiologic studies provides no evidence of a threshold for cognitive effects in children across the range of BLLs examined.'' This body of evidence includes studies which found effects on children's cognition in some groups of children with prenatal and early childhood blood lead or concurrent blood lead in the range of <1 to 10 μg/dL (Ref. 5).

For further information regarding lead and its health effects, see the TSD for this rulemaking and the 2024 ISA for lead (Refs. 5 and 12).

B. Federal Actions To Reduce Lead Exposures

Title X of the Housing and Community Development Act (also known as the Residential Lead-Based Paint Hazard Reduction Act of 1992 or ''Title X''), codified primarily at 42

U.S.C. 4822 and 4851 *et seq.* (Ref. 1), was a Federal response to the national crisis of childhood lead exposure and assigned responsibilities to Federal agencies with the overall goal of developing a ''national strategy to build the infrastructure necessary to eliminate lead-based paint hazards in all housing as expeditiously as possible'' (42 U.S.C. 4851(a)(1)). Subtitle B of Title X (106 Stat. 3912 through 3924), addressing lead exposure reduction, added Title IV to TSCA (codified at 15 U.S.C. 2681 *et seq.*) (Ref. 18).

Since the establishment of Title X, EPA and HUD have promulgated both joint and separate regulatory actions in an effort to eliminate LBP hazards. Those actions include requirements for disclosure of known LBP or any known LBP hazards (Ref. 4), training and certification requirements for contractors performing LBP activities (Ref. 19), the establishment in 2001 of standards that identify lead-based paint hazards and post-abatement clearance levels (*i.e.,* the DLHS and DLCL) (in the rule entitled, ''Identification of Dangerous Levels of Lead,'' see 66 FR 1206, January 5, 2001 (FRL–6763–5), also known as the 2001 LBP Hazards Rule) (Refs. 2, 3 and 20), regulations covering renovation or remodeling activities (Refs. 21, 22 and 23), provisions for interested States, territories, and Tribes to apply for and receive authorization to administer their own LBP Activities and renovation, repair and painting (RRP) programs, and requirements to control LBP and LBP hazards in federally assisted target housing (Ref. 24). Additional description of and background on Federal actions to reduce lead exposure can be found in the 2021 Final Rule (Ref. 3).

In addition, the Federal Lead Action Plan, which was written by the President's Task Force on Environmental Health Risks and Safety Risks to Children, consisting of 17 Federal departments and offices, states: ''Lead exposure to children can result from multiple sources and can cause irreversible and life-long health effects. No safe blood lead level in children has been identified'' (Refs. 7 and 25). The Agency has also developed an EPA Lead Strategy to lay out an all-of-EPA plan to strengthen public health protections and address legacy lead contamination for communities with the greatest exposures and promote environmental justice (*https://www.epa.gov/lead/final-strategy-reduce-lead-exposures-and-disparities-us-communities*). EPA plans to continue its work to equitably protect people of all races, ethnic groups, income levels, disabilities, and life stages, including young children and pregnant women, who are the most vulnerable to the toxic effects of lead. The actions in this final rule are part of those efforts, as dust-lead from lead-based paint remains one of the leading causes of lead exposure in the United States (Ref. 8).

C. Applicability and Uses of DLRL and DLAL

The reportable level and action level reconsidered in this regulation support EPA's LBP activities program (*i.e.,* inspections, risk assessments, and abatements) (codified at 40 CFR part 745, subpart L), which applies to target housing (*i.e.,* most pre-1978 housing) and COFs (pre-1978 properties where children under 6 years of age spend a significant amount of time such as daycare centers and kindergartens). The statutory definition of target housing was amended by Congress in 2017, and EPA is making the necessary conforming regulatory changes, including finalizing the age to under 6 years of age, in this rulemaking; see Unit IV.F.1. for more information. Apart from COFs, no other public or commercial buildings are covered by this proposal.

The DLRL and DLAL are incorporated into requirements for risk assessment and post-abatement work. When conducted, LBP activities must be performed by a certified individual or firm (40 CFR 745.220) in accordance with the work practices outlined in the 1996 LBP Activities Rule (40 CFR 745.227). EPA administers the LBP activities program only where States (including the District of Columbia and the Commonwealth of Puerto Rico), territories, or Tribes are not authorized by EPA to operate their own lead abatement programs (see 40 CFR part 745, subpart Q). Currently the States in which the LBP program is administered by EPA are Alaska, Arizona, Florida, Idaho, Montana, Nevada, New Mexico, New York, South Carolina, South Dakota, and Wyoming. EPA also administers the LBP program in the territories of American Samoa, Guam, Northern Marianas, and the U.S. Virgin Islands, as well as most Tribal Lands. All other States have EPA-authorized LBP programs. Additionally, the Cherokee Nation, Upper Sioux Community, Lower Sioux Indian Community, and the Bois Forte Band of Chippewa have EPA-authorized LBP programs, which ultimately must be at least as protective of human health and the environment as EPA's program and provide adequate enforcement (this rule's impact on authorized programs is discussed briefly in Unit V.A.).

1. Dust-Lead Reportable Levels

The DLRL support and implement major provisions of TSCA Title IV and provide the basis for risk assessors to determine whether dust-lead hazards are present during a risk assessment or a lead hazard screen. A risk assessment, where dust wipe testing occurs, may be required by the LSHR in certain circumstances (*e.g.,* for certain properties receiving Federal assistance) or by other laws or regulations where dust-lead testing occurs in response to the discovery of a child with a BLL that exceeds a Federal, State, or local threshold, or in a situation to comply with State or local requirements. Additional information on the LSHR and the subparts which require risk assessment are discussed in the EA (Ref. 10). The objective of a risk assessment is to determine, and then report, the existence, nature, severity, and location of LBP hazards in residential dwellings and COFs through an on-site investigation, which includes both a visual assessment and a collection of environmental samples. The visual inspection for a risk assessment includes an examination to determine the existence of deteriorated (*e.g.,* cracking, flaking, chipping, peeling) LBP or other potential sources of LBP hazards. The environmental samples include, among other things, dust wipe samples (taken using documented methodologies as defined in 40 CFR 745.227(a)(3)) from floors and window sills. Those samples are required to be analyzed by a laboratory that is recognized under NLLAP, which is an EPA program that defines the minimum standards that laboratories must meet to attain EPA recognition as an accredited testing laboratory (the standards for the program are laid out in the Laboratory Quality Standards for Recognition) (Ref. 26). A risk assessor compares the results of the dust wipe samples to the applicable hazard standard (currently the DLHS and, upon implementation of this final rule, the DLRL). If the dust-lead loadings from the samples are at or above the applicable standard, then a dust-lead hazard is present (40 CFR 745.227(d)).

Ultimately, the risk assessor prepares a risk assessment report for the property owner or manager, which lists any LBP hazards (including a dust-lead hazard) that were found and includes any recommendations for next steps, such as acceptable options for controlling the hazards via interim controls and/or abatement. These options are intended to allow the property owner to make an informed decision about what actions to take to protect the health of current and

future residents. Under EPA's rule, a risk assessment or risk assessment report does not compel or require action; rather it simply provides property owners with recommendations as appropriate (40 CFR 745.227(d)). However, HUD and some State or local governments may require action depending on whether a LBP hazard is present; see Unit V. for more information on the impacts of this final rule.

A lead hazard screen also includes a visual inspection and collection of environmental samples, although it is not as comprehensive as a risk assessment nor conducted as often. A lead hazard screen may be used to determine if a full risk assessment is necessary. During a lead hazard screen, a risk assessor checks for deteriorated LBP and collects two composite dust samples (in residential dwellings), one from floors and one from window sills (more composite dust samples are required in multi-family dwellings or COFs). Samples are taken using documented methodologies. The risk assessor prepares a lead hazard screen report but is not required to include determinations about the LBP hazards or recommendations for interim controls and/or abatement but could include information on whether a follow-up risk assessment is warranted (40 CFR 745.227(c)).

Both risk assessments and lead hazard screens can only be performed by risk assessors certified according to the procedures in 40 CFR 745.226.

2. Dust-Lead Action Levels

The DLAL are incorporated into the post-abatement work practices outlined in the LBP Activities Rule and represent ''the amount of lead in dust on a surface following completion of an abatement activity'' (40 CFR 745.227, 745.223) (Ref. 19). TSCA section 401 defines abatements as ''measures designed to permanently eliminate lead-based paint hazards'' (15 U.S.C. 2681(1)), while interim controls are ''designed to temporarily reduce human exposure or likely exposure to lead-based paint hazards'' (40 CFR 745.83 and 745.223). Abatement and/or interim controls could be recommended in a risk assessment report to inform the property owner about potential future action(s) they could take. After an abatement is complete (40 CFR 745.227(e)(8)) and after interim control work above HUD's de minimis level of paint disturbance, under HUD's Lead Safe Housing Rule is complete (24 CFR 35.1340(b)), a risk assessor or inspector determines whether there are any ''visible amounts of dust, debris or residue,'' which need to be removed before dust-wipe sampling takes place (40 CFR 745.227(e)(8)). Once the area is free of visible dust, debris, and residue, and one hour or more after final post-abatement cleaning ceases, sampling for dust-lead (via dust wipe samples) can take place and will be conducted ''using documented methodologies that incorporate adequate quality control procedures'' (40 CFR 745.227(e)(8)). Only a properly trained and certified risk assessor or inspector can conduct clearance sampling. An NLLAP-recognized laboratory must analyze the dust wipe samples and a risk assessor or inspector must compare the results from window sills, floors, and window troughs to the appropriate DLAL.

Every post-abatement sample must test below the DLAL in order to fulfill the post-abatement work practices of the LBP Activities Rule. If a single sample is equal to or greater than the corresponding DLAL, then the abatement fails to be successfully completed and the components represented by the failing sample must be recleaned and retested (40 CFR 745.227(e)(8)). After all dust wipe samples show dust-lead loadings below the DLAL, an abatement report is prepared (in accordance with the requirements in 40 CFR 745.227(e)(10)), copies of any reports required under the LBP Activities Rule are provided to the building owner (and to potential lessees and purchasers under the LBP Disclosure Rule by those building owners or their agents), and all required records are retained by the abatement firm or by the individuals who developed each report for no fewer than three years (40 CFR 745.227(i)).

D. Limitations of DLRL and DLAL

The DLRL are intended to identify dust-lead hazards during risk assessments, while the DLAL are part of post-abatement work practices. Both regulatory values have several key limitations. Since the DLRL and DLAL were established and revised for the purposes of Title X and TSCA Title IV only, they do not apply to housing and COFs built during or after 1978, nor do they apply to pre-1978 housing that does not meet the definition of target housing (40 CFR 745.61 and 745.223). If one chooses to apply the DLRL or the DLAL to situations beyond the scope of Title X and TSCA Title IV, care must be taken to ensure that the action taken in such settings is appropriate, and that the action is adequate to provide any necessary protection for children or other individuals exposed.

These standards cannot be used to identify that housing is free from all risks from exposure to lead including but not limited to dust-lead, soil-lead, or lead in drinking water, as risks are dependent on many factors. For instance, the physical condition of a property that contains LBP may change over time, resulting in an increase in risk. Plus, EPA's DLRL do not require the owners of properties covered by this rule to evaluate their properties for the presence of dust-lead hazards, nor to take action if dust-lead hazards are identified (although these standards can be incorporated into certain requirements mandated by State, Tribal and local governments, as well as other Federal agencies). Additionally, consistent with the 2021 Court Opinion that instructed EPA to consider only health factors when setting the DLHS (described as DLRL moving forward) and affirmed that EPA must consider other factors (*i.e.,* reliability, effectiveness, and safety) when setting the DLCL (described as DLAL moving forward), EPA is finalizing the DLAL as greater than the DLRL based on EPA's consideration of other factors (*e.g.,* laboratory capabilities/capacity, and achievability after an abatement). As a result and given the change in the definition of abatement discussed in Unit IV.E. of this preamble, there may be dust-lead remaining that meets the definition of a LBP hazard after an abatement is considered complete, due to dust-lead levels that are reportable but are less than the DLAL. Also, as has been the case historically, achieving the DLAL after an abatement does not mean that the home is lead safe or is free from all exposure to lead, including from other media such as soil-lead or lead in drinking water. EPA will continue coordinating with other Federal agencies to encourage best practices for owners and occupants of post-abatement properties to conduct ongoing maintenance that will help to continue to lower dust-lead levels, as well as working collectively among the Agency's offices to reduce overall lead exposure through all pathways.

E. Litigation Overview

As previously discussed, EPA revised the DLHS to 10 μg/ft^2 for floors and 100 μg/ft^2 for window sills in a final rule in July 2019 (Ref. 2). On May 14, 2021, in response to a Petition for Review that was filed shortly after the final rule was published, the Court remanded the 2019 Final Rule without vacatur and directed EPA to revisit it in conjunction with a reconsideration of the DLCL (Ref. 9). In its opinion accompanying the remand, the Court instructed EPA to consider only health factors when setting the DLHS (described by EPA as DLRL

moving forward) and affirmed that EPA must continue to consider non-health factors when setting the DLCL (described by EPA as DLAL moving forward). Specifically, the 2021 Court Opinion held that EPA's 2019 Final Rule ''looked to other factors, including feasibility and efficacy,'' when setting the DLHS, instead of ''set[ting] the hazard standards at the point at which the level [of] dust-lead creates hazards to human health'' *A Cmty. Voice,* 997 F.3d at 989 and 990. The Court also held that ''TSCA [Title] IV gives the EPA latitude to consider 'reliability, effectiveness, and safety' '' when promulgating regulations ''[w]ith respect to implementation, including abatement,'' thus enabling consideration of practicability when setting the DLCL. *Id.* at 995. The Court explained that ''[t]his is in line with the overall statutory scheme that differentiates between identification of hazards and implementation of remedial measures.'' *Id.* The Court also explained elsewhere in the 2021 Court Opinion that, if an agency relies on uncertainty for regulatory action or inaction, the agency must ''provide reasons why uncertainty justifies their actions'' *Id.* at 993. Consistent with the 2021 Court Opinion, EPA is finalizing revisions to the DLRL in this rulemaking based only on health considerations.

In addition, the Court held that EPA violated TSCA Title IV by leaving the soil-lead hazard standards (SLHS) at the values set in 2001, reasoning that EPA had an ongoing duty to update the standards. The SLHS identify lead-contaminated soil at target housing and pre-1978 COFs that would result in adverse human health effects. Soils that contain lead at levels determined to be hazardous to human health are considered contaminated. Lead inspectors, risk assessors, and abatement professionals use the SLHS to determine if soil-lead hazards are present and to inform options for reducing risk, such as during the risk assessment process. Due to resource considerations and to act as expeditiously as possible to revise the DLRL and DLAL, EPA will address the SLHS in a separate rulemaking. (For more background on resource constraints under TSCA, please see Congressional testimony from EPA leadership (Refs. 27, 28, 29, 30 and 31)). EPA listed this SLHS rulemaking in the Spring 2024 Unified Agenda of Regulatory and Deregulatory Actions under RIN 2070–AL12 as a long-term action, indicating the Agency's commitment to meet the statutory requirement of addressing the SLHS revision but indicating that the Agency does not expect to propose this action in the 12 months following the agenda entry (Ref. 32). EPA has, however, initiated work on the SLHS rulemaking and is continuing to allocate additional resources to it as this reconsideration rulemaking is finalized. The Agency also intends to build off of the technical analysis utilized for this rulemaking for the SLHS rulemaking, mirroring where possible so as to reduce resource constraints and considerations. EPA plans to issue a proposed SLHS rulemaking in 2026.

The Court also held that, to be consistent with its health-only interpretation of a LBP hazard (*i.e.,* soil, dust), the definition of LBP must ''encompass all levels of lead in paint that lead to adverse human health effects.'' *A Cmty. Voice,* 997 F.3d at 992. The Court stated that ''EPA ha[d] not explained why uncertainty justifies its decision to leave the definition of lead-paint as-is.'' *Id.* at 993. The Court also noted that much knowledge has been gained since Congress adopted the 1992 definition and that the U.S. Consumer Product Safety Commission (CPSC) has adopted a regulation that bans the production of paint with lead content of over 0.009 percent by weight. The CPSC standard, however, applies to *new* paint while TSCA is concerned with the hazards posed by *existing* paint in pre-1978 structures and different information and considerations are relevant in that context. The definition of LBP (1.0 milligrams per square centimeter or more than 0.5 percent by weight) is incorporated throughout the LBP regulations of both EPA and HUD, and application of this definition is central to how LBP programs function. In the 2019 Final Rule, EPA discussed the Agency's need for more information to establish a statistically valid causal relationship between concentrations of lead at low levels in paint and dust lead loadings that cause lead exposure. Additionally, information is still needed to quantify the direct ingestion of paint through consumption of paint chips or through teething on painted surfaces. Finally, it is important to understand how capabilities among various LBP testing technologies would be affected under a possible revision to the definition, such as field portable X-ray fluorescence devices (XRFs), which are the primary tools for lead inspections and risk assessments. They are calibrated to the current definition of LBP, and so EPA needs to fully understand the repercussions such a revision to the definition may have on these portable field technologies to ensure the technological feasibility.

On November 1 and 2, 2023, EPA and HUD held a virtual public workshop to hear stakeholder perspectives on specific topics related to detection of and exposure to potential lead hazards from existing residential LBP and to obtain additional information needed to address data gaps related to the definition of LBP that were outlined in the 2019 Final Rule. This virtual workshop was held over two days and gathered critical input on innovative methods to address LBP and reduce lead exposure across the United States.

In preparation for the LBP technical workshop, the Agency performed a literature review for sources relevant to the definition of LBP, consulted other Federal agencies, and refreshed materials that were developed for the 2019 rulemaking. While the data gaps did not change since the 2019 rule, they were refined to add further specificity, which allowed for a more targeted scope for both continued investigation and for the technical workshop held in November 2023. The more specific data gaps that EPA continues to investigate include empirical data on the relationship between low levels of lead in paint and dust-lead, as well as data on the common exposure scenarios that may inform this relationship (for example, dust-lead generation during a renovation scenario versus slowly deteriorating paint). Currently the available empirical data and modeling approaches for estimating the relationship between lead content in on-the-wall paint and lead in related environmental media, including dust, are applicable at or above the current LBP definition. EPA believes that to use the available empirical data and modeling approaches to estimate dust-lead loadings at low levels of lead in paint (particularly levels that are lower than the current definition by an order of magnitude or more) will introduce significant uncertainty to any estimations. Data and models applicable to lower levels of lead in paint are needed to develop an approach to estimate dust-lead from low levels of lead in paint, which will allow EPA to estimate incremental blood lead changes and associated health effect changes that may occur due to low levels of lead in paint. For the ingestion exposure pathway, EPA is exploring possible modeling solutions as well as seeking quantitative measures of ingestion and exposure (such as data on duration and frequency of consumption, and common paint chip characteristics). Studies on this subject have documented this behavior as a risk factor for exposure to

lead from LBP; however, the studies have not provided quantitative estimates of paint ingestion, which are needed to quantify exposure. Lastly, EPA continues to investigate constraints to the field measurement options for low levels of lead in paint. Different technologies have different limitations in accuracy, processing time, detection limits, accessibility, and destructiveness among other factors. These practical considerations are important to consider in understanding how a change in the definition may affect the ability of the regulated community to use certain technologies, potentially impacting the residents of target housing and occupants of COFs. On top of these data gaps and as outlined in the document *Definition of Lead-Based Paint Considerations* from May 2019 (Ref. 33), EPA is exploring the relationship between the two different units used in the current definition (milligram per square centimeter and percent by weight) to inform whether and, if so, how to develop a conversion between the two. The search for relevant information to develop the conversion and exploration of the uncertainty involved with such a conversion is underway.

The presenters at the workshop covered a wide range of topics. One of the most prominent discussions, covered by several presentations, was the potential and limitations of extending current technologies (particularly the XRF analyzer) to thresholds at or below the current definition, as well as the reliability of the analyzer's lead detection estimates in general. Also discussed extensively were the capabilities of other testing methods, strategies to use these methods alongside XRF testing, and the impact on test kits of lowering the definition of LBP. The challenge of characterizing the relationship between mass-per-mass and mass-per-surface area definitions of LBP was also examined, with one speaker presenting a regression analysis to derive an overall relationship between the two.

Other topics discussed during the workshop included trends in childhood lead exposure the capability of community outreach and involvement in assisting to address the LBP problem, and to some extent the relationship between lead in paint and dust-lead. On the latter point, however, the relationship between low levels of lead in paint and levels of lead in dust-lead was not examined in depth. Nor was the impact of paint condition, maintenance, age, and other factors. The ingestion pathway was also not examined. EPA and HUD continue to process the information gathered and the status of the data gaps that remain. Also, EPA and HUD hope to gain additional insight from a wider audience via public comments on the workshop's docket, which was open until June 30, 2024.

Similar to the SLHS rulemaking, due to resource considerations and EPA's interest in acting as expeditiously as possible to revise the DLRL and DLAL and to hold the aforementioned LBP technical workshop, EPA will address the definition of lead-based paint in a separate rulemaking. EPA has listed this rulemaking on the definition of LBP in the Spring 2024 Unified Agenda of Regulatory and Deregulatory Actions under RIN 2070–AL11 as a long-term action, indicating the Agency's commitment to meet the statutory requirement of addressing the definition of LBP revision but that the Agency does not expect to propose this action in the 12 months following the agenda entry (Ref. 34).

Rulemakings such as those necessary for revisions to SLHS and the definition of LBP are complex, highly resource-intensive activities. A rulemaking's development generally entails scientific, economic, legal, and other technical analyses. For many rulemakings, this includes research and data gathering, which itself can sometimes necessitate exercising other information collection tools and following appropriate procedural requirements (*e.g.,* Paperwork Reduction Act). To develop a rulemaking, EPA also often consults with governments and key stakeholders. Federal law may require such consultations based on anticipated regulatory impacts (*e.g.,* the Unfunded Mandates Reform Act and the Regulatory Flexibility Act). Additionally, various executive orders may also require the Agency to engage in such consultations.

A rulemaking package often requires the development of complex supporting documents including an EA and a TSD, similar to those included alongside this reconsideration rulemaking (Refs. 10 and 12). A complete TSD includes several components that may require internal and external stakeholder dialogue and scientific peer review, including model and input data revisions, health and exposure metrics of interest, environmental fate and exposure mechanisms for either soil or the definition of LBP, characterization of uncertainties in modeling, and literature reviews (which have not been done for soil since before the 2001 LBP Rule was finalized). If existing models and analytical methods are insufficient to conduct the analysis to support the rulemaking, then they must be developed as part of the technical work done in support of the rulemaking effort. Developing new models can take a considerable length of time and novel analyses may require peer-review, further extending the rulemaking timeline. The magnitude and effort of an SLHS TSD would mirror previous DLHS and DLCL TSDs (and the TSD for this rule); see the technical documents prepared in support of the 2019 Final Rule, the 2021 Final Rule, or this reconsideration rulemaking (Refs. 12, 35, and 36).

An EA includes various components such as a description of the need for Federal regulation; a profile of affected industries and populations; an overview of existing Federal, State and local regulations; a specification of the baseline state of the world and estimate of the number of events affected by the regulation; thorough analysis on the consequences of regulatory policy being considered and how regulated entities will respond; quantification and monetization of the regulation's costs, benefits, and net benefits; a description of unquantified or qualitative benefits; and an assessment of uncertainty surrounding estimates. An EA also includes various additional analyses related to statutory compliance and executive orders, including but not limited to small business impacts, unfunded State, local, or Tribal mandates, paperwork reduction, environmental justice, protection of children, federalism, coordination with Tribal governments, and energy effects. A rulemaking also involves developing **Federal Register** documents to present, generally, the preamble to and regulatory text of the proposed and final rule. Such published documents reflect the culmination of the development and review of the complex supporting documents and the resulting decision-making, which includes internal steps at the Agency to reach officewide agreement, as well as external to the Agency, such as holding potential public consultations, completing interagency review and convening a Small Business Advocacy Review Panel, as necessary. These processes can also take many months or years. The proposed and final rules also present statutory and executive order review analyses.

The current rulemaking on the DLRL and DLAL is one more step toward complete implementation of TSCA Title IV. Given the complications for the SLHS and the definition of LBP discussed earlier in this section, EPA does not believe that either the SLHS or the definition of LBP could have been reconsidered on this current

rulemaking's timeline. Instead, EPA will reconsider the SLHS and the definition of LBP as important next steps. Courts ''have recognized that, under the 'pragmatic' one-step-at-a-time doctrine, 'agencies have great discretion to treat a problem partially' and 'regulat[e] in a piecemeal fashion.' '' *Transportation Div. of the Int'l Ass'n of Sheet Metal, Air, Rail & Transportation Workers* v. *Fed. R.R. Admin.,* 10 F.4th 869, 875 (D.C. Cir. 2021) (quoting *Ctr. for Biological Diversity* v. *EPA,* 722 F.3d 401, 409–10 (D.C. Cir. 2013)); *cf. Massachusetts* v. *EPA,* 549 U.S. 497, 524 (2007) (recognizing that ''[a]gencies, like legislatures, do not generally resolve massive problems in one fell regulatory swoop''). EPA intends to conduct rulemakings on the SLHS and the definition of LBP, as identified in the Spring 2024 Unified Agenda of Regulatory and Deregulatory Actions, to address the issues identified by the Ninth Circuit in its May 2021 opinion (Refs. 9, 32 and 34).

F. Public Comments Summary

The proposed rule provided a 60-day public comment period, which ended on October 2, 2023. EPA received a total of 21,309 comments in docket number EPA–HQ–OPPT–2023–0231. This included 393 unique comments that were submitted as well as the transcript from a public webinar that EPA held on the proposed rule on August 23, 2023, where numerous public comments were received verbally. The majority of the 21,309 comments were submitted as part of five mass mail campaigns (two that expressed support for the proposed rule and three that did not). One of the supportive mass mail campaigns accounted for roughly 20,723 or 97% of the total number of comments. Comments were received from private citizens, landlords, State/local governments (including State health departments), potentially affected lead-based paint businesses, lead laboratories, trade associations, non-governmental organizations and environmental and public health advocacy groups.

Numerous commenters supported EPA's proposed ''greater than zero'' approach to revising the DLHS (described as DLRL moving forward) codified as ''any reportable level'' based on their view that there is no safe level of lead exposure (*e.g.,* two commenters pointed to a ''voluminous body of recent research [that] documents unequivocally that no level of lead exposure is safe for a fetus or young child''). Public commenters also supported the proposed approach for a variety of related reasons, such as making the public more aware of the risk dust-lead may pose, preventing more children from lead poisoning, and emphasizing the importance of cleaning. Commenters also noted their view that prevention is the best solution to lead exposure in children, and that due to neurological and cognitive development, children are particularly susceptible to these impacts. (Note that interventions that are implemented before there is evidence of a disease or injury are defined as primary preventions by CDC (Ref. 37)).

For the proposed approach there were several key concerns, raised predominately by lead-based paint professionals, laboratories and trade associations, that fall into several general categories: concerns over dust-lead source and that the DLRL would fall below background levels of dust-lead; laboratory concerns including that a laboratory's reportable level can vary considerably between establishments; impacts this DLRL would have on existing housing stock, particularly affordable housing; the cost of implementation; concerns over decoupling DLRL from DLAL; and possible liability issues and confusion within the public and regulated community due to leaving a hazard behind after an abatement is considered complete. For more information on the rationale of the final DLRL approach of ''any reportable level'' see Unit IV.B.

Multiple commenters, predominately advocacy organizations, supported EPA's proposed DLCL (described as DLAL moving forward) of 3 μg/ft², 20 μg/ft², and 25 μg/ft², for floors, window sills and window troughs, respectively, in order to protect children from lead exposure. EPA also received numerous public comments opposing the reduction in the DLAL, and requests that the values remain at the current levels of 10 μg/ft², 100 μg/ft², and 400 μg/ft², for floors, window sills and window troughs. A few commenters also supported the proposed alternative DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft², for floors, window sills and window troughs. The concerns public commenters highlighted were related to laboratory technology shifts, costs, turnaround times, laboratory capacity, and the practicability/achievability of the lower levels of 3 μg/ft², 20 μg/ft², and 25 μg/ft².

EPA received several comments during the public comment period from a variety of organizations including industry, environmental and public health advocacy organizations, among others, requesting that EPA revise the terminology of the standards (specifically the terms of DLHS and DLCL) in order to better communicate to the public their purpose and to reduce confusion. Another concern raised by numerous public commenters was the confusion created by the messaging of ''greater than zero'' (which was the terminology used to describe ''any reportable level'' in the proposed rule). Under this final rule the term ''greater than zero'' is being replaced with ''any reportable level'' in the preamble and within any implementation materials that accompany this final rule. For more information on the terminology changes see Unit IV.A.

In this preamble, EPA has responded to the major comments relevant to this final rule. In addition, the more comprehensive version of EPA's response to comments related to this final action, including comments not mentioned in this preamble, can be found in the Response to Comments document that accompanies this rulemaking (Ref. 38).

III. Technical Analyses

In its evaluation of options for reconsidering the DLRL and DLAL, EPA estimated children's BLL and associated IQ decrements expected to result from lead exposures with each option. These estimates provide the means to quantitatively compare risk posed to young children by exposure to the dust-lead loading levels analyzed. EPA also estimated BLL in adolescents and adults for the various dust-lead loading levels, and associated risk of ADHD diagnosis, cardiovascular mortality risk, and changes in low birthweight, to inform the benefits analysis accompanying this rule. The TSD (Ref. 12) and EA (Ref. 10) accompanying this rulemaking provide the complete analyses and associated estimates of expected impacts of the candidate DLRL and DLAL options on BLLs of exposed children, adolescents, and adults in target housing and associated changes in occurrence of adverse health impacts. See Unit IV. on the rationale for the revisions to DLRL and DLAL.

The TSD uses both mechanistic and empirical models to predict possible BLLs in children that reside in target housing and are exposed to homogenous candidate values for dust-lead levels (*e.g.,* candidate options for the DLRL or DLAL); the TSD also probabilistically accounts for variation in children's BLLs due to other sources of lead exposure and differences in biological response to lead exposure. The first approach uses mechanistic modeling of lead exposure and uptake that takes into account age-specific ingestion rates, activity patterns, and background exposures. Specifically, the mechanistic

blood lead modeling for children in this rulemaking reflects the application of an extensively peer-reviewed model (the Stochastic Human Exposure and Dose Simulation—Integrated Exposure Uptake Biokinetic model coded in R, referred to as R–SHEDS–Pb) using updated data sources and tailored to the dust-lead target housing scenario, described in depth in appendix E of the TSD. The empirical approach used data that includes co-reported dust-lead and BLL measurements in the homes of children; these dust-lead and BLL data are used to develop an empirical relationship to estimate BLLs for each candidate dust-lead level. Estimates derived from the two approaches (mechanistic and empirical) are compared; and similarity between the results increased confidence in the estimates of the relationship between dust-lead loadings and BLL (Section 9.3 of the TSD, Ref. 12). The various components of the model and input parameters used for children in this rulemaking have been the subject of multiple Science Advisory Board Reviews, workshops and publications in the peer reviewed literature focused on dust-lead (Refs. 15, 39, 40, 41, 42, and 43).

The mechanistic blood lead modeling for adolescents and adults in this rulemaking was performed using an extensively peer-reviewed model (the All-Ages Lead Model, referred to as AALM) using updated data sources tailored to the dust-lead target housing scenario as was done for children using R–SHEDS–Pb (See section 4 and appendix F of the TSD). The TSD uses AALM version 3.0 to predict possible BLLs in adolescents and adults that reside in target housing and are exposed to dust-lead loadings at the candidate DLRL and DLAL. This model takes into account age-specific ingestion rates and background exposures (Section 4.2.1 of the TSD) (Ref. 12). The various components of the AALM version 2.0 model and input parameters have been the subject of a Science Advisory Board review (Ref. 44) and the AALM version 3.0 model been used to support recent EPA guidance and rulemakings (Ref. 45 and 46).

Detailed discussion of the limitations and uncertainties in blood lead modeling at the low dust-lead exposures and associated BLLs considered for this rulemaking can be found in Sections 13.3.1 and 13.3.2 of the TSD (Ref. 12). Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) version 2.0, as a standalone biokinetic model, was evaluated for performance in groups of children for which the geometric mean BLL is as low as 2.3 μg/dL (Ref. 47). Mean estimated BLLs for groups of children at some of the lowest levels of dust lead exposure modeled for this rulemaking were lower than this value (between 0.81 and 1.12 μg/dL depending upon age) and are outside the range for which the underlying biokinetic model (IEUBK) has been evaluated. In order to address this lack of model evaluation at BLLs of interest, EPA conducted an evaluation of the R–SHEDS–Pb model used in this analysis with a dataset for which the geometric mean BLL in children aged 1 to 2 years old is 1.09 μg/dL. This evaluation found BLL estimates for 1- to 2-year-old children from the R–SHEDS–Pb model agreed well with the reference dataset at low percentiles, at the median, and at the 95th percentile. See table 13–2 and appendix D in the TSD (Ref. 12). AALM version 3.0 was validated against a panel of datasets including pharmacokinetic data from dosing studies in adults (Ref. 48), biomonitoring data including longitudinal studies of lead workers (Refs. 49, 50), and biokinetic studies in infants with estimated lead intakes (Refs. 51, 52). Additionally, AALM version 3.0 was evaluated at relatively low exposures and associated BLLs (~1 μg/dL) against the IEUBK predictions for children at birth until age 7 and the predictions were found to compare well, with a 5% discrepancy (0.07 μg/dL) between the two models at age 2 for a 10 μg/day continuous lead dose (See Figure 13–1 in the TSD).

In contrast to the TSD, which estimates the health risk and exposure associated with dust-lead loading candidates for a hypothetical population of children in target housing without consideration to how many children are actually affected by the rule, the EA estimates benefits that accrue to only the subpopulation that would be impacted by the final rule's revisions. Rather than assuming all households living in target housing are impacted by the regulatory change, the EA instead estimates benefits solely for instances when dust-lead levels would be tested. These instances of dust wipe testing are henceforth referred to as ''triggering events.'' For the subpopulation of individuals who are affected by these events, the EA estimates quantified benefits from avoided lead-associated IQ decrements, avoided cases of ADHD or cardiovascular mortality, and changes in birthweight. The EA uses real world data to characterize: (1) variability in the housing stock that is affected; (2) how surface-by-surface dust-lead loadings change due to the DLRL/DLAL; (3) the number of individuals living in affected housing units; and (4) resultant changes in BLLs and IQ decrement, ADHD, low birthweight, and cardiovascular mortality risk that are expected. In modeling the relationships between dust-lead loadings and BLL/IQ, the EA presents results based on both the empirical and mechanistic approaches laid out in the TSD. EPA considered several methods to quantitatively represent the relationship between BLL and IQ for BLLs below the lowest lifetime average BLL (1.47 μg/dL) in the set of epidemiologic studies which the BLL–IQ concentration-response equations were based upon, and a range of IQ decrement estimates based on the methods considered are presented in the TSD and EA (see TSD section 6 and EA Section 6.4). The IQ decrement estimates presented in Unit IV. and in Section 12 of the TSD were derived using a linearization method, which resulted in the highest estimates of IQ decrements.

