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Proclamation 10671 of November 9, 2023

The President

American Education Week, 2023

By the President of the United States of America

A Proclamation

The promise of America has always been tied to the promise of our public education. This American Education Week, we celebrate our schools as beacons of hope and possibility, pillars of our communities, and cornerstones of our democracy. We recommit to investing in all the schools, educators, and staff—the kite strings that keep our national ambitions aloft.

A great education opens doors and changes lives. From our astronauts, artists, scientists, and software developers to our engineers, entrepreneurs, manufacturers, and medical professionals, countless Americans first discovered their potential in our public schools. Many further honed their talents in our universities, community colleges, Registered Apprenticeship programs, and career and technical education programs. That is what makes our Nation one of possibilities: Here in the United States everyone has the chance to learn, grow, and pursue their dreams, no matter who they are or where they grew up. But there is more we can still do to ensure every child has a fair shot. Despite heroic efforts by our Nation's teachers, the pandemic further deepened existing achievement gaps after years of flat or declining achievement in math and reading nationwide.

That is why my Administration has secured a historic \$130 billion for America's K–12 schools. This funding has put more teachers in our classrooms and more counselors, social workers, and other staff in our schools. Additionally, this funding is providing high-quality tutoring, supporting record expansions of summer and after-school programming, improving air quality in schools, addressing environmental and safety needs in aging school buildings, and creating other critical initiatives designed to support our students. We also recognize that our students cannot thrive at school unless they are healthy and safe. The American Rescue Plan also made our country's biggest-ever investment in mental health and substance use programs, supplying the resources to recruit, train, and support more providers at the State and local levels—including in our schools. I also signed the Bipartisan Safer Communities Act into law—the first major Federal gun safety legislation passed in nearly 30 years, getting us closer to a world where every school in America is free from the threat of gun violence. This legislation also included historic levels of funding to address youth mental health, including \$2 billion to create safe, inclusive learning environments for students and hire and train more mental health professionals for schools, which is where students are most likely to receive these crucial services. My Administration also released a national strategy to end hunger and reduce diet-related diseases in America by 2030—including by advancing a pathway to provide free, healthy school meals for all children.

We are fighting for our youngest learners too. We know that if we start early in both reading and math and make kindergarten a sturdy bridge between the early years and early grades, we set the stage for their lasting academic success. In fact, providing America's children with a strong foundation during their first 5 years can form the basis for lifelong health and well-being as well as achievement in education and their future careers.

I will continue to press for high-quality, free preschool for all three- and four-year-olds.

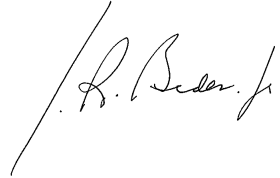
My Administration also secured nearly \$40 billion for colleges and universities in the American Rescue Plan. Importantly, we have invested billions of dollars in Historically Black Colleges and Universities, Tribal Colleges and Universities, and Minority Serving Institutions, such as Hispanic-Serving Institutions and Asian American and Native American Pacific Islander-Serving Institutions. I have made it a priority to make college more affordable for Americans, and have worked with the Congress to increase the maximum Pell Grant by \$900 since the beginning of my Administration, helping over 6 million eligible students pay for school. Further, my Administration has approved \$127 billion in student loan debt relief for nearly 3.6 million borrowers—more than any President in history. We have also fixed the Public Service Loan Forgiveness program so that borrowers who go into public service, including public school teachers, get the debt relief they have earned. Borrowers who work in public service can apply for the Public Service Loan Forgiveness program at www.studentaid.gov/pslf. Our SAVE plan, once fully implemented, will make student loan repayment more affordable than ever before, slashing payments to \$0 for borrowers who earn less than about \$15 an hour, saving them over \$1,000 a year, and ending the runaway student loan interest responsible for ballooning balances. Enrolling in SAVE takes less than 10 minutes.

While we are making historic investments in colleges and universities, we also believe that every person in our Nation deserves access to the American Dream, whether they have a college degree or not. That is why we have invested more in Registered Apprenticeships and technical career training programs than any administration in history. These programs empower workers to earn while they learn and offer them a path toward good-paying jobs. In addition, the Departments of Education and Labor are collaborating to expand Registered Apprenticeships for educators. To help raise a new generation of talented educators from underrepresented backgrounds, we are working to increase high-quality teacher preparation programs and strengthen and diversify the teacher pipeline.

During American Education Week, we recognize the critical role education plays in realizing the defining creed of our Nation—that we are a land of possibilities. We celebrate all the dedicated educators, school counselors, nurses, bus drivers, security guards, custodians, cafeteria workers, and other school staff, who keep our schools running and support our students' health, safety, and success. Together, we will ensure that every student has the resources and opportunities they need to thrive.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 12 through November 18, 2023, as American Education Week. I call upon all Americans to mark this week with appropriate programs, ceremonies, and activities honoring those who devote their talents and energies to helping our children reach their full potential and to building school communities where all students feel they belong.