Both the TSD and the EA present estimated changes in BLL and associated changes in health effects (IQ decrement, ADHD, low birthweight, and cardiovascular mortality risk). However, these estimates represent populations of exposed individuals characterized in differing ways. The TSD presents the expected response for a hypothetical dust-lead exposure, accounting for varying sources of background exposure (*e.g.,* food, soil, water) and biological variability. The EA estimates expected responses to triggering events, recognizing that exposures at the higher end of the distribution of hypothetical conditions in the TSD are not realized in all target residences because dust-lead levels across target housing are generally lower than the current hazard standards and clearance levels (10 μg/ft^2 and 100 μg/ft^2 on floors and window sills respectively) (Ref. 53) and existing abatements/interim controls typically overshoot the current clearance levels considerably (Ref. 54). Thus, the distributions of BLLs and health effects estimated in the TSD represent the impact of individuals' exposures to hypothetical dust-lead levels while the EA estimates distributions of BLLs and health effects across individuals living in housing that is directly impacted by this rule. The analyses that EPA developed and presented for young children in the TSD and EA for this rule were specifically designed to estimate BLLs and associated risk of effects on IQ that might accrue to the population of interest (*i.e.,* children living in pre-1978 housing). EPA notes that its different program offices estimate exposures for different populations, different media,

and under different statutory requirements and thus different models or parameters may be a better fit for their purposes. Accordingly, the approach and modeling parameters chosen for this rulemaking should not necessarily be construed as appropriate for, or consistent with, those of other EPA programs or those of other Federal agencies.

Public comments were received on the TSD and EA accompanying the proposed rule. EPA's responses are included in Sections 9 and 10 of the Response to Comments filed under docket number EPA–HQ–OPPT–2023–0231.

IV. Final Rule

As explained in Unit II.E., the 2021 Court Opinion of the U.S. Court of Appeals for the Ninth Circuit held that EPA must reconsider the DLHS in conjunction with the DLCL (described by EPA as DLRL and DLAL moving forward) (Ref. 9). EPA carefully considered all public comments related to the proposed rule and is finalizing a nomenclature change from the terminology of DLHS and DLCL, to the dust-lead reportable level (abbreviated as DLRL) and the dust-lead action level (abbreviated DLAL), as well as revisions to lower both standards. In this final rule, EPA is revising the DLHS from 10 μg/ft² and 100 μg/ft² for floors and window sills to a non-static DLRL represented by any reportable level of dust-lead as analyzed by an NLLAP-recognized laboratory. Lowering the DLRL (independent of the DLAL revisions) provides the regulatory benefit of additional disclosure of LBP hazards in target housing and COFs. This results in an estimated increase in individuals who are aware of the presence of dust-lead and the various actions that can be taken to minimize dust-lead hazards and take actions to protect themselves from exposure (even if LBP is not present). See Unit IV.B. for additional information describing the final DLRL of ''any reportable level.''

EPA is also finalizing revisions to the DLCL from 10 μg/ft², 100 μg/ft² and 400 μg/ft² for floors, window sills, and troughs to a DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft², which are the current DLCL in New York City (NYC). See Unit IV.C. for additional information describing the final DLAL.

A. Nomenclature Changes

EPA received several comments during the public comment period from a variety of organizations including industry, environmental and public health advocacy organizations, a local health department, the Attorneys General of several States and the District of Columbia, and a lead-based paint professional, suggesting EPA revise the terminology of DLHS and DLCL in order to better communicate to the public the purpose of the standards and to reduce confusion. Commenters highlighted that removing the use of ''hazard'' would be beneficial since it could imply that immediate action is needed or create confusion within the public when no action is recommended. Commenters also emphasized that changing the use of ''clearance'' could avoid any misconception that after an abatement no hazards remain. One commenter even noted that because this rule is shifting how the standards have worked together historically (*i.e.,* decoupling the hazard standards and clearance levels for floors and sills), it may be helpful to both the public and the regulated community to make this shift even more transparent with a terminology change. Another commenter noted that EPA should consider how these terms are used in other Federal and State regulations.

EPA received recommendations for new terminology for both standards, including dust-lead hazard level, disclosure level, lead dust disclosure level, contamination level, or lead-contaminated dust goal for the DLHS and action level or dust-lead action level for the DLCL, among other suggestions. EPA is finalizing a nomenclature change from the term DLHS to dust-lead reportable level (abbreviated DLRL) and from the term DLCL to dust-lead action level (abbreviated DLAL). The new term DLAL received the most support by public commenters, with the largest number of requests, whereas EPA believes DLRL captures the essence of the suggestion from the public commenters but avoids any confusion with the already well-established Disclosure Rule or disclosure program.

While this exact terminology was not in the proposed rulemaking, EPA recognizes the value of these changes and agrees with commenters that the new terminology more clearly communicates the intention of the standards to the public and the regulated community. EPA believes this updated nomenclature aligns better and more intuitively with the operational function of the amendments EPA had proposed and is finalizing in this action. For example, the new terminology makes it clear that if a dust-lead loading falls below the DLAL but above the DLRL, that dust-lead is still present in the environment, but that the levels are below those prioritized for action. To implement this nomenclature change, EPA is adding a definition of ''action levels'' in 40 CFR 745.223 to replace ''clearance levels'' and making other minor, conforming amendments in phrasing of the regulations. The term DLAL also emphasizes its new role, as the trigger for the recommendation for action due to the changes to the definition of abatement for dust-lead hazards (see Unit IV.E. for more information on the revisions to the definition of abatement). Ultimately, when the regulated community clears a project after an abatement, it would be to below the action levels. EPA intends any continuing use of the ''clearance'' term in the abatement context to describe such efforts (*i.e.,* achieving loadings below the action level). EPA also appreciates that the reportable terminology in particular aligns with the regulatory definition that is being finalized of ''any reportable level.'' Note that within EPA's regulatory landscape, dust-lead levels that are at or above the DLRL are still considered a LBP hazard, specifically a dust-lead hazard. EPA believes that messaging to the public and regulated community should revolve around explaining that any dust-lead levels at or above DLRL are above the level at which the LBP community must report a hazard on a risk assessment report, but that EPA recommends action only when levels are above the DLAL. Language around a reportable level should still clearly communicate that a dust-lead hazard is still present.

Another concern raised by numerous public commenters was the confusion caused by the messaging of ''greater than zero'' (which was the terminology used to describe ''any reportable level'' in the proposed rule). In this final rule the terminology ''greater than zero'' is being replaced with ''any reportable level'' in the preamble and within any implementation materials that accompany this final rule. EPA agrees with the public that the concept of GTZ is confusing as it implies that if one has dust-lead loadings below any reportable level then there is zero or no dust-lead present. EPA wants to avoid this misconception and will refer to what was previously ''greater than zero'' as the ''any reportable level'' approach to avoid any further confusion.

A more comprehensive version of EPA's response on these communication and nomenclature comments can be found in Section 5 of the Response to Comments document that accompanies this final rule (Ref. 38).

B. Dust-Lead Reportable Level Approach

In the 2001 LBP Hazards Rule EPA discussed the dilemma the Agency

faced when establishing a dust-lead hazard standard, especially the challenges associated with choosing ''which [BLLs] are truly hazardous'' and how to interpret the statutory criteria from TSCA section 401 (*i.e.,* ''would result in adverse human health effects'' (15 U.S.C. 2681(10)) given the uncertainties that existed (Ref. 20). As a result, historically EPA took a pragmatic approach to setting the DLHS (described moving forward as the DLRL) and focused on the potential for risk reduction, cost-benefit balancing and other relevant factors, establishing the standards at 40 μg/ft² and 250 μg/ft² for floors and sills, respectively. The Agency did not establish a DLHS (described moving forward as the DLRL) for troughs as it found that window sills and troughs were highly correlated and concluded that testing both surfaces would not improve a risk assessor's ability to characterize risk.

Building off the precedent established in 2001, the 2019 Final Rule ''evaluated the relationship between dust-lead levels and children's health, and . . . the application of those standards in lead risk reduction programs.'' In addition, when establishing the 2019 standards, EPA also assessed laboratory capabilities, resources for addressing LBP hazards and consistency across the Federal government (Ref. 2). At that time EPA reasonably believed it had the discretion to set the DLHS (described as DLRL moving forward) based on both risk reduction and whether the standards were achievable, especially given the existing programs in place to reduce LBP hazards and revised the standards to 10 μg/ft² and 100 μg/ft² for floors and sills, respectively (Ref. 2).

Ultimately, the 2021 Court Opinion, which is discussed in Unit II.E., led EPA to undertake a major shift in its approach to residential LBP hazard control and the LBP activities program because the Court found that EPA did not have the authority, when setting the DLHS, to consider non-health factors (*e.g.,* laboratory capabilities, resources for addressing LBP hazards, consistency across the Federal government, or cost-benefit balancing). Consistent with the 2021 Court Opinion, EPA proposed revisions to the DLHS (described as DLRL moving forward) in August 2023 and is finalizing those changes in this rulemaking based only on health considerations (Ref. 55). EPA intends health-only considerations in this context to refer to the effects of lead on health after exposure to dust-lead loadings, considering the statutory definition's focus on ''any condition that causes exposure to lead from lead-contaminated dust . . . that would result in adverse human health effects'' (15 U.S.C. 2681(10)). These health-only considerations do not include broader public health concerns (such as health trade-offs and policy impacts on Federally assisted housing). See Unit IV.B.1.d. for more discussion on public health considerations and public feedback.

1. Rationale for Selecting the Final DLRL

EPA is finalizing a non-static DLRL that is any reportable level of dust-lead for floors and window sills as analyzed by an NLLAP-recognized laboratory. Setting a DLRL for floors and window sills only is consistent with current practice and regulatory history, which has not included a hazard standard or reportable level specifically for troughs.

Given the statutory language in TSCA section 401 that defines what a ''LBP hazard'' is (*i.e.,* as conditions of LBP and lead-contaminated dust and soil that ''would result in adverse human health effects''), EPA believes that it cannot set the DLRL at zero because zero exposure to dust-lead loadings would not cause adverse health effects. EPA is not attempting to establish a safe level of dust-lead as, at this time, no BLL threshold at which no adverse effects occur in children has been identified (Ref. 5, 56), and EPA did not identify a level of dust-lead exposure at which there is no effect on BLL. The standard being established—''any reportable level''—is an appropriate non-zero DLRL and is based on dust-lead related health factors only. It was developed in accordance with the 2021 Court Opinion by taking into consideration the exposure modeling data outlined in TSD and the current state of the science on the health effects of lead exposure. The final DLRL approach represents a shift in the LBP activities program to a more inclusive and protective standard, compared with the 2019 levels. The DLRL approach will be inclusive of any reportable level of dust-lead and will not distinguish based on health risk posed.

EPA received public comments on the ''any reportable level'' approach to the DLRL, which are discussed in more depth in Unit IV.B.1.d. Additionally, two other approaches were also considered for revising the DLRL, including a numeric standard based entirely on the modeling data laid out in the TSD (summarized in TSD table 2–2), and an approach that would use the background dust-lead levels of housing built in or after 1978 (called post-1977 background); both are briefly discussed in Unit IV.B.2.

a. DLRL and the LQSR Action Level

The DLRL is being finalized as any reportable level as analyzed by an NLLAP-accredited laboratory. ''Reportable level'' had not previously been defined in EPA's regulations at 40 CFR part 745 or EPA's current guidance for NLLAP-recognized laboratories, titled Laboratory Quality Standards for Recognition (or LQSR 4.0). EPA is finalizing the definition of ''reportable level'' as proposed to mean the lowest analyte concentration (or amount) that does not contain a ''less than'' qualifier and that is reported with confidence for a specific method by an NLLAP-recognized laboratory. In other words, EPA interprets ''any reportable level'' of dust-lead to be any level greater than or equal to the lowest value a laboratory can reliably report to a client or the regulated community, and a report of zero concentration is not permitted under the LQSR. For target housing or a COF to achieve no dust-lead hazard, an NLLAP-recognized laboratory would need to provide a result that was less than (<) their reporting limit. Any numeric value that is above an NLLAP-recognized laboratory's reporting limit would be considered a dust-lead hazard and would need to be disclosed as such, for example, on a risk assessment report prepared by a certified risk assessor.

In terms of the standards being finalized in this rule and their impact on laboratories, given that the DLRL is a non-static value, the DLAL, rather than the DLRL, would be considered the ''action level'' as described in the LQSR 4.0, as well as for when a risk assessor would recommend an abatement (see Unit IV.E. for more information on EPA's revisions to the definition of abatement). Under the LQSR 4.0, NLLAP-recognized laboratories that analyze dust wipe samples for lead must show that they can achieve a quantitation limit ''equal to or less than . . . 80% of the lowest action level [*i.e.,* regulatory limit] for dust wipe samples''; this is a shift from LQSR 3.0 where it was 50% (Refs. 26 and 57). The quantitation limit must also be ''at least 1.6 times but no greater than 10 times the method detection limit'' (Ref. 26). Thus, EPA's minimum standards for testing will rely on the numerical DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills and window troughs to establish the quantitation limit that any laboratory (that wishes to maintain or obtain NLLAP recognition) must be able to demonstrate (Ref. 26). The DLRL of ''any reportable level'' is considered distinct from the DLAL and not to affect the quantitation limit under the LQSR. Based on these minimum

standards for NLLAP-recognized laboratories and previous laboratory stakeholder input, EPA expects that the lowest reportable level will be equivalent to the laboratory's quantitation limit. Note that only laboratories that are NLLAP accredited can perform dust-wipe testing for lead under the existing regulations at 40 CFR part 745.

EPA received public comments raising concerns that the DLRL is non-static and would change among laboratories depending given technology sensitivity, conditions etc. Commenters, including an NLLAP accrediting body, requested that the area wiped, instrumentation and/or method detection limit be defined to provide more consistency. EPA fully acknowledges that the reportable level under the final DLRL will potentially vary from laboratory to laboratory due to different capabilities. EPA believes establishing a DLRL based on the capabilities of individual laboratories is a strength of the final DLRL because it allows room for improvement and the possibility of getting as low as reliably reportable depending on the sensitivity of the technology—in turn allowing the regulated community to be able to disclose lower levels. This will also limit the need for future revisions to the DLRL, unless there is a compelling reason to, such as a threshold for adverse effects being identified. Note that the trigger for the recommendation of work has been shifted to the DLAL (rather than the DLHS, described as DLRL moving forward, as has been the case historically). See Unit IV.F. for more information on the change to the definition of abatement.

While EPA understands the request for some form of minimum laboratory requirements, EPA disfavors requiring laboratories to use a specific type of technology for analysis, as that will limit some laboratories who have or would like to have more sensitive capabilities. Note that EPA does include standards that act as an upper bound within EPA's LQSR 4.0 as discussed previously (*e.g.,* every laboratory must have a quantitation limit equal to or less than 80% of the action level for each surface of interest, such as floors, window sills and troughs), among other standards, which effectively function to promote consistency between laboratories. For dust-wipe testing of floors, EPA does recommend that LBP professionals wipe at least two square feet as needed to help the NLLAP-recognized laboratory achieve the LQSR's standard for the quantitation limit. Similarly, HUD already recommends using at least two square feet for LBP professionals conducting dust-lead testing of floors (in circumstances where needed for laboratory capabilities) for HUD's current dust-lead action levels for its Lead Hazard Reduction grant programs (Ref. 58). EPA also recommends that LBP professionals document the sample size in order to inform the NLLAP-recognized laboratory either through already established practices or the Chain of Custody form. EPA does note that there may be laboratories with more sensitive technology that can meet the LQSR minimum standards without testing two square feet on floors.

Overall EPA disagrees that the types of specifications requested by some commenters are required for the DLRL to work as intended. EPA recommends, if there are concerns, that the regulated community work directly with laboratories. Understanding the laboratory's reporting limits and attaining consistent levels across larger projects is possible for the regulated community through contracts (*i.e.,* arrangements incorporated into the project to use either the same laboratory or those with the same reporting values and technology), and through understanding various laboratories' reporting limits. EPA acknowledges the potential challenges of inconsistency that may arise from the final DLRL, but EPA does not believe this can be considered when setting the DLRL or that it outweighs the benefit of additional disclosures to the public that will result from this approach.

b. No Threshold Has Been Identified

According to TSCA Title IV, EPA should identify the level of dust-lead exposure that ''would result in adverse human health effects'' as a type of LBP hazard (15 U.S.C. 2681(10)). Any reportable level of lead in dust is a more protective approach compared with the current regulatory landscape. Any reportable level of lead in dust also acknowledges the current state of scientific evidence. Based on the epidemiological evidence available, EPA observed in the 2013 and 2024 Integrated Science Assessments that there is no evidence of a threshold below which there are no harmful effects on cognition from lead exposure (Refs. 5 and 56). Depending on the exposure and other factors, effects on IQ associated with childhood lead exposure may persist into adolescence and adulthood (Refs. 5 and 6). EPA also favored such an approach for the DLRL under TSCA Title IV in part because a more protective approach to DLRL, such as any reportable level, aligns with the Congressional purpose for disclosure elsewhere under Title X (notably, as implemented in the Lead Disclosure Rule) and because Congress used the word ''hazard'' in the ''lead-based paint hazard'' term, even though the definition uses more risk-like language by introducing consideration of the level of *exposure* that would result in adverse health effects.

The EPA 2024 Lead ISA stated that effects of lead exposure on children's cognition were best substantiated to occur in study populations with mean BLLs between 2 and 8 μg/dL and noted that, extending the evidence described in the 2013 Lead ISA, associations with effects on cognition were also observed in groups with mean BLLs below 2 μg/dL (though not all studies with mean BLL below 2 μg/dL reported positive associations between BLL and IQ decrements). Further, despite there being some uncertainty in epidemiological studies on lead exposure and BLLs (especially for older children and adults), the 2024 ISA stated that ''the collective body of epidemiologic studies provides no evidence of a threshold for cognitive effects in children across the range of BLLs examined.'' This body of evidence includes studies which found effects on children's cognition in some groups of children with prenatal and early childhood blood lead or concurrent blood lead in the range of <1 to 10 μg/dL. (Ref. 5). This statement was based on a synthesis of the extensive literature examining the relationship between BLL and cognitive function, including a landmark pooled cohort study by Lanphear et al. (Refs. 59 and 60), the results of which have been confirmed by repeated re-analysis (Refs. 61 and 62). The 2024 ISA's statement on a threshold for cognitive function decrements in children is consistent with the 2013 ISA (Refs. 5 and 56), despite the evaluation of over 10 years of additional scientific evidence. The Federal Lead Action Plan, developed by the President's Task Force on Environmental Health Risks and Safety Risks to Children, which is comprised of 17 Federal departments and offices, states that ''no safe blood lead level in children has been identified.'' (Ref. 7). Further, the analysis that supports this rule examined the 95th percentile of children's modeled BLLs and the associated IQ losses (Ref. 12), which for all options considered is at or above the group mean BLLs for which IQ loss is observed in the literature examined in the ISA (Ref. 5 and 12).

EPA understands the limitations of the epidemiological analyses of BLL and children's IQ and the heterogeneity observed in scientific studies evaluating

groups with mean BLLs below 2 μg/dL, and acknowledges that a threshold could exist that is currently unidentified; but ultimately in its assessment of the available scientific research findings in the 2024 ISA for lead, the Agency observed that ''the collective body of epidemiologic studies provides no evidence of a threshold for cognitive effects in children across the range of BLLs examined.'' This body of evidence includes studies which found effects on children's cognition in some groups of children with prenatal and early childhood blood lead or concurrent blood lead in the range of <1 to 10 μg/dL (Ref. 5). EPA continues to acknowledge the aforementioned uncertainties and notes that science is constantly evolving and, as additional data become available (*e.g.,* exposure and health impacts), then EPA may undertake a new rulemaking to propose changing the standards in the future to reflect any new data or information about an acceptable threshold of effects on cognition in children.

Additionally, the CDC acknowledges that ''[s]cientific evidence suggests that there is no known safe [BLL], because even small amounts of lead can be harmful to a child's developing brain'' (Ref. 63). When the original DLHS and DLCL were proposed and finalized in 1998 and 2001 the CDC had set a ''level of concern'' for children's BLL at ≥10 μg/dL (Refs. 64 and 65). In 1991, when that level was established as a level that should prompt public health actions, the CDC concurrently recognized that a BLL of 10 μg/dL did not define a threshold for the harmful effects of lead (Ref. 64). One goal for the level was that ''all lead poisoning prevention activities should be to reduce children's BLLs below 10 μg/dL'' (Ref. 64). Accordingly, in the 1998 proposal EPA stated that, ''[a]lthough the scientific community has not been able to identify a threshold of exposure below which adverse health effects do not occur, the evidence of health effects below 10 μg/dL is not sufficiently strong to warrant concern'' (Ref. 66). In the final rule in 2001, EPA determined the lowest candidate DLHS by using a 1 to 5% probability of an individual child developing a BLL of 10 μg/dL (Ref. 20).

In the 2019 Final Rule, EPA recognized that ''[a]lthough health risks to young children decrease with decreasing dust-lead levels, no non-zero lead level, including background levels, can be shown to eliminate health risk entirely.'' At that time, EPA also recognized the CDC's 2012 decision to discontinue its use of a 10 μg/dL blood lead ''level of concern'' and to introduce a population-based blood lead reference value (BLRV) to identify children exposed to more lead than most other children in the United States (Ref. 67). The BLRV represents the 97.5th percentile of the U.S. population BLL distribution in children ages 1 to 5 from the National Health and Nutrition Examination Surveys (NHANES). This means that by definition 2.5 percent of children ages 1 to 5 in the NHANES survey have a BLL greater than the BLRV. This metric was established in part because ''no safe blood lead level in children ha[d] been identified,'' (Ref. 67). In 2012 the BLRV was 5 μg/dL, based on young children's BLL in the 2007–2010 NHANES, and in 2021 it was lowered to 3.5 μg/dL based on the children's lower BLLs observed in the 2015–2018 NHANES (Ref. 65). The BLRV is not based on a health endpoint, but rather is a statistical point in the distribution of children's BLLs in the United States used as a policy tool to identify children who have higher levels of lead in their blood compared with most children.

Establishing a health-based only standard for DLRL, as well as DLAL that considers other factors (*i.e.,* taking into account reliability, effectiveness, and safety), is similar to EPA's implementation of some other programs governing lead exposure. For example, under the Safe Drinking Water Act (SDWA), EPA is required to establish a maximum contaminant level goal (MCLG) at a level at which, in the Administrator's judgment, ''no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety.'' SDWA section 1412(b)(4). EPA established a health based MCLG of zero for lead in drinking water. National Primary Drinking Water Regulations include either an enforceable maximum contaminant level (MCL) or treatment technique requirements, EPA can set a treatment technique requirement in lieu of an MCL if ''it is not economically or technologically feasible to ascertain the level of the contaminant.'' SDWA section 1412(b)(7)(A). In addition to the MCLG, EPA established treatment technique requirements for lead taking into account several factors (56 FR 26460). Unlike many other drinking water contaminants, lead is generally not present in source water but enters drinking water from corrosion of plumbing materials that contain lead including lead service lines and premise plumbing. Occurrence of lead in drinking water is variable within a system and across systems due to factors such as the amount of lead in any individual site's plumbing, physical and chemical characteristics of the water, and consumer use patterns. Additionally, sources of lead can be beyond the control of the water system to replace, such as premise plumbing. Water systems can adjust or add treatment to control the corrosivity of the water to reduce lead leaching from lead pipes and premise plumbing. EPA is required to consider technical feasibility and costs when establishing the treatment technique. Under EPA's treatment technique rule for lead in drinking water, EPA established a non-health-based action level that, if exceeded, requires water systems to take actions to reduce elevated levels of lead in drinking water.

c. Modeling Discussion and Results

The Technical Support Document estimated BLL and IQ decrements (among other health endpoints, see Unit III. for more information) in children exposed to hypothetical dust-lead loading values (*i.e.,* it evaluated the estimated impacts of exact dust-lead exposures). These estimates for BLLs of children exposed to the DLRL dust-lead loadings were evaluated for children at each age up to age six, including age two (generally, age two is the age of greatest modeled exposure), and lead-related reduction in IQ at age six was estimated from the lifetime average BLL (average of BLLs across the period prior to age six). This approach is consistent with the study from which the BLL concentration-IQ response function was drawn. This study related IQ quantified at about six years of age to each child's lifetime average BLLs (based on blood lead measurements taken from six months up to age of the IQ test (Refs. 59 and 60). In the following discussion towards the end of this section, both the model results for two-year BLL and the estimates of IQ change at six years are represented, and EPA refers to them as the results for ''young children'' for brevity.

Ultimately, the results from the TSD show that as dust-lead levels in housing decrease below the current standard (*i.e.,* 10 μg/ft^2 and 100 μg/ft^2 for floors and window sills), so do children's BLL and IQ decrement from lead exposure, which supports the final approach of any reportable level and the concept of disclosure. These values are estimated to help EPA analyze the impacts of this rulemaking on the health (*i.e.,* IQ decrement, which is a measure of cognitive function) and dust-lead exposure of the population in question (*i.e.,* young children in pre-1978 buildings and COFs), as well as to inform a costs and benefits analysis in the EA. Two other approaches to

revising the DLHS (described as DLRL moving forward) and their dust-lead loading candidates were considered and were both discussed in depth in the 2023 Proposed Rule and evaluated in the TSD. See Unit IV.B.2. for more information.

When choosing health or exposure metrics to evaluate the DLRL approaches based on the TSD results, the Agency considered three factors: (1) the CDC's BLRV (which is a not a health-based end point but rather is a statistical measure of relative exposure); (2) responsiveness to feedback received previously from various scientific bodies; and (3) Agency precedent. The TSD considers BLL and IQ changes in two ways: relative to aggregate/total lead exposure (which includes exposure from other media: soil, diet, water, and air in addition to dust) and relative to incremental/dust-only lead exposure (Ref. 12). For example, in 2001 the lowest DLHS candidate was identified by using a 1 to 5% probability of an individual child developing a BLL of 10 µg/dL (Ref. 20), which represented total BLL, inclusive of exposure to lead through other media.

In the TSD analyses for this final rule, EPA compared BLL in young children, with an emphasis on 2-year-old children because this is the age of greatest modeled exposure, from aggregate or total exposure from all media (*i.e.,* dust, soil, diet, water, and air) to the CDC BLRV of 3.5 µg/dL. This BLL value is not health based and does not represent a toxicity threshold (and is subject to change over time, since the CDC BLRV changes as the BLLs in the population change); however, CDC explains that it can still be used as a tool to ''(1) help determine whether medical or environmental follow-up actions should be initiated for an individual child and (2) prioritize communities with the most need for primary prevention of exposure and evaluate the effectiveness of prevention efforts'' (Ref. 65). Importantly, even at zero dust-lead (which again is not a candidate of interest but is being used for comparison and informational purposes only), children are estimated to have a 5.7% probability of exceeding the BLRV given the impact of background lead exposures from other media (*e.g.,* soil, diet, water, and air) (Ref. 12).

TABLE 1—PERCENT EXCEEDANCE VALUES FOR ZERO DUST-LEAD, AGE: 2-YEAR-OLD (30 MONTHS)

Approach	Floor (µg/ft²)	Sill (µg/ft²)	Probability			
			Total BLL >3.5 µg/dL (%)	Total BLL >5 µg/dL (%)	Dust only BLL >1 µg/dL (%)	Dust only BLL >2.5 µg/dL (%)
Zero [1]	0	0	5.7	2.2	0.0	0.0

[1] The exceedance values for zero dust-lead are provided for comparison with the DLRL candidates; it is not a candidate value and is for informational purposes only.

In 2011, EPA's Scientific Advisory Board (SAB) and in 2012 the Children's Health Protection Advisory Committee (CHPAC) both expressed support for an incremental BLL approach that focuses on dust-lead exposure only. In 2011 SAB reviewed EPA's *Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft)* and *Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)* and provided feedback that there are several key advantages to the incremental approach (*e.g.,* reducing uncertainty from estimating exposures from other media) and provided that a change in BLL ''of 1 or 2 µg/dL at the 90th percentile'' could be an example of a target risk level. Similarly, CHPAC expressed support for using an incremental approach and preferred levels such that an adverse change in BLL is ''no greater than 1 or 2.5 µg/dL'' (Ref. 68).

As a result, EPA also estimated what dust-lead levels (considering only the dust-lead component in the multi-media exposure modeling) would result in incremental BLL change ranging between 1 and 2.5 µg/dL based on exposure assumptions described in the TSD (Ref. 12).

For this reconsideration rulemaking the Agency considered the estimated total/aggregate IQ change (*i.e.,* the estimated total or aggregate IQ change from modeled BLL including all modeled sources of lead exposure) at age six and compared it to a threshold of 1 to 2 points. IQ changes due to background exposures to lead in other media (*e.g.,* soil, diet, water, and air) are estimated to already have a 48.7% probability to exceed 2 points for children in target housing without also considering additional dust-lead exposure (Ref. 12).

TABLE 2—PERCENT EXCEEDANCE VALUES FOR ZERO DUST-LEAD, AGE: 6-YEAR-OLD (72 MONTHS)

Approach	Floor (µg/ft²)	Sill (µg/ft²)	Probability			
			Total IQ decrement >1pt (%)	Total IQ decrement >2pt (%)	Dust only IQ decrement >1pt (%)	Dust only IQ decrement >2pt (%)
Zero [1]	0	0	88.9	48.7	0.0	0.0

[1] The exceedance values for zero dust-lead are provided for comparison with the DLRL candidates; it is not a candidate value and is for informational purposes only.

In addition to total/aggregate IQ change, EPA determined BLLs that were estimated to result in an incremental loss of 1 to 2 IQ points from exposure to only dust-lead (*i.e.,* exclusive of lead in other media such as soil, diet, water, and air). This metric is explicitly health-based, in that it is an estimated health effect. There is EPA precedence for using the metric of an incremental change in IQ with a range of values of 1 to 2 points to inform national standards decisions. This includes the 2008 and 2016 decisions on the primary national ambient air quality standard (NAAQS) for lead, which was informed by consideration of air-related IQ decrement estimates based on an evidence-based framework, with a focus on the at-risk subpopulation of children living near sources who are likely to be

most highly exposed to air-related lead (Ref. 69). In their review of various technical documents supporting both the 2008 and 2016 NAAQS reviews, the Clean Air Scientific Advisory Committee (CASAC) supported using an incremental 1-to-2-point IQ decrement approach for consideration during development of the air standard (Refs. 69 and 70).

When modeling the ''any reportable level'' approach in the TSD to compare to these health and exposure metrics of interest (as discussed previously), EPA used estimated dust-lead loadings ranging from 0.8 to 2.0 μg/ft² for floors and 0.8 to 4.3 μg/ft² for window sills. These are estimated values for an any reportable level DLRL paired with both the proposed DLAL (3 μg/ft², 20 μg/ft², and 25 μg/ft² for floors, window sills, and window troughs respectively) and the proposed alternative DLAL (5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills and window troughs respectively, which is being finalized in this rulemaking). These estimated dust-lead loadings account for the lower reporting thresholds that EPA estimates laboratories will realistically attain under this rule. EPA collected information on real-world laboratory reporting limits from stakeholder outreach conversations. These any reportable level values listed in this unit are based on the average of reporting limits (which can vary across laboratories) that currently report numeric dust wipe loadings at levels 80% of the DLAL options. For the details of these calculations, see Section 2.4.6 of the EA (Ref. 10). Once again, EPA also used a hypothetical dust-lead loading value of zero, for comparison purposes only, to better understand the estimated impact that lead exposure from other matrices is expected to have on a young child without any dust-lead exposure.

The dust-lead reportable level will be used as a tool to identify when there are LBP hazards, particularly dust-lead hazards present, and to disclose those hazards to the individuals who requested the work. EPA's analysis for the final DLRL (any reportable level partnered with the final DLAL of 5 μg/ft2 and 40 μg/ft2 for floors and window sills) shows that after implementation of this standard, young children in target housing are estimated to have a 9.8% probability of exceeding an incremental BLL of 1 μg/dL (tables 12–2 and 12–3 in the TSD). In contrast, under the 2019 DLHS of 10 μg/ft2 and 100 μg/ft2, such children would have a 36.7% probability of exceeding that BLL.

When evaluating the final DLRL of any reportable level partnered with the final DLAL of 5 μg/ft² and 40 μg/ft² for floors and window sills by its impact on the metric of total BLL, the modeling includes exposure from other media such as soil, diet, water, and air. Importantly, even at zero dust-lead, 2-year-old children in target housing are estimated to have a 5.7% probability of exceeding the BLRV given the impact of these other exposures. This is because children who reside in target housing (built before 1978) have higher exposures to lead in soil and water relative to the overall population of US children (Ref. 71). However, the TSD modeling results did show that for any reportable level approach partnered with the final DLAL, there was a 10% probability of exposed 2-year-old children's BLL exceeding the CDC BLRV given their likely exposures to other sources of lead, an increase of 4.3% from the 5.7% probability at zero dust-lead and a reduction from the 2019 DLHS levels of 18%.

TABLE 3—PERCENT EXCEEDANCE VALUES FOR DLRL CANDIDATES, AGE: 2-YEAR-OLD (30 MONTHS)

Approach	Floor (μg/ft²)	Sill (μg/ft²)	Probability			
			Total BLL >3.5 μg/dL (%)	Total BLL >5 μg/dL (%)	Dust only BLL >1 μg/dL (%)	Dust only BLL >2.5 μg/dL (%)
Zero [1]	0	0	5.7	2.2	0.0	0.0
ARL With 3/20 DLAL	0.8	0.8	8.4	3.0	4.2	0.2
ARL With 5/40 DLAL	2.0	4.3	10.0	3.8	9.8	0.9
Current Standard	10	100	18.0	7.5	36.7	6.5

[1] The exceedance values for zero dust-lead are provided for comparison with the DLRL candidates; it is not a candidate value and is for informational purposes only.

DLRL candidates with the any reportable level approach are also estimated to be associated with a considerable reduction in the percent exceedance values for the lowest IQ decrements when compared with the current DLHS of 10/100 μg/ft² for floors and window sills. Any reportable level partnered with the final DLAL option (5 μg/ft², 40 μg/ft²) is estimated to have an 8.4% probability of greater than 2 points of IQ decrement associated with dust-exposure, keeping the percentage of exceedance of 2 points of IQ decrement below 10% probability compared with the previous 2019 DLHS of 37.9%.

TABLE 4—PERCENT EXCEEDANCE VALUES FOR DLHS CANDIDATES, AGE: 6-YEAR-OLD (72 MONTHS)

Approach	Floor (μg/ft²)	Sill (μg/ft²)	Probability			
			Total IQ decrement >1pt (%)	Total IQ decrement >2pt (%)	Dust only IQ decrement >1pt (%)	Dust only IQ decrement >2pt (%)
Zero [1]	0	0	88.9	48.7	0.0	0.0
ARL With 3/20 DLAL	0.8	0.8	96.4	71.0	20.3	2.7
ARL With 5/40 DLAL	2.0	4.3	97.7	78.0	39.2	8.4
Current Standard	10	100	99.4	90.3	75.8	37.9

[1] The exceedance values for zero dust-lead are provided for comparison with the DLRL candidates; it is not a candidate value and is for informational purposes only.

d. Public Comment Input

EPA received a number of comments during the public comment period that supported the proposed DLHS approach (described as DLRL moving forward) of ''any reportable level'' based on their view that there is no safe level of lead exposure. Multiple commenters also emphasized the dangers of lead exposure and were supportive as the DLRL will make the public and the regulated community aware of the risk lead dust may pose. Comments were also received expressing a lack of support for any reportable level, highlighting several primary concerns: that this approach would lead to larger public health impacts, create housing instability, encompass background levels of lead or lead sources that are not from lead-based paint, that the level would vary or be inconsistent from laboratory to laboratory, concerns over liability, and the impacts that an increase in costs would have.

EPA's responsibility when revising the DLRL (which is being done in accordance with the May 2021 Court Opinion and EPA's statutory authority) is to identify ''any condition that causes exposure to *lead* from lead-contaminated dust . . . that would result in adverse human health effects'' (emphasis added) (15 U.S.C. 2681(10)). These health-only considerations do not include broader public health concerns and are specifically focused on the health impacts of dust-lead exposure, without consideration of housing instability, source of the lead in the dust, cost, etc. In 2019 when EPA originally revised the DLHS, the Agency did so based on other factors such as risk management, consistency across the U.S. government, and laboratory capacity and capability, among other reasons. The 2021 Court opinion clearly explained that EPA must reconsider the 2019 DLHS and do so using health-only factors.

Firstly, EPA agrees with public commenters about the importance of the availability of affordable housing in the United States and wants to highlight actions this Administration has taken on this issue, such as the May 2022 Housing Supply Action Plan which was last updated in July 2023 with actions to further lower housing costs and boost supply (Refs. 72 and 73). Access to secure housing is an important social determinant of health (Ref. 74). Research finds negative health effects resulting from three key mechanisms of housing insecurity: lack of housing affordability leading to stress and material deprivation (Refs. 75, 76, 77 and 78), lack of housing stability (Refs. 79, 80, 81, 82 and 83), and lack of safe and adequate housing (Refs. 84, 85, 86, 87 and 88). EPA does not want to negatively impact the availability of housing stock with this final rulemaking nor disincentivize participation in any Federal programs and plans to work closely with HUD to try to help mitigate any such consequences. See Unit V.B. for more information on the implications of this rulemaking on HUD programs.

Secondly, EPA acknowledges that lead is naturally occurring and that it is impossible to entirely remove lead from nature. EPA acknowledges that background concentrations of dust-lead could be higher than any reportable level as analyzed by an NLLAP-recognized laboratory, depending on the sensitivity of the dust-wipe sampling technology being used and the background levels themselves. However, in EPA's 2001 LBP Hazards Rule establishing the original dust-lead standards, including the DLHS and DLCL (described as DLRL and DLAL moving forward), EPA explained that the Agency would not exclude from coverage under TSCA Title IV certain dust or soil based on its lead source due to both statutory and technical reasons. The 2001 Response to Comment Document (that accompanies the 2001 LBP Hazards Rule) rightly pointed out that the definitions of ''lead-contaminated soil'' and ''lead-contaminated dust'' from TSCA section 401 do not include mention of lead-paint or any reference to paint as the source of lead in dust or soil. Additionally, the definition of a ''lead-based paint hazard'' lists exposure to lead from lead-contaminated dust and soil as sources of lead contamination separate from—and not explicitly linked to—lead-contaminated paint. The 2001 Response to Comment Document continues that in addition to soil, paint and dust being defined separately and distinctly in the statute, TSCA section 403 directs EPA to ''promulgate regulations which shall identify, for the purposes of [TSCA Title IV] and the Residential Lead-Based Paint Hazard Reduction Act of 1992, lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil'' (15 U.S.C. 2683). If the definitions for lead-contaminated dust and soil were meant to include only lead from paint, it would not be necessary to list them separately in TSCA section 403. EPA ultimately concluded, based on the ''breadth of the definition for lead-contaminated dust and soil taken together with the structures of both Title X and TSCA demonstrate that the lead source in lead-contaminated dust and soil covered by these statutes is not limited to lead from paint.'' For the full discussion, see the 2001 response to comments document (Ref. 89).

Separately, EPA also pointed out in the 2001 response to comments document the complexity of identifying a method for distinguishing the risks based on different types of lead (*i.e.,* from different sources). It is not possible to determine easily and with good precision what element of lead in dust or soil is from what specific source or building component. EPA concluded at the time that ''there is a distinct absence of a scientific method to determine conclusively that the source of lead in dust or soil is not paint on a routine basis.'' EPA believes that this conclusion has not changed, and while there are some studies that involve stable isotope ratios (see 2001 response to comments document for more information), those are not a viable solution for the LBP activities program which includes numerous properties that fall under the definition of target housing and COFs, with risk assessments and testing happening across the United States on a routine basis.

Note that the U.S. Court of Appeals for the District of Columbia Circuit upheld this interpretation pertaining to source apportionment in 2002 in *Nat'l Multi Housing Council* v. *EPA,* 292 F.3d 232 (D.C. Cir. 2002). Based on the epidemiological evidence available, EPA observed in the 2013 and 2024 Integrated Science Assessments that there is no evidence of a threshold below which there are no harmful effects on cognition from lead exposure, (Refs. 5 and 56), and that conclusion is not impacted by the source of that lead exposure. EPA is also unaware of any information that points to different health effects based on different types of dust-lead (*i.e.,* dust-lead from soil vs. dust-lead from household paint).

Thirdly, EPA agrees with the commenters that the final DLRL (previously referred to as DLHS) will potentially vary from laboratory to laboratory. EPA sees this as a strength of the final DLRL: that there is room for improvement and the possibility of getting as low as reliably reportable depending on the sensitivity of the technology, which in turn allows the regulated community to be able to disclose lower levels. In addition, EPA sets the minimum standards laboratories need to meet, outlined in the latest LQSR version 4.0. Therefore, EPA feels the potential for variability that the commenters are raising is limited and any variability would be below the 80%

of the lowest action level for dust wipe samples per specific surface area (*i.e.,* equal to or less than 4 μg/ft² for floors, 32 μg/ft² for window sills and 80 μg/ft² for troughs). This will also reduce the need to revise the DLRL, unless there is a compelling reason to, such as a threshold for adverse effects being identified. EPA also notes that it has previously adopted and continues to apply an analogous concept in the disclosure program (40 CFR part 745, subpart F and 24 CFR part 35, subpart A), where disclosable records and reports have included any information regarding LBP or LBP hazards, including dust-lead levels below the DLHS (described as DLRL moving forward). As laboratory testing protocols have improved, so has the quality of the information in the records and reports based on such testing, which are ultimately provided to the home/building owner or lessee.

EPA points the regulated community to other changes being finalized in the rulemaking, such as the definition of abatement and the nomenclature change, which will adjust the terminology used for the standards. EPA is finalizing a change in the definition of abatement that results in the recommendation for action being shifted to the DLAL (rather than the DLHS, described as DLRL moving forward, as has been the case historically). The DLAL is being finalized as 5 μg/ft², 40 μg/ft² and 100 μg/ft² for floors, window sills, and window troughs. EPA also recommends that all local, Federal and authorized programs make similar changes, to change their trigger for recommending action, for the same reasons EPA has explained that this rulemaking adopts such changes. EPA believes this change will also alleviate some of the concerns surrounding laboratory inconsistency if the recommendation for action hinges off of the DLAL rather than the DLRL. See Unit IV.A. and Unit IV.E. for more information on these amendments.

Additionally, due to feedback from public comments (see Section 5 of the response to comments document that accompanies this final rule for more information), EPA is also finalizing changes to the nomenclature of DLHS and DLCL, to dust-lead reportable level and dust-lead action level (abbreviated DLRL and DLAL). EPA believes these revisions will better communicate to the public the purpose of the standards and to reduce confusion. EPA believes these changes will also help address some of the commenters' concerns about potential liability for LBP professionals or landlords from allowing dust-lead hazards to remain.

A more comprehensive version of EPA's responses on all of these issues can be found in the response to comments document that accompanies this rulemaking (Ref. 38).

2. Other Approaches EPA Considered in the Proposed Rule

EPA considered two other approaches for revising the DLHS (described as DLRL moving forward): a ''numeric standard'' approach and a ''post-1977 background'' approach. Both approaches were discussed in depth in the proposed rule, which also included requests for comment. All three approaches (*i.e.,* any reportable level, numeric standard, and post-1977 background) would take different analytical paths to revising the DLRL based only on health considerations. EPA is finalizing any reportable level, see Unit IV.B.1. for more information; however, the other two approaches EPA considered are summarized briefly elsewhere in this unit (Unit.IV.B.2.). See the 2023 Proposed Rule for more detailed information (Ref. 55).

The ''numeric standard'' approach would have been based on the probability of exceedance of one or more IQ or BLL metrics as determined by the Agency, meaning that the Agency would establish a DLRL with a rationale based solely on the interpretation of the TSD results and using a selected metric. To do this, the Agency would need to establish a health or exposure metric of interest (*i.e.,* target BLL or IQ change) that would be acceptably protective of human health, such as the metrics used in the TSD and described in Unit IV.B.1.c. Within the TSD and for the 2023 Proposed Rule, EPA evaluated several numeric DLRL candidates that the Agency thought were appropriate given the health and exposure metrics of interest and the uncertainty of the model at low loading values. The numeric DLRL candidates discussed in the proposed rule were 1/10 μg/ft² (*i.e.,* 1 μg/ft² for floors and 10 μg/ft² for sills), 2/20 μg/ft², 3/30 μg/ft², and 5/40 μg/ft² and those values were compared with the specified BLL and IQ metrics to estimate the probability of exceeding the BLL or IQ targets.

In 2001 and 2019, EPA expressed the challenges of meeting the statutory criterion for defining a LBP hazard (15 U.S.C. 2681(10)) because it requires EPA to choose a cutoff for when unacceptable risk exists. EPA noted in 2001, even if the science and environmental-lead prevalence data were perfect, there would likely be no agreement on the level, or certainty, of risk that is envisioned in the phrase ''would result in adverse human health effects.'' Thus, EPA explained that it ''would not be appropriate to base a [LBP] hazard standard on any specific probability of exceeding any specific [BLL].'' (Refs. 2 and 20).

For this numeric approach the Agency would need to establish a health or exposure metric of interest (*i.e.,* target BLL or IQ change) that would be acceptably protective of human health. Under this numeric standard approach, EPA planned to use the threshold of 5% probability of exceedance for a child from the population of interest (*i.e.,* young children living in pre-1978 housing and COFs). This is similar to the 1 to 5% probability that was used in 2001 for the lowest DLHS candidate (Ref. 20). However, EPA ultimately continues to agree with the challenges that were highlighted in 2001 and 2019, and the complexity with identifying a cutoff of risk or specific IQ/BLL metrics of interest that would be acceptable for purposes of setting the DLRL. Accordingly, EPA continues to favor the ''any reportable level'' approach.

EPA also considered and requested comment on the ''post-1977'' background approach that would use the average background dust-lead levels of housing built in 1978 and beyond as the DLRL. This approach would align target housing dust-lead levels with dust-lead levels in housing built after lead-based paint was banned. In 1978, the CPSC banned lead in paint and similar surface-coating materials for consumer use in excess of 0.06% and revised the level in 2009 to 0.009% following the Consumer Product Safety Improvement Act of 2008 (Pub. L. 110–314). As a result of CPSC's 1978 lead paint ban, the focus of EPA's LBP activities program is target housing, which includes most pre-1978 housing and COFs. This approach would result in lowering the DLRL to the dust-lead background levels of housing built after 1977 (known as ''post-1977 background''), which are presumably not from paint on the house in question containing more than 0.06% lead.

Post-1977 background dust-lead values were calculated from a weighted geometric mean of the dust-lead loadings from the American Healthy Homes Survey II and were found to be 0.2 μg/ft² for floors and 0.8 μg/ft² for window sills (Refs. 10 and 53). Setting the DLRL at the post-1977 background dust-lead levels would allow EPA to focus on dust-lead hazards above what is expected in housing without LBP (*i.e.,* after CPSC established a maximum level of lead in paint for consumer products, including home paints). Establishing DLRL for target housing and COFs in this way, using post-1977 background

dust-lead levels, would address disparities in the dust-lead levels that children in target housing may be exposed to and the corresponding disparate health risks. This approach would also align with the focus of Title X on lead hazards in housing constructed before 1978. However, there are questions about whether the post-1977 background approach would directly address the 2021 Court Opinion as the ''any reportable level'' approach does.

See the 2023 Proposed Rule for more detailed information about these two approaches, including a description of their estimated modeling results, such as BLL/IQ decrement impacts (Ref. 55). EPA did not receive significant public comment for either of these approaches and given the 2021 Court Opinion remanding the DLHS for reconsideration based only on health factors, the results of the analysis in the TSD, and the lack of a discernible threshold in the evidence for the association of blood lead with harmful effects on cognition in young children, EPA is finalizing revisions to the 2019 DLHS to any reportable level of lead analyzed by an NLLAP-recognized laboratory, as proposed.

C. Dust-Lead Action Level Approach

TSCA Title IV granted EPA the authority to regulate LBP activities, and to take into account reliability, effectiveness, and safety (15 U.S.C. 2682(a)(1)) when setting those regulations (including the DLAL). While considering those three criteria, the 2001 LBP Hazards Rule modified the work practice standards to include DLCL (described as DLAL moving forward), which ''are used to evaluate the effectiveness of cleaning following an abatement'' (Ref. 20). In both the 2001 LBP Hazards Rule and the 2021 Final Rule, the DLCL were finalized as the same value as the DLHS (described as DLRL moving forward) for floors and window sills. When originally established, EPA considered the DLCL in the broader context of Title X, and selected DLCL that were compatible with a ''workable framework for lead-based paint hazard evaluation and reduction.'' EPA chose DLCL that were consistent with the DLHS in part to ensure they were ''as easy as possible to understand and implement'' (Ref. 66). At that time EPA established the DLCL and the DLHS at 40 μg/ft² and 250 μg/ft² for floors and window sills, with a separate DLCL of 400 μg/ft² for troughs.

In 2021 the DLCL set by EPA continued to mirror the DLHS as it had done historically, as the Agency explained that it wanted to update the DLCL to achievable levels that would demonstrate elimination of dust-lead hazards under the 2019 DLHS of 10 μg/ft² for floors and 100 μg/ft² for window sills. The 2021 updates to the DLCL restored consistency between the DLCL and DLHS, which had been lowered in 2019 without a corresponding amendment to the DLCL. Previous public comments received on the 2018 DLHS proposal and 2020 DLCL proposal favored lowering the DLCL to be consistent with the DLHS (Refs. 90 and 91). As a result, in 2021 EPA finalized DLCL of 10 μg/ft² for floors and 100 μg/ft² for window sills (the same levels as the DLHS), and ''EPA considered the achievability of these levels, how the lower dust-lead loadings can be reliably detected by laboratories, the effectiveness of these levels, and consistency with the revised 2019 standards and across the Federal Government'' (Ref. 3).

The 2021 Court Opinion affirmed that ''TSCA [Title] IV gives the EPA latitude to consider 'reliability, effectiveness, and safety''' when promulgating regulations ''[w]ith respect to implementation, including abatement.'' *A Cmty. Voice,* 997 F.3d at 995 (Ref. 9). This would include the DLCL/DLAL as they represent part of post-abatement work practices. The Court continued by emphasizing that this gives EPA more discretion when setting the DLCL because they are relevant to the implementation of remedial measures, rather than the identification of a hazard (*i.e.,* DLHS/DLRL). The Court analogized this dichotomy to other environmental statutory schemes (see also Unit IV.B.1.b. for EPA's discussion of the SDWA). The Court also held that the DLCL and DLHS are directly related and must be reconsidered together. Yet the Court recognized the difference in statutory authority and considerations (see Unit IV.B. for more information on DLRL, previously referred to as DLHS).

In accordance with the 2021 Court Opinion, EPA is finalizing revisions to the DLAL (previously referred to as the DLCL) in the same proceeding as the reconsideration of the 2019 DLHS (described as DLRL moving forward). Given the Court's direction for the considerations for how to revise the DLHS and DLCL and similar to what was proposed in 2023, EPA is finalizing dust-lead action levels that are decoupled from the dust-lead reportable levels (see Unit I.B. and C. for more background on decoupling). EPA evaluated the 2021 DLCL in accordance with the statute and is finalizing revisions to lower the levels to the alternative option that was proposed in 2023, from 10 μg/ft², 100 μg/ft² and 400 μg/ft² for floors, window sills, and troughs, respectively, to 5 μg/ft², 40 μg/ft², and 100 μg/ft² and is finalizing a change in the terminology to DLAL.

1. Rationale for Selecting the Final DLAL

EPA is finalizing the DLAL given the statutory criteria of reliability, effectiveness, and safety, based on consideration of HUD's Lead Hazard Control Clearance Survey (LHCCS), an evaluation of laboratory capabilities and capacity, the potential for risk reduction compared to the 2021 DLCL by lowering exposure to dust-lead, resource considerations and the Agency's careful review of the public comments received on the proposal. EPA chose 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills and window troughs, respectively, as the DLAL based on these consideration as well as high confidence that these standards can be successfully implemented, as shown by the use of these clearance levels currently in NYC. Another consideration supporting the choice of these DLAL is to avoid potentially spreading the limited resources for LBP hazard mitigation so broadly that they may be diverted from scenarios that present the greatest risk.

a. Lead Hazard Control Clearance Survey.

EPA collaborated with HUD to develop the 2015 LHCCS. The survey aimed to examine whether HUD's Office of Lead Hazard Control and Healthy Homes (OLHCHH) Lead Hazard Control (LHC) grantees could achieve DLCL (described as DLAL moving forward) below the standards in place at that time (*i.e.,* below 40 μg/ft², 250 μg/ft² and 400 μg/ft² for floors, window sills and troughs, respectively). LHC work performed by the grantees must be conducted by LBP certified individuals. Since most of the LHC grantees use commercial firms in their area, HUD OLHCHH believes that the grantees are conducting a large percentage of these activities and are therefore representative of the regulated community.

98 LHC grantees completed the 2015 survey, giving HUD information from housing units in which lead hazard control activities took place from 2010 through 2012, for a total dataset of 1,552 housing units including 7,211 floor samples and 4,893 window sill samples (Ref. 54). The data were analyzed to determine the percentage of samples cleared at or below specific values. Numerical modeling was performed to estimate loadings that fell below laboratory detection limits. For more information on how that analysis was

conducted please see appendix D of the EA (Ref. 10). Since the 2015 LHCCS report was published, to the Agency's knowledge, there has not been any data or source of information of this magnitude in terms of clearance samples alongside the details of the process, including the number of tests performed (with results) and the type of additional work or cleaning performed. EPA found this 2015 LHCCS report still relevant and recent enough to provide meaningful input to inform this reconsideration rulemaking.

EPA's analysis of the LHCCS data indicates that 72% of samples from 2010 to 2012 showed dust-lead levels at or below 5 μg/ft² for floors, 88% were at or below 40 μg/ft² for window sills, and 93% were at or below 100 μg/ft² for window troughs. As a result, EPA believes that the final DLAL of 5 μg/ft² for floors, 40 μg/ft² for window sills and 100 μg/ft² for troughs are achievable by LBP professionals, especially since the survey respondents were only required to achieve clearance below the 2001 DLCL at that time (40 μg/ft² for floors, 250 μg/ft² window sills, and 400 μg/ft² for window troughs). It is possible that the percentage of samples achieving clearance may be even higher today, due to the 2021 revision of the DLCL to 10 μg/ft² for floors and 100 μg/ft² for window sills, meaning clearance has had to be achieved at these lower levels or below, since that time. As a result, EPA has high confidence that the 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills, and window troughs DLAL option is achievable by LBP professionals, considering reliability and effectiveness.

b. Laboratory Capabilities for DLAL

In order to better understand how laboratory capabilities would be impacted by the proposed DLAL (previously referred to as DLCL) of 3 μg/ft², 20 μg/ft², and 25 μg/ft² for floors, window sills and troughs, respectively, and the final DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft², EPA spoke with eighteen NLLAP-recognized laboratories, nine prior to the 2023 Proposed Rule and nine after the public comment period was complete (Refs. 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108 and 109). EPA wanted to collect additional information from NLLAP-recognized laboratories about their dust-wipe programs, especially given that a non-static DLRL would shift the LQSR ''action level'' to the DLAL (see Unit IV.B.1.a. for more information). As explained in the proposal, EPA was interested in information from laboratories who had high dust wipe testing capacity and laboratories that had both a flame atomic absorption spectroscopy (FAAS) and the more sensitive laboratory instruments such as inductively coupled plasma atomic emission spectroscopy (ICP–AES) (also referred to as inductively coupled plasma optical emission spectroscopy or ICP–OES) or an inductively coupled plasma mass spectroscopy (ICP–MS). The Agency wanted additional background on ICP instruments and their use for dust wipe testing in general. After the public comment period, EPA wanted to continue building on the outreach that had been previously performed and further refine the Agency's understanding of the threshold for FAAS technology in terms of a lower limit of sensitivity by meeting with nine additional laboratories (eighteen total) and physically touring one location (Ref. 101, 102, 103, 104, 105, 106, 107, 108 and 109). Among the laboratories EPA spoke to in 2022, 2023 and 2024, 14 were accredited to use FAAS, 10 were accredited to use ICP–AES, and 2 were accredited to use ICP–MS to analyze dust wipe samples for lead, some being accredited for multiple types of technology. Seventeen of the eighteen laboratories provide commercial testing services, four of which are among the largest U.S. lead laboratories by dust wipe test volume. For additional details about the laboratory capabilities, see Section 2.4 in the EA that accompanies this rulemaking (Ref. 10).

FAAS has been the most popular choice for lead dust wipe testing for some time due in part to its low purchase price and operating cost, speed, and ease of use. Over two-thirds of laboratories recognized under the NLLAP for lead dust wipe testing currently use FAAS, and over half of these NLLAP laboratories rely solely on FAAS (Ref. 10). The laboratories using ICP–AES for dust-wipes tested an order of magnitude fewer dust-wipe samples than laboratories using FAAS. Some of the laboratories accredited for both types of instruments only use their ICP instrument for wipes being analyzed for multiple metals for industrial hygiene analyses or analysis of air or water samples instead of for dust-wipes related to EPA's lead-based paint activities rule (Refs. 97, 101, 104, 107, 108). One laboratory that uses both FAAS and ICP–AES indicated that it used FAAS for 95% of the samples tested and ICP–AES for only 5% (Ref. 98). Another laboratory that uses both FAAS and ICP–AES stated that it used the ICP–AES instrument to test approximately 20 dust-wipes per year, out of 34,000 to 36,000 lead dust-wipes that it analyzes each year (Ref. 104).

The information received from the laboratory outreach that was performed in preparation for the proposed rule indicated that if finalized as proposed, ICP–AES would likely become the instrument standard for dust wipe testing for lead at the NLLAP laboratories, as FAAS instruments were not reported to consistently meet the quantitation limits associated with the proposed DLCL. ICP–AES instruments can detect lead at lower levels than FAAS instruments, but ICP–AES instruments are more expensive to purchase, have higher operating costs for consumable supplies, require a more experienced technician to operate, and need more time for sample preparation, analysis, and quality control requirements than FAAS instruments. Laboratories raised several concerns about switching to ICP instruments, including the reduction in the throughput rate, the need for multiple instruments and staff to operate them, higher prices, delayed turnaround times, and concerns over maintaining the current sample volume. For example, one laboratory EPA spoke to estimated that they would have to purchase three to six new instruments, hire several highly qualified technicians, and run the laboratory on shifts over 24 hours to meet current demand for dust wipe tests conducted solely by ICP (Ref. 96). Several laboratories questioned whether they would keep dust-wipe testing in their portfolio if EPA finalized the levels from the 2023 Proposed Rule (Refs. 96, 98, 103, 107).

This shift in instrumentation that would have been needed as a result of the clearance levels in the proposed rule would increase both cost per sample as well as turnaround time. Dust wipe testing by ICP–AES is approximately two to four times more expensive per sample than testing by FAAS (Refs. 96, 98, 100, 104, 108). Laboratories also mentioned that a substantial portion of their dust-wipe testing clients request results in one day or less (in some cases in as little as several hours) following a lead hazard reduction activity, so that residents can quickly reoccupy their homes (Refs. 95, 101, 103). Some of the laboratories using FAAS indicated that they offered turnaround times as short as several hours (Refs. 96, 104, 107). Several laboratories doubted the feasibility of providing same-day or next-day turnarounds at sufficient volume should they switch to ICP technology (Refs. 96, 98, 104, 108). Longer turnaround times would delay when individuals who temporarily

moved out can reoccupy their homes, requiring them to spend more time in temporary accommodations (Ref. 91) which can increase the costs of lead hazard reduction activities, thus potentially reducing the number of abatements and interim control that would be funded.

EPA found that several laboratories forecast that dust-wipe test volumes will continue to grow over the next decade even in the absence of this rule (Refs. 96, 97 and 102). First, a growing proportion of laboratories' dust-wipe testing business comes from landlords who need to comply with municipal housing regulations set by States or localities. Laboratories expect similar regulations to be enacted in the coming years, increasing demand for dust-wipe testing for clearance (Ref. 97). Second, in recent years laboratories have received an increased volume of test samples generated by disaster recovery programs. When there is a natural disaster (such as a major flood) that requires clean-up and re-construction of pre-1978 housing, laboratories can receive an unexpected spike in dust-wipe tests. Laboratories pointed out that the increasing rate of disaster-related demand spikes may overwhelm their capacity if only ICP can be used for dust-wipe testing.

Finally, laboratories also expressed concern that increases in costs for activities such as testing, cleaning, and temporary accommodations due to the dust-lead levels EPA originally proposed would reduce the number of housing units where lead hazards would be addressed, in part because State and local municipalities often have a fixed budget for their housing and health programs (Refs. 96 and 108). The laboratories felt that the 2023 Proposed Rule could have the unintended result of exposing more individuals to elevated dust-lead levels for a longer period of time (Refs. 108 and 109). Given the information gathered via EPA's outreach to laboratories, EPA is concerned that setting action levels too low would deter participation in lead-hazard control programs and activities that require dust-wipe testing or cause a market failure that does not allow the current volume of testing to continue.

EPA is finalizing a DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills and troughs. EPA has increased confidence that, relative to the proposed 2023 DLCL (*i.e.,* 3 μg/ft², 20 μg/ft², and 25 μg/ft²), laboratories can numerically quantify dust-lead levels of 5 μg/wipe with FAAS technology and attain a quantitation limit of equal to or less than 80% of the final DLAL (*i.e.,* 4 μg/ft², 32 μg/ft², and 80 μg/ft²) for floors, window sills and troughs. EPA believes that the final DLAL, rather than the proposed 2023 DLCL, partnered with the changes incorporated into LQSR 4.0, allows NLLAP-recognized laboratories to continue using FAAS technology. This would mitigate any unintended reductions in dust wipe capacity (*e.g.,* throughput time, cost, labor, etc.) due to having to switch to more sensitive technology such as ICP–AES. While some NLLAP-recognized laboratories may opt for more sensitive technologies, EPA does not foresee any concerns reporting to 5 μg/ft², 40 μg/ft², and 100 μg/ft² even for those surfaces with a smaller area such as on window sills or troughs if laboratories successfully attain a regulatory limit of 5 μg/ft².

c. Final DLAL Modeling Results

EPA must understand the estimated health impacts of dust-lead exposure when selecting a DLAL that is reliable, effective, and safe, as well as to help inform the economic analysis. The TSD that accompanies this rule includes an evaluation of dust-lead loadings, specifically the 2021 DLCL of 10 μg/ft² and 100 μg/ft² for floors and window sills, the proposed DLAL of 3 μg/ft² and 20 μg/ft² for floors and window sills and the final DLAL of 5 μg/ft² and 40 μg/ft² for floors and window sills, compared to estimated BLL and IQ decrements. The unique dust-lead contribution to exposure from window troughs has not been distinguished from window sills given the strong correlation between dust-lead loadings on the two surface types, the lack of data on access to window troughs and window sills by children, and the paired impacts in window sills and window troughs from intervention studies addressing lead paint in window trim and casings. Further discussion on exposure to window troughs can be found in the TSD in appendix C. As a result, exposure to window trough dust-lead and resultant benefits from a lowered DLAL for troughs is not calculated separately for this rulemaking. The TSD also describes modeling of dust-lead exposures at the specific DLAL options for window sills and floors only and estimates of both BLLs that were evaluated for children at each age up to age six, including age two (generally, this is the age of greatest modeled exposure), and lead-related reduction in IQ at age six was estimated from the lifetime average BLL (average of BLLs across the period prior to age six). See Unit IV.B.1.c. for more specific information on which BLL and IQ decrements were chosen for comparison, and Unit III. for more details on estimated potential impacts from dust-lead exposures analyzed in the TSD. Tables 5 and 6 represent the percent exceedance of highlighted metrics at dust-lead loadings corresponding to the 2021 DLCL (10 μg/ft² and 100 μg/ft² for floors and window sills), the final DLAL (5 μg/ft² and 40 μg/ft² for floors and window sills) and zero (for comparison purposes only).

The final DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills and troughs represents a 50% or more reduction of dust-lead left on a surface following the completion of an abatement, when compared to the 2021 DLCL (10 μg/ft², 100 μg/ft², and 400 μg/ft²). As a result, DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² would be beneficial to maintaining lower children's BLLs and protecting against associated health outcomes such as decreased IQ. The modeling results provided in the TSD show that 2-year-old children in pre-1978 housing exposed to dust-lead loadings of 5 μg/ft² for floors and 40 μg/ft² for window sills would have an estimated 13.9% probability of exceeding a total BLL of 3.5 μg/dL (CDC's BLRV). Total BLL includes exposure from other media such as soil, diet, water, and air; even at zero dust-lead, 2-year-old children would still have a 5.7% probability of exceeding the CDC's BLRV from these other sources. The 13.9% probability of exceeding the BLRV is significantly lower than the 18.0% probability of exceedance of the BLRV when exposed to the current DLCL of 10 μg/ft² for floors and 100 μg/ft² on window sills (see table 5).

When considering dust-lead exposure only (not including other estimated lead exposures from soil, diet, water, and air), 2-year-old children in pre-1978 housing exposed to the final DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² would have a 3.2 to 23.0% probability of exceeding a BLL of 1 to 2.5 μg/dL based on the modeled results. The final DLAL is also estimated to be associated with a 22.4% probability of exceeding 2 points of IQ decrement in 6-year-old children. As with total BLL, this is a considerable reduction from the 37.9% chance of exceeding 2 points of IQ decrement for 6-year-old children living in target housing who are exposed the current DLCL (table 6). Overall, the modeling within the TSD indicated that the 5 μg/ft², 40 μg/ft², and 100 μg/ft² DLCL for floors, window sills and troughs represents a substantial reduction in risk from the current clearance levels of 10 μg/ft², 100 μg/ft², and 400 μg/ft² for floors, window sills, and window troughs.

TABLE 5—PERCENT EXCEEDANCE VALUES FOR THE FINAL DLAL CANDIDATE, AGE: 2-YEAR-OLD (30 MONTHS)

Approach	Floor (μg/ft²)	Sill (μg/ft²)	Probability			
			Total BLL > 3.5 μg/dL (%)	Total BLL > 5 μg/dL (%)	Dust Only BLL > 1 μg/dL (%)	Dust Only BLL > 2.5 μg/dL (%)
Zero [1]	0	0	5.7	2.2	0.0	0.0
5/40 DLAL	5	40	13.9	5.5	23.0	3.2
Current Standard	10	100	18.0	7.5	36.7	6.5

[1] The exceedance values for zero dust-lead are provided for comparison with the DLRL candidates; it is not a candidate value and is for informational purposes only.

TABLE 6—PERCENT EXCEEDANCE VALUES FOR THE FINAL DLAL CANDIDATE, AGE: 6-YEAR-OLD (72 MONTHS)

Approach	Floor (μg/ft²)	Sill (μg/ft²)	Probability			
			Total IQ Decrement > 1pt (%)	Total IQ Decrement > 2pt (%)	Dust Only IQ Decrement > 1pt (%)	Dust Only IQ Decrement > 2pt (%)
Zero [1]	0	0	88.9	48.7	0.0	0.0
5/40 DLAL	5	40	98.8	85.1	62.7	22.4
Current Standard	10	100	99.4	90.3	75.8	37.9

[1] The exceedance values for zero dust-lead are provided for comparison with the DLRL candidates; it is not a candidate value and is for informational purposes only.

These estimates represent post-abatement exposure at the exact dust-lead loadings of the final DLAL, but levels below those values must be achieved in order for an abatement to be considered complete. The subpopulation of children affected by this rule (*i.e.,* children with pre-abatement dust-lead exposures above the action level) experience pre-abatement dust lead loadings that are in the upper percentiles of children living in target housing (Ref. 71). As a result, it is likely that actual exceedances among the full population of children in target housing (*i.e.,* not only those who are affected by this rule, but all children who reside in housing constructed before 1978) are lower than what is represented in the TSD for the subpopulation affected by this rule. In contrast to the TSD, which estimates the health risk and exposure associated with dust-lead loading candidates for a hypothetical population of children in target housing without consideration to how many children are actually affected by the rule, the EA estimates benefits that accrue to only the subpopulation that would be impacted by the DLRL and DLAL revisions. See the Technical Support Document and Economic Analysis that accompany this rulemaking for more information (Refs. 10 and 12).

d. New York City

Between 2019 and 2021 NYC Department of Health and Mental Hygiene lowered their lead dust clearance and lead dust hazard risk assessment testing standards twice. NYC lowered their standards for floors, window sills and window wells (*i.e.,* troughs), respectively, from 40 μg/ft², 250 μg/ft², and 400 μg/ft² to 10 μg/ft², 50 μg/ft², and 100 μg/ft² in 2019 (effective June 12, 2019) and again to 5 μg/ft², 40 μg/ft², 100 μg/ft² in 2021 (effective June 1, 2021) (Refs. 110 and 111). The Agency spoke to the New York City Department of Health and Mental Hygiene and received feedback during the development of the proposed rule that although there was a transitionary period that lasted several months and had various challenges, overall, the regulated community was able to adjust and comply with the new lower standards (Ref. 112). EPA believes that NYC's experience supports considering the final DLAL of 5 μg/ft², 40 μg/ft², 100 μg/ft² for floors, window sills and window troughs to be effective and reliable.

e. Public Comment Input

EPA received a number of comments during the public comment period that supported the proposed DLCL approach (described as DLAL moving forward) of 3 μg/ft², 20 μg/ft², and 25 μg/ft² for floors, window sills and troughs, respectively, on the grounds that lowering the levels will further protect children from lead exposure. A mass mail campaign, which consisted of a coalition of 76 organizations and twelve individuals affirmed that the proposed levels promoted the greatest safety for those living in target housing, ensuring remedial measures meaningfully reduce the amount of dust-lead that remains in homes and child care facilities. Multiple comments were also received expressing a lack of support for the proposed DLCL (described as DLAL moving forward). Many commenters requested that the levels remain at the current 2021 values of 10 μg/ft², 100 μg/ft², and 400 μg/ft² for floors, window sills, and window troughs, respectively. Several commenters also requested the alternative DLCL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills, and window troughs rather than the proposed levels. Of those comments that expressed opposition to the proposed DLCL, the concerns were focused around a reduction of laboratory capacity (due to needing to switch to an ICP, which is more sensitive technology), the lack of adequate surface area for both window sill and trough sampling, the potential for this being a deterrent within the industry from performing LBP activities due to an increase in cost, burden, complexity, and a reduction in contractor availability.