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

A handwritten signature in black ink, appearing to read "Joe Biden", with a long, sweeping diagonal line extending upwards and to the left from the start of the signature.

Presidential Documents

Proclamation 10672 of November 9, 2023

National Apprenticeship Week, 2023

By the President of the United States of America

A Proclamation

I have always believed that the middle class built America and unions built the middle class, and Registered Apprenticeship programs across our country have produced some of the best-trained workers in the world. During National Apprenticeship Week, we recommit to supporting Registered Apprenticeship programs, which offer America's workers direct pathways to good-paying jobs with dignity and respect.

I ran for office to build an economy from the middle out and bottom up—one in which every American willing to work hard can get a job wherever they call home. Registered Apprenticeships make that possible for so many by honing their skills, paying them while they learn, and putting them on a path to get a good-paying job. Apprenticeships not only strengthen our workforce today, they give workers the skills needed for industries of the future—whether it is modernizing our infrastructure and building clean energy technologies or addressing cybersecurity threats.

That is why we have invested more in Registered Apprenticeships and career technology education programs than any previous administration in American history. Our American Rescue Plan and Bipartisan Infrastructure Law have invested billions of dollars in workforce training for good jobs, including significant investments to help States, employers, labor organizations, educational institutions, and workforce intermediaries develop and expand Registered Apprenticeship and pre-apprenticeship programs. My Administration's efforts have already helped develop over 4,000 new Registered Apprenticeship programs and led to the hiring of more than one million new apprentices. Through enhanced tax credits our Inflation Reduction Act provides strong incentives for employers to connect Registered Apprentices with clean energy projects that are essential in our work to build a clean energy future in America.

Last year, my Administration launched programs designed to strengthen and diversify Registered Apprenticeships across industries. Our Apprenticeship Ambassador Initiative assembles a national network of more than 200 organizations committed to increasing the number of apprentices across many industries while recruiting people from historically underrepresented communities to join the American workforce and participate in industries of the future. These organizations have already committed to hiring over 10,000 new apprentices. This initiative includes creating clean energy apprenticeships and jobs in communities that have suffered legacy pollution. Additionally, these Registered Apprenticeships help employers build a more diverse workforce while empowering workers with the resources they need to thrive, including on-the-job learning experience, job-related instruction with a mentor, and a clear pathway to a good-paying job. Through the Department of Labor's Women in Apprenticeship and Nontraditional Occupations grant program, my Administration is also continuing to invest in training women to enter the skilled trades and other occupations where they have long been underrepresented.

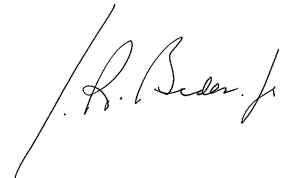
In addition, we are working within industries to address workforce needs in critical sectors. Through my Administration's Advanced Manufacturing

Sprint and Workforce Hubs Initiative, we are working to secure private-sector, union, State, and local commitments to expand pre-apprenticeship and Registered Apprenticeship programs. The Department of Education and the Department of Labor have helped expand K–12 teacher Registered Apprenticeship programs to 27 States with over 1,500 teacher apprentices to ensure our schools have enough educators to teach the next generation of leaders. Through the Department of Labor’s Scaling Apprenticeship Readiness Across the Building Trades Initiative, we are enrolling at least 7,000 people in construction industry apprenticeships to build roads, bridges, and highways, so that America can have the best infrastructure in the world once again. Our 90-day Trucking Apprenticeship Challenge has helped get more truck drivers on the road, keeping our supply chains moving. And our 120-day Cybersecurity Apprenticeship Sprint has resulted in thousands of apprentices getting hired, who will learn the skills needed to protect our personal information and national interests from cyberthreats.

I have often said that America can be defined in one word: possibilities. That is what Registered Apprenticeships are all about—giving workers the skills and opportunity to support their families while building the industries of the future. During National Apprenticeship Week, we celebrate the apprentices across our country who lift our workforce to new heights and the apprenticeship programs that make their success possible. We recommit to doing what has always worked best for our Nation: investing in America and American workers.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim November 12 through November 18, 2023, as National Apprenticeship Week. I urge the Congress, State and local governments, educational institutions, industry and labor leaders, apprentices, and all Americans to support Registered Apprenticeship programs in the United States of America and to raise awareness of their importance in building a diverse and robust workforce to strengthen our national economy.

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

A handwritten signature in black ink, appearing to read "Joe Biden", with a long, sweeping horizontal line extending to the left.

Rules and Regulations

Federal Register

Vol. 88, No. 219

Wednesday, November 15, 2023

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

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

[Docket ID: OPM-2023-0017]

RIN 3206-AO60

Prevailing Rate Systems; Abolishment of Allegheny, Pennsylvania, as a Nonappropriated Fund Federal Wage System Wage Area

AGENCY: Office of Personnel Management.