Firstly, in response to the support for the proposed DLCL, EPA agrees and acknowledges that according to the results from the technical support document, as dust-lead levels in housing dust-lead levels in housing decrease below the current DLCL (*i.e.,* 10 μg/ft², 100 μg/ft², and 400 μg/ft² for floors, window sills, and window troughs), children's BLLs and associated IQ decrements from lead exposure are also expected to decrease. As a result, a lower DLAL is assumed to be more protective at a particular site than one that results in higher dust-lead loadings. However, based on the public feedback and the response to the 2023 Proposed Rule, as well as laboratory outreach, (see Unit IV.C.1.b. ''Laboratory capabilities

for DLAL'' for more information), EPA is concerned that if the DLAL were set too low, limited resources for LBP mitigation would be distributed more broadly, diverting them from the most vulnerable communities or situations that present more serious risks to those that present lower risks. EPA is also concerned that increased costs due to the proposed DLCL could result in less LBP work taking place overall. EPA's analysis indicates that the final rule's approach to the DLAL is the most cost-effective option analyzed for both the cost per lost IQ point avoided and the cost per ADHD case avoided, as explained in Section 7 of the UMRA Statement. These two benefit types accrue to the most sensitive population affected by this final rule (*i.e.,* children). Assuming limited resources for LBP mitigation, achieving these benefits more cost effectively would result in more lost IQ points avoided and more ADHD cases avoided. Additionally, EPA believes that access to housing is also an important social determinant of health and research finds negative health effects resulting from a lack of safe and adequate housing. Due to the public comments received, EPA has concerns that the proposed DLCL could unintentionally contribute to housing insecurity and longer turnaround times for post-abatement testing, which could impact access.

Secondly, safety is only one aspect of the statutory authority for reconsidering the DLAL (*i.e.,* reliability, effectiveness and safety). In particular, the Ninth Circuit affirmed that when reconsidering the clearance levels ''we must give effect to Congress's clear intent for EPA to consider both health and nonrisk factors.'' *Cmty. Voice,* 997 F.3d at 995. As a result, the DLAL is not a solely health-based standard; rather it also considers what cleanup after an abatement is adequately reliable and effective. EPA agrees with commenters that the 2023 proposed DLCL of 3 μg/ft², 20 μg/ft², and 25 μg/ft² for floors, window sills, and window troughs respectively, partnered with the revisions in LQSR 4.0 would not present a problem, in terms of testing sensitivity, for laboratories using ICP–AES/OES. However, the majority of laboratories recognized under the NLLAP for lead dust wipe testing currently favor the less sensitive FAAS. EPA continues to believe that if the Agency finalized the DLCL as proposed, then ICP–AES would likely become the instrument standard for dust wipe testing for lead at the NLLAP laboratories. As a result, numerous public comments were received expressing concern over this switch; FAAS has been the most popular choice for lead dust wipe testing for some time due in part to its low purchase price and operating cost, speed, and ease of use. During the laboratory outreach that was performed for rule development, laboratories raised several concerns about switching to ICP instruments, the reduction in the throughput rate, the need for multiple instruments and staff to operate them, higher prices, delayed turnaround times, and concerns over maintaining the current sample volume. See Unit IV.C.1.b. for more discussion surrounding laboratory capabilities and capacity. Ultimately, due to public comments received, laboratory outreach and concerns raised about the reliability and effectiveness of the lower proposed DLCL, EPA is finalizing the alternative values of 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills, and window troughs respectively. EPA does not want to create a program that raises significant feasibility concerns, or that inadvertently reduces the number of abatement jobs that the regulated community is able to perform (due to a dilution of intervention resources), thus potentially impacting families and children and resulting in less of an overall reduction in dust-lead.

A more comprehensive version of EPA's responses on all of these issues can be found in the response to comments document that accompanies this rulemaking (Ref. 38).

2. Other Approach EPA Considered in the Proposed Rule

In 2023 EPA proposed to revise the 2021 DLCL from 10 μg/ft², 100 μg/ft² and 400 μg/ft² for floors, window sills, and troughs to 3 μg/ft², 20 μg/ft², and 25 μg/ft², and requested comment on an alternative DLCL option of 5 μg/ft², 40 μg/ft², and 100 μg/ft². According to the 2015 LHCCS report, 64% of the 2010 to 2012 samples showed dust-lead levels at or below 3 μg/ft² for floors, 64% were at or below 20 μg/ft² for window sills, and 64% were at or below 25 μg/ft² for window troughs. As a result, approximately 64% of samples from the LHCCS data had dust-lead levels at or below the primary DLCL option of 3 μg/ft² for floors, 20 μg/ft² for window sills and 25 μg/ft² for troughs, which EPA thought was achievable, especially since the survey respondents were only required to achieve clearance below the 2001 DLCL at that time (40 μg/ft², 250 μg/ft², and 400 μg/ft² for floors, window sills and troughs, respectively). However, given the concerns highlighted by public commenters and during laboratory outreach, EPA is finalizing the alternative DLCL option of 5 μg/ft², 40 μg/ft², and 100 μg/ft² along with the terminology change to DLAL. See the 2023 Proposed Rule for more detailed discussion about the proposed DLCL (Ref. 55).

D. Cross Reference With HUD Regulations

EPA is finalizing modifications to 40 CFR 745.227(h) to clarify that the final DLAL would differ from the final DLRL, and that the Agency does not intend to compel LBP professionals to reduce dust-lead loadings all the way below the DLRL, just to below the DLAL. EPA is interested in alleviating any potential regulatory confusion surrounding clearance to the DLAL. HUD's LSHR clearance regulations at 24 CFR 35.1340(d), which apply to both abatement and interim control and paint stabilization activities above HUD's de minimis amount of disturbance of paint known or presumed to be lead-based paint at 24 CFR 35.1350(d), currently refer to 24 CFR 35.1320(b)(2). HUD's regulations at 24 CFR 35.1320(b)(2) in turn cross-references EPA's regulations at 40 CFR 745.227(h), which currently discusses EPA's DLHS (described by EPA as DLRL moving forward) but not EPA's DLCL (described by EPA as DLAL moving forward). See Unit III.A.3.f the 2019 Final Rule for additional background on this topic (Ref. 2). As explained earlier in this preamble, prompted by analysis conducted following the 2021 Court Opinion, EPA is finalizing a DLRL that is no longer the same value as the DLAL. As a result, EPA is amending the language at 40 CFR 745.227(h), so it is clear when referenced by the LSHR, that EPA does not intend to compel clearance below the DLRL, but below the DLAL, whether in federally assisted housing or not.

In the course of reviewing this amendment to 40 CFR 745.227(h), EPA realized that the regulation at 40 CFR 745.227(h)(2)(i) inadvertently refers to ''dust hazard levels identified in [40 CFR] 745.227(b).'' 40 CFR 745.227(b) actually addresses how to conduct an inspection and does not address dust hazard levels. Based on its context and the parallel language in 40 CFR 745.65(a)(1), the cross-reference in 40 CFR 745.227(h)(2)(i) was intended to refer to 40 CFR 745.65(b), which does identify what constitutes a dust-lead hazard. EPA has updated the cross-reference accordingly in order to remove any ambiguity.

E. Definition of Abatement

EPA is finalizing amendments to the definition of abatement in EPA's LBP activities regulations, specifically for dust-lead hazards, and thus modifying

the trigger for when EPA recommends an abatement. This change is a key element of the final rulemaking and is intended to align with the decoupling of the DLRL and DLAL, ultimately focusing the impacted entities' resources (*e.g.,* HUD, city, State) on the situations that present the most risk while still identifying and disclosing lower levels of concern. EPA has narrowly focused the amendments on the portions of the definition that address dust-lead. The abatement definition still applies unchanged with respect to paint-lead and soil-lead. TSCA section 401(1) defines an abatement as ''any set of measures designed to permanently eliminate lead-based paint hazards in accordance with standards established by the Administrator under [TSCA Title IV]'' and includes ''the removal of lead-based paint and lead-contaminated dust, the permanent containment or encapsulation of lead-based paint . . . and all preparation, cleanup, disposal, and post-abatement clearance testing activities associated with such measures.'' EPA included a definition of abatement, which closely resembles the statutory language, within the LBP activities regulations at 40 CFR 745.223. An abatement under the LBP activities regulations (40 CFR 745.223) is described as ''any measure or set of measures designed to permanently eliminate lead-based paint hazards'' and specifically includes ''projects resulting in permanent elimination of lead-based paint hazards . . .''.

The 2021 Court Opinion stated that ''TSCA [Title] IV gives the EPA latitude to consider 'reliability, effectiveness, and safety''' when promulgating regulations ''[w]ith respect to implementation, including abatement'' (Ref. 9). In addition, the statutory definition of abatement in TSCA section 401(1) specifically references the elimination of hazards ''in accordance with standards established by the Administrator under [TSCA Title IV].'' Hence, in considering revising the DLAL as part of TSCA section 402's ''standards for performing [LBP] activities,'' EPA must and has considered whether reliability, effectiveness and safety support changing the regulatory definition of abatement. Given that under this statutory scheme EPA only intends to compel post-abatement clearance to the final DLAL, the Agency is also changing the regulatory definition of abatement so that the recommendation for action applies when dust-lead loadings are at or above the DLAL (which continues to incorporate non-health-based factors such as reliability), rather than at or above the hazard standards, described as DLRL moving forward, as has been the case historically (but which, going forward in accordance with the 2021 Court Opinion, can no longer incorporate non-health-based factors such as reliability). This revision is necessary due to the decoupling of the DLRL from the DLAL and EPA's desire to avoid situations where abatements are designed to eliminate dust-lead levels to the DLRL and are unable to do so in a reliable and effective manner. Otherwise, EPA would be recommending an abatement if dust-lead levels are between the DLRL and the DLAL, even though such an abatement would only need to attain dust-lead loadings below the DLAL. Also, where an abatement is conducted, a cyclical pattern could result, where an abatement could successfully pass clearance below the DLAL but an abatement would still have been recommended by EPA if dust-lead levels were at or above the DLRL. Thus, EPA is revising the regulatory definition to require that abatements eliminate dust-lead hazards to below the DLAL to ensure that successful abatements can be considered complete in accordance with this rule's updated standards. Relatedly, as explained in Unit IV.F., EPA is proposing amendments to the abatement report to help protect from exposure even after the abatement is complete.

An additional benefit to modifying the trigger for when EPA recommends an abatement is that it allows the regulated community to focus resources on situations that present more risk. As discussed in the 2001 and 2019 final rules, an important concern for EPA is having the resources for LBP hazard mitigation distributed so broadly that they may be diverted from situations that present the greatest risk.

As a result, EPA is changing the regulatory definition of abatement to permanently eliminate dust-lead hazards to below the DLAL. EPA concludes that this amendment to the regulatory definition most appropriately applies the statutory definition in the context of this rule, where the statute requires EPA to consider reliability, effectiveness, and safety for purposes of EPA's TSCA section 402 LBP activities regulations (including the DLAL). Furthermore, as noted earlier in this section, the statutory definition of abatement in TSCA section 401 states that the set of measures covered by the term are to be ''in accordance with the standards established by the Administrator'' under TSCA Title IV, which refers to the ''standards for performing [LBP] activities'' as what EPA's TSCA section 402 regulations shall contain. Thus, EPA has concluded that the amended regulatory definition most appropriately implements the statutory instruction that abatement measures be ''in accordance with'' this rule's updated section 402 standards (notably, the revised DLAL). Note that nothing in this rulemaking changes the fact that owners of properties covered by the LBP Activities Rule are not compelled to evaluate their properties for the presence of dust-lead hazards, nor compelled by EPA to take action (such as an abatement) if dust-lead hazards are identified at or above the DLAL, although HUD and some State or local governments may require action.

F. Abatement Report

As explained in Units IV.A., B. and C., EPA is finalizing a nomenclature change to the terminology for the standards, and lowering the current DLRL to any reportable level as analyzed by an NLLAP-recognized laboratory. Additionally, EPA is finalizing the DLAL to 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills and troughs, respectively. The DLRL identify when pre-1978 housing or a COF has a dust-lead hazard present. Given this decoupling of the floor and sill values, it is likely that once a project passes clearance and the abatement can be considered complete, there could still be dust-lead hazards present due to the DLRL being any reportable level. The Agency realizes the challenge this creates for the regulated community and, to keep dust-lead levels down and mitigate exposure, EPA is proposing to amend the requirements for what needs to be included in an abatement report.

After the completion of an abatement, the certified supervisor or project designer is required to develop a report. The list of what needs to be included in the abatement report is described at 40 CFR 745.227(e)(10), and consists of elements such as the start and completion dates of the abatement, information about the risk assessor or inspector conducting the sampling, any post-abatement dust-lead testing and soil analyses, etc. EPA is modifying 40 CFR 745.227(e)(10) to include a requirement to add specific language into each abatement report, when dust-lead levels are between the DLRL and the DLAL. That language refers the public to a useful reference titled ''*Protect Your Family From Lead in Your Home*'' and acknowledges that LBP hazards (particularly dust-lead hazards) could remain after an abatement. The goal of including this language in an abatement report is to

ensure that occupants are provided with information about actions they can take to minimize dust-lead hazards and protect themselves from exposure even after an abatement is complete.

The certified firm (or individual who prepared the report) must keep the abatement reports for at least 3 years and must provide a copy to the individual or entity who ''contracted for its services'' (40 CFR 745.227(i)).

G. Other Amendments

In order to conform the regulations to a statutory change, make several other amendments to improve efficiency of the program and make several regulatory text corrections, EPA is finalizing the amendments to 40 CFR part 745, subparts E (Residential Property Renovation), F (Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards Upon Sale or Lease of Residential Property), and L (Lead-Based Paint Activities).

1. Definition of Target Housing

EPA is finalizing changes to the definition of target housing in 40 CFR 745.103 and 40 CFR 745.223 to align with the statutory changes made in 2017 and is making conforming edits to language in 40 CFR 745.223 and 40 CFR 745.227. Target housing defines which housing is subject to EPA's LBP rules. Within section 237(a) through (c) of Title II of Division K of the Consolidated Appropriations Act, 2017 (Pub. L. 115–31, 131 Stat. 788 and 789), Congress amended HUD and EPA's statutory definitions of target housing to include 0-bedroom dwellings if a child less than 6 years of age resides or is expected to reside in such housing (42 U.S.C. 4822(e); 42 U.S.C. 4851(b)(27); 15 U.S.C. 2681(17)). The change to the definition of target housing in 40 CFR 745.103 and 40 CFR 745.223 conforms to the statutory language by defining target housing as any housing constructed prior to 1978, except housing for older adults or persons with disabilities or any 0-bedroom dwelling (unless any child who is less than 6 years of age resides or is expected to reside in such housing). For consistency, EPA is also finalizing revisions to the definition of living area in 40 CFR 745.223 to change the age from 6 and under to less than 6 years of age. Similarly, language describing the age of children in 40 CFR 745.227(c)(2)(i), (c)(2)(iv), (c)(2)(v), (d)(3), (d)(5), and (d)(6)(ii) was updated from 6 years of age and under to under age 6 to conform to the statutory language as amended.

In the course of reviewing this amendment to 40 CFR 745.227(c)(2)(v), EPA realized that the regulation inadvertently refers to a paragraph (c)(1)(iii) of the section when no such provision exists. Based on its context, this cross-reference in paragraph (c)(2)(v) was intended to refer to the floor and window samples required by the immediately preceding provision (*i.e.,* paragraph (c)(2)(iv)). EPA has updated the cross-reference accordingly in order to remove any ambiguity.

2. Definition of Child-Occupied Facility (COF) and Living Areas

EPA is finalizing revisions to the definition of COF in 40 CFR 745.223 and related regulatory language in 40 CFR 745.227 to establish consistency throughout the LBP regulations. The LBP Activities regulations define COFs as buildings or portions of buildings, constructed prior to 1978, in which the same child regularly visits on at least two different days within any given week, with their visits lasting at least 3 hours with combined visits of at least 6 hours, and combined annual visits lasting at least 60 hours. COFs may include, but are not limited to, day-care centers, preschools and kindergarten classrooms. Living areas are defined as any area of a residential dwelling used by one or more children, which includes, but is not limited to, living rooms, kitchen areas, dens, play rooms, and children's bedrooms. Currently, the definition of COF at 40 CFR 745.223 identifies children impacted by the LBP Activities regulations as age 6 and under, while the definition of COF in the RRP regulations at 40 CFR 745.83 identifies children impacted by the RRP regulations as under 6 years of age. In order to establish consistency in age throughout the LBP regulations, including with the definition of target housing and the RRP regulations' definition of COF, EPA is finalizing the change to the language in the definition of COF in 40 CFR 745.223 to less than 6 years of age. Language describing the age of children in 40 CFR 745.227(d)(7) was also changed from 6 years of age and under to under age 6 to conform language throughout the LBP regulations.

3. Electronic Submissions

EPA is finalizing the requirement for submissions for application payments, applications, and notices to be done electronically. This rule specifically defines ''electronic'' in 40 CFR 745.83 and 40 CFR 745.223 to mean ''the submission of an application, payment, or notice using the Agency's Central Data Exchange (CDX), or a successor platform.'' In 2016, the U.S. Treasury Department changed their process so that paper checks would no longer be allowed for payment of fees associated with RRP or abatement programs. Since that time, applications that require payment, such as individual and firm certifications as well as training provider accreditation applications, have been submitted electronically via CDX. Therefore, EPA is amending 40 CFR 745.89(a)(1), 40 CFR 745.92(c)(2), and 40 CFR 745.238(e)(2) to conform to the 2016 U.S. Treasury Department process and require payments to be made only electronically via CDX or a successor platform.

Currently there is no specific submission method defining how to submit applications in EPA's LBP regulations. This ambiguity allows for the potential of written applications being submitted, which requires time consuming activities such as data entry and accrues administrative costs. Therefore, EPA is finalizing the amendments to 40 CFR 745.89(a)(1), (b)(1), (b)(1)(i), and (c)(1); 40 CFR 745.225(b)(1), (e)(5), (f)(2), and (j)(2); 40 CFR 745.226(a), (e), (f), and (h)(1)(iii); 40 CFR 745.227(e)(4)(vii) and 40 CFR 745.238(d), and (e) to reflect the requirement of submitting applications electronically via CDX or a successor platform. This will add further clarification and uniformity to this process.

Additionally, EPA is finalizing the requirement for abatement and training notifications to be submitted electronically via CDX or a successor platform. Requiring electronic submissions and eliminating fax submissions removes the need for fax machine maintenance and also reduces phone service costs. Therefore, EPA is finalizing their amendments to 40 CFR 745.225(c)(13)(vi) and (14)(iii) to require submission of abatement and training notifications to occur electronically via CDX or a successor platform.

4. Disclosure Rule Warning Statement

EPA is finalizing the proposed update to the Disclosure Rule's Lead Warning Statement in 40 CFR 745.113(b)(1) to address a drafting error. Both the preamble of the Disclosure Rule (required by section 1018 of Title X), and the relevant public sample form include the following language: ''Before renting pre-1978 housing, lessors must disclose the presence of known lead-based paint and/or lead-based paint hazards in the dwelling,'' which is consistent with EPA and HUD's adaptation to leasing contracts of the statutory language in section 1018 (Ref. 4). However, the Lead Warning Statement in 40 CFR 745.113(b)(1) does not currently include the word ''known.'' To conform this regulatory

text with the statutory and preamble language, EPA is finalizing the amendment to the Lead Warning Statement to include the word ''known'' when discussing lessors disclosing the presence of LBP and/or LBP hazards in the dwelling.

5. Disclosure Rule Reference

EPA is finalizing the proposed amendment to the Disclosure Rule at 40 CFR 745.113(a)(4) and 40 CFR 745.113(b)(4) to include the correct lead hazard information pamphlet reference, 15 U.S.C. 2686. This reference further discusses the requirements for the lead hazard information pamphlet and is the basis for its statutory authority. The current reference of 15 U.S.C. 2696 does not exist and was a drafting error.

6. Definition of Housing for the Elderly

EPA is finalizing the proposed addition of the definition of ''housing for the elderly'' to 40 CFR 745.223 in order to clarify the term ''elderly'' used in the definition of ''target housing,'' also in 40 CFR 745.223. EPA already defines ''housing for the elderly'' in 40 CFR 745.103 as ''retirement communities or similar types of housing reserved for households composed of one or more persons 62 years of age or more at the time of initial occupancy'' under Subpart F, ''Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards Upon Sale or Lease of Residential Property.'' Note that HUD's LSHR (for federally owned or federally assisted target housing) caveats its definition of ''housing for the elderly'' at 24 CFR 35.110 to rely on an age other than 62 years ''if recognized as elderly by a specific Federal housing assistance program.'' The finalized definition of ''housing for the elderly,'' which is the same definition in Subpart F ''Disclosure of Known Lead-Based Paint and/or Lead-Based Paint Hazards Upon Sale or Lease of Residential Property,'' adds clarity and consistency throughout the LBP program.

7. Obsolete Regulatory Text

EPA is finalizing the proposed revisions and deleting obsolete regulatory text where language was out of date or no longer applicable in 40 CFR 745.81(a)(4)(i) and (b); 40 CFR 745.90(a)(3) and (4); 40 CFR 745.225(i)(2); and 40 CFR 745.226(f)(5). For example, 40 CFR 745.81(b) currently reads: ''Before December 22, 2008, renovators or firms performing renovations in State and Indian Tribal areas without an authorized program may provide owners and occupants with either of the following EPA pamphlets: *Protect Your Family From Lead in Your Home* or *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools.* After that date, *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools* must be used exclusively.'' This information is outdated; therefore, EPA is finalizing this section to read: ''After December 22, 2008, renovators or firms performing renovations in States and Indian Tribal areas without an authorized program must provide owners and occupants the following EPA pamphlet: *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools.*'' EPA is also deleting 40 CFR 745.227(a)(4) because EPA added the provision in the 1996 LBP Activities Rule and it became obsolete with the 2001 LBP Hazards Rule that first promulgated regulatory clearance levels. Other regulatory provisions now apply.

8. Incorporation by Reference (IBR)

As proposed, EPA is also incorporating by reference two voluntary consensus standards, each of which is already included in the definition of ''wipe sample'' at 40 CFR 745.63: American Society for Testing and Materials (ASTM) E1728 and ASTM E1792. EPA is incorporating by reference the most recent version of each standard: ASTM E1728/E1728M–20, Standard Practice for Collection of Settled Dust Samples Using Wipe Sampling Methods for Subsequent Lead Determination, approved January 1, 2020; and ASTM E1792–20, Standard Specification for Wipe Sampling Materials for Lead in Surface Dust, approved September 1, 2020. ASTM E1728/E1728M–20 covers the collection of settled lead-containing dust on surfaces using the wipe sampling method. ASTM E1792–20 covers requirements for the wipes that are used to collect settled dust on surfaces for the subsequent determination of lead.

This material is reasonably available to interested parties. All approved incorporation by reference (IBR) material is available for inspection at EPA. Copies of the ASTM materials incorporated by reference in this rule may be obtained from ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428–2959, or by calling (877) 909–ASTM, or at *https://www.astm.org.* If you have a disability and the format of these materials intended for incorporation by reference interferes with your ability to access the information, please contact EPA's Rehabilitation Act section 508 (29 U.S.C. 794d) Program at *https://www.epa.gov/accessibility/forms/contact-us-about-section-508-accessibility* or via email at *section508@epa.gov.* To enable us to respond in a manner most helpful to you, please indicate the nature of the accessibility issue, the web address of the requested material, the format you prefer to receive the material in (electronic format (ASCII, etc.), standard print, large print, etc.), and your contact information.

V. Implications of the Final Rule for Existing HUD and EPA Programs

A. LBP Activities Authorized Programs

This subsection (Unit V.A.) is specifically relevant to any States, territories or federally recognized Tribes that are authorized to administer their own LBP activities program. Pursuant to TSCA section 404 and EPA's regulations at 40 CFR part 745, subpart Q, interested States, territories, and federally recognized Tribes may apply for and receive authorization to administer their own LBP activities programs (as briefly described in Unit II.C.), as long as their programs are at least as protective of human health and the environment as EPA's program, and provide adequate enforcement.

As part of the authorization process, States, territories, and federally recognized Tribes must demonstrate to EPA that they meet the requirements of the LBP Activities Rule. Additionally, a State, territory, or federally recognized Tribe must demonstrate that it meets any new requirements imposed by this rulemaking in its application for authorization or, if already authorized, in a report submitted under 40 CFR 745.324(h) no later than two years after the effective date of the new requirements (which in this case would be by January 11, 2027). If an application for authorization has been submitted but not yet approved, the State, territory, or federally recognized Tribe must demonstrate that it meets the new requirements either by amending its application, or in a report it submits under 40 CFR 745.324(h) no later than two years after the effective date of the new requirements (40 CFR 745.325(e)). EPA recommends that the authorized programs work closely with their EPA regional office in order to keep the Agency up to date on their progress.

Given the breadth and nature of the revisions in this final rule, in particular those to the dust-lead reportable level, the definition of abatement and the shift in terminology, EPA recommends all authorized States, territories and federally recognized Tribes broadly review their LBP activities programs

and consider more significant changes such as any triggers for work using the dust-lead action level rather than the dust-lead reportable level (or historically the dust-lead hazard standards). For example, if there is a program that requires LBP professionals to do a risk assessment every time a property is rented by a new tenant, instead of requiring that dust-lead loadings must be less than the dust-lead reportable level, EPA recommends that the authorized program in question utilizes the dust-lead action level instead. It will be important to disclose that dust-lead hazards are present above any reportable level (as analyzed by an NLLAP-recognized laboratory) but EPA does not recommend action such as an abatement when there are dust-lead loadings below the dust-lead action level. Changing the trigger for work within authorized programs could considerably reduce the financial burden that this final rulemaking may have on entities funding the work in those authorized States, territories and Tribes, including the local level and more specifically those environmental and health departments that assist in running these programs. EPA does, however, recommend use of best practices such as: using a vacuum with a high-efficiency particulate air filter on furniture and other items returned to the work area, and regularly cleaning hard surfaces with a damp cloth or sponge and a general all-purpose cleaner when any dust-lead hazard or LBP is present, even if it is below the dust-lead action level. For more information on how to continue to reduce lead exposure see *Protect Your Family From Lead in Your Home.*

As authorized States, territories and federally recognized Tribes broadly review their LBP activities programs, EPA also recommends reconsideration of the terminology of any lead-free or lead-safe programs, as this language could cause confusion or be an oversimplification. If dust-lead levels fall above the DLRL, a LBP hazard, specifically a dust-lead hazard, can be present after an abatement is considered complete even in situations where a house or COF is considered LBP free (*i.e.,* below the regulatory definition of LBP). Ultimately, target housing or COFs that are considered LBP free could still contain lead or even LBP hazards, particularly dust-lead hazards given the DLRL. Also, if target housing or COFs are found to be free of LBP hazards (*e.g.,* dust-lead levels below the DLRL) that does not mean that no lead is present. As a result, identifying lead-free or lead-safe housing/COFs given these final revisions to the DLRL will be extremely challenging and could cause confusion or misunderstanding within the public. EPA also recommends any triggers for action become the DLAL (rather the DLHS, described as DLRL moving forward, as has been the case historically). EPA suggests that authorized programs work closely with their EPA regional office as needed to help inform this process, as an authorized program must demonstrate that it meets the new requirements imposed by this final rule in a report submitted under 40 CFR 745.324(h) by January 11, 2027.

B. HUD Programs

1. Lead-Safe Housing Rule

HUD has specific authority to control LBP and LBP hazards in certain federally owned and federally assisted target housing (Ref. 24). HUD's regulations at 24 CFR 35.1320(b)(2) cross-reference EPA's regulations at 40 CFR 745.227(h), which currently discusses EPA's DLHS but not EPA's DLCL (described by EPA moving forward as DLRL and DLAL). Due to the current cross-reference, the HUD regulations have been read as requiring entities receiving government funding currently to conduct post-abatement clearance until the levels are below EPA's DLHS, which at the time this cross-reference was made, were the same values as EPA's DLCL. Clearance testing is also required following interim controls and renovation, repair, and painting events that incidentally disturb more than the HUD-specified de minimis amount of lead-based paint in assisted housing. Due to the 2021 Court Opinion, EPA is now finalizing regulatory changes that decouple the DLHS and DLCL and rename them as DLRL and DLAL as explained in Unit IV. EPA is also finalizing modifications to 40 CFR 745.227(h) to clarify that the Agency does not intend to compel clearance down to the DLRL but to the DLAL, including for HUD's programs. EPA has taken this action for the reasons discussed in Unit IV.D. of this notice. HUD plans to conduct a rulemaking to make its determination on any appropriate amendments under its own regulations.

Other impacts of this final rule could include a possible decrease in the number of landlords participating in HUD's rental assistance and rehabilitation programs. If there are fewer homes that can meet the revised dust-lead standards at costs and project durations acceptable to landlords, there will be fewer affordable housing units available to families to rent. For example, if a family with a Housing Choice Voucher cannot find a landlord that can attain dust-lead levels below the revised DLAL (previously referred to as the dust-lead clearance levels) and accept their voucher, they will have longer search times. In some cases, the family may lose their voucher if they are unable to find a unit within established timeframes, and they will have to revert back to unassisted housing, attempting to rent housing without rental assistance, which has been shown to be associated with a higher prevalence of LBP hazards (Refs. 71 and 113) and higher BLLs (Ref. 114). However, the Economic Analysis that accompanies this final rulemaking estimates that only a small fraction of low-income households living in housing subject to LSHR Subpart M (which affects the Housing Choice Vouchers discussed in the text) are likely to lose their assisted housing and ultimately end up in private market housing that is higher cost and/or has dust-lead levels higher than their baseline. See Section 10.3 of the EA (Ref. 10) for more information. Note that the factors that EPA can consider in setting the DLHS (described as DLRL moving forward) do not include broader public health concerns (such as health trade-offs and policy impacts on public Federally assisted housing).

As discussed in Unit II.A., lead exposure, even in small amounts, can cause substantial and long-lasting health problems, particularly through its effects on children's development. Access to secure housing is also an important social determinant of health (Ref. 74). Research finds negative health effects resulting from three key mechanisms of housing insecurity: lack of housing affordability leading to stress and material deprivation (Refs. 75, 76, 77 and 78), lack of housing stability (Refs. 79, 80, 81, 82 and 83), and lack of safe and adequate housing (Refs. 84, 85, 86, 87 and 88). HUD's housing assistance programs play a critical role in helping nearly 5 million households (Ref. 115) avoid housing insecurity and its harmful effects on physical and mental health (Refs. 114, 116, 117, 118 and 119). Despite such Federal assistance, the nation faces a critical shortage of affordable rental housing affecting about 8 million very low-income households (Ref. 120). EPA considered the final changes to the DLRL and DLAL and the potential impacts on HUD's housing programs within the EA (see Section 10.3 for this discussion) (Ref. 10). Existing research on landlord participation in the Housing Choice Voucher program (Refs. 121,

122, 123 and 124) suggests that more stringent standards or uncertainty as to how to meet those standards could be a disincentive for private target housing providers to participate in HUD's rental assistance programs including the Housing Choice Voucher program (tenant-based rental assistance program) and the project-based assistance programs, which could in turn reduce access to affordable and stable housing associated with a relatively lower prevalence of LBP hazards than unassisted housing. As a result, EPA requested information and comment on whether the proposed rulemaking would lead to an increase in housing insecurity or lead exposures. EPA received multiple public comments that expressed concern over housing stock, in particular affordable housing, and that highlighted the negative consequences that the revised standards could lead to an increase in lead exposure due to less lead projects being done overall due to less available funds. As a result, EPA is finalizing the higher, alternative DLAL (previously referred to as the DLCL), the language in the abatement report for when post-abatement dust-lead levels falls between the DLRL and DLAL, as well as the change to the definition of abatement, so that abatement is triggered based on the DLAL rather than the DLRL; see Unit IV.C., E., and F for more information on the final DLAL, the revisions to the abatement report, and the definition of abatement. EPA is also committed to working closely with HUD for communicating these changes to the regulated community, in order to best reduce and diminish any impact this final rule could have on the availability of affordable housing for families.

As explained in section 10.3 of EPA's Economic Analysis for the rule (Ref. 10), the owners of properties regulated under some of the LSHR Subparts seem unlikely to stop participating in HUD programs as a result of this rule. For example, Subpart F of the LSHR covers HUD-owned single family housing properties for sale that are sold under a HUD mortgage program. HUD (*i.e.,* the Federal government) would be responsible for all costs associated with compliance to a stricter DLRL/DLAL before selling the property. While modest delays may occur in closing on sale transactions for these properties, a reduction in housing supply covered under this subpart is unlikely. Subpart G of the LSHR covers multi-family housing where either HUD is the owner of a mortgage, or the owner of a property receives mortgage insurance under a program run by HUD. Housing covered under this subpart of the LSHR has risk assessment, interim control, and LBP maintenance requirements. Private landlords for these properties directly seek out Federal funds, and even if some of the federally provided money is spent complying with a stricter DLRL/DLAL to comply with the LSHR, participating grantees should typically have a positive net return. These landlords can opt-out of HUD mortgage assistance, by finding alternative financing or selling the property. Once the property opts out, the families must move unless they can afford market-rate rents, which is unlikely. Owners can also elect to not renew their Housing Assistance Payment contract upon expiration. HUD has suggested that the largest impact from changing the DLRL/DLAL will likely be HUD's tenant-based rental assistance programs. Under Subpart M of the LSHR, if an inspector identifies deteriorated paint in a unit with a child under age 6, they must perform paint stabilization and meet clearance for the unit to be eligible for housing assistance payments. A landlord faced with this option could decline to perform the work, and rent instead to a family without a voucher. This is an unintended consequence that may be magnified by the new clearance standard, and HUD will seek comment on this potential impact before it finalizes changes to the LSHR to implement the new DLRL/DLAL standards.