ACTION: Final rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing a final rule to abolish the Allegheny, Pennsylvania, nonappropriated fund (NAF) Federal Wage System (FWS) wage area and redefine Cuyahoga County, Ohio, to the Macomb, Michigan, NAF wage area; Trumbull County, OH, to the Niagara, New York, NAF wage area; Allegheny and Butler Counties, PA, to the Cumberland, PA, NAF wage area; Harrison County, West Virginia, to the Prince William, Virginia, NAF wage area; and Westmoreland County, PA, will no longer be defined. These changes are necessary because NAF FWS employment in the survey area is now below the minimum criterion of 26 wage employees to maintain a wage area, and the local activities no longer have the capability to conduct local wage surveys.

DATES:

Effective date: This regulation is effective December 15, 2023.

Applicability date: This change applies on the first day of the first applicable pay period beginning on or after December 15, 2023.

FOR FURTHER INFORMATION CONTACT: Ana Paunoiu, by telephone at (202) 606-2858 or by email at pay-leave-policy@opm.gov.

SUPPLEMENTARY INFORMATION: On August 15, 2023, OPM issued a proposed rule (88 FR 55421) to abolish the Allegheny,

PA, NAF FWS wage area and redefine Cuyahoga County, OH, as an area of application county to the Macomb, MI, NAF wage area; Trumbull County, OH, as an area of application county to the Niagara, NY, NAF wage area; Allegheny and Butler Counties, PA, as an area of application counties to the Cumberland, PA, NAF wage area; and Harrison County, WV, as an area of application county to the Prince William, VA, NAF wage area. Westmoreland County, PA, will no longer be defined to a NAF wage area. The Federal Prevailing Rate Advisory Committee, the national labor-management committee responsible for advising OPM on matters concerning the pay of FWS employees, reviewed and recommended these changes by consensus.

The proposed rule had a 30-day comment period, during which OPM received no comments. Therefore, this final rule adopts the proposed rule at 88 FR 55421 without change.

Expected Impact of This Rule

Section 5343 of title 5, U.S. Code, provides OPM with the authority and responsibility to define the boundaries of NAF FWS wage areas. Any changes in wage area definitions can have the long-term effect of increasing pay for Federal employees in affected locations. OPM expects this final rule to impact approximately 26 NAF FWS employees. Considering the small number of employees affected, OPM does not anticipate this rule will substantially impact local economies or have a large impact in local labor markets. As this and future wage area changes may impact higher volumes of employees in geographical areas and could rise to the level of impacting local labor markets, OPM will continue to study the implications of such impacts in this or future rules as needed.

Regulatory Review

Executive Orders 13563, 12866, and 14094 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). This rule is not a "significant regulatory action" under the provisions of Executive Order 14094 and, therefore, was not reviewed by OMB.

Regulatory Flexibility Act

The Director of OPM certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Federalism

OPM has examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

Civil Justice Reform

This rule meets the applicable standard set forth in Executive Order 12988.

Unfunded Mandates Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act or CRA) (5 U.S.C. 801 *et seq.*) requires most final rules to be submitted to Congress before taking effect. OPM will submit to Congress and the Comptroller General of the United States a report regarding the issuance of this rule before its effective date. The Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this rule is not a major rule as defined by the CRA (5 U.S.C. 804).

Paperwork Reduction Act

This rule does not impose any reporting or record-keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

Accordingly, OPM amends 5 CFR part 532 as follows:

PART 532—PREVAILING RATE SYSTEMS

■ 1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

■ 2. In Appendix D to subpart B, amend the table by revising the wage area listing for the States of Michigan, New York, Pennsylvania, and Virginia to read as follows:

Appendix D to Subpart B of Part 532—Nonappropriated Fund Wage and Survey Areas

Definitions of Wage Areas and Wage Area Survey Areas

* * * * *

MICHIGAN

Macomb

Survey Area

Michigan:
Macomb

Area of Application. Survey area plus:

Michigan:
Alpena
Calhoun
Crawford
Grand Traverse
Huron
Iosco
Kent
Leelanau
Ottawa
Saginaw
Washtenaw
Wayne

Ohio:
Cuyahoga
Lucas
Ottawa

* * * * *

NEW YORK

Jefferson

Survey Area

New York:
Jefferson

Area of Application. Survey area plus:

New York:
Albany
Oneida
Onondaga
Ontario
Schenectady
Steuben

Kings-Queens

Survey Area

New York:

Kings
Queens

Area of Application. Survey area plus:

New Jersey:

Essex
Hudson
New York:
Bronx
Nassau
New York
Richmond
Suffolk

Niagara

Survey Area

New York:
Niagara

Area of Application. Survey area plus:

New York:
Erie
Genesee
Ohio:
Trumbull
Pennsylvania:
Erie

Orange

Survey Area

New York:
Orange

Area of Application. Survey area plus:

New York:
Dutchess
Westchester
* * * * *

PENNSYLVANIA

Cumberland

Survey Area

Pennsylvania:
Cumberland

Area of Application. Survey area plus:

Pennsylvania:
Allegheny
Blair
Butler
Franklin

York

Survey Area

Pennsylvania:
York

Area of Application. Survey area plus:

Pennsylvania:
Lebanon
* * * * *

VIRGINIA

Alexandria-Arlington-Fairfax

Survey Area

Virginia (city):
Alexandria
Virginia (counties):
Arlington
Fairfax

Area of Application. Survey area.

Chesterfield-Richmond

Survey Area

Virginia (city):
Richmond
Virginia (county):
Chesterfield

Area of Application. Survey area plus:

Virginia (cities):
Bedford
Charlottesville
Salem

Virginia (counties):
Caroline
Nottoway
Prince George

West Virginia:
Pendleton

Hampton-Newport News

Survey Area

Virginia (cities):
Hampton
Newport News

Area of Application. Survey area plus:

Virginia (city):
Williamsburg
Virginia (county):
York

Norfolk-Portsmouth-Virginia Beach

Survey Area

Virginia (cities):
Norfolk
Portsmouth
Virginia Beach

Area of Application. Survey area plus:

North Carolina:
Pasquotank
Virginia (cities):
Chesapeake
Suffolk
Virginia (counties):
Accomack
Northampton

Prince William

Survey Area

Virginia:
Prince William

Area of Application. Survey area plus:

Virginia:
Fauquier
West Virginia:
Harrison
* * * * *

[FR Doc. 2023–25154 Filed 11–14–23; 8:45 am]

BILLING CODE 6325–39–P

**OFFICE OF PERSONNEL
MANAGEMENT****5 CFR Part 532**

[Docket ID: OPM–2023–0018]

RIN 3206–AO61

**Prevailing Rate Systems; Redefinition
of the Northeastern Arizona and Utah
Appropriated Fund Federal Wage
System Wage Areas****AGENCY:** Office of Personnel
Management.**ACTION:** Final rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing a final rule to redefine the geographic boundaries of the Northeastern Arizona and Utah appropriated fund Federal Wage System (FWS) wage areas for pay-setting purposes. The final rule will redefine Washington County, UT, and several National Parks portions of Garfield, Grand, Iron, San Juan, and Wayne Counties, UT, to the Northeastern Arizona wage area.

DATES:

Effective date: This regulation is effective December 15, 2023.

Applicability date: This change applies on the first day of the first applicable pay period beginning on or after December 15, 2023.

FOR FURTHER INFORMATION CONTACT: Ana Paunoiu, by telephone at (202) 606–2858 or by email at *pay-leave-policy@opm.gov*.

SUPPLEMENTARY INFORMATION: On August 15, 2023, OPM issued a proposed rule (88 FR 55423) to redefine the geographic boundaries of the Northeastern Arizona and Utah appropriated fund FWS wage areas. The rulemaking proposed to redefine Washington County, UT; and the Bryce Canyon, Capitol Reef, and Canyonlands National Parks portions of Garfield County, UT; the Arches and Canyonlands National Parks portions of Grand County, UT; the Cedar Breaks National Monument and Zion National Park portions of Iron County, UT; the Canyonlands National Park portion of San Juan County, UT; and the Capitol Reef and Canyonlands National Parks portions of Wayne County from the Utah wage area to the Northeastern Arizona wage area. The Federal Prevailing Rate Advisory Committee, the national labor-management committee responsible for advising OPM on matters concerning the pay of FWS employees, reviewed and recommended these changes by consensus.

The 30-day comment period ended on September 15, 2023. OPM received one

public comment expressing general concerns about economic growth around National Parks that is outside the scope of this rulemaking. Therefore, this final rule adopts the proposed rule at 88 FR 55423 without change.

Expected Impact of This Rule

Section 5343 of title 5, U.S. Code, provides OPM with the authority and responsibility to define the boundaries of FWS wage areas. Any changes in wage area boundaries can have the long-term effect of increasing pay for FWS employees in affected locations. OPM expects this rule to impact approximately 100 FWS employees. Of the changes this rule implements, the most significant change in terms of the number of impacted employees would be in Washington County, UT, where approximately 32 FWS employees would be affected. Considering the small number of employees affected, OPM does not anticipate this rule will have a substantial impact on the local economies or a large impact in the local labor markets. However, OPM will continue to study the implications of such impacts in this or future rules as needed, as this and future changes in wage area definitions may impact higher volumes of employees in geographical areas and could rise to the level of impacting local labor markets.

Regulatory Review

Executive Orders 13563, 12866, and 14094 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). This rule is not a “significant regulatory action” under the provisions of Executive Order 14094 and, therefore, was not reviewed by OMB.

Regulatory Flexibility Act

The Director of OPM certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Federalism

OPM has examined this rule in accordance with Executive Order 13132, Federalism, and have determined that this rule will not have any negative impact on the rights, roles and responsibilities of State, local, or tribal governments.

Civil Justice Reform

This rule meets the applicable standard set forth in Executive Order 12988.

Unfunded Mandates Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (known as the Congressional Review Act or CRA) (5 U.S.C. 801 *et seq.*) requires most final rules to be submitted to Congress before taking effect. OPM will submit to Congress and the Comptroller General of the United States a report regarding the issuance of this rule before its effective date. The Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this rule is not a major rule as defined by the CRA (5 U.S.C. 804).