2. Grantee Programs

On February 16, 2017, HUD issued policy guidance to establish new and more protective requirements for dust-lead action levels for its Lead-Based Paint Hazard Control and Lead Hazard Reduction Demonstration grantees (the requirements also apply to related HUD grants authorized by Title X, section 1011 (42 U.S.C. 4852), under similar names, including Lead Hazard Reduction grants and their High Impact Neighborhoods and Highest Lead-Based Paint Abatement Needs grant categories) (Ref. 58). The guidance adopted dust-lead action levels of 10 μg/ft² for floors and 100 μg/ft² for window sills, respectively, for initiating lead hazard control activities under these grant programs, and lead clearance action levels of 10 μg/ft² for floors, and 100 μg/ft² for window sills and troughs, respectively, for clearing such lead hazard control activities (Ref. 58). Given the revisions of this final rule that are discussed in Unit IV., Lead-Based Paint Hazard Control and Lead Hazard Reduction Demonstration grantees would be required by EPA's regulations to clear lead abatement projects to the updated DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills, and troughs respectively. Due to the changes EPA is finalizing, HUD has informed the Agency that it will likely issue new policy guidance on initiating lead hazard control activities and on clearing lead abatement projects under these grant programs, and that it would consider issuing new policy guidance on clearing interim control projects under these grant programs.

3. EPA–HUD Disclosure Rule

To administer the disclosure program, EPA and HUD jointly developed regulations (known as the Disclosure Rule under section 1018 of Title X (42 U.S.C. 4852d)) requiring a seller or lessor of most pre-1978 housing to disclose the presence of any known LBP and/or LBP hazards, such as soil-lead hazards or dust-lead hazards, to the purchaser or lessee (24 CFR part 35, subpart A; 40 CFR part 745, subpart F). Under the Disclosure Rule (Ref. 4), prospective sellers and lessors of target housing, which is most pre-1978 housing, must provide purchasers and renters with a federally approved lead hazard information pamphlet and disclose known LBP and/or LBP hazards, and any available records, reports, and additional information pertaining to LBP and/or LBP hazards (40 CFR 745.107(a)(4); 24 CFR 35.88(a)(4)). Leases of target housing are exempt from disclosure requirements in limited circumstances, such as where the housing has been found to be LBP free by a certified inspector (24 CFR 35.82; 40 CFR 745.101).

The information disclosure activities are required before a purchaser or renter is obligated under a contract to purchase or lease target housing. The records or reports pertaining to LBP and/or LBP hazards include, among other things, results from risk assessments, regardless of whether the levels of dust-lead are above or below the dust-lead hazard standards (described by EPA as DLRL moving forward), and from post-abatement dust wipe testing, above or below the clearance levels (described by EPA as DLAL moving forward). Because disclosure is required in target housing regardless of whether dust levels are above or below the DLRL or DLAL, finalizing the ''any reportable level'' approach for the dust-lead reportable level and lowering the dust-lead action level would not result in more disclosures; rather it would result in more of the disclosures indicating that a lead-based paint hazard is present (since the final DLRL is lower than the previous DLHS from 2019). EPA is also finalizing changes to the definition of

''target housing'' (40 CFR 745.223), which expands the universe of housing subject to the Disclosure Rule requirements. This is reflective of a change to the statutory definition (P.L. 115–37, Consolidated Appropriations Act, 2017, Division K, Title II, section 237(c)). This final conforming change to the regulatory definition of target housing to include 0-bedroom dwellings where a child resides may slightly increase the number of disclosures issued.

Note that leases (which does not include sales) of target housing are exempt from disclosure requirements in limited circumstances, such as where the housing has been found to be LBP free by a certified inspector (24 CFR 35.82; 40 CFR 745.101), even if the dust-lead level is at or above the DLRL.

4. HUD Guidelines

The HUD Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing (*https://www.hud.gov/program_offices/healthy_homes/lbp/hudguidelines*) were developed in 1995 under section 1017 of Title X. The Guidelines provide detailed, comprehensive, and technical information on how to identify LBP hazards in residential housing and COFs, and how to control such hazards safely and efficiently. The Guidelines were revised in 2012 to incorporate new information, technological advances, and new Federal regulations, including EPA's LBP hazard standards. Due to the changes EPA is finalizing, HUD has informed the Agency that it will likely revise Chapter 5 of the Guidelines on risk assessment and reevaluation, Chapter 12 on abatement, and Chapter 15 on clearance, and make conforming changes elsewhere as needed (Ref. 125).

C. EPA LBP Programs

1. LBP Activities Rule

LBP activities include risk assessments, inspections, and abatements. As a reminder, the States where the LBP program is currently administered by EPA are Alaska, Arizona, Florida, Idaho, Montana, Nevada, New Mexico, New York, South Carolina, South Dakota, and Wyoming. EPA also administers the LBP program in the territories of American Samoa, Guam, Northern Marianas, and the U.S. Virgin Islands, as well as most Tribal Lands. This final rule impacts a variety of LBP activities, including: the definition of abatement, what is considered a dust-lead hazard, the DLAL (which is used to determine whether an abatement can be considered complete) and the definition of target housing. Within the States, territories and federally recognized Tribes that have EPA run LBP activities programs, this rule will become effective 60 days after publication in the **Federal Register**. However, certain elements of the rule such as the DLRL, DLAL and the change to the abatement report language have a compliance timeframe of one-year after the effective date of the final rule (see Unit VI. for more information on the timing of this rule's revisions).

As stated earlier in this preamble, EPA's risk assessment work practice standards provide the basis for risk assessors to determine whether LBP hazards are present in target housing and COFs. As part of a risk assessment, dust samples are taken from floors and window sills to determine if dust-lead levels exceed the DLRL. The results of the sampling, among other things, are documented in a risk assessment report, which is required under the LBP Activities Rule (Ref. 19). In addition to the sampling results, the report must describe the location and severity of any dust-lead hazards found and describe interim controls or abatement measures needed to address the hazards.

Under this final rule, sampling results reporting any level of lead as analyzed by an NLLAP-recognized laboratory will indicate that a dust-lead hazard is present on the surfaces tested. EPA expects that the DLRL will result in more hazards being identified in a portion of target housing and COFs that undergo risk assessments. This rule does not change any other risk assessment requirements; however, it does revise the definition of abatement, which is discussed in the following paragraph.

Abatements are currently defined as any measures or set of measures designed to permanently eliminate lead-based paint hazards and include activities such as the removal of paint and dust, the permanent enclosure or encapsulation of lead-based paint, the replacement of painted surfaces or fixtures, and all preparation, cleanup, disposal, and post-abatement dust wipe testing activities associated with such measures. The change to the definition of abatement shifts the recommendation for an abatement based on dust-lead to when the dust-lead loadings are at or above the DLAL (rather than the DLHS, described as DLRL moving forward, as has been the case historically). Because EPA is finalizing DLAL that are lower than the 2019 DLHS, more recommendations for abatement are expected. However, not every circumstance where dust-lead hazards are identified will result in an EPA recommendation for abatement. In particular, when dust-lead loadings are at or above the DLRL, but below the DLAL, EPA recommends use of best practices such as: using a vacuum with a high-efficiency particulate air filter on furniture and other items returned to the work area, and regularly cleaning hard surfaces with a damp cloth or sponge and a general all-purpose cleaner. EPA is also including a requirement to add specific language into each abatement report when dust-lead levels are between the DLRL and the DLAL. That language refers the public to a useful reference titled *Protect Your Family From Lead in Your Home* and acknowledges that LBP hazards (particularly dust-lead hazards) could remain after an abatement. The goal of including this language in an abatement report is to ensure that occupants are provided with information about actions they can take to minimize dust-lead hazards and protect themselves from exposure even after an abatement is complete. Similar to abatement, EPA recommends interim controls only in circumstances when dust-lead loadings are at or above the DLAL, rather than the DLRL, for the reasons explained in this unit.

After LBP abatements are conducted, EPA's regulations require a certified inspector or risk assessor to conduct post-abatement dust wipe testing of the abated area. If the dust wipe sample results show dust-lead loadings equal to or exceeding the applicable DLAL, ''the components represented by the failed sample shall be recleaned and retested.'' See 40 CFR part 745.227(e)(8)(vii). In other words, the abatement is not complete until the dust wipe samples in the work area are below the DLAL. Once the relevant compliance deadline has passed, inspectors and risk assessors working in any State, territory or federally recognized Tribe with an EPA run LBP activities program must compare dust wipe sampling results for floors, window sills and troughs to the revised DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft², respectively. Dust wipe sampling results at or above the DLAL would indicate that the components represented by the sample must be recleaned and retested. Due to lowering the DLAL from the 2021 levels, including the trough values, EPA expects a slight increase in the amount of recleaning and retesting that is required after an abatement in order for it to be considered complete, especially shortly after the change is enacted.

Lastly, as described in Unit IV.G.1., this final rule conforms the regulatory definition of target housing with the statute to include any 0-bedroom

dwellings constructed prior to 1978 if a child less than 6 years of age resides or is expected to reside in such housing, which could increase the number of homes covered by this regulation. In addition, EPA is finalizing regulatory changes to adjust the age requirements from 6 years of age and under, to under age 6 for the definition of target housing, COFs and living area, which could reduce the number of homes and COFs covered by this regulation; see Units IV.G.1. and 2. for more information.

States, territories, and federally recognized Tribes that are authorized to run their own LBP activities programs will also need to incorporate these Federal changes into their statutory and regulatory landscape no later than two years after the effective date of this final rule. See Unit V.A. for more information about the impacts of this action on authorized programs.

2. Previous LBP-Related Activities

Since the DLRL do not compel specific EPA actions, revisions to the DLRL would not in and of themselves compel any actions under the LBP Activities Rule, retroactively or otherwise, but actions would be compelled under other laws or regulations, including HUD's LSHR and possibly those of some State, local, Tribal or territorial governments. Inspection reports and risk assessments describe conditions at a specific time. A report that indicates no presence of LBP and/or a LBP hazard should not imply the absence of those conditions in perpetuity. Additionally, the DLRL may be incorporated into requirements mandated by State, Federal, Tribal, and other programs that may require actions based on the revised DLRL. Those other authorities may want to consider guidance or other communications with their regulated communities, so those entities understand how to comply with the various programs that reference the DLRL. As a reminder, all new requirements imposed by this final rule must be incorporated into any authorized programs no later than two years after the effective date of the new requirements (see Unit V.A. for more information).

The DLAL, however, are used to evaluate the effectiveness of a cleaning following an abatement. After the dust wipe samples show dust-lead loadings below the DLAL (and any other aspects of the abatement such as additional testing are also complete), an abatement report is prepared, copies of any reports required under the LBP Activities Rule are provided to the building owner (and to potential lessees and purchasers under the LBP Disclosure Rule by those building owners or their agents), and all required records are also retained by the abatement firm or by the individuals who developed each report. The final DLAL of 5 μg/ft² for floors, 40 μg/ft² for window sills, and 100 μg/ft² for troughs would not impose retroactive requirements on regulated entities that have previously performed post-abatement clearance. These updated DLAL would only apply to post-abatement dust-lead sampling and analysis conducted after the compliance date for that portion of the final rule (*i.e.,* one year after the effective date of the final rule) for any LBP activities programs specifically run by EPA, which include, as of the publication of this rule: Alaska, Arizona, Florida, Idaho, Montana, Nevada, New Mexico, New York, South Carolina, South Dakota, Wyoming, American Samoa, Guam, Northern Marianas, and the U.S. Virgin Islands, as well as most Tribal Lands.

In addition, this rulemaking does not impose retroactive requirements to regulated entities that have previously complied with the Disclosure Rule. In accordance with 40 CFR 745.107, a seller or lessor generally must properly disclose any available records or reports pertaining to known LBP and/or LBP hazards before the purchaser or lessee is obligated under any contract to purchase or lease target housing. The seller or lessor is not required to disclose reports or records that may be created in the future, after the close of that transaction. Additionally, any LBP-free certification that was issued by a certified inspector and was issued before the effective date of this rulemaking, is still valid going forward and may continue to be used for exemption of leases from the Disclosure Rule under 40 CFR 745.101(b), as will any LBP-free certification issued on or after the effective date of this rulemaking.

3. Renovation, Repair, and Painting Rule

The DLRL and DLAL would not trigger new requirements under the existing RRP Rule (40 CFR part 745, subpart E). The existing RRP work practices are required where LBP is present (or assumed to be present) and are not predicated by dust-lead loadings exceeding the DLRL. The existing RRP regulations do not require dust-lead sampling prior to or at the conclusion of a renovation and are not affected by a change to the DLRL or DLAL. Therefore, RRP regulations will not be directly affected by the final revisions to the DLRL or the DLAL. However, certified renovators and RRP firms should be aware of the conforming amendments to the definition of ''target housing'' and the amendments for consistency about electronic payments.

The RRP Rule does require specific post-renovation cleaning verification under 40 CFR 745.85(b), but the rule does not require dust wipe sampling and analysis using the DLAL. EPA received several public comments pointing out that there are many more homes and projects that fall under the RRP program (*i.e.,* rather than the LBP activities program), and that the visual inspection is less rigorous than clearance, requesting that EPA expand lead clearance testing to its RRP program. EPA notes that although optional under the RRP Rule, dust wipe sampling for clearance using the DLAL (previously known as the DLCL) in accordance with the LBP Activities Rule (40 CFR 745.227(e)(8)) may be required by contract or by another Federal, State, territorial, Tribal, or local law or regulation. At this time, other than HUD's Lead Safe Housing Rule, for renovations of assisted target housing, EPA is not aware of other laws and regulations that require clearance testing using EPA's DLAL.

EPA understands that the RRP program is larger than the LBP activities program; however, the LBP activities program (*i.e.,* inspections, risk assessments, and abatements) is focused more specifically on addressing a LBP concern, such as due to non-EPA requirements triggered by a child with a higher BLL. Additionally, besides the conforming amendment to the definition of ''target housing,'' amendments for consistency about electronic payments, the removal of time-expired provisions (as discussed in Unit IV.G.), and the conforming terminology change at 40 CFR 745.85(c)(3) to refer to the final dust-lead action levels for optional RRP clearance testing, no other changes to the RRP program were included in the proposed rule that published in August 2023 (Ref. 55) or within this final rulemaking. Additionally, in 2018 EPA reviewed the RRP rule pursuant to section 610 of the Regulatory Flexibility Act and reaffirmed the Agency's previous conclusions not to include dust-wipe testing or clearance requirements on renovations. However, since 2018 the clearance or dust-lead action levels have been revised twice. While EPA is finalizing no additional changes to clearance or the cleaning verification process for RRP in this rulemaking, the Agency may consider whether to revise the RRP program at a later date.

Finally, certified renovators and RRP firms should be aware of the change in

the definition of target housing to include 0-bedroom dwellings if a child less than 6 years of age resides or is expected to reside in such housing. Any certified renovators or RRP firms should be aware of whether they work in an EPA-administered RRP program State, territory, or federally recognized Tribe or a State, territory, or federally recognized Tribe that is authorized to run its own RRP program, as this will impact the timing for the revisions to the definition of target housing. For any EPA-administered programs, this amendment to target housing will be effective 60 days after this final rule is published in the **Federal Register**. Any authorized program will have up to two years after the effective date of this rule to incorporate any changes into their program, so RRP professionals should be aware those changes will eventually be incorporated.

4. Laboratory Quality Standards for Recognition

As discussed previously in Unit II.C., NLLAP is an EPA program under which an accrediting organization assesses whether a paint chip, dust, or soil testing laboratory meets minimum standards for laboratory analysis to attain EPA recognition as an accredited lead testing laboratory (*https://www.epa.gov/lead/national-lead-laboratory-accreditation-program-nllap*). Laboratories and other testing firms recognized under NLLAP follow the LQSR. This rulemaking does not modify the minimum standards outlined in the latest LQSR version 4.0. However, changes to the action level (*i.e.,* the proposed DLAL) would impact the quantitation limit that NLLAP-recognized laboratories would attain to participate in the NLLAP, as under LQSR 4.0 the quantitation limit must be equal to or less than 80% of the lowest action level for dust wipe samples per specific surface area (*i.e.,* floors, window sills, window troughs) (Ref. 26). The lowest action level for dust wipe samples would be the DLAL of 5 μg/ft² for floors, 40 μg/ft² for window sills and 100 μg/ft² for troughs. As a result, the quantitation limit for NLLAP-recognized labs would be equal to or less than 4 μg/ft² for floors, 32 μg/ft² for window sills and 80 μg/ft² for troughs. Note that only laboratories that are NLLAP accredited can perform dust-wipe testing for lead under the existing regulations at 40 CFR part 745.

D. Lead-Based Paint Professionals

LBP activities (*i.e.,* inspections, risk assessments, and abatements) may only be performed by a certified individual or firm (40 CFR 745.220) in accordance with the work practices outlined in the 1996 LBP Activities Rule (40 CFR 745.227). Any certified risk assessor, inspector or abatement firm should understand if they are performing LBP work in an authorized State, territory, or federally recognized Tribe or if they are working within an EPA administered LBP activity program, as it will impact the timing of when they need to comply with the revisions of this final rule. A certified LBP professional working within the jurisdiction of an EPA-administered LBP activity program (*i.e.,* at the time of publication of this notice, Alaska, Arizona, Florida, Idaho, Montana, Nevada, New Mexico, New York, South Carolina, South Dakota, Wyoming, American Samoa, Guam, Northern Marianas, the U.S. Virgin Islands, and within most Tribal Lands) should see Unit VI. for more information on the effective date and compliance timeframes for this rule. Those LBP professionals should also familiarize themselves with Unit IV. of this final notice in order to fully understand the revisions. If questions remain, LBP professionals may wish to coordinate with their EPA Regional Lead Coordinator as necessary, consult the EPA lead page (*https://www.epa.gov/lead*), or contact the technical person or the National Lead Information Center listed under **FOR FURTHER INFORMATION CONTACT** if needed. Note that HUD or local jurisdictions may have slightly different requirements, so when applicable, EPA recommends coordinating directly with those specific programs, in order to avoid any confusion and to best understand how these rule changes will impact risk assessments, LBP inspections, and abatement work.

In contrast, any LBP professionals that work within a State, territory or federally recognized Tribe that has an EPA-authorized LBP activity program, should be aware that the authorized program will need to incorporate these Federal changes into their statutory and regulatory landscapes no later than two years after the effective date of this rule. As a result, LBP professionals should be mindful of and monitor any changes to the LBP programs within their State, territory or Tribe. See Unit V.A. for more information about the impacts of this action on authorized programs.

EPA received numerous public comments on the proposed rule requesting additional outreach and assistance throughout the implementation process in order to better communicate with the public about what the revisions are and how they impact various segments of the regulated community. Commenters urged EPA provide clear and accessible information in multiple languages regarding the general risks of lead exposure, the implications of this rulemaking for renters and property owners, and information regarding financial or other support available for the cleanup and removal of lead. EPA appreciates the need for clear and effective communication given the shift these revisions are triggering in the LBP activities programs (*i.e.,* decoupling the DLRL and DLAL). As a result, EPA plans to coordinate closely with its communications teams, HUD and others to effectively update the public and the regulated community as appropriate, including revising *Protect Your Family From Lead in Your Home,* and any other EPA LBP trainings or public materials. EPA also plans on holding public webinars shortly after the rule is finalized in the **Federal Register**. LBP professionals should utilize any updated materials as they become available, and EPA welcomes their participation in any upcoming public webinars or educational opportunities.

VI. Effective and Compliance Dates

EPA has considered both the public comments received on the proposed rulemaking and the impacts of the DLRL and DLAL on NLLAP-recognized laboratories, and is finalizing a compliance timeframe of one year after the effective date of the final rule for certain provisions (*i.e.,* DLRL, DLAL, and the change to the abatement report language). The compliance date for these provisions is on January 12, 2026. This extended compliance date is intended to provide a reasonable amount of time for NLLAP-recognized laboratories to take actions to meet the LQSR quantitation limit (80% of the lowest action level for dust wipe samples under LQSR 4.0) for the lower DLAL of this rule so they can continue providing dust wipe testing services to the regulated community without any significant disruption in service, including in urgent situations.

To obtain a better understanding of laboratories' capability and capacity for dust wipe testing, EPA conducted teleconferences with eighteen NLLAP-recognized laboratories over the course of the rulemaking process (Refs. 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108 and 109). As explained in Unit IV.C., based on the information EPA received from this outreach, EPA believes that laboratories with ICP–AES instruments and optimized methods should be able to comfortably satisfy the LQSR dust wipe testing procedures and the regulatory limit of the final DLAL option of 5 μg/

ft² for floors, 40 μg/ft² for window sills and 100 μg/ft² for troughs (quantitation limit of 4 μg/ft² for floors, 32 μg/ft² for window sills and 80 μg/ft² for troughs). However, FAAS is the most ubiquitous equipment used, and EPA believes that with the LQSR 4.0 dust-wipe procedures partnered with the final DLAL, NLLAP-laboratories should be able to continue using FAAS after this rule is finalized. Some laboratories may need to buy newer FAAS to meet the lower LQSR limits or adjust their methods. However, due to the outreach performed, EPA is aware of laboratories that already utilize FAAS and are currently able to meet the final DLAL without any modification. A few NLLAP-laboratories may still opt to buy more sensitive instruments such as ICP–AES. If that is the case, however, the accreditation process through the accrediting bodies is time consuming and could take anywhere from six to eighteen months or more based on feedback EPA received from NLLAP-laboratories. Given the range of timing and that EPA assumes the majority of laboratories will retain FAAS, EPA determined one year from the effective date was appropriate as a compliance date for the amended DLRL and DLAL (*i.e.,* 14 months from the publication of the final rule).

Several public commenters, including State and local government agencies and a mass mailer that consisted of a coalition of 76 organizations and twelve individuals, agreed with the NLLAP-laboratories that if the proposed DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills, and troughs was adopted in the final rule, the compliance timeframe of one-year after the effective date would be an adequate time for laboratories and companies to buy any needed equipment, hire staff, and become accredited, especially since the AIHA LAP's policy states that accreditation is expected to occur within 12 months or less once an application is submitted (Refs. 38 and 126). Public commenters also believed that the one-year compliance timeframe would allow enough time for laboratories, inspectors, contractors, and State and local programs to complete trainings for testing larger surface areas, update the standards and specification documents managed by ASTM Technical Committees, and allow HUD to update its guidelines. Commenters who requested a compliance timeframe of 2+ years were almost exclusively discussing it in relation to if EPA adopted the proposed primary DLCL of 3 μg/ft², 20 μg/ft², and 25 μg/ft² for floors, window sills, and troughs (Ref. 38). As a result, EPA is finalizing a one-year compliance date for the DLRL, DLAL, and the abatement report language revisions (which directly pertains to the final standards). The Agency is also interested in revising both standards at the same time to reduce any confusion and avoid any concerns within the regulated community that may be caused by staggering the DLRL and the DLAL compliance dates. EPA believes that since the DLRL are non-static, which is different than they have been historically, and as the program is shifting to the DLAL becoming the ''action level'' for the LQSR, it is important to allow ample time for the regulated community to adapt to the revised DLRL and DLAL. Additionally, if the DLRL compliance date occurred before the DLAL compliance date, EPA is concerned it might trigger unnecessary confusion for laboratories.

VII. Severability

EPA intends that each provision of this rulemaking be severable, with one exception identified below. In the event of litigation staying, remanding, or invalidating a portion of EPA's amendments in this rule, EPA intends to preserve the amendments for all other portions of the rule to the fullest extent possible. The Agency evaluated each issue on its own merits and EPA's amendments (with the one exception identified below) function independently from one another. Further, the Agency crafted this rule so that different regulatory decisions are reflected in different provisions or elements of the rule that are capable of operating independently. Accordingly, the Agency has organized the rule so that if any provision or element of this rule is determined by judicial review or operation of law to be invalid, that partial invalidation will not render the remainder of this rule invalid.

The limited circumstance in which severability is not intended would be where the decoupled approach is determined to be invalid. If the decoupled approach is determined to be invalid, the revisions to the definition of abatement (at 40 CFR 745.223) and the abatement report language (at 40 CFR 745.227(e)(10)(vii)) would not be necessary or helpful. In contrast, however, EPA does intend severability in the inverse scenario: if either the definition of abatement or the amended abatement report language were determined to be invalid, EPA intends severability of all other provisions, including the decoupled approach.

VIII. References

The following is a list of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

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IX. Statutory and Executive Order Reviews

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

A. Executive Orders 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review

This action is a ''significant regulatory action'' as defined under section 3(f)(1) of Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under Executive Order 12866. Documentation of any changes made in response to the Executive Order 12866 review is available in the docket. The Agency prepared an analysis of the potential costs and benefits associated with this action (Ref. 10), which is available in the docket and is summarized in Unit I.E.

B. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for review and approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR No. 2760.02 and OMB Control No. 2070–0227 (Ref. 127). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The ICR addresses the incremental changes to the existing reporting, notification, and recordkeeping programs that are currently approved under OMB Control Nos. 2070–0151 and 2070–0195. As approved under OMB Control No. 2070–0151 and pursuant to 24 CFR part 35, subpart A, and 40 CFR 745, Subpart F, sellers and lessors of target housing must already provide purchasers or lessees any available records or reports ''pertaining to'' LBP and/or LBP hazards available to the seller or lessor. Accordingly, a seller or lessor must disclose any reports showing dust-lead levels, regardless of the value. A lower hazard standard may prompt a different response on the already required lead disclosure form (*i.e.,* that a lead-based paint hazard is present rather than not), which would occur when a dust-lead level is below the 2019 standard but at or above a lower final reportable level. However, for existing target housing, this action would not result in additional disclosures because the lead disclosure form is required regardless of whether dust-lead is present at or below the hazard standard or reportable level. Note that leases (which does not include sales) of target housing are exempt from disclosure requirements in limited circumstances, such as where the housing has been found to be LBP free by a certified inspector (24 CFR 35.82; 40 CFR 745.101), even if the dust-lead level is at or above the DLRL. Nevertheless, due to the change in target housing definition, EPA estimates an additional 967 disclosure events will occur annually, which will affect 3,040 respondents at an average burden and cost of 0.11 hours and $4.58 per respondent, resulting in a total annual burden of 337 hours at a total annual cost of $13,910.

Next, as approved under OMB Control No. 2070–0195, the ICR addresses the information collection activities associated with the reporting and recordkeeping requirements for individuals, firms and State and local government entities conducting LBP activities or renovations of target housing and COFs; training providers; and States/territories/Tribes/Alaska Native villages. These information collection activities include the following:

- LBP activity firm pre-abatement reports and occupant protection plans, abatement activity notifications, post-abatement reports and recordkeeping;
- Applications for certification of individuals performing LBP activities, and related recordkeeping;
- LBP activities training provider accreditation applications, training notifications, and recordkeeping;
- LBP activity firm certification applications and recordkeeping;
- Distribution of pre-renovation lead hazard information pamphlet and post-renovation checklists documenting lead-safe work practices;
- RRP and LBP professionals classroom training time related to recordkeeping compliance;
- RRP training provider accreditation applications, training notifications, and recordkeeping;
- Private RRP firm and Government-employed RRP professional certification applications and recordkeeping; and
- Submission of related fees.

Incremental abatement notifications would be required when an abatement occurs due to the DLRL/DLAL and does not occur in the baseline; EPA estimates that 1,779 to 2,687 such notifications will incur average annual paperwork-associated costs of $161. Additional LBP workers may need to be hired and subsequently trained and certified to accommodate the additional dust-lead remediation activities triggered by the DLRL/DLAL. EPA estimates that 1,304 to 2,551 respondents will incur average annual paperwork-associated costs of $457. Because the EA finds that the DLRL/DLAL would increase the average number of new lead hazard reduction events per firm by up to 16 per year, EPA assumes that existing LBP activity firms would cover this new work and new entrants are unlikely to emerge. As such, EPA does not estimate any paperwork costs associated with LBP activity firm certification. Similarly, the EA finds that there would be fewer than 1 incremental event per affected RRP firm and therefore EPA expects no new RRP firms or employees will enter the market in response to the DLRL/DLAL. As such, EPA does not estimate any paperwork costs associated with RRP firm certification or RRP training.

The revisions to the definition of target housing will result in paperwork costs in two dimensions. First, abatement firms operating in newly defined target housing are expected to incur reporting and recordkeeping costs for those additional events. EPA estimates that 25 respondents will incur an average annual cost of $96 for these activities. Second, renovation service firms performing renovation activities in newly defined target housing are required to perform disclosure activities. This will result in recurring disclosure event, recordkeeping, and materials costs. EPA estimates that 1,977 respondents will incur an average annual cost of $16.

In addition, EPA currently receives approximately 90 percent of required notifications as well as applications for accreditation, certification, and re-certification from training providers, firms, and lead abatement individuals through EPA's Central Data Exchange (CDX). The paperwork activities, related burden and costs with CDX user registration for those who elect to exercise the electronic submission option established under the Agency's Cross-media Electronic Reporting Rule (CROMERR) (40 CFR part 3) are described in an ICR approved under OMB Control No. 2025–0003. The amended information collection activities contained in this rule are designed to assist the Agency in meeting its responsibility under TSCA to receive, process, and review reports, data, and other information. Accordingly, this rule requires regulated parties to submit notifications and applications through CDX.

The ICR prepared for this rule addresses the incremental burden changes related to the expected increase in the number of responses to the activities considered in the other existing ICRs, as well as the changing response obligation for the use of CDX from voluntary to mandatory.

Respondents/affected entities: Persons engaged in selling or leasing certain residential dwellings built before 1978; persons who are engaged in lead-based paint activities and/or perform renovations of target housing or child-occupied facilities for compensation, dust sampling, or dust testing; persons who perform lead-based paint inspections, lead hazard screens, risk assessments or abatements in target housing or child-occupied facilities; persons who provide training or operate a training program for individuals who perform any of these activities; State, territorial or Tribal agencies that administer lead-based paint activities and/or renovation programs. See also Unit I.A.

Respondent's obligation to respond: Mandatory (Title X and 40 CFR part 745).

Estimated number of respondents: 8,123 to 10,278 (per year).

Frequency of response: On occasion.

Total estimated burden: 16,982 to 29,462 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: $0.9 million to $1.6 million (per year), includes no annualized capital or operation and maintenance costs.

Under the PRA, an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for certain EPA's regulations in 40 CFR are listed in 40 CFR part 9, and on associated collection instruments. When OMB approves this ICR, EPA will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of the DLRL and DLAL are small businesses that are landlords who may incur costs for lead hazard reduction measures in compliance with the HUD's LSHR; elementary and secondary schools or child day care services (who may incur costs associated with lead hazard reduction measures in COFs); residential remodelers (who may incur costs associated with additional cleaning and sealing in houses undergoing rehabilitation or ongoing lead-based paint maintenance subject to the HUD LSHR); and abatement firms (who may also incur costs associated with additional cleaning and sealing under the LSHR). The Agency has determined that approximately 18,000 small businesses would be directly affected by the DLRL and DLAL, of which 85% to 86% have cost impacts less than 1% of revenues, 12% to 13% have impacts between 1% and 3% of revenues, and 2% have impacts greater than 3% of revenues. The total estimated costs to small businesses are between $45 million and $89 million per year.

Additionally, the rule's other amendments may potentially affect four types of small entities: property owners that will incur recordkeeping and material costs for real estate disclosures in newly defined target housing; renovation firms that will incur renovation disclosure costs and lead-safe work practice costs in newly defined target housing; LBP activities firms that will incur reporting and recordkeeping costs for abatement activities in newly defined target housing; and EPA-certified training providers that may incur costs for submitting reports electronically. The Agency has determined that approximately 2,998 small businesses would be directly affected by the amendment to the target housing definition, of which 100% have cost impacts less than 1% of revenues. The Agency has determined that approximately 86 small businesses would be directly affected by the amendment to the electronic reporting requirement, of which 100% have cost impacts less than 1% of revenues. All details of the analysis of potential costs and benefits associated with this action are presented in EPA's EA, which is available in the docket (Ref. 10).

The EA estimates potential costs from the DLRL and DLAL for activities in two types of target housing and COFs—those subject to the HUD LSHR and those where a child with a blood lead level exceeding a Federal or State threshold lives. Importantly, the DLRL do not require the owners of properties covered by this rule to evaluate their properties for the presence of dust-lead hazards, or to act if dust-lead hazards are identified. Although the DLRL and DLAL do not compel specific actions under EPA's LBP Activities Rule to address identified LBP hazards, the DLHS and DLCL are directly cross-referenced in certain requirements mandated by HUD in the housing subject to the LSHR. Aside from the HUD regulations, and perhaps some State or local regulations, the DLRL and DLAL do not impose new Federal requirements on small entities.

D. Unfunded Mandates Reform Act (UMRA)

As discussed in Unit I.E.6., this action contains a Federal mandate that may result in expenditures of $183 million in 2023 dollars ($100 million in 1995 dollars adjusted for inflation using the GDP implicit price deflator) or more as described in UMRA, 2 U.S.C. 1531–1538, for State, local and Tribal governments, in the aggregate, or the private sector in any one year. However, this action is not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments. Additionally, EPA does not believe that this action would impose an unfunded mandate on Tribal governments or otherwise have substantial direct effects on one or more federally recognized Indian Tribes. EPA has prepared the written statement required under section 202 of UMRA (Ref. 13). The statement is included in the docket for this action and is briefly summarized here.

This rulemaking is issued under the authority of TSCA sections 401, 402, 403, 404, and 406, 15 U.S.C. 2601 *et seq.,* as amended by Title X (Pub. L. 102–550) (Ref. 1) and section 237(c) of Title II of Division K of the Consolidated Appropriations Act, 2017 (Pub. L. 115–31, 131 Stat. 789), as well as sections

1004 and 1018 of Title X (42 U.S.C. 4851b, 4852d), as amended by section 237(b) of Title II of Division K of the Consolidated Appropriations Act, 2017.

The EA (Ref. 10) presents the costs of the rule as well as various regulatory options, and is summarized in Unit I.E. The rule is estimated to result in total compliance costs of $207 million to $348 million per year. Thus, the annual cost of the rule to the private sector (and State, local, and Tribal governments) in the aggregate exceeds the inflation-adjusted $100 million UMRA threshold.

This rule will reduce exposures to lead, resulting in benefits from avoided adverse health effects. For the subset of health effects where the results were quantified, the estimated annualized benefits are $1.54 billion to $10.315 billion per year using a 2% discount rate. There may be additional unquantified benefits due to other avoided health effects.

Net benefits are the difference between benefits and costs. The rule is estimated to result in quantified net benefits of $1.367 billion to $9.966 billion per year using a 2% discount rate. EPA considers unquantified health benefits to be potentially important non-monetized impacts that contribute to the overall net benefits of this rule.

Under section 205 of UMRA, before promulgating a rule for which a written statement is required, EPA must identify and consider a reasonable number of regulatory alternatives. From those alternatives, EPA must select the least costly, most cost-effective, or least burdensome alternative that achieves the rule's objectives, unless the Administrator publishes with the final rule an explanation why the least costly, most cost-effective, or least burdensome method was not adopted; or the provisions of section 205 are inconsistent with applicable law.

EPA considered several regulatory alternatives in the economic analysis for the final rule. One of these options, DLRL and DLAL of 10 μg/ft², 100 μg/ft², and 400 μg/ft² for floors, window sills and window troughs, would have lower costs than the alternative selected for the final rule. This alternative option would be more cost-effective than the final rule in terms of the cost per case of premature cardiovascular mortality avoided. However, the final rule is the most cost-effective option analyzed for both the cost per lost IQ point avoided and the cost per ADHD case avoided. The final rule also avoids far more IQ loss and cases of cardiovascular mortality risk and ADHD than does the alternative option.

Compared with DLAL of 10 μg/ft², 100 μg/ft², and 400 μg/ft², DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² represents a reduction of 50% or more in the allowable level of dust-lead loadings following the completion of an abatement. As a result, DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² would be beneficial to maintaining lower children's BLLs and protecting against associated health outcomes such as decreased IQ. The TSD modeling shows that young children in pre-1978 housing exposed to dust-lead loadings of 5 μg/ft² for floors and 40 μg/ft² for window sills would have an estimated 13.9% probability of exceeding a total BLL of 3.5 μg/dL (CDC's BLRV). This is significantly lower than the 18.0% probability of exceedance of the BLRV when exposed to DLAL of 10 μg/ft² for floors and 100 μg/ft² on window sills.

When considering dust-lead exposure only, young children in pre-1978 housing exposed to DLAL of 5 μg/ft², 40 μg/ft², and 100 μg/ft² would have a 22.4% probability of exceeding 2 points of IQ loss. This is considerably less than the 37.9% chance of exceeding 2 points of IQ loss for children exposed to DLAL levels of 10 μg/ft², 100 μg/ft², and 400 μg/ft². Overall, the TSD modeling indicates that the 5 μg/ft², 40 μg/ft², and 100 μg/ft² DLAL represents a substantial reduction in risk compared with DLAL of 10 μg/ft², 100 μg/ft², and 400 μg/ft².

EPA's analysis of the HUD LHCCS data indicates that 72% of samples showed dust-lead levels at or below 5 μg/ft² for floors, 88% were at or below 40 μg/ft² for window sills, and 93% were at or below 100 μg/ft² for window troughs. The respondents to HUD's survey were only required to achieve clearance below the dust-lead clearance levels that were in effect at that time (which were 40 μg/ft² for floors, 250 μg/ft² window sills, and 400 μg/ft² for window troughs), and the percentage of samples achieving these post-abatement dust-lead loadings may be even higher today (due to the 2021 Final Rule revising the clearance levels to 10 μg/ft² for floors and 100 μg/ft² for window sills, described as dust-lead action levels moving forward). Furthermore, New York City lowered its standards for floors, window sills and window wells (*i.e.,* troughs), respectively, to 5 μg/ft², 40 μg/ft², 100 μg/ft² in 2021. As a result, EPA has high confidence that the 5 μg/ft², 40 μg/ft², and 100 μg/ft² for floors, window sills, and window troughs DLAL option is achievable.

Therefore, EPA has concluded that the final rule option better achieves the objectives of reliability, effectiveness and safety than does the alternative option of 10 μg/ft², 100 μg/ft², and 400 μg/ft² for floors, window sills and troughs.

EPA sought input from State and local government representatives early in the rulemaking process during the joint intergovernmental consultation initiated in November 2022. EPA's experience in administering the existing LBP activities program under TSCA section 402 suggests that these governments will play a critical role in the successful implementation of the national program to reduce exposures to LBP hazards.

E. Executive Order 13132: Federalism

EPA has concluded that this action has federalism implications, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because of the potential effects on public housing authorities. While some HUD grant funding for LBP projects exists, the Federal government may not provide the funds necessary to pay the entirety of the costs. State and local governments may provide additional funding to pay for some of these costs. These costs to public housing authorities—estimated at $27 million per year—cover additional lead hazard reduction activities, cleaning, and dust-lead testing to ensure that public housing units are in compliance with the LSHR. Public school districts that administer COFs are also estimated to have annual compliance costs of approximately $850,000 per year. Additionally, States that have authorized LBP activities programs must demonstrate that they meet any new requirements imposed by this rulemaking and are at least as protective as the levels at 40 CFR 745.65 and 40 CFR 745.227. However, authorized States are under no obligation to continue to administer the LBP activities program, and if they do not wish to adopt the DLRL and DLCL they can relinquish their authorization. In the absence of a State authorization, EPA will administer these requirements.

EPA provides the following federalism summary impact statement. EPA consulted with State and local officials early in the process of developing the proposed action to permit them to have meaningful and timely input into its development. EPA invited the following national organizations representing State and local elected officials to a consultation meeting on November 10, 2022: National Governors' Association, National Conference of State Legislatures, U.S. Conference of Mayors, National League of Cities, Council of State Governments, International City/County Management Association, National Association of Counties, National Association of Towns and Townships, County Executives of America, and Environmental Council of

the States. Additionally, the agency invited professional organizations that represent or have State and local government members, such as Public Housing Authorities Directors Association, Council of Large Public Housing Authorities, Association of State and Territorial Health Officials, American Public Works Association, and other groups to participate in the meeting. The comments received during this consultation, and EPA's response thereto, are discussed in Unit IX.E. of the notice of proposed rulemaking (88 FR 50477).

EPA notes that according to the 2021 Court Opinion the Agency cannot take into account non-health factors, such as costs, when revising the DLHS. However, the Agency can and did consider non-health factors when revising the DLAL. Accordingly, as described elsewhere in this notice, EPA is promulgating DLAL that are higher than those it originally proposed. This will allow laboratories to continue using FAAS instruments for dust-wipe testing. This will limit increases in laboratory testing costs and turnaround times, including for abatements in properties owned by public housing authorities and public-school districts.

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

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes. Federally recognized Tribes that have authorized LBP activities programs must demonstrate that they meet any new requirements imposed by this rulemaking and are at least as protective as the levels at 40 CFR 745.65 and 40 CFR 745.227. However, these authorized Tribes are under no obligation to continue to administer the LBP activities program, and if they do not wish to adopt the new DLRL and DLAL they can relinquish their authorization. In the absence of a Tribal authorization, EPA will administer these requirements. This action does not create an obligation for Tribes to administer LBP activities programs or alter EPA's authority to administer these programs. For these reasons, Executive Order 13175 does not apply to this action.

Consistent with the EPA Policy on Consultation and Coordination with Indian Tribes, EPA consulted with Tribal officials during the development of this action. The Agency provided an opportunity for consultation from July 24, 2023, to September 22, 2023, with consultation sessions on August 9 and 10, 2023. Tribal officials were given the opportunity to meaningfully interact with EPA concerning the dust-lead standards, and all other amendments in the proposed rulemaking. During the consultation sessions, EPA covered the legal and regulatory history of this rulemaking, the approach to revising both dust-lead standards, other amendments such as the definition of target housing, the potential Tribal impacts and the estimated economic costs and benefits, as well as provided resources and information to Tribal officials about how to submit written comments to the Agency. Beyond a few clarifying questions, Tribal officials raised no related issues or concerns to EPA during or in follow-up to those meetings (Ref. 128). EPA received no additional written comments from Tribes as part of this consultation opportunity.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is subject to Executive Order 13045 because it is a significant regulatory action under section 3(f)(1) of Executive Order 12866 (as amended by Executive Order 14094), and EPA believes that the environmental health or safety risk addressed by this action has a disproportionate effect on children as they are more susceptible to the adverse health effects of lead due to their behavior and physiology. Accordingly, we have evaluated the environmental health or safety effects of dust-lead exposure on children.

The results of this evaluation are contained in Unit I.E., and in the EA and TSD, where the health impacts of lead exposure on children are discussed more fully (Refs. 10 and 12). The documents referenced in this unit are available in the public docket for this action.

This action is preferred over other regulatory options analyzed because the DLRL aligns with the current state of the science, which does not support identifying a threshold of dust-lead exposure below which there would be no adverse human health effects. EPA has set the DLAL taking into account the statutory criteria of reliability, effectiveness, and safety.

Furthermore, EPA's 2021 Policy on Children's Health also applies to this action. Discussion about how the Agency applied this policy is presented in Unit I.E.5.

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

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy.

I. National Technology Transfer and Advancement Act (NTTAA) and 1 CFR Part 51

This action involves technical standards under NTTAA section 12(d), 15 U.S.C. 272 *note.* ASTM E1728 and ASTM E1792 are already cited in an existing regulatory definition of ''wipe sample'' at 40 CFR 745.63. EPA is formally incorporating the most current version of these standards (*i.e.,* ASTM E1728–20 and ASTM E1792–20). Additional information about these standards, including how to access them, is provided in Unit IV.F.8.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All

EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with environmental justice concerns consistent with Executive Order 14096 (88 FR 25251, April 26, 2023) (building on and supplementing E.O. 12898 (59 FR 7629, February 16, 1994)). See discussion in Section 8.6 of the EA (Ref. 10) concerning existing disproportionate impacts of lead pollution faced by individuals in low-income households and households of people of color and/or Indigenous peoples, and the measured extent to which this action particularly benefits the health of individuals in low-income households.

EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with environmental justice concerns. For example, 50% of children under age 6

who will benefit from the rule are members of households below the poverty line, compared with 17% of children under age 6 nationally who live below the poverty line. An estimated 48% of total monetized IQ benefits from this rule accrue to children under age 6 living in a household below the poverty line. An estimated 28% of children under age 6 who will benefit from the rule are non-Hispanic Black, compared with 12% of children under age 6 nationally who are non-Hispanic Black. An estimated 23% of total monetized IQ benefits from this rule accrue to non-Hispanic Black children.

For children ages 0 to 15 at the time of exposure reduction benefiting from this rulemaking due to reduced cases of ADHD, 53% of those live in a household with an annual income below the poverty line, compared to 19% of children ages 0 to 15 in target housing who live below the poverty line. An estimated 40% of total monetized ADHD benefits from this rule accrue to children ages 0 to 15 living in a household below the poverty line. Additionally, 36% of children ages 0 to 15 benefiting from this rulemaking are non-Hispanic Black, compared to the 13% of children in target housing who similarly identify. However, only an estimated 27% of total monetized ADHD benefits from this rule accrue to non-Hispanic Black children.

Similarly, 49% of the adults benefiting from this rulemaking live in a household with annual income below the poverty line, compared to 13% of adults in target housing who live below the poverty line. Adults living in a household below the poverty line receive an estimated 43% of total monetized cardiovascular mortality avoidance benefits from this rule. Moreover, 39% of adults benefitting from this rulemaking are non-Hispanic Black, compared to the 13% of adults in target housing who identify as non-Hispanic Black. An estimated 49% of total monetized cardiovascular mortality avoidance benefits from this rule accrue to non-Hispanic Black adults.

There is some uncertainty, however, regarding the environmental justice implications of this rule on HUD-assisted housing. If the rule inadvertently limits the availability of federally assisted affordable housing, a subset of low-income individuals or families currently residing in assisted housing may face higher housing costs on the private market, disruptions caused by an involuntary loss of housing, and the potential for dust lead levels that exceed those in their baseline LSHR-regulated housing.

EPA additionally identified and addressed environmental justice concerns through public comment and collaboration with State, Tribal, and other co-regulatory bodies related to the EJ2020 action agenda and the development of the EPA Lead Strategy. Through the EPA Lead Strategy, EPA has engaged with key stakeholders, communities, and organizations with vested interests in addressing lead exposures. Disparities in lead pollution are a national area of focus in the EJ2020 action agenda (Ref. 129), and this rulemaking's protective standards will deliver demonstrative progress on addressing childhood lead exposure and health disparities to members of overburdened communities.

The information supporting the Executive Order 12898 review is contained in the EA (Ref. 10) and EPA Lead Strategy (Ref. 8), both of which are available in the docket.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action meets the criteria set forth in 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 745

Environmental protection, Abatement, Child-occupied facility, Clearance levels, Hazardous substances, Incorporation by reference, Lead, Lead poisoning, Lead-based paint, Target housing.

Michael S. Regan,

Administrator.

Therefore, for the reasons set forth in the preamble, 40 CFR chapter I is amended as follows:

PART 745—LEAD-BASED PAINT POISONING PREVENTION IN CERTAIN RESIDENTIAL STRUCTURES

■ 1. The authority citation for part 745 continues to read as follows:

Authority: 15 U.S.C. 2605, 2607, 2681–2692 and 42 U.S.C. 4852d.

■ 2. Amend § 745.61 by adding paragraph (d) to read as follows:

§ 745.61 Scope and applicability.

* * * * *

(d) Before January 13, 2025, the levels identified in 40 CFR 745.227(e)(8)(viii) were referred to as clearance levels. On or after January 13, 2025, the levels identified in § 745.227(e)(8)(viii) are referred to as action levels.

■ 3. Amend § 745.63 by adding in alphabetical order the definitions of ''Reportable level'' and revising the definition of ''Wipe sample'' to read as follows:

§ 745.63 Definitions.

* * * * *

Reportable level means the lowest analyte concentration (or amount) that does not contain a ''less than'' qualifier and that is reported with confidence for a specific method by a laboratory recognized by EPA under TSCA section 405(b).

* * * * *

Wipe sample means a sample collected by wiping a representative surface of known area, as determined by ASTM E1728/E1728M–20 (incorporated by reference, see § 745.67), or equivalent method, with an acceptable wipe material as defined in ASTM E1792–20 (incorporated by reference, see § 745.67).

■ 4. Amend § 745.65 by revising paragraph (b) to read as follows:

§ 745.65 Lead-based paint hazards.

* * * * *

(b) *Dust-lead hazard.* Before January 12, 2026, a dust-lead hazard is surface dust in a residential dwelling or child-occupied facility that contains a mass-per-area concentration of lead equal to or exceeding 10 μg/ft² for floors or 100 μg/ft² for interior window sills based on wipe samples. On or after January 12, 2026, a dust-lead hazard is surface dust in a residential dwelling or child-occupied facility that contains a mass-per-area concentration of any reportable level of lead for floors or for interior window sills based on wipe samples analyzed by an NLLAP-recognized laboratory.

* * * * *

■ 5. Add § 745.67 to Subpart D to read as follows:

§ 745.67 Incorporation by reference.

Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Environmental Protection Agency (EPA) and at the National Archives and Records Administration (NARA). Contact EPA at: OPPT Docket in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading room is

(202) 566–1744, and the telephone number for the OPPT Docket is (202) 566–0280. For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations* or email *fr.inspection@nara.gov.* The material may be obtained from the following sources:

(a) *ASTM.* ASTM International, 100 Barr Harbor Dr., P.O. Box C700, West Conshohocken, PA 19428–2959; (877) 909–ASTM; *www.astm.org.*

(1) ASTM E1728/E1728M–20, Standard Practice for Collection of Settled Dust Samples Using Wipe Sampling Methods for Subsequent Lead Determination, Approved January 1, 2020; IBR approved for § 745.63.

(2) ASTM E1792–20, Standard Specification for Wipe Sampling Materials for Lead in Surface Dust, Approved September 1, 2020; IBR approved for § 745.63.

(b) [Reserved]

■ 6. Amend § 745.81 by revising paragraphs (a)(4) and (b) to read as follows:

§ 745.81 Effective dates.

(a) * * *

(4) *Work practices.* On or after July 6, 2010, all renovations must be performed in accordance with the work practice standards in § 745.85 and the associated recordkeeping requirements in § 745.86(b)(1) and (b)(6) in target housing or child-occupied facilities, unless the renovation qualifies for the exception identified in § 745.82(a).

* * * * *

(b) *Renovation-specific pamphlet.* On or after December 22, 2008, renovators or firms performing renovations in States and Indian Tribal areas without an authorized program must provide owners and occupants the following EPA pamphlet: *Renovate Right: Important Lead Hazard Information for Families, Child Care Providers and Schools.*

* * * * *

■ 7. Amend § 745.83 by adding in alphabetical order the definition of ''Electronic'' to read as follows:

§ 745.83 Definitions.

* * * * *

Electronic means the submission of an application, payment, or notification using the Agency's Central Data Exchange (CDX), or successor platform.

* * * * *

■ 8. Amend § 745.85 by revising paragraph (c)(3) to read as follows:

§ 745.85 Work practice standards.

* * * * *

(c) * * *

(3) The renovation firm is required to re-clean the work area until the dust sample results are below the dust-lead action levels in § 745.227(e)(8) or any applicable State, Territorial, Tribal, or local standard.

* * * * *

■ 9. Amend § 745.89 by revising paragraphs (a)(1), introductory text of paragraph (b)(1), (b)(1)(i), and (c)(1) to read as follows:

§ 745.89 Firm certification.

(a) * * *

(1) Firms that perform renovations for compensation must electronically apply to EPA for certification to perform renovations or dust sampling. To apply, a firm must submit to EPA a completed ''Application for Firms,'' signed by an authorized agent of the firm, and pay electronically at least the correct amount of fees. If a firm pays more than the correct amount of fees, EPA will reimburse the firm for the excess amount.

* * * * *

(b) * * *

(1) *Timely and complete application.* To be re-certified, a firm must submit a complete electronic application for re-certification. A complete application for re-certification includes a completed ''Application for Firms'' which contains all of the information requested by the form and is signed by an authorized agent of the firm, noting on the form that it is submitted as a re-certification. A complete application must also include at least the correct amount of fees. If a firm pays more than the correct amount of fees, EPA will reimburse the firm for the excess amount.

(i) An application for re-certification is timely if it is electronically submitted 90 days or more before the date the firm's current certification expires. If the firm's application is complete and timely, the firm's current certification will remain in effect until its expiration date or until EPA has made a final decision to approve or disapprove the re-certification application, whichever is later.

* * * * *

(c) * * *

(1) To amend certification, a firm must electronically submit a completed ''Application for Firms,'' signed by an authorized agent of the firm, noting on the form that it is submitted as an amendment and indicating the information that has changed. The firm must also pay at least the correct amount of fees.

* * * * *

■ 10. Amend § 745.90 by revising paragraphs (a)(3) and (4) and paragraph (c)(1) to read as follows:

§ 745.90 Renovator certification and dust sampling technician certification.

(a) * * *

(3) Individuals who have successfully completed an accredited lead-based paint inspector or risk assessor course before October 4, 2011 may take an accredited refresher dust sampling technician course in lieu of the initial training to become a certified dust sampling technician. Individuals who are currently certified as lead-based paint inspectors or risk assessors may act as certified dust sampling technicians without further training.

(4) To maintain renovator certification or dust sampling technician certification, an individual must complete a renovator or dust sampling technician refresher course accredited by EPA under § 745.225 or by a State or Tribal program that is authorized under Subpart Q of this part within 5 years of the date the individual completed the initial course described in paragraph (a)(1) of this section. If the individual does not complete a refresher course within this time, the individual must re-take the initial course to become certified again. Individuals who take a renovator refresher course that does not include hands-on training will be certified for 3 years from the date they complete the training. Individuals who take a refresher training course that includes hands-on training will be certified for 5 years. Individuals who take the renovator refresher without hands-on training must, for their next refresher course, take a refresher course that includes hands-on training to maintain renovator certification.

* * * * *

(c) * * *

(1) Must collect dust samples in accordance with § 745.227(e)(8), must send the collected samples to a laboratory recognized by EPA under TSCA section 405(b), and must compare the results to the action levels in accordance with § 745.227(e)(8).

* * * * *

■ 11. Amend § 745.92 by revising paragraph (c)(2) to read as follows:

§ 745.92 Fees for the accreditation of renovation and dust sampling technician training and the certification of renovation firms.

* * * * *

(c) * * *

(2) Submit the application and a payment of $15 electronically in

accordance with the instructions provided with the application package.

* * * * *

■ 12. Amend § 745.103 by revising the definition of ''Target housing'' to read as follows:

§ 745.103 Definitions.

* * * * *

Target housing means any housing constructed prior to 1978, except housing for the elderly or persons with disabilities or any 0-bedroom dwelling (unless any child who is less than 6 years of age resides or is expected to reside in such housing).

* * * * *

■ 13. Amend § 745.113 by revising paragraphs (a)(4), (b)(1) and (4) to read as follows:

§ 745.113 Certification and acknowledgement of disclosure.

(a) * * *

(4) A statement by the purchaser affirming receipt of the information set out in paragraphs (a)(2) and (3) of this section and the lead hazard information pamphlet required under 15 U.S.C. 2686.

* * * * *

(b) * * *

(1) A Lead Warning Statement with the following language:

Housing built before 1978 may contain lead-based paint. Lead from paint, paint chips, and dust can pose health hazards if not managed properly. Lead exposure is especially harmful to young children and pregnant women. Before renting pre-1978 housing, lessors must disclose the presence of known lead-based paint and/or lead-based paint hazards in the dwelling. Lessees must also receive a federally approved pamphlet on lead poisoning prevention.

* * * * *

(4) A statement by the lessee affirming receipt of the information set out in paragraphs (b)(2) and (3) of this section and the lead hazard information pamphlet required under 15 U.S.C. 2686.

* * * * *

■ 14. Amend § 745.223 by:

■ a. Revising the definition of ''Abatement'';

■ b. Adding in alphabetical order the definition of ''Action levels'';

■ c. Revising the definitions of ''Certified inspector'', ''Certified risk assessor'' and ''Child-occupied facility'';

■ d. Removing the definition of ''Clearance levels'';

■ e. Adding in alphabetical order the definitions of ''Electronic'' and ''Housing for the elderly'';

■ f. Revising the definitions of ''Living area'' and ''Target housing''; and

■ g. Removing the definition for ''Visual inspection for clearance testing'' and adding in its place the definition ''Visual inspection for abatement-related testing''.

The revisions and additions read as follows:

§ 745.223 Definitions.

* * * * *

Abatement means any measure or set of measures designed to permanently eliminate lead-based paint hazards, in the case of dust-lead hazards to below the action levels. Abatement includes, but is not limited to:

(1) The removal of paint and dust (in the case of dust-lead hazards to below the action levels), the permanent enclosure or encapsulation of lead-based paint, the replacement of painted surfaces or fixtures, or the removal or permanent covering of soil, when lead-based paint hazards are present in such paint, dust or soil; and

(2) All preparation, cleanup, disposal, and post-abatement testing activities associated with such measures.

(3) Specifically, abatement includes, but is not limited to:

(i) Projects for which there is a written contract or other documentation, which provides that an individual or firm will be conducting activities in or to a residential dwelling or child-occupied facility that:

(A) Shall result in the permanent elimination of lead-based paint hazards, in the case of dust-lead hazards to below the action levels; or

(B) Are designed to permanently eliminate lead-based paint hazards, in the case of dust-lead hazards to below the action levels, and are described in paragraphs (1) and (2) of this definition.

(ii) Projects resulting in the permanent elimination of lead-based paint hazards, in the case of dust-lead hazards to below the action levels, conducted by firms or individuals certified in accordance with § 745.226, unless such projects are covered by paragraph (4) of this definition;

(iii) Projects resulting in the permanent elimination of lead-based paint hazards, in the case of dust-lead hazards to below the action levels, conducted by firms or individuals who, through their company name or promotional literature, represent, advertise, or hold themselves out to be in the business of performing lead-based paint activities as identified and defined by this section, unless such projects are covered by paragraph (4) of this definition; or

(iv) Projects resulting in the permanent elimination of lead-based paint hazards, in the case of dust-lead hazards to below the action levels, that are conducted in response to State or local abatement orders.

(4) Abatement does not include renovation, remodeling, landscaping or other activities, when such activities are not designed to permanently eliminate lead-based paint hazards, in the case of dust-lead hazards to below the action levels, but, instead, are designed to repair, restore, or remodel a given structure or dwelling, even though these activities may incidentally result in a reduction or elimination of lead-based paint hazards. Furthermore, abatement does not include interim controls, operations and maintenance activities, or other measures and activities designed to temporarily, but not permanently, reduce lead-based paint hazards, in the case of dust-lead hazards to below the action levels.

* * * * *

Action levels are the values that indicate the amount of lead in dust on a surface following completion of an abatement activity. To complete abatement when dust sampling is required, values below these levels must be achieved. EPA previously used the term ''clearance levels'' to refer to these levels.

* * * * *

Certified inspector means an individual who has been trained by an accredited training program, as defined by this section, and certified by EPA pursuant to § 745.226 to conduct inspections. A certified inspector also samples for the presence of lead in dust and soil for the purposes of abatement-related testing.

* * * * *

Certified risk assessor means an individual who has been trained by an accredited training program, as defined by this section, and certified by EPA pursuant to § 745.226 to conduct risk assessments. A risk assessor also samples for the presence of lead in dust and soil for the purposes of abatement-related testing.

* * * * *

Child-occupied facility means a building, or portion of a building, constructed prior to 1978, visited regularly by the same child, under 6 years of age, on at least two different days within any week (Sunday through Saturday period), provided that each day's visit lasts at least 3 hours and the combined weekly visit lasts at least 6 hours, and the combined annual visits last at least 60 hours. Child-occupied facilities may include, but are not limited to, day-care centers, preschools and kindergarten classrooms.

* * * * *

Electronic means the submission of an application, payment, or notification using the Agency's Central Data Exchange (CDX), or successor platform.

* * * * *

Housing for the elderly means retirement communities or similar types of housing reserved for households composed of one or more persons 62 years of age or more at the time of initial occupancy.

* * * * *

Living area means any area of a residential dwelling used by one or more children under age 6 including, but not limited to, living rooms, kitchen areas, dens, play rooms, and children's bedrooms.

* * * * *

Target housing means any housing constructed prior to 1978, except housing for the elderly or persons with disabilities or any 0-bedroom dwelling (unless any child who is less than 6 years of age resides or is expected to reside in such housing).

* * * * *

Visual inspection for abatement-related testing means the visual examination of a residential dwelling or a child-occupied facility following an abatement to determine whether or not the abatement has been successfully completed.

* * * * *

■ 15. Amend § 745.225 by:

■ a. Revising the introductory text of paragraph (b)(1), paragraphs (c)(13)(vi) and (14)(iii), paragraphs (d)(1)(vi), (3)(xi), (4)(v), and (7)(v), paragraph (e)(5), and paragraph (f)(2);

■ b. Removing and reserving paragraph (i)(2)(ii); and

■ c. Revising paragraph (j)(2).

The revisions read as follows:

§ 745.225 Accreditation of training programs: target housing and child-occupied facilities.

* * * * *

(b) * * *

(1) A training program seeking accreditation shall submit an electronic application to EPA containing the following information:

* * * * *

(c) * * *

(13) * * *

(vi) Notification must be accomplished electronically. Instructions can be obtained online at *https://www.epa.gov/lead* or from the NLIC at 1–800–424–LEAD (5323). Hearing- or speech-impaired persons may reach this telephone number through TTY by calling the toll-free Federal Communications Commission's Telecommunications Relay Service at 711.

* * * * *

(14) * * *

(iii) Notification must be accomplished electronically. Instructions can be obtained online at *https://www.epa.gov/lead* or from the NLIC at 1–800–424–LEAD (5323).

(d) * * *

(1) * * *

(vi) Action levels and testing, including random sampling.

* * * * *

(3) * * *

(xi) Action levels and testing.

* * * * *

(4) * * *

(v) Action levels and testing for large scale abatement projects.

* * * * *

(7) * * *

(v) Action levels and testing.

* * * * *

(e) * * *

(5) A training program seeking accreditation to offer refresher training courses only shall submit an electronic application to EPA containing the following information:

* * * * *

(f) * * *

(2) A training program seeking re-accreditation shall submit an electronic application to EPA no later than 180 days before its accreditation expires. If a training program does not submit its application for re-accreditation by that date, EPA cannot guarantee that the program will be re-accredited before the end of the accreditation period.

* * * * *

(i) * * *

(2) * * *

(ii) [Reserved]

* * * * *

(j) * * *

(2) To amend an accreditation, a training program must electronically submit a completed ''Accreditation Application for Training Providers,'' signed by an authorized agent of the training provider, noting on the form that it is submitted as an amendment and indicating the information that has changed.

* * * * *

■ 16. Amend § 745.226 by:

■ a. Revising paragraph (a)(1)(i) and (ii);

■ b. Removing and reserving paragraph (a)(2);

■ c. Revising paragraph (a)(3), introductory text of paragraph (e)(1), and (2), and (f)(2) and (3);

■ d. Removing and reserving paragraph (f)(5); and

■ e. Revising paragraph (h)(1)(iii).

The revisions read as follows:

§ 745.226 Certification of individuals and firms engaged in lead-based paint activities: target housing and child-occupied facilities.

(a) * * *

(1) * * *

(i) Submit to EPA an electronic application demonstrating that they meet the requirements established in paragraphs (b) or (c) of this section for the particular discipline for which certification is sought; or

(ii) Submit to EPA an electronic application attaching a copy of a valid lead-based paint activities certification (or equivalent) from a State or Tribal program that has been authorized by EPA pursuant to Subpart Q of this part.

(2) [Reserved]

(3) Following the submission of an electronic application demonstrating that all the requirements of this section have been meet, EPA shall certify an applicant as an inspector, risk assessor, supervisor, project designer, or abatement worker, as appropriate.

* * * * *

(e) * * *

(1) To maintain certification in a particular discipline, a certified individual shall apply electronically to and be re-certified by EPA in that discipline by EPA either:

* * * * *

(2) An individual shall be re-certified if the individual successfully completes the appropriate accredited refresher training course and electronically submits a valid copy of the appropriate refresher course completion certificate.

* * * * *

(f) * * *

(2) A firm seeking certification shall electronically submit to EPA an application attesting that the firm shall only employ appropriately certified employees to conduct lead-based paint activities, and that the firm and its employees shall follow the work practice standards in § 745.227 for conducting lead-based paint activities.

(3) From the date of receiving the firm's electronic application requesting certification, EPA shall have 90 days to approve or disapprove the firm's request for certification. Within that time, EPA shall respond with either a certificate of approval or a letter describing the reasons for a disapproval.

* * * * *

(5) [Reserved]

* * * * *

(h) * * *

(1) * * *

(iii) Misrepresented facts in its application for certification to EPA.

* * * * *

■ 17. Amend § 745.227 by
■ a. Removing paragraph (a)(4);
■ b. Revising paragraphs (c)(2)(i), (iv) and (v), (d)(3), (5), (6)(ii) and (7), (e)(4)(ii), (vii), the introductory text of paragraph (8), (8)(i) through (v), (vii) and (viii), the introductory text of paragraph (9), (9)(ii), and (iii), and (10)(iv), and (v);
■ c. Adding paragraph (e)(10)(vii); and
■ d. Revising paragraph (h)(2)(i) and (3).

The revisions and additions read as follows:

§ 745.227 Work practice standards for conducting lead-based paint activities: target housing and child-occupied facilities.

(a) * * *

(4) [Removed]

* * * * *

(c) * * *

(2) * * *

(i) Background information regarding the physical characteristics of the residential dwelling or child-occupied facility and occupant use patterns that may cause lead-based paint exposure to one or more children under age 6 shall be collected.

* * * * *

(iv) In residential dwellings, two composite dust samples shall be collected, one from the floors and the other from the windows, in rooms, hallways or stairwells where one or more children, under age 6, are most likely to come in contact with dust.

(v) In multi-family dwellings and child-occupied facilities, in addition to the floor and window samples required in paragraph (c)(2)(iv) of this section, the risk assessor shall also collect composite dust samples from common areas where one or more children, under age 6, are most likely to come into contact with dust.

* * * * *

(d) * * *

(3) Background information regarding the physical characteristics of the residential dwelling or child-occupied facility and occupant use patterns that may cause lead-based paint exposure to one or more children under age 6 shall be collected.

* * * * *

(5) In residential dwellings, dust samples (either composite or single-surface samples) from the interior window sill(s) and floor shall be collected and analyzed for lead concentration in all living areas where one or more children, under age 6, are most likely to come into contact with dust.

(6) * * *

(ii) Other common areas in the building where the risk assessor determines that one or more children, under age 6, are likely to come into contact with dust.

(7) For child-occupied facilities, interior window sill and floor dust samples (either composite or single-surface samples) shall be collected and analyzed for lead concentration in each room, hallway or stairwell utilized by one or more children, under age 6, and in other common areas in the child-occupied facility where one or more children, under age 6, are likely to come into contact with dust.

* * * * *

(e) * * *

(4) * * *

(ii) Notification for lead-based paint abatement activities required in response to an elevated blood lead level (EBL) determination, or Federal, State, Tribal, or local emergency abatement order should be received by EPA as early as possible before, but must be received no later than, the start date of the lead-based paint abatement activities. Should the start date and/or location provided to EPA change, an updated notification must be received by EPA on or before the start date provided to EPA. Documentation showing evidence of an EBL determination or a copy of the Federal/State/Tribal/local emergency abatement order must be included in the notification to take advantage of this abbreviated notification period.

* * * * *

(vii) Notification must be accomplished electronically. Instructions can be obtained online at *https://www.epa.gov/lead,* or from the NLIC at 1–800–424–LEAD (5323).

* * * * *

(8) The following post-abatement procedures shall be performed only by a certified inspector or risk assessor:

(i) Following an abatement, a visual inspection shall be performed to determine if deteriorated painted surfaces and/or visible amounts of dust, debris or residue are still present. If deteriorated painted surfaces or visible amounts of dust, debris or residue are present, these conditions must be eliminated prior to the continuation of the post-abatement testing procedures.

(ii) Following the visual inspection and any post-abatement cleanup required by paragraph (e)(8)(i) of this section, post-abatement sampling for lead in dust shall be conducted. Post-abatement sampling may be conducted by employing single-surface sampling or composite sampling techniques.

(iii) Dust samples for post-abatement testing purposes shall be taken using documented methodologies that incorporate adequate quality control procedures.

(iv) Dust samples for post-abatement testing purposes shall be taken a minimum of 1 hour after completion of final post-abatement cleanup activities.

(v) The following post-abatement testing activities shall be conducted as appropriate based upon the extent or manner of abatement activities conducted in or to the residential dwelling or child-occupied facility:

* * * * *

(vii) The certified inspector or risk assessor shall compare the residual lead level (as determined by the laboratory analysis) from each single surface dust sample with action levels in paragraph (e)(8)(viii) of this section for lead in dust on floors, interior window sills, and window troughs or from each composite dust sample with the applicable action levels for lead in dust on floors, interior window sills, and window troughs divided by half the number of subsamples in the composite sample. If the residual lead level in a single surface dust sample equals or exceeds the applicable action level or if the residual lead level in a composite dust sample equals or exceeds the applicable action level divided by half the number of subsamples in the composite sample, the components represented by the failed sample shall be recleaned and retested.