Paperwork Reduction Act

This rule does not impose any reporting or record-keeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

Office of Personnel Management.

Kayyonne Marston,
Federal Register Liaison.

Accordingly, OPM amends 5 CFR part 532 as follows:

**PART 532—PREVAILING RATE
SYSTEMS**

■ 1. The authority citation for part 532 continues to read as follows:

Authority: 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

■ 2. In Appendix C to subpart B, amend the table by revising the wage area listings for the States of Arizona and Utah to read as follows:

Appendix C to Subpart B of Part 532— Appropriated Fund Wage and Survey Areas

Definitions of Wage Areas and Wage Area Survey Areas

* * * * *

ARIZONA

Northeastern Arizona

Survey Area

Arizona:

Apache
Coconino
Navajo

New Mexico:

McKinley
San Juan

Area of Application. Survey area plus:

Colorado:

Dolores
Gunnison (Only includes the Curecanti
National Recreation Area portion)

La Plata

Montezuma

Montrose

Ouray

San Juan

San Miguel

Utah:

Garfield (Only includes the Bryce Canyon,
Capitol Reef, and Canyonlands National
Parks portions)

Grand (Only includes the Arches and
Canyonlands National Parks portions)

Iron (Only includes the Cedar Breaks
National Monument and Zion National
Park portions)

Kane

San Juan

Washington

Wayne (Only includes the Capitol Reef and
Canyonlands National Parks portions)

Phoenix

Survey Area

Arizona:

Gila
Maricopa

Area of Application. Survey area plus:

Arizona:

Pinal
Yavapai

Tucson

Survey Area

Arizona:

Pima

Area of Application. Survey area plus:

Arizona:

Cochise
Graham
Greenlee
Santa Cruz

* * * * *

UTAH

Utah

Survey Area

Utah:

Box Elder

Davis

Salt Lake

Tooele

Utah

Weber

Area of Application. Survey area plus:

Utah:

Beaver

Cache

Carbon

Daggett

Duchesne

Emery

Garfield (Does not include the Bryce
Canyon, Capitol Reef, and Canyonlands
National Parks portions)

Grand (Does not include the Arches and
Canyonlands National Parks portions)

Iron (Does not include the Cedar Breaks
National Monument and Zion National
Park portions)

Juab

Millard

Morgan

Piute

Rich

Sevier

Sanpete

Summit

Uintah

Wasatch

Wayne (Does not include the Capitol Reef
and Canyonlands National Parks
portions)

* * * * *

[FR Doc. 2023–25155 Filed 11–14–23; 8:45 am]

BILLING CODE 6325–39–P

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

[Docket ID FCIC–23–0007]

RIN 0563–AC84

Early Harvest Insurance Flexibility for Sugar Beets

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

ACTION: Final rule with request for
comments.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) is amending the Common Crop Insurance Regulations, Sugar Beet Crop Insurance Provisions. This rule makes the early harvest adjustment an option, providing producers with maximum flexibility to tailor their insurance policy to meet the unique risk management needs of their operation. This rule also incorporates comments to improve the early harvest adjustment that were received on a prior final rule amending the Sugar Beet Crop Insurance Provisions, published in the

Federal Register on November 29, 2019. The changes will be effective for the 2024 and succeeding crop years for counties with a contract change date on or after November 30, 2023, and for the 2025 and succeeding crop years for counties with a contract change date prior to November 30, 2023.

DATES:

Effective date: November 30, 2023.

Comment date: We will consider comments that we receive by the close of business January 16, 2024. FCIC will consider the comments received and may conduct additional rulemaking in the future based on the comments.

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

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and search for Docket ID FCIC–23–0007. Follow the instructions for submitting comments.

All comments will be posted without change and will be publicly available on www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Francie Tolle; telephone (816) 926–7829; or email francie.tolle@usda.gov. Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720–2600 (voice) or (844) 433–2774 (toll-free nationwide).

SUPPLEMENTARY INFORMATION:

Background

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

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

CFR chapter IV. Throughout this rule, the terms “Crop Provisions,” “Special Provisions,” and “policy” are used as defined in the Common Crop Insurance Policy (CCIP) Basic Provisions in 7 CFR part 457.8. Additional information and definitions related to Federal crop insurance policies are in 7 CFR 457.8.

In this rule, FCIC is making the early harvest adjustment an option and making other improvements to the early harvest adjustment in response to public comments and other input from the American Sugarbeet Growers Association (ASGA) and AIPs. The FCIC has a long history of working closely with the ASGA and AIPs in tailoring this program to the unique risk management needs of sugar beet growers.