(viii) Before January 12, 2026, the action levels for lead in dust are 10 μg/ft² for floors, 100 μg/ft² for interior window sills, and 400 μg/ft² for window troughs. On or after January 12, 2026, the action levels for lead in dust are 5 μg/ft² for floors, 40 μg/ft² for interior window sills, and 100 μg/ft² for window troughs.

(9) In a multi-family dwelling with similarly constructed and maintained residential dwellings, random sampling for the purposes of post-abatement testing may be conducted provided:

* * * * *

(ii) A sufficient number of residential dwellings are selected for dust sampling to provide a 95 percent level of confidence that no more than 5 percent or 50 of the residential dwellings (whichever is smaller) in the randomly sampled population exceed the appropriate action levels.

(iii) The randomly selected residential dwellings shall be sampled and evaluated according to the post-abatement testing procedures found in paragraph (e)(8) of this section.

(10) * * *

(iv) The name, address, and signature of each certified risk assessor or inspector conducting post-abatement sampling and the date of sampling.

(v) The results of post-abatement dust-lead testing and all soil analyses (if applicable) and the name of each recognized laboratory that conducted the analyses.

* * * * *

(vii) On or after January 12, 2026, when post-abatement dust-lead testing results are below the dust-lead action levels and at or above the dust-lead reportable levels, a dust-lead hazard statement with the following language must be included:

Although the completed abatement project achieved dust-lead below action levels, some dust-lead hazards remain because any reportable level of dust-lead is considered a dust-lead hazard by the U.S. Environmental Protection Agency in a residential dwelling or child-occupied facility. In order for abatement work to be considered complete under EPA regulations, dust-lead levels must be below the action levels, which are established based on reliability, effectiveness and safety. To continue to reduce lead exposure from dust, the EPA pamphlet entitled *Protect Your Family From Lead in Your Home* includes recommendations such as: using a vacuum with a high-efficiency particulate air (HEPA) filter on furniture and other items returned to the work area, and regularly cleaning hard surfaces with a damp cloth or sponge and a general all-purpose cleaner. For more information on how to continue to reduce lead exposure, see *Protect Your Family From Lead in Your Home.*

* * * * *

(h) * * *

(2) * * *

(i) On any friction surface that is subject to abrasion and where the lead dust levels on the nearest horizontal surface underneath the friction surface (*e.g.,* the window sill or floor) are equal to or greater than the dust hazard levels identified in § 745.65(b);

* * * * *

(3) Dust-lead hazards and dust-lead action levels are identified for residential dwellings and child-occupied facilities as follows:

(i) Before January 12, 2026, a dust lead-hazard is present in a residential dwelling or child-occupied facility on floors and interior window sills when the weighted arithmetic mean lead loading for all single surface or composite samples of floors and interior window sills are equal to or greater than 10 μg/ft² for floors and 100 μg/ft² for interior window sills, respectively; for projects where post-abatement dust-lead testing is required or otherwise performed, levels of lead in dust must be below 10 μg/ft² for floors, 100 μg/ft² for interior window sills, and 400 μg/ft² for window troughs for purposes of the action levels; on or after January 12, 2026, a dust lead-hazard is present in a residential dwelling or child-occupied facility on floors and interior window sills when the lead loading for any single surface or composite sample of floors and interior window sills is equal to or greater than any reportable level of dust-lead for floors and for interior window sills; for projects where post-abatement dust-lead testing is required or otherwise performed, levels of lead in dust must be below 5 μg/ft² for floors, 40 μg/ft² for interior window sills, and 100 μg/ft² for window troughs for purposes of clearing the action level;

(ii) A dust lead-hazard is present on floors or interior window sills in an unsampled residential dwelling in a multi-family dwelling, if a dust-lead hazard is present on floors or interior window sills, respectively, in at least one sampled residential unit on the property (and, for projects where post-abatement dust-lead testing is required or otherwise performed, levels of lead in dust must be below the applicable value from paragraph (i) of this paragraph for purposes of the action levels); and

(iii) A dust lead-hazard is present on floors or interior window sills in an unsampled common area in a multi-family dwelling, if a dust-lead hazard is present on floors or interior window sills, respectively, in at least one sampled common area in the same common area group on the property (and, for projects where post-abatement dust-lead testing is required or otherwise performed, levels of lead in dust must be below the applicable value from paragraph (i) of this paragraph for purposes of the action levels).

* * * * *

■ 18. Amend § 745.238 by

■ a. Revising paragraphs (d)(1) and (2);

■ b. Removing paragraph (d)(3); and

■ c. Revising the introductory text of paragraph (e)(1) and (2).

The revisions read as follows:

§ 745.238 Fees for accreditation and certification of lead-based paint activities.

* * * * *

(d) * * *

(1) *Certification and re-certification.*

(i) *Individuals.* Submit a completed application electronically (titled ''Application for Individuals to Conduct Lead-based Paint Activities''), the materials described at § 745.226, and the application fee(s) described in paragraph (c) of this section.

(ii) *Firms.* Submit a completed application electronically (titled ''Application for Firms''), the materials described at § 745.226, and the application fee(s) described in paragraph (c) of this section.

(2) *Accreditation and re-accreditation.* Submit a completed application electronically (titled ''Accreditation Application for Training Programs''), the materials described at § 745.225, and the application fee described in paragraph (c) of this section.

(3) [Removed]

* * * * *

(e) * * *

(1) Parties seeking identification card or certificate replacement shall electronically complete the applicable portions of the appropriate application in accordance with the instructions provided. The appropriate applications are:

* * * * *

(2) Submit application and payment electronically in the amount specified in paragraph (c)(3) of this section in accordance with the instructions.

* * * * *

■ 19. Amend § 745.325 by revising paragraphs (d)(3)(ii) and (iii) to read as follows:

§ 745.325 Lead-based paint activities: State and Tribal program requirements.

* * * * *

(d) * * *

(3) * * *

(ii) Abatements permanently eliminate lead-based paint hazards, in the case of dust-lead hazards to below the action levels, and are conducted in a way that does not increase the hazards of lead-based paint to the occupants of the dwelling or child-occupied facility.

(iii) Abatements include post-abatement lead in dust sampling and conformance with the action levels established or adopted by the State or Indian Tribe.

* * * * *

[FR Doc. 2024–25070 Filed 11–8–24; 8:45 am]

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Part V

Department of Defense

General Services Administration

National Aeronautics and Space Administration

48 CFR Chapter 1

Federal Acquisition Regulations; Federal Acquisition Circular 2025–01; Introduction, Prohibition on Unmanned Aircraft Systems From Covered Foreign Entities, Clarification of System for Award Management Preaward Registration Requirements, and Small Entity Compliance Guide; Final Rules

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR–2024–0051, Sequence No. 6]

Federal Acquisition Regulation; Federal Acquisition Circular 2025–01; Introduction

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Summary presentation of interim rules.

SUMMARY: This document summarizes the Federal Acquisition Regulation (FAR) rules agreed to by the Civilian Agency Acquisition Council and the Defense Acquisition Regulations Council (Councils) in this Federal Acquisition Circular (FAC) 2025–01. A companion document, the *Small Entity Compliance Guide* (SECG), follows this FAC.

DATES: For effective dates see the separate documents, which follow.

ADDRESSES: The FAC, including the SECG, is available at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: The analyst whose name appears in the table below in relation to the FAR case. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.*

RULES LISTED IN FAC 2025–01

Item	Subject	FAR case	Analyst
I	Prohibition on Unmanned Aircraft Systems from Covered Foreign Entities	2024–002	Collins.
II	Clarification of System for Award Management Preaward Registration Requirements	2023–018	Collins.

SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these FAR rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2025–01 amends the FAR as follows:

Item I—Prohibition on Unmanned Aircraft Systems From Covered Foreign Entities (FAR Case 2024–002)

This interim rule amends the FAR to implement a prohibition on procuring, operating, or using Federal funds on, unmanned aircraft systems (*e.g.,* drones) that are manufactured or assembled by an American Security Drone Act-covered foreign entity. This rule implements the American Security Drone Act of 2023 (subtitle B, title XVIII of the National Defense Authorization Act for Fiscal Year 2024, Pub. L. 118–31, 41 U.S.C. 3901 note prec.). This rule applies to all solicitations and contracts, including contracts at or below the micro-purchase threshold and to contracts for commercial products (including commercially available off-the-shelf items) or for commercial services. The change is not expected to have a significant economic impact on a substantial number of small entities. This interim rule is being implemented as a national security measure to protect sensitive Government information and operations.

Item II—Clarification of System for Award Management Preaward Registration Requirements (FAR Case 2023–018)

This interim rule amends the FAR to clarify System for Award Management preaward registration requirements. Offerors are required to be registered at the time of proposal submission and at time of award, rather than continuously in between. This change is expected to have a positive impact on small businesses who have a minor lapse in registration.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Federal Acquisition Circular (FAC) 2025–01 is issued under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator of National Aeronautics and Space Administration.

Unless otherwise specified, all Federal Acquisition Regulation (FAR) and other directive material contained in FAC 2025–01 is effective November 12, 2024.

John M. Tenaglia,

Principal Director, Defense Pricing, Contracting, and Acquisition Policy, Department of Defense.

Jeffrey A. Koses,

Senior Procurement Executive/Deputy CAO, Office of Acquisition Policy, U.S. General Services Administration.

Marvin L. Horne,

Deputy Assistant Administrator for Procurement, National Aeronautics and Space Administration.

[FR Doc. 2024–26060 Filed 11–8–24; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 4, 13, 39, 40, and 52

[FAC 2025–01, FAR Case 2024–002, Item I, Docket No. 2024–0002, Sequence No. 1]

RIN 9000–AO70

Federal Acquisition Regulation: Prohibition on Unmanned Aircraft Systems From Covered Foreign Entities

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Interim rule.

SUMMARY: DoD, GSA, and NASA are issuing an interim rule amending the Federal Acquisition Regulation (FAR) to implement a prohibition on the procurement and operation of unmanned aircraft systems manufactured or assembled by an American Security Drone Act-covered foreign entity.

DATES:

Effective date: November 12, 2024.

Applicability date: Contracting officers shall include the clause at FAR 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities, in solicitations issued, and contracts awarded, on or after November 12, 2024, in accordance with FAR 1.108(d); see also section II of this preamble.

Comment date: Interested parties should submit written comments to the Regulatory Secretariat Division at the address shown below on or before January 13, 2025, to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAC 2025–01, FAR Case 2024–002 to the Federal eRulemaking portal at *https://www.regulations.gov* by searching for ''FAR Case 2024–002''. Select the link ''Comment Now'' that corresponds with ''FAR Case 2024–002''. Follow the instructions provided on the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2024–002'' on your attached document. If your comment cannot be submitted using *https://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 ''FAR Case 2024–002'' in all correspondence related to this case. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. Public comments may be submitted as an individual, as an organization, or anonymously (see frequently asked questions at *https://www.regulations.gov/faq*). To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two-to-three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Mr. Benjamin Collins, Procurement Analyst, at 850–826–0058 or by email at *benjamin.collins@gsa.gov.* For information pertaining to status, publication schedules, or alternate instructions for submitting comments if *https://www.regulations.gov* cannot be used, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAC 2025–01, FAR Case 2024–002.

SUPPLEMENTARY INFORMATION:

I. Background

This interim rule revises the FAR to implement the American Security Drone Act of 2023 (subtitle B, title XVIII, National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2024, Public Law 118–31, 41 U.S.C. 3901 note prec.) enacted December 22, 2023.

The unmanned aircraft system (UAS), also referred to as a drone, market has grown substantially in the last decade. Federal agencies use UAS for land-use research, data collection, monitoring the border, and various other tasks. Reliance on UAS, however, complicates the ability of the Federal Government to protect the security of this data, in part because the majority of UAS are manufactured and assembled by foreign-owned entities with affiliations that have divergent interests from those of the United States. Security is imperative when data is collected, stored, and transmitted by UAS for sensitive missions. Use of UAS, without adequate protection for security, increases adversaries' capabilities to disrupt U.S. Government operations. Compromises to cybersecurity and physical security controls may lead to potential physical effects such as sabotage of Federal property and assets.

This interim rule is intended to respond to these threats by prohibiting the procurement, operation, or use of Federal funds on UAS prohibited by the Federal Acquisition Security Council (FASC).

II. Applicability Dates

Contracting officers shall include the clause at FAR 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities, in solicitations issued, and contracts awarded, on or after November 12, 2024.

If exercising an option or modifying an existing contract to extend the period of performance, contracting officers shall include the clause at FAR 52.240–1. When exercising an option, agencies should consider modifying the existing contract to add the clause in a sufficient amount of time to both provide notice for exercising the option and provide contractors with adequate time to comply with the clause. Additionally, contracting officers shall modify existing indefinite-delivery contracts to include the clause at FAR 52.240–1 in sufficient amount of time to apply to future orders in accordance with FAR 1.108(d)(3).

Note: Although FAR part 37, Service Contracting, is not addressed explicitly, the FAR changes are applicable to supply and service solicitations and contracts.

III. Discussion and Analysis

DoD, GSA, and NASA are amending the FAR consistent with the American Security Drone Act of 2023 (the Act) to prohibit executive agencies from procuring a FASC-prohibited UAS and, on or after December 22, 2025, operating FASC-prohibited UAS. Additionally, the FAR is amended consistent with the Act to prohibit Federal contractors from using Federal funds for the procurement or operation of a FASC-prohibited UAS.

Terminology used throughout this rule is described here to aid in readability. For the purposes of this rule, the term ''FASC-prohibited unmanned aircraft system (UAS)'' means a UAS manufactured or assembled by an American Security Drone Act-covered foreign entity. In accordance with section 1822 of the Act, the list of American Security Drone Act-covered foreign entities is to be developed and maintained by the FASC and published in the System for Award Management (SAM) at *https://www.sam.gov.*

Additionally, the FAR and other agency acquisition regulations include instances of similar terms to those used in the Act (''covered foreign country,'' ''covered entity,'' etc.) with definitions corresponding to other statutes (*e.g.,* section 889 of the NDAA for FY 2019, section 848 of the NDAA for FY 2020, section 1634 of the NDAA for FY 2018). These terms may be inadvertently confused with the specific prohibited sources addressed by the Act implemented in this rule. Thus, while this rule uses the term ''covered foreign entity'' in titles of sections and clauses for brevity and parallelism to the Act, it more specifically refers to ''American Security Drone Act-covered foreign entity'' in this preamble and FAR text for clarity.

Finally, while the Act refers to ''covered'' UAS, the definition provided in the Act does not differentiate from that of a UAS. Accordingly, to aid in readability and clarity there is no reference to ''covered'' UAS, but simply UAS.

A. Policy

This rule amends FAR part 40, Information Security and Supply Chain

Security, by establishing subpart 40.2, currently reserved, as Security Prohibitions and Exclusions. In subpart 40.2, the rule adds new sections 40.200, Scope of subpart, 40.201, Definitions, and 40.202, Prohibition on the Procurement and Operation of Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities, with a corresponding new contract clause at 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities. In accordance with section 1833 of Public Law 118–31, 41 U.S.C. 3901 note prec., the requirements of section 40.202 expire on December 22, 2028.

The rule adds a cross-reference in part 39, Acquisition of Information Technology, to call the attention of contracting officers potentially utilizing UAS in broader information technology procurements to the new prohibition. This rule also adds a cross-reference in part 13, Simplified Acquisition Procedures, for awareness of applicability to actions at or below the micro-purchase threshold. Finally, while this prohibition is established in subpart 40.2 as this is the intended primary location for security prohibitions and exclusions going forward, other security prohibitions and exclusions still reside in other areas of the FAR. Accordingly, a cross-reference is added in FAR part 4, Information and Information Matters, where many of the existing security prohibitions and exclusions reside.

B. Prohibition

The prohibition at FAR 40.202–4 includes a phased implementation. Effective immediately, agencies are prohibited from procuring a FASC-prohibited UAS, as published in SAM at *https://www.sam.gov.* Effective on or after December 22, 2025, agencies are also prohibited from procuring services for the operation of a FASC-prohibited UAS, and Federal contractors are prohibited from using Federal funds on FASC-prohibited UAS (see 40.202–3). The prohibitions are implemented through contract clause 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities.

In the near-term, the phased prohibition permits the continued use of previously-acquired UAS that were subsequently identified as FASC-prohibited, as well as contractor operation of UAS in services where the UAS is not a deliverable (*e.g.,* a contractor flies a UAS for aerial surveillance on a security contract or a contractor uses a UAS for analyzing crop and soil conditions as part of services performed under an agriculture-related contract). This is consistent with the effectivity of the prohibition in sections 1823 and 1826 of Public Law 118–31 (41 U.S.C. 3901 note prec.), with the enactment of the NDAA of FY 2024 (December 22, 2023) and the effectivity of sections 1824 and 1825 deferred until two years later (December 22, 2025).

C. Statute Implementation Considerations

The Act includes numerous sections pertaining to Federal acquisition. The sections include differing scope, timelines, and audiences. For example, both sections 1823 and 1826 immediately prohibit agencies from procuring FASC-prohibited UAS, whereas section 1824 goes into effect in December 2025 and prohibits agencies from operating (or contracting for the operation of) FASC-prohibited UAS. Section 1825 also goes into effect December 2025 and prohibits the use of Federal funds for the procurement or operation of FASC-prohibited UAS.

While piecemeal implementation of the various sections could be accommodated through numerous rulemaking undertakings, a consolidated and integrated rule for the implementation of the Act, as a whole, more efficiently fulfills the FAR's purpose of establishing uniform policies and procedures for acquisition by all executive agencies in accordance with FAR 1.101 (see 41 U.S.C. 1121(b)). For example, while the prohibition on operation of a FASC-prohibited UAS is not effective until December 2025, publishing and incorporating the rule into the FAR now better prepares agencies and contractors to more efficiently plan for, and comply with, the Act's prohibitions given typical acquisition and rulemaking timelines.

This rule seeks to harmonize and simplify the disparate, but interrelated, sections of the Act pertinent to Federal contracting. Thus, while precise references are provided where appropriate, the rule often speaks more broadly to the Act versus a specific section of the Act. Additionally, a few conservative adjustments between statute and regulation were made where needed for more efficient administration. For example, the statute's frequently used ''in the connection with the operation of'' a FASC-prohibited UAS was implemented more simply as ''operation of.'' While ''in connection with'' could conceivably capture an activity ancillary to operation (*e.g.,* a contractor servicing the airfield where a FASC-prohibited UAS may fly out of), it is unclear how far that may extend. DoD, GSA, and NASA perceived the principal aim of this terminology to be the operation of a FASC-prohibited UAS. This perception was based upon a plain reading of the statute as well as supporting documentation, such as the Committee on Homeland Security and Governmental Affairs United States Senate Report 118–87 to accompany Senate bill 473, which more simply focused on the prohibition on the ''operation of'' the UAS versus the less defined ''in connection with the operation of'' a UAS. This implementation was viewed as not only a readability improvement but also a streamlining of an otherwise unwieldy and open-ended phrase that may inhibit understanding and compliance by the acquisition community.

D. Exemptions, Exceptions, and Waivers

The Act includes exemptions, exceptions, and waivers. As shown at FAR 40.202–4(a), exemptions apply to the Department of Homeland Security, the Department of Defense, the Department of State, and the Department of Justice if the procurement or operation is determined to be in the national interest of the United States and meets specific criteria outlined in the statute.

Exemptions also apply to the Department of Transportation for UAS in support of the safe, secure, or efficient operation of the National Airspace System and maintenance of public safety, among other activities. These exemptions are summarized in FAR 40.202–4(b).

Similarly, an exemption applies to the National Transportation Safety Board (NTSB) for the purposes of conducting safety investigations. This exemption is summarized in FAR 40.204–4(c). It should be noted that while Congress authorized this NTSB safety investigation exemption for agency procurement and operation (sections 1823 and 1824 of the Act), it did not provide a parallel NTSB safety investigation exemption for use of Federal funds (section 1825). Thus, for purposes of consistency in implementation, and to carry out the intent of Congress, the FAR Council has conformed the NTSB safety investigation exemption for not only agency procurement and operation, but also contractor use of Federal funds.

Finally, an exemption is afforded to the National Oceanic and Atmospheric Administration for meeting science or

management objectives or operational mission. This exemption is summarized in FAR 40.202–4(d).

In accordance with section 1832 of the Act, FAR 40.202–5 outlines exceptions for wildfire management operations, search and rescue operations, intelligence activities, and Tribal law enforcement. Additionally, FAR 40.202–6 authorizes heads of executive agencies waiver authority, on a case-by-case basis, with approval from the Director of the Office of Management and Budget, after consultation with the FASC, and upon notification to appropriate congressional committees.

E. Definitions

Section 40.201 is created to define the terms ''American Security Drone Act-covered foreign entity,'' ''unmanned aircraft,'' and ''unmanned aircraft system,'' which are derived from statute. A UAS is comprised of both an unmanned aircraft and the associated elements required for the operator to operate safely and efficiently in the national airspace system. Also of note, while the term ''drone'' is used in the title of the statute being implemented, it is not a defined term in the Act or this rule. Nevertheless, ''drone'' is referenced for plain language purposes in several instances and is considered roughly equivalent to ''unmanned aircraft'' (*i.e.,* the air vehicle itself versus the more comprehensive system required to operate the drone). While the term ''unmanned aircraft'' is defined in statute and provided in section 40.201, the term ''associated elements'' is not.

Section 1823 of the Act tasks the FASC, in coordination with the Secretary of Transportation, with developing and updating a list of associated elements. The FASC definition of associated elements was not available in time for the publication of this rule. However, the FAR Council does intend to incorporate the FASC's definition of associated elements in the final rule. Additionally, although the tasking to the FASC for defining associated elements is only referenced in section 1823, the FAR Council anticipates it applying to the broader implementation of the Act (*e.g.,* pertinent to sections 1824, 1825, 1826, etc.).

The term ''FASC-prohibited unmanned aircraft system'' is created to aid in the readability of the FAR text, provide better linkage to FASC-maintained list on SAM.gov, and provide for more specificity than simply ''prohibited'' given other prohibitions that may be involved in a specific acquisition (*e.g.,* debarred contractor, contractor with delinquent tax liabilities or felony convictions). This new term is defined as a UAS manufactured or assembled by an American Security Drone Act-covered foreign entity.

It should also be noted that while the prohibition clearly applies to an American Security Drone Act-covered foreign entity that manufactures or assembles a UAS (*i.e.,* an unmanned aircraft or associated element), it does not necessarily prevent an American Security Drone Act-covered foreign entity from supplying a part, for example, that may be used by another entity to assemble or manufacture the unmanned aircraft or associated element. Agencies are encouraged to consult agency-specific guidelines or procedures, as well as emerging Governmentwide policies for the procurement of UAS (see section 1829 of the Act), for more detail on security considerations at levels of assembly below that of a UAS (*i.e.,* an unmanned aircraft or associated element).

F. Applicability to Actions at or Below the Micro-Purchase Threshold

The rule also adds text in subpart 13.2, Actions at or Below the Micro-Purchase Threshold, to address the prohibition with regard to micro-purchases.

IV. Specific Questions for Comment

DoD, GSA, and NASA considered implementation of various compliance elements when drafting this rule. Specifically, DoD, GSA, and NASA are considering adding requirements for offerors and contractors to disclose and report certain information to contracting officers.

A contemplated disclosure requirement would provide offerors a mechanism for identifying the proposed or contemplated delivery or use of a FASC-prohibited UAS to the contracting officer, and why it may be appropriate (*e.g.,* how a FASC-prohibited UAS is proposed to be modified to preclude transfer to, or download data from, an American Security Drone Act-covered foreign entity or otherwise pose no national security or cybersecurity risk).

Finally, a contemplated reporting requirement would compel contractors in procurements with no exemption, exception, or waiver to maintain awareness of changes to the FASC-maintained list of American Security Drone Act-covered foreign entities and inform the contracting officer if a utilized UAS which was not prohibited at the time of solicitation or award was subsequently prohibited. Additionally, contemplated reporting requirements could compel contractors to report specific information to agency officials if a UAS (FASC-prohibited or otherwise) was compromised and information or operations made vulnerable.

DOD, GSA, and NASA welcome input on the following considerations:

- What challenges do you anticipate regarding compliance with the contemplated disclosure requirement?
- What challenges do you anticipate regarding compliance with the contemplated reporting requirement?
- Would more detail regarding ''Federal funds'' (*e.g.,* text similar to FAR 52.203–12(b)) be helpful in complying with the prohibition on the use of Federal funds in the procurement or operation of FASC-prohibited UAS?
- What other suggestions do you have to ensure Government customers are aware of, and can mitigate, risks posed by FASC-prohibited UAS?

V. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items), or for Commercial Services

This rule adds a new contract clause at FAR 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities, to implement the requirements of the Act.

A. Applicability to Contracts at or Below the Simplified Acquisition Threshold

The statute at 41 U.S.C. 1905 governs the applicability of laws to acquisitions at or below the SAT. Section 1905 generally limits the applicability of new laws when agencies are making acquisitions at or below the SAT, but provides that such acquisitions will not be exempt from a provision of law under certain circumstances, including when the FAR Council makes a written determination and finding that it would not be in the best interest of the Federal Government to exempt contracts and subcontracts in amounts not greater than the SAT from the provision of law. The FAR Council made a determination to apply this statute to acquisitions at or below the SAT.

B. Applicability to Contracts for the Acquisition of Commercial Products (Including Commercially Available Off-The-Shelf (COTS) Items), or for Commercial Services

The statute at 41 U.S.C. 1906 governs the applicability of laws to contracts for the acquisition of commercial products and commercial services and is intended to limit the applicability of

laws to contracts for the acquisition of commercial products and commercial services. Section 1906 provides that if the FAR Council makes a written determination that it is not in the best interest of the Federal Government to exempt commercial contracts, the provision of law will apply to contracts for the acquisition of commercial products and commercial services.

The statute at 41 U.S.C. 1907 states that acquisitions of COTS items will be exempt from certain provisions of law unless the Administrator for Federal Procurement Policy makes a written determination and finds that it would not be in the best interest of the Federal Government to exempt contracts for the procurement of COTS items.

The FAR Council made a determination to apply this statute to acquisitions for commercial products and commercial services. The Administrator for Federal Procurement Policy made a determination to apply this statute to acquisitions for COTS items.

C. Determinations

The FAR Council has determined that it is in the best interest of the Government to apply the rule to contracts at or below the SAT and for the acquisition of commercial products and commercial services. The Administrator for Federal Procurement Policy has determined that it is in the best interest of the Government to apply this rule to contracts for the acquisition of COTS items.

While the law does not specifically address acquisitions of commercial products and commercial services, including COTS items, there is an unacceptable level of risk for the Government in allowing the procurement, provision, or utilization of UAS manufactured or assembled by an American Security Drone Act-covered foreign entity, or products or services in connection with the operation of such UAS. This level of risk is not alleviated by the fact that the service or product being acquired has been sold or offered for sale to the general public, either in the same form or a modified form as sold to the Government (*i.e.,* that it is a commercial product or COTS item), nor by the small size of the purchase (*i.e.,* at or below the SAT). In fact, Senate Report 118–87 specifically highlights the commercial UAS market as an area of concern given market share dominance and potential cybersecurity risks posed by many of these COTS UAS. As a result, agencies may face increased risk of exposure if use of such UAS is allowed on a contract for commercial services or commercial products (including COTS items). The prohibitions on procuring, providing, or using such UAS in the performance of a Federal contract is a national security measure to protect sensitive Government information and operations.

VI. Severability

While this rule is intended to be implemented in full, reasoned consideration has been given for potential partial implementation scenarios. If any portion (*e.g.,* section, clause, sentence) of this rule is held to be invalid or unenforceable facially, or as applied to any entity or circumstance, it shall be severable from the remainder of this rule, and shall not affect the remainder thereof, or its application to entities not similarly situated or to other dissimilar circumstances. The various portions of this rule are independent and serve distinct purposes. Even if one aspect were rendered invalid, the other benefits of the rule would still be applicable. As an illustrative but not exhaustive example, were a court to stay or invalidate the prohibition on the operation of a FASC-prohibited UAS effective December 22, 2025, the agencies would intend the prohibition on the procurement of a FASC-prohibited UAS would remain effective.

VII. Expected Impact of the Rule

This rule is not expected to have a significant economic impact on businesses. Federal expenditure in the sector is expected to remain largely unchanged. The Congressional Budget Office cost estimate for the Act estimated any net changes in spending would be less than $500,000 over the 2024 to 2033 period. While the prohibitions on procurement, operation, and use of funds may drive further change to the UAS supplier base for the Federal Government, that change is already underway across numerous agencies. Alternative suppliers exist and continue to emerge.

Additionally, while the changes require Federal agencies and prime contractors engaged in the use of UAS to further scrutinize their sources of supply, the fundamental tools for supply chain awareness and security should be in place and largely unchanged.

The overall benefit of this rule is to protect Government information and operations from vulnerabilities associated with FASC-prohibited UAS.

VIII. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 (as amended by E.O. 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 is a significant regulatory action and, therefore, was subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

IX. Congressional Review Act

Pursuant to the Congressional Review Act, DoD, GSA, and NASA will send this rule to each House of the Congress and to the Comptroller General of the United States. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget has determined that this rule does not meet the definition in 5 U.S.C. 804(2).

X. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this interim rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601–612. Nevertheless, an Initial Regulatory Flexibility Analysis (IRFA) has been performed and is summarized as follows:

DoD, GSA, and NASA are amending the FAR to implement the prohibition on procuring, operating, or using Federal funds on, UAS that are manufactured or assembled by an American Security Drone Act-covered foreign entity.

This interim rule is being implemented as a national security measure to protect sensitive Government information and operations. The legal basis for the rule is the American Security Drone Act of 2023 (subtitle B, title XVIII of the NDAA for FY 2024, Pub. L. 118–31, 41 U.S.C. 3901 note prec.), which prohibits procurement and operation of UAS manufactured or assembled by American Security Drone Act-covered foreign entities, as well as contractor use of Federal funds on such UAS. Promulgation of the FAR is authorized by 40 U.S.C. 121(c); 10 U.S.C. chapter 4 and 10 U.S.C. chapter 137 legacy provisions (see 10 U.S.C. 3016); and 51 U.S.C. 20113.

This rule applies to entities, small and other than small entities, that provide to Government agencies UAS and on or after December 22, 2025, operation of a UAS. While drones may be used in many types of contracts, a specific Product and Service Code (PSC), 1550—Unmanned Aircraft, is available for contracting officers to explicitly identify procurements for unmanned aircraft. PSC 1550 applies to complete unmanned aircraft systems and subordinate air vehicles and includes unmanned aircraft systems and

drones specifically designed for uses such as targeting, training, surveillance, photographic reconnaissance, weapons delivery, communications relay/network gateway, electronic warfare, search and rescue, and various other operations. According to Federal Procurement Data System (FPDS) data for FY 2023, 100 unique entities were awarded Federal contracts under PSC 1550, with a total contract value of $2,411,790,985. Small entities accounted for less than 10 percent of the contracted dollar value ($218 million of the $2.4 billion) but constituted 68 percent of the unique entities. Based on this dataset, approximately 68 small entities would be impacted by this rule.

The rule does not include any reporting or recordkeeping requirements. Other compliance requirements are not expected to carry significant burden. Small entities that do business with the Federal Government should be familiar with other similar prohibitions, including the Federal Acquisition Supply Chain Security Act Orders, which function in a comparable manner. Based upon FPDS data for PSC 1550 in FY 2023, all 68 small entities awarded contracts were incorporated in the United States and 65 of the 68 indicated the United States as the country of product or service origin and 64 of the 68 indicated the United States as the place of manufacture. While place of manufacture is not the sole factor in the FASC's determination of American Security Drone Act-covered foreign entities, it is a significant factor. Accordingly, while small entities conducting drone-related business with the Federal Government will need to familiarize themselves with the new clause at 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act-Covered Foreign Entities, relatively limited impact is anticipated to the Federal contract small entity industrial base.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no available alternatives to the interim rule to accomplish the desired objective of the statute. Because of the nature of the prohibition enacted by the American Security Drone Act of 2023, it is not possible to exempt small entities from coverage of the rule.

The Regulatory Secretariat Division has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat Division. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this interim rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2024–002), in correspondence.

XI. Paperwork Reduction Act

This rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501–3521).

XII. Determination To Issue an Immediately Effective Interim Rule

A determination has been made under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator of the National Aeronautics and Space Administration that urgent and compelling reasons exist to promulgate this interim rule effective immediately without prior opportunity for public comment, see 41 U.S.C. 1707(d). This action is necessary to implement the prohibition in the American Security Drone Act of 2023 (the Act) on the procurement of unmanned aircraft systems (UAS) prohibited by the Federal Acquisition Security Council (FASC) that was effective with the enactment of the National Defense Authorization Act (NDAA) for Fiscal Year (FY) 2024 (Pub. L. 118–31, 41 U.S.C. 3901 note prec.) on December 22, 2023, in accordance with sections 1823 and 1826.

Sections 1824 and 1825 of the Act also require implementation through the FAR, although the associated prohibitions are not effective until two years after the enactment of the NDAA for FY 2024, or December 22, 2025. Section 1824 prohibits the operation of FASC-prohibited UAS, and section 1825 prohibits the use of Federal funds on FASC-prohibited UAS. Despite the deferred effectivity, the Act requires the Federal Acquisition Regulatory Council to prescribe regulations or guidance necessary for implementation of section 1825 within 180 days of the enactment of the NDAA for FY 2024.

This interim rule is being implemented as a national security measure to protect sensitive Government information and operations. Issuing an immediately effective interim rule facilitates uniformity and consistency across Government, limits the chance of incorrect implementation, prevents the need for contracting officers to relearn or change procedures if agency-specific guidance differs from the FAR implementation, and aids industry with compliance. However, pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), the Department of Defense, General Services Administration, and National Aeronautics and Space Administration will consider public comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 48 CFR Parts 4, 13, 39, 40, and 52

Government procurement.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR parts 4, 13, 39, 40, and 52 as set forth below:

■ 1. The authority citation for 48 CFR parts 4, 13, 39, 40, and 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 4 and 10 U.S.C. chapter 137 legacy provisions (see 10 U.S.C. 3016); and 51 U.S.C. 20113.

PART 4—ADMINISTRATIVE AND INFORMATION MATTERS

■ 2. Revise section 4.000 to read as follows:

4.000 Scope of part.

(a) This part prescribes policies and procedures relating to the administrative aspects of contract execution, contractor-submitted paper documents, distribution, reporting, retention, and files.