Early Harvest Adjustment Option

For the 2019 crop year, FCIC added an early harvest adjustment to the Crop Provisions in the Common Crop Insurance Regulations; Sugar Beet Crop Insurance Provisions final rule, published in the **Federal Register** on September 10, 2018 (83 FR 45535–45539). In response to public comments, FCIC made additional changes in the Common Crop Insurance Regulations; Sugar Beet Crop Insurance Provisions final rule published in the **Federal Register** on November 29, 2019 (84 FR 65627–65639). The early harvest adjustment, as amended, was created to limit the effects to producers’ Approved Production History (APH) databases from processor requirements to harvest sugar beets before they reach full maturity. Sugar beets that are harvested early are smaller in size and have a lower percent of sugar than beets harvested at full maturity, resulting in a lower net weight in the producer’s APH database for that year. The lower yield remains in the producer’s APH database for a minimum of 10 years, reducing their future potential insurance guarantee.

Prior to this rule, the early harvest adjustment applied if the threshold in the Special Provisions was exceeded. For those acres harvested early, the producer’s yield in their APH database was automatically adjusted upwards by one percent per day covering the time until the sugar beets would have reached full maturity. This adjustment was intended to protect their future guarantee.

With the publication of the 2019 final rule, concerns were raised during the public comment period by ASGA that the early harvest adjustment could affect a producer’s claim or possible claim in the event of an insurable cause of loss. For example, if some acres were early

harvested and the yield was adjusted upwards, but the producer subsequently had an insured cause of loss that reduced their yield, the upward early harvest adjustment could have an offsetting effect on the claim for indemnity.

ASGA requested that the early harvest adjustment be made an optional feature of the Crop Provisions. Making the early harvest adjustment optional will allow producers greater flexibility and limit the possible negative impacts to a producer’s APH due to technological yield improvements.

In this rule, FCIC is making the early harvest adjustment optional, which allows producers to opt-in to the early harvest adjustment. Producers choosing this option will be required to select the option by the sales closing date. The producer will be able to choose which years from their APH database to apply the early harvest adjustment for production that was harvested early. The producer’s premium will reflect the additional coverage between the adjusted yields and actual yields selected by the producer. The producer may have a higher approved yield and insurance coverage when an actual yield is adjusted in an APH database. If adjusting a yield will result in an increased approved yield, a higher insurance guarantee and greater indemnity payment could occur due to the early harvest adjustment. The producer will pay a higher premium for the increase in coverage. For example, a producer with a 65 percent coverage level may get a yield guarantee equivalent to a higher coverage level, such as 70 percent. Because of the early harvest adjustment option, the premium charged will reflect the higher effective coverage level (70 percent for this example) and higher risk of loss. If a producer elects the early harvest adjustment option, their premium will be adjusted while other producers who did not elect the option will not pay additional premium. It will be the AIP’s responsibility to ensure that the approved yield is calculated correctly, which determines the appropriate premium amount.

In making the early harvest adjustment an option, all producers will be required to recertify their APH database with their AIP to remove those yields from their database from the years that the adjustment was automatically applied. This will ensure that only those producers who elect the option going forward, will be charged the additional premium associated with the adjusted yields.

To elect the early harvest adjustment option, producers must choose the

option by the sales closing date and must have additional coverage (that is, not a Catastrophic Risk Protection Endorsement). The option will remain in effect for future years, unless cancelled. On or before the production reporting date, the producer can replace actual yields with early harvested adjusted yields. The adjustment will only be made if a threshold of at least 15 percent of the insured acreage in the unit is early harvested, unless the Special Provisions specify a different threshold. The adjustment will not be made if the sugar beets are damaged by an insurable cause of loss and leaving the crop in the field would reduce production.

During the decision-making process for this rule, FCIC was committed to reaching a desirable outcome for all program stakeholders. FCIC regularly communicated with ASGA, on behalf of their grower constituency, and AIPs to gain consensus on the framework of the proposed changes and overcome challenges and points of disagreement.

AIPs expressed concerns regarding additional administrative burdens on producers who will be required to recertify their APH databases. FCIC worked closely with ASGA to confirm, on behalf of their producer constituency, their support for these changes, including the requirement for producers to recertify their APH databases to implement these requested changes.

Additionally, ASGA requested to exclude the adjustments to early harvested productions on acreage with a claim. However, as identified by AIPs, due to the discretion producers have in choosing which acreage to early harvest, waiving adjustments on acreage with a claim would have introduced unwanted moral hazard in the program. FCIC believes it has landed on common, middle ground, as these choices give the producer maximum flexibility to tailor their insurance to their operation, while maintaining the actuarial soundness of the Federal crop insurance program.

Early Harvest Adjustment Cap

Following the comment period for the 2019 final rule, AIPs raised additional concerns, on behalf of their insured producers, with the limits (commonly referred to as a “cap”) on the early harvest adjustment. The cap is the maximum amount a particular actual yield can be adjusted to. The early harvest adjustment was capped at the higher of the approved yield (the average of all yields in an APH database and the basis for which the unit guarantee is calculated) or the actual yield of the production harvested after

full maturity from the unit. Due to improvements in sugar beet technology, yield potential has increased, and it is possible that a producer's early harvested actual yield exceeds the limit even before the adjustment was applied. In these cases, the actual yield was capped at the approved yield even though the actual yield was higher than the approved yield.