(b) Additionally, this part includes policies and procedures to implement security prohibitions and exclusions that restrict Federal agencies from procuring, obtaining, or using certain products, services, or sources. Additional security prohibitions and exclusions are found at subparts 25.7 and 40.2.

PART 13—SIMPLIFIED ACQUISITION PROCEDURES

■ 3. Amend section 13.201 by adding paragraph (m) to read as follows:

13.201 General.

* * * * *

(m) The prohibitions on unmanned aircraft systems (*e.g.,* drones) in 40.202 apply to purchases at or below the micro-purchase threshold.

PART 39—ACQUISITION OF INFORMATION TECHNOLOGY

■ 4. Amend section 39.101 by adding paragraph (i) to read as follows:

39.101 Policy.

* * * * *

(i) Executive agencies must comply with the prohibitions on unmanned aircraft systems (*e.g.,* drones) in accordance with 40.202.

PART 40—INFORMATION SECURITY AND SUPPLY CHAIN SECURITY

■ 5. Add subpart 40.2 to read as follows:

Subpart 40.2—Security Prohibitions and Exclusions

Sec.
40.200 Scope of subpart.
40.201 Definitions.
40.202 Prohibition on the procurement and operation of unmanned aircraft systems manufactured or assembled by American Security Drone Act-covered foreign entities.
40.202–1 Scope.
40.202–2 Applicability.
40.202–3 Prohibition.
40.202–4 Exemptions.
40.202–5 Exceptions.
40.202–6 Waivers.
40.202–7 Procedures.
40.202–8 Contract clause.

Subpart 40.2—Security Prohibitions and Exclusions

40.200 Scope of subpart.

(a) This subpart provides policies and procedures to implement security prohibitions and exclusions that restrict Federal agencies from procuring, obtaining, or using certain products, services, or sources.

(b) The following prohibitions and exclusions are implemented in this subpart:

(1) The American Security Drone Act of 2023, of the National Defense Authorization Act for Fiscal Year 2024 (Pub. L. 118–31, 41 U.S.C. 3901 note prec.), which provides a prohibition on the procurement and operation of unmanned aircraft systems.

(2) [Reserved]

(c) Additional security prohibitions and exclusions are found at subparts 4.20 through 4.23 and 25.7.

40.201 Definitions.

As used in this subpart—

American Security Drone Act-covered foreign entity means an entity included on a list developed and maintained by the Federal Acquisition Security Council (FASC) and published in the System for Award Management (SAM) at *https://www.sam.gov* (section 1822 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

FASC-prohibited unmanned aircraft system means an unmanned aircraft system manufactured or assembled by an American Security Drone Act-covered foreign entity.

Unmanned aircraft means an aircraft that is operated without the possibility of direct human intervention from within or on the aircraft (49 U.S.C. 44801(11)).

Unmanned aircraft system means an unmanned aircraft and associated elements (including communication links and the components that control the unmanned aircraft) that are required for the operator to operate safely and efficiently in the national airspace system (49 U.S.C. 44801(12)).

40.202 Prohibition on the procurement and operation of unmanned aircraft systems manufactured or assembled by American Security Drone Act-covered foreign entities.

40.202–1 Scope.

(a) Section 40.202 prescribes policies and procedures regarding the procurement and operation of unmanned aircraft systems, which includes unmanned aircraft (*i.e.,* drones) and associated elements.

(b) The authorities in 40.202 expire on December 22, 2028 (section 1833 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

40.202–2 Applicability.

Section 40.202 applies to all acquisitions, including contracts at or below the micro-purchase threshold and to contracts for commercial products or for commercial services.

40.202–3 Prohibition.

Unless an exemption, exception, or waiver applies (see 40.202–4, 40.202–5, and 40.202–6, respectively), executive agencies are prohibited from—

(a) Procuring a FASC-prohibited unmanned aircraft system (section 1823 and 1826 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.). The prohibition includes extending or renewing a contract (*e.g.,* exercising an option);

(b) On or after December 22, 2025, procuring services for the operation of a FASC-prohibited unmanned aircraft system (section 1824 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.). The prohibition includes extending or renewing a contract (*e.g.,* exercising an option); and

(c) On or after December 22, 2025, using Federal funds for the procurement or operation of a FASC-prohibited unmanned aircraft system (section 1825 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

40.202–4 Exemptions.

The prohibitions in 40.202 do not apply to the following (see sections 1823, 1824, and 1825 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.):

(a) *Department of Homeland Security, Department of Defense, Department of State, and the Department of Justice exemptions.* The Secretary of Homeland Security, the Secretary of Defense, the Secretary of State, and the Attorney General are exempt from the prohibitions in 40.202 if the procurement or operation is required in the national interest of the United States and—

(1) Is for the sole purposes of research, evaluation, training, testing, or analysis for electronic warfare, information warfare operations, cybersecurity, or development of unmanned aircraft system or counter-unmanned aircraft system technology;

(2) Is for the sole purposes of conducting counterterrorism or counterintelligence activities, protective missions, or Federal criminal or national security investigations, including forensic examinations, or for electronic warfare, information warfare operations, cybersecurity, or development of an unmanned aircraft system or counter-unmanned aircraft system technology; or

(3) Is an unmanned aircraft system that, as procured or as modified after procurement but before operational use, can no longer transfer to, or download data from, an American Security Drone Act-covered foreign entity and otherwise poses no national security cybersecurity risks as determined by the exempting official, as described in agency procedures.

(b) *Department of Transportation exemption.* The Secretary of Transportation is exempt from the prohibitions in 40.202 if the operation or procurement is deemed to support the safe, secure, or efficient operation of the National Air Space System or maintenance of public safety.

(c) *National Transportation Safety Board exemption.* The National Transportation Safety Board, in consultation with the Secretary of Homeland Security, is exempt from the prohibitions in 40.202 if the operation or procurement is necessary for the sole purpose of conducting safety investigations.

(d) *National Oceanic and Atmospheric Administration (NOAA) exemption.* The Administrator of NOAA, in consultation with the Secretary of Homeland Security, is exempt from the prohibitions of 40.202 if the operation or procurement for the purposes of meeting NOAA's science or management objectives or operational mission.

40.202–5 Exceptions.

The prohibitions in this section do not apply to the following (section 1832 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.):

(a) *Wildfire management operations and search and rescue operations exception.* The prohibitions in 40.202

do not apply to an appropriate Federal agency to the extent that an authorized official at the agency, in consultation with the Secretary of Homeland Security, determines that the procurement or operation is necessary for the purposes of supporting the full range of wildfire management operations or search and rescue operations.

(b) *Intelligence activities exception.* The prohibitions of 40.202 do not apply to any activity subject to the reporting requirements under title V of the National Security Act of 1947 (50 U.S.C. 3091 *et seq.*), any authorized intelligence activities of the United States, or any activity or procurement that supports an authorized intelligence activity.

(c) *Tribal law enforcement or emergency service agency exception.* The prohibitions in 40.202 do not apply to Tribal law enforcement or Tribal emergency service agencies to the extent that an authorized official at the agency, in consultation with the Secretary of Homeland Security, determines that the procurement or operation is necessary for the purposes of supporting the full range of law enforcement operations or search and rescue operations on Indian lands.

40.202–6 Waivers.

The head of the agency may waive the prohibitions under 40.202 on a case-by-case basis in accordance with agency procedures and based on the statutory waiver provisions (sections 1823, 1824, and 1825 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.)—

(a) With the approval of the Director of the Office of Management and Budget, after consultation with the FASC; and

(b) Upon notification to—

(1) The Committee on Homeland Security and Governmental Affairs of the Senate;

(2) The Committee on Oversight and Accountability in the House of Representatives; and

(3) Other appropriate congressional committees of jurisdiction.

40.202–7 Procedures.

(a) *Documenting exemptions, exceptions, or waivers.* The contracting officer shall document the file with any exemption, exception, or waiver provided by the program office or requiring activity. Additionally, the contracting officer shall work with the program office or requiring activity to ensure the presence and scoping of any such exemptions, exceptions, or waivers are identified in the solicitation and resultant contract.

(b) *Assessment of unmanned aircraft systems.* Except where an exemption, exception, or waiver applies, the contracting officer shall work with the program office or requiring activity to review proposals to ensure they are not proposing delivery of a FASC-prohibited unmanned aircraft system. On or after December 22, 2025, this assessment shall expand to include review for not only proposed delivery, but also operation, of a FASC-prohibited unmanned aircraft system.

40.202–8 Contract clause.

Insert the clause at 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act—Covered Foreign Entities, in all solicitations and contracts.

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 6. Amend section 52.212–5 by—

■ a. Revising the date of the clause;

■ b. Redesignating paragraphs (b)(63) and (64) as paragraphs (b)(64) and (65) and adding a new paragraph (b)(63);

■ c. Redesignating paragraph (e)(1)(xxvi) as paragraph (e)(1)(xxvii) and adding a new paragraph (e)(1)(xxvi); and

■ d. In alternate II:

■ i. Revising the date of the alternate; and

■ ii. Redesignating paragraph (e)(1)(ii)(Y) as paragraph (e)(1)(ii)(Z) and adding a new paragraph (e)(1)(ii)(Y).

The additions and revisions read as follows:

52.212–5 Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services.

* * * * *

Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services (Nov 2024)

* * * * *

(b) * * *

__(63) 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act—Covered Foreign Entities (Nov 2024) (Sections 1821–1826, Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

* * * * *

(e)(1) * * *

(xxvi) 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act—Covered Foreign Entities (Nov 2024) (Sections 1821–1826, Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

* * * * *

Alternate II (Nov 2024).* * *

(e)(1) * * *

(ii) * * *

(Y) 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act—Covered Foreign Entities (Nov 2024) (Sections 1821–1826, Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

* * * * *

■ 7. Amend section 52.213–4 by—

■ a. Revising the date of the clause and paragraph (a)(2)(vii); and

■ b. Redesignating paragraph (b)(1)(xxii) as paragraph (b)(1)(xxiii) and adding a new paragraph (b)(1)(xxii).

The revisions and addition read as follows:

52.213–4 Terms and Conditions—Simplified Acquisitions (Other Than Commercial Products and Commercial Services).

* * * * *

Terms and Conditions—Simplified Acquisitions (Other Than Commercial Products and Commercial Services) (Nov 2024)

(a) * * *

(2) * * *

(vii) 52.244–6, Subcontracts for Commercial Products and Commercial Services (Nov 2024).

* * * * *

(b) * * *

(1) * * *

(xxii) 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act—Covered Foreign Entities (Nov 2024). (Sections 1821–1826, Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

* * * * *

■ 8. Add section 52.240–1 to read as follows:

52.240–1 Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act—Covered Foreign Entities.

As prescribed in 40.202–8, insert the following clause:

Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act—Covered Foreign Entities (Nov 2024)

(a) *Definitions.* As used in this clause—

American Security Drone Act—covered foreign entity means an entity included on a list developed and maintained by the Federal Acquisition

Security Council (FASC) and published in the System for Award Management (SAM) at *https://www.sam.gov* (section 1822 of the National Defense Authorization Act for Fiscal Year 2024, Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

FASC-prohibited unmanned aircraft system means an unmanned aircraft system manufactured or assembled by an American Security Drone Act—covered foreign entity.

Unmanned aircraft means an aircraft that is operated without the possibility of direct human intervention from within or on the aircraft (49 U.S.C. 44801(11)).

Unmanned aircraft system means an unmanned aircraft and associated elements (including communication links and the components that control the unmanned aircraft) that are required for the operator to operate safely and efficiently in the national airspace system (49 U.S.C. 44801(12)).

(b) *Prohibition.* The Contractor is prohibited from—

(1) Delivering any FASC-prohibited unmanned aircraft system, which includes unmanned aircraft (*i.e.,* drones) and associated elements (sections 1823 and 1826 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.);

(2) On or after December 22, 2025, operating a FASC-prohibited unmanned aircraft system in the performance of the contract (section 1824 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.); and

(3) On or after December 22, 2025, using Federal funds for the procurement or operation of a FASC-prohibited unmanned aircraft system (section 1825 of Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

(c) *Procedures.* The Contractor shall search SAM at *https://www.sam.gov* for the FASC-maintained list of American Security Drone Act—covered foreign entities prior to proposing, or using in performance of the contract, any unmanned aircraft system. Additionally, the Contractor shall ensure any effort or expenditure associated with a FASC-prohibited unmanned aircraft system is consistent with a corresponding exemption, exception, or waiver determination expressly stated in the contract.

(d) *Exemptions, exceptions, and waivers.* The prohibitions in this clause do not apply where the agency has determined an exemption, exception, or waiver applies and the contract indicates that such a determination has been made. See sections 1823 through 1825 and 1832 of Public Law 118–31 (41 U.S.C. 3901 note prec.) for statutory requirements pertaining to exemptions, exceptions, and waivers.

(e) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (e), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial products or commercial services.

(End of clause)

■ 9. Amend section 52.244–6 by—

■ a. Revising the date of the clause; and

■ b. Redesignating paragraph (c)(1)(xxiii) as paragraph (c)(1)(xxiv) and adding a new paragraph (c)(1)(xxiii).

The revision and addition read as follows:

52.244–6 Subcontracts for Commercial Products and Commercial Services.

* * * * *

Subcontracts for Commercial Products and Commercial Services (Nov 2024)

* * * * *

(c)(1) * * *

(xxiii) 52.240–1, Prohibition on Unmanned Aircraft Systems Manufactured or Assembled by American Security Drone Act—Covered Foreign Entities (Nov 2024) (Sections 1821–1826, Pub. L. 118–31, 41 U.S.C. 3901 note prec.).

* * * * *

[FR Doc. 2024–26061 Filed 11–8–24; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Part 52

[FAC 2025–01, FAR Case 2023–018; Item II; Docket No. FAR–2023–0018; Sequence No. 1]

RIN 9000–AO66

Federal Acquisition Regulation: Clarification of System for Award Management Preaward Registration Requirements

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Interim rule.

SUMMARY: DoD, GSA, and NASA are issuing an interim rule amending the Federal Acquisition Regulation (FAR) to clarify System for Award Management preaward registration requirements.

DATES:

Effective date: November 12, 2024.

Comment date: Interested parties should submit written comments to the Regulatory Secretariat Division at the address shown below on or before January 13, 2025, to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAC 2025–01, FAR Case 2023–018 to the Federal eRulemaking portal at *https://www.regulations.gov* by searching for ''FAR Case 2023–018''. Select the link ''Comment Now'' that corresponds with ''FAR Case 2023–018''. Follow the instructions provided on the ''Comment Now'' screen. Please include your name, company name (if any), and ''FAR Case 2023–018'' on your attached document. If your comment cannot be submitted using *https://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 ''FAR Case 2023–018'' in all correspondence related to this case. Comments received generally will be posted without change to *https://www.regulations.gov,* including any personal and/or business confidential information provided. Public comments may be submitted as an individual, as an organization, or anonymously (see frequently asked questions at *https://www.regulations.gov/faq*). To confirm receipt of your comment(s), please check *https://www.regulations.gov,* approximately two to three days after submission to verify posting.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Mr. Benjamin Collins, Procurement Analyst, at 850–826–0058 or by email at *benjamin.collins@gsa.gov.* For information pertaining to status or publication schedules, or alternative instructions for submitting comments if *https://www.regulations.gov* cannot be used, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* Please cite FAC 2025–01, FAR Case 2023–018.

SUPPLEMENTARY INFORMATION:

I. Background

This interim rule revises the solicitation provision at FAR 52.204–7, System for Award Management, to clarify the System for Award Management (SAM) preaward registration requirements in paragraph (b)(1) of the provision. DoD, GSA, and NASA published a final rule in the **Federal Register** at 83 FR 48691 on September 26, 2018, to update instructions for registration in SAM and correct an inconsistency involving timing of registration. One of the updates to the provision at FAR 52.204–7, System for Award Management,

included language that has been construed in some cases as levying a requirement for offerors to maintain a continuous, uninterrupted, registration during the entirety of the preaward process. This interim rule clarifies that the offeror must be registered at time of offer submission and at time of contract award, but would not be required to be registered at every moment in between those two points.

II. Discussion and Analysis

Prior to the issuance of the September 26, 2018 rule, the FAR required registration in SAM at contract award in some instances (*e.g.,* FAR 4.1102 and 52.204–7) and at the point of offer submission in others (*e.g.,* FAR 52.204–8). The rule aimed to correct these inconsistencies.

FAR 52.204–7(b)(1) was changed from ''By submission of an offer, the offeror acknowledges the requirement that a prospective awardee shall be registered in the SAM database prior to award, during performance . . .'' to ''An Offeror is required to be registered in SAM when submitting an offer or quotation, and shall continue to be registered until time of award, during performance . . . .''

The predominant FAR text changes centered on ensuring offerors understood registration was required at the point of offer submission versus contract award—as that was the earliest point for assessing compliance.

This particular change has proven to be pivotal in recent bid protest decisions by the Government Accountability Office (GAO) (*e.g.,* TLS Joint Venture, LLC, B–422275, April 1, 2024) and the United States Court of Federal Claims (COFC) (*e.g., Myriddian, LLC* v. *The United States*, 165 Fed. Cl. 650 (May 23, 2023)). While the nature of the procurements and associated remedies varied, the decisions were uniform in highlighting FAR 52.204–7(b)(1) as requiring an offeror to be registered at the point of offer submission and maintain that registration through contract award.

While this continuous, active, registration is the anticipated normal state expected of offerors and contractors conducting business via Federal contract, the Government is now directing that the minimum preaward registration compliance is at the points of offer submission (prior to offer evaluation) and contract award (prior to contract execution).

Other FAR references (*e.g.,* FAR 32.1110(a)(1), FAR 52.204–13) allude to a contractor being required to ''maintain'' registration; however, this is ''during contract performance, and through final payment'', which is after contract award. This requirement reflects the need to maintain SAM registration to support contract execution, namely to ensure payments can be mechanized. No other FAR text carries the ''continuous'' preaward registration language. This rule also updates the provision at FAR 52.204–7, System for Award Management, to remove references to registration requirements applicable after contract award (*i.e.,* ''during contract performance, and through final payment''). A pointer to FAR clause 52.204–13, System for Award Management Maintenance, has been added in the provision, however, to ensure offerors do not mistakenly perceive the removal of the language as a removal of the requirement if awarded a contract.

III. Applicability to Contracts at or Below the Simplified Acquisition Threshold (SAT) and for Commercial Products (Including Commercially Available Off-the-Shelf (COTS) Items) or for Commercial Services

This rule amends the provision at FAR 52.204–7, System for Award Management. However, this rule does not impose any new requirements on contracts at or below the SAT, for commercial products (including COTS items), or for commercial services. The provision continues to apply to acquisitions at or below the SAT, acquisitions for commercial products (including COTS items), and commercial services.

IV. Expected Impact of the Rule

Offerors are required to be registered in SAM to participate in the Federal marketplace, with some exceptions listed in FAR 4.1102. Registration in SAM will be required upon submission of an offer or quote and at the time of the award as a result of this rule, which amends FAR 52.204–7(b)(1). Offerors will continue to be required to register in SAM to participate in the Federal marketplace. There is no increase in burden.

This rule makes clear that a lapse in registration that occurs after offer submission and is corrected before contract award will not render an offeror ineligible for award under FAR 52.204–7(b)(1). The view that such a lapse makes an offeror ineligible has resulted in loss of resources for otherwise successful small business offerors (*e.g.,* time and costs of litigation, lost income) and the Government (*e.g.,* loss of best-value provider, delays in mission execution via intended contract solution).

Ambiguity regarding the perceived intent at FAR 52.204–7(b)(1) has led to disparate agency interpretations and uncertainty in the acquisition community. In practice, contracting officers, in the preaward environment, generally verify registration status of offerors at the points of offer submission and contract award and not the time between those two points. Contracting officers typically do this registration review as part of a broader responsibility and qualification review in SAM (*e.g.,* reviewing the entity's status for possible debarment, suspension, proposed debarment, or other Governmentwide exclusion).

While the provision at FAR 52.204–7 speaks to offeror responsibilities and does not impose a requirement on agencies to confirm an offeror has been registered at any and all moments between offer submission and award, the recent COFC and GAO decisions make it clear that failure to do so imperils the award decision.

In summary, this rule is expected to mitigate the risk of more litigation and mission delays.

V. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 (as amended by E.O. 14094) 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 (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993.

VI. Congressional Review Act

Pursuant to the Congressional Review Act, DoD, GSA, and NASA will send this rule to each House of the Congress and to the Comptroller General of the United States. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has determined that this rule does not meet the definition in 5 U.S.C. 804(2).

VII. Regulatory Flexibility Act

DoD, GSA, and NASA do not expect this interim rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility

Act, 5 U.S.C. 601–612, because this rule makes a minor change in SAM registration requirements for offerors. This change will help small businesses stay eligible for contract awards. However, an Initial Regulatory Flexibility Analysis (IRFA) has been performed and is summarized as follows:

DoD, GSA, and NASA are amending the FAR to clarify System for Award Management preaward registration requirements. This interim rule changes the provision at FAR 52.204–7, System for Award Management, to clarify that an offeror must be registered at time of offer submission and at time of contract award, but would not be required to be registered at every moment in between those two points. The current language has led to interpretations that have disrupted Government procurements and resulted in lost business opportunities for some companies, including small businesses.

This interim rule addresses registration requirements for offerors in SAM. The implementation of SAM, which combined the functional capabilities of numerous legacy systems, was in response to the E-Government Act of 2002 (Pub. L. 107–347) to improve the management and promotion of electronic Government services and processes. Promulgation of the FAR is authorized by 40 U.S.C. 121(c); 10 U.S.C. chapter 4 and 10 U.S.C. chapter 137 legacy provisions (see 10 U.S.C. 3016); and 51 U.S.C. 20113.

This rule applies to entities, including small entities, that submit offers to the Federal Government for acquisitions that exceed the micro-purchase threshold. As of the end of calendar year 2023, of the 486,551 active registrants in SAM for ''all awards,'' 356,528 (73 percent) represented their size as small for their primary North American Industry Classification System code. It is estimated that not more than half of those small entities will submit an offer in a given year.

This rule does not introduce any new reporting or recordkeeping requirements. Small entities that do business with the Federal Government are already familiar with SAM registration requirements. The burden to provide the information required by the provision at FAR 52.204–7, System for Award Management, is covered by OMB Control Number 9000–0189, Certain Federal Acquisition Regulation Part 4 Requirements: FAR Sections Affected: 52.204–3, 52.204–6, 52.204–7, 52.204–12 thru 52.204–15, 52.204–20, 52.204–23, 52.212–1(j), 52.212–3(b), and 52.212–3(l). However, no changes to this information collection requirement are made by this interim rule.

The rule does not duplicate, overlap, or conflict with any other Federal rules.

There are no available alternatives to the interim rule to accomplish the desired objective. The changes in this rule help preserve the Government's intent for SAM preaward registration requirements and protect offerors from unintended consequences of momentary lapses in registration. Thus, it is not possible, or desirable, to exempt small entities from coverage of the rule.

The Regulatory Secretariat Division has submitted a copy of the IRFA to the Chief Counsel for Advocacy of the Small Business Administration. A copy of the IRFA may be obtained from the Regulatory Secretariat Division. DoD, GSA, and NASA invite comments from small business concerns and other interested parties on the expected impact of this interim rule on small entities.

DoD, GSA, and NASA will also consider comments from small entities concerning the existing regulations in subparts affected by the rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (FAR Case 2023–018), in correspondence.

VIII. Paperwork Reduction Act

The Paperwork Reduction Act (44 U.S.C. 3501–3521) applies to the information collection described in this rule; however, these changes to the FAR do not impose additional information collection requirements to the paperwork burden previously approved under OMB Control Number 9000–0189, Certain Federal Acquisition Regulation Part 4 Requirements: FAR Sections Affected: 52.204–3, 52.204–6, 52.204–7, 52.204–12 thru 52.204–15, 52.204–20, 52.204–23, 52.212–1(j), 52.212–3(b), and 52.212–3(l).

IX. Determination To Issue an Immediately Effective Interim Rule

A determination has been made under the authority of the Secretary of Defense, the Administrator of General Services, and the Administrator of the National Aeronautics and Space Administration that urgent and compelling reasons exist to promulgate this interim rule effective immediately without prior opportunity for public comment, see 41 U.S.C. 1707(d). This action is necessary to protect contractors and the Federal Government from the costs and delays of bid protest litigation associated with the provision at FAR 52.204–7, System for Award Management.

DoD, GSA, and NASA attempted to clarify the timing requirements for registration in SAM through a final rule in the **Federal Register** at 83 FR 48691 on September 26, 2018. Prior to the aforementioned rule the provision at 52.204–7 stated an offeror needed to be registered ''prior to award'' whereas other areas of the FAR required offerors to be registered with the submission of the offer and at the time of award. The 2018 rule was intended to clarify that ''prior to award'' meant both at the time of offer submission and at award.

Since the rule was issued, however, post-award bid protests have increasingly focused on temporary lapses in registration, between offer submission and contract award, by the apparently successful offeror. The May 23, 2023, Myriddian, LLC v. United States decision perpetuated an interpretation that the 2018 rule introduced a new requirement for absolutely uninterrupted, continuous, registration during the entirety of the preaward period with failure to do so rendering an offeror ineligible for award. After the Myriddian decision, bid protests have continued to be filed on lapses of registration (see, *e.g., Hanford Tank Disposition Alliance, LLC* v. *United States* (June 23, 2023); *Independent Rough Terrain Center, LLC* v. *United States* (July 1, 2024); TLS Joint Venture, LLC, B–422275 (April 1, 2024); VivSoft Technologies, LLC, B–421561.15, B–421561.17 (April 11, 2024); *Zolon PSC II, LLC* v. *United States* (August 2024)). The 2018 rule's purpose was clarifying in nature and not intended to introduce new requirements with such severe ramifications for offerors.

The unintended interpretation applied in recent bid protest decisions represents an unwitting barrier to entry and significant disruption to the industrial base and the Federal agencies they support, which warrants immediate action. If left unclarified, perpetuation of this interpretation will:

(1) Introduce significant risk of lost income for contractors, particularly small businesses, due to temporary lapses in registration often for minor and technical reasons;

(2) Put agencies at unnecessary high risk for the cost and delay of protests if award is made to an offeror that had a temporary lapse in registration between offer submission and award;

(3) Cause undue confusion and frustration for small businesses working through registration renewals and attempting to win Federal contracts;

(4) Cause undue confusion and frustration for contracting officers attempting to verify compliance with the registration requirement; and

(5) Unnecessarily complicate the ability of the Government to meet its mission needs with best-value solutions.

Issuing an immediately effective interim rule will allow the Government to issue, in a timely manner, the needed clarification to accurately preserve preaward registration requirements for offerors while also eliminating unintended litigation risks presented to contractors and their agency customers,

which divert resources, deny business earned income, and hamper mission success. This rule simply clarifies preaward registration requirements, so there is little risk the interim rule will impose a requirement on the public on which they have not already had the opportunity to comment. However, pursuant to 41 U.S.C. 1707 and FAR 1.501–3(b), the Department of Defense, General Services Administration, and National Aeronautics and Space Administration will consider public comments received in response to this interim rule in the formation of the final rule.

List of Subjects in 48 CFR Part 52

Government procurement.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, DoD, GSA, and NASA amend 48 CFR part 52 as set forth below:

PART 52—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 1. The authority citation for 48 CFR part 52 continues to read as follows:

Authority: 40 U.S.C. 121(c); 10 U.S.C. chapter 4 and 10 U.S.C. chapter 137 legacy provisions (see 10 U.S.C. 3016); and 51 U.S.C. 20113.

■ 2. Amend section 52.204–7 by revising the date of the provision and paragraph (b)(1) to read as follows:

52.204–7 System for Award Management.

* * * * *

System for Award Management (Nov 2024)

* * * * *

(b)(1) An Offeror is required to be registered in SAM when submitting an offer or quotation and at time of award (see FAR clause 52.204–13, System for Award Management Maintenance, for the requirement to maintain SAM registration during performance and through final payment).

* * * * *

[FR Doc. 2024–26062 Filed 11–8–24; 8:45 am]

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DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Chapter 1

[Docket No. FAR–2024–0051, Sequence No. 6]

Federal Acquisition Regulation; Federal Acquisition Circular 2025–01; Small Entity Compliance Guide

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Small Entity Compliance Guide (SECG).

SUMMARY: This document is issued under the joint authority of DoD, GSA, and NASA. This *Small Entity Compliance Guide* has been prepared in accordance with section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. It consists of a summary of the rules appearing in Federal Acquisition Circular (FAC) 2025–01, which amends the Federal Acquisition Regulation (FAR). Interested parties may obtain further information regarding these rules by referring to FAC 2025–01, which precedes this document.

DATES: November 12, 2024.

ADDRESSES: The FAC, including the SECG, is available at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact the analyst whose name appears in the table below. Please cite FAC 2025–01 and the FAR Case number. For information pertaining to status or publication schedules, contact the Regulatory Secretariat Division at 202–501–4755 or *GSARegSec@gsa.gov.* An asterisk (*) next to a rule indicates that a regulatory flexibility analysis has been prepared.

RULES LISTED IN FAC 2025–01

Item	Subject	FAR case	Analyst
*I	Prohibition on Unmanned Aircraft Systems from Covered Foreign Entities	2024–002	Collins.
*II	Clarification of System for Award Management Preaward Registration Requirements	2023–018	Collins.

SUPPLEMENTARY INFORMATION: Summaries for each FAR rule follow. For the actual revisions and/or amendments made by these FAR rules, refer to the specific item numbers and subjects set forth in the documents following these item summaries. FAC 2025–01 amends the FAR as follows:

Item I—Prohibition on Unmanned Aircraft Systems From Covered Foreign Entities (FAR Case 2024–002)

This interim rule amends the FAR to implement a prohibition on procuring, operating, or using Federal funds on, unmanned aircraft systems (*e.g.,* drones) that are manufactured or assembled by an American Security Drone Act-covered foreign entity. This rule implements the American Security Drone Act of 2023 (subtitle B, title XVIII of the National Defense Authorization Act for Fiscal Year 2024, Pub. L. 118–31, 41 U.S.C. 3901 note prec.). This rule applies to all solicitations and contracts, including contracts at or below the micro-purchase threshold and to contracts for commercial products (including commercially available off-the-shelf items) or for commercial services. The change is not expected to have a significant economic impact on a substantial number of small entities. This interim rule is being implemented as a national security measure to protect sensitive Government information and operations.

Item II—Clarification of System for Award Management Preaward Registration Requirements (FAR Case 2023–018)

This interim rule amends the FAR to clarify System for Award Management preaward registration requirements. Offerors are required to be registered at the time of proposal submission and at time of award, rather than continuously in between. This change is expected to have a positive impact on small businesses who have a minor lapse in registration.

William F. Clark,

Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.

[FR Doc. 2024–26065 Filed 11–8–24; 8:45 am]

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Vol. 89, No. 218

Tuesday, November 12, 2024

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The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

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FEDERAL REGISTER PAGES AND DATE, NOVEMBER

87259–87460 1
87461–87762 4
87763–87930 5
87931–88114 6
88115–88630 7
88631–88870 8
88871–89476 12

CFR PARTS AFFECTED DURING NOVEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
10845 87259
10846 87763
10847 87765
10848 87767
10849 87769
10850 87771
10851 87773
10852 87775
10853 87777
10854 87781
10855 88871

Administrative Orders:
Memorandums:
Memorandum of October 16, 2024 87461
Memorandum of October 21, 2024 87463
Notices:
Notice of November 1, 2024 87761
Notice of November 7, 2024 88867
Notice of November 7, 2024 88869

7 CFR

1773 88631

Proposed Rules:
981 88661
3565 87801

10 CFR

Proposed Rules:
430 ..... 87803, 88661

12 CFR

X 88875
209 88877

Proposed Rules:
1239 87730
1261 87730
1273 87730

14 CFR

39 ..... 88115, 88878, 88881, 88884, 88886
71 ..... 87465, 87466

Proposed Rules:
39 ..... 87311, 87314, 87317, 87821, 88173, 88174, 88681, 88906, 88908, 88910, 88913
71 ..... 87985, 87988, 87989, 88177, 88178, 88181, 88182, 88184, 88683, 88915

15 CFR

734 87783
740 87783
742 87783
744 ..... 87261, 87279, 87783
746 ..... 87279, 87783
774 87783

Proposed Rules:
734 87825
740 87825
742 87825
744 87825
746 87825
774 87825

16 CFR

801 89216
803 89216
1112 87467
1130 87467
1243 87467

Proposed Rules:
1250 88684

17 CFR

37 88594
38 88594
40 88594

21 CFR

80 88635

23 CFR

624 88118
630 87282

24 CFR

Proposed Rules:
5 87518
902 87518

26 CFR

54 88642
301 87784

Proposed Rules:
1 88686
301 88686

27 CFR

1 87931
4 87931
5 87931
6 87931
8 87931
9 87931
10 87931
11 87931
13 87931
16 87931
17 87931
18 87931
19 87931
20 87931
21 87931
22 87931
24 87931
25 87931

26 87931
27 87931
28 87931
29 87931
30 87931
31 87931
40 87931
41 87931
44 87931
45 87931
46 87931
53 87931
70 87931
71 87931
72 87931

29 CFR

2560 88642
2590 88642

30 CFR

Proposed Rules:
117 87990

31 CFR

802 88128

33 CFR

100 ....87787, 88646
117 87498
165 ....87299, 87789, 87791, 87953, 88137, 88648

34 CFR

Proposed Rules:
Ch. III 88185

38 CFR

70 88888

Proposed Rules:
1 88686
3 88917
4 88917
14 88192
36 88192

39 CFR

Proposed Rules:
3050 87319

40 CFR

9 88650
51 88653
52 ....87500, 87505, 87955, 87960, 88139
79 88653
80 88653
85 88653
97 87960
122 88653
180 ....87509, 88657
257 88650
271 87512
300 88653
372 88653
501 88653
704 88653
745 ....88653, 89416
763 88653
790 88653
1036 88653
1037 88653

Proposed Rules:
51 88940
52 ....87320, 87826, 87828, 88688, 88690
81 87828
180 ....87321, 88948
257 88694

41 CFR

302 87977

42 CFR

410 89084
413 89084
424 88354
483 88354
484 88354
494 89084
512 89084

44 CFR

61 87299
62 87299

45 CFR

1304 87977
2584 88147

47 CFR

8 87309
52 88890
54 87516
64 87982
76 87983

Proposed Rules:
14 88695
64 88695
76 87322

48 CFR

Ch. 1 ....89464, 89475
4 89464
13 89464
39 89464
40 89464
52 ....89464, 89472

Proposed Rules:
570 87993

49 CFR

40 87792

Proposed Rules:
386 87532
387 87532
1500 88488
1503 88488
1520 88488
1570 88488
1580 88488
1582 88488
1584 88488
1586 88488

50 CFR

32 88147
648 87309
665 88170
679 ....87798, 87799

Proposed Rules:
18 88216
229 87322
665 87838

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 October 8, 2024

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