In this rule, FCIC is modifying the limits to the early harvest adjustment to account for situations where early harvested actual yields would have surpassed the previous cap. The changes address the cases where the actual early harvest yield prior to the early harvest adjustment exceeds the approved yield. The cap was intended to ensure adjustments don't exceed realistic yields; it was never the intent of the cap to reduce an actual yield.

Clarifications and Grammatical Corrections

In this rule, FCIC is capitalizing "Crop Provisions" in two places to be consistent with the CCIP Basic Provisions. In section 17, FCIC is clarifying that the Stage Removal Option is only available if provided in the actuarial documents.

Effective Date, Notice and Comment, and Exemptions

The Administrative Procedure Act (APA, 5 U.S.C. 553) provides that the notice and comment and 30-day delay in the effective date provisions do not apply when the rule involves specified actions, including matters relating to contracts. This rule governs contracts for crop insurance policies and therefore falls within that exemption.

This rule is exempt from the regulatory analysis requirements of the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996. The requirements for the regulatory flexibility analysis in 5 U.S.C. 603 and 604 are specifically tied to the requirement for a proposed rule under 5 U.S.C. 553 or any other law; in addition, the definition of rule in 5 U.S.C. 601 is tied to the publication of a proposed rule.

For major rules, the Congressional Review Act requires a delay of the effective date of 60 days after publication to allow for Congressional review. This rule is not a major rule under the Congressional Review Act, as defined by 5 U.S.C. 804(2). Therefore, this final rule is effective on November 30, 2023. Although not required by APA or any other law, FCIC has chosen to request comments on this rule.

Executive Orders 12866 and 13563

Executive Order 12866, "Regulatory Planning and Review," and Executive Order 13563, "Improving Regulation and Regulatory Review," direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The requirements in Executive Orders 12866 and 13563 for the analysis of costs and benefits apply to rules that are determined to be significant or economically significant.

The Office of Management and Budget (OMB) has designated this rule as not significant under Executive Order 12866, "Regulatory Planning and Review," and therefore, OMB has not reviewed this rule and analysis of the costs and benefits is not required under either Executive Order 12866 or 13563.

Clarity of the Regulation

Executive Order 12866, as supplemented by Executive Order 13563, requires each agency to write all rules in plain language. In addition to your substantive comments on this rule, we invite your comments on how to make the rule easier to understand. For example:

- Are the requirements in the rule clearly stated? Are the scope and intent of the rule clear?
- Does the rule contain technical language or jargon that is not clear?
- Is the material logically organized?
- Would changing the grouping or order of sections or adding headings make the rule easier to understand?
- Could we improve clarity by adding tables, lists, or diagrams?
- Would more, but shorter, sections be better? Are there specific sections that are too long or confusing?
- What else could we do to make the rule easier to understand?

Environmental Review

The environmental impacts of this final rule have been considered in a manner consistent with the provisions of the National Environmental Policy Act (NEPA, 42 U.S.C. 4321–4347), the regulations of the Council on Environmental Quality (40 CFR parts 1500–1508), and because USDA will be making the payments to producers, the USDA regulation for compliance with

NEPA (7 CFR part 1b). As specified in 7 CFR 1b.4(b)(4), FCIC is categorically excluded from the preparation of an Environmental Analysis or Environmental Impact Statement unless the FCIC Manager (agency head) determines that an action may have a significant environmental effect. The FCIC Manager has determined this rule will not have a significant environmental effect. Therefore, FCIC will not prepare an environmental assessment or environmental impact statement for this action and this rule serves as documentation of the programmatic environmental compliance decision.

Executive Order 12988

This rule has been reviewed under Executive Order 12988, "Civil Justice Reform." This rule will not preempt State or local laws, regulations, or policies unless they represent an irreconcilable conflict with this rule. Before any judicial actions may be brought regarding the provisions of this rule, the administrative appeal provisions of 7 CFR part 11 are to be exhausted.

Executive Order 13175

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

The Risk Management Agency (RMA) has assessed the impact of this rule on Indian Tribes and determined that this rule does not, to our knowledge, have Tribal implications that require Tribal consultation under Executive Order 13175. The regulation changes do not have Tribal implications that preempt Tribal law and are not expected have a substantial direct effect on one or more Indian Tribes. If a Tribe requests consultation, RMA will work with the USDA Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified in this rule are not expressly mandated by Congress.

The Unfunded Mandates Reform Act of 1995

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

Federal Assistance Program

The title and number of the Assistance Listing,¹ to which this rule applies is No. 10.450—Crop Insurance.

Paperwork Reduction Act of 1995

The purpose of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35, subchapter I), among other things, are to minimize the paperwork burden on individuals, and to require Federal agencies to request and receive approval from the Office of Management and Budget (OMB) prior to collecting information from ten or more persons. This rule does not change the information collection approved by OMB under control numbers 0563–0053.

USDA Non-Discrimination Policy

In accordance with Federal civil rights law and U.S. Department of Agriculture (USDA) civil rights regulations and policies, USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family or parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs).

Remedies and complaint filing deadlines vary by program or incident.

Individuals who require alternative means of communication for program information (for example, braille, large print, audiotope, American Sign Language, etc.) should contact the responsible Agency or the USDA TARGET Center at (202) 720–2600 (voice and text telephone (TTY)) or dial 711 for Telecommunications Relay Service (both voice and text telephone users can initiate this call from any telephone). Additionally, program information may be made available in languages other than English.

To file a program discrimination complaint, complete the USDA Program Discrimination Complaint Form, AD–3027, found online at <https://www.usda.gov/oascr/how-to-file-a-program-discrimination-complaint> and at any USDA office or write a letter addressed to USDA and provide in the letter all the information requested in the form. To request a copy of the complaint form, call (866) 632–9992. Submit your completed form or letter to USDA by: (1) mail to: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) fax: (202) 690–7442; or (3) email: program.intake@usda.gov.

USDA is an equal opportunity provider, employer, and lender.

List of Subjects in 7 CFR Part 457

Acreage allotments, Crop insurance, Reporting and recordkeeping requirements.

For the reasons discussed in the supplementary information, FCIC amends 7 CFR part 457, as follows:

PART 457—COMMON CROP INSURANCE REGULATIONS

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

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

■ 2. Amend § 457.109 by:

- a. In the introductory paragraph, remove the words “for effective for the 2023 and succeeding crop years in states with a November 30 contract change date and for the 2024” and add the words “effective for the 2024 and succeeding crop years in states with a November 30 contract change date and for the 2025” in their place;
- b. In section 1, add definitions of “Early harvest” and “Full maturity (date of)” in alphabetical order;
- c. In section 8, remove the words “crop provisions” and add “Crop Provisions” in each place they appear;
- d. In section 14:

- i. Remove paragraph (f); and
- ii. Redesignate paragraphs (g) and (h) as paragraphs (f) and (g);
- e. In section 17:
- i. Redesignate paragraphs (a)(1) through (4) as paragraphs (a)(2) through (5); and
- ii. Add new paragraph (a)(1); and
- f. Add a new section 18.

The revisions and additions read as follows:

§ 457.109 Sugar Beet Crop Insurance Provisions.

* * * * *

Definitions

* * * * *

Early harvest. Harvest of sugar beets prior to full maturity.

Full maturity (date of). The date the sugar beets would have reached full maturity is 45 days prior to the calendar date for the end of the insurance period, unless otherwise specified in the Special Provisions.

* * * * *

17. Stage Removal Option

- (a) * * *
- (1) If provided in the actuarial documents, you may elect the Stage Removal Option.

* * * * *

18. Early Harvest Adjustment Option

- (a) Applicability:
 - (1) If provided in the actuarial documents, you may elect the Early Harvest Adjustment Option to adjust your actual yield(s) for early harvested production.
 - (2) You must have additional coverage to elect this option.
 - (3) You must elect this option in writing on or before the sales closing date.
 - (4) This election is continuous, in accordance with section 2 of the Basic Provisions, unless canceled by the cancellation date. Your election of the Catastrophic Risk Protection Endorsement for your sugar beets will cancel this option.
- (b) Insurance Guarantees:
 - (1) APH database—On or before the production reporting date, you may replace actual yields with early harvest adjusted yields in your APH database, if this option is elected.
 - (i) The early harvest adjusted yields will be used in the same manner as actual yields for the purpose of calculating the approved yield.
 - (ii) Once an early harvest adjusted yield replaces an actual yield, the early harvest adjusted yield will remain in effect until such time as that crop year is no longer included in the APH

¹ See <https://sam.gov/content/assistance-listings>.

database, this option is canceled in accordance with section 18(a)(4), or the insured chooses to no longer replace that actual yield(s) by the production reporting date.

(iii) If you cancel the option, the actual yield will be used in the APH database.

(2) Premium—Your approved yield will be used to determine your amount of premium owed. The premium will be increased to cover the additional risk associated with the resulting higher yields.

(3) Adjustment—The adjustment will equal an increase of your actual yield by 1 percent per day for each day the sugar beets were harvested prior to full maturity.

(4) Threshold—The adjustment will only be made if the early harvested percentage of insured acreage in the unit meets or exceeds 15 percent, unless otherwise specified in the Special Provisions.

(5) Cap—The adjustment cannot result in a yield greater than the higher of:

(i) Your approved yield from the unit;
(ii) The actual yield of the acreage harvested after full maturity from the unit; or

(iii) The unadjusted actual yield of the early harvested acreage from the unit.

(6) Processor requirement—The adjustment will only be made if:

(i) Early harvest is required in the production agreement; or
(ii) The processor requests early harvest.

(c) Settlement of Claim—If this option is elected, production to count from the unit will be determined by:

(1) The adjustment will be made for any early harvested production if the threshold is exceeded for the unit.

(2) The adjustment will not be made if the sugar beets are damaged by an insurable cause of loss and leaving the crop in the field would reduce production.

(3) If the production agreement does not require early harvest and the processor has not requested early harvest, and the processor:

(i) Accepts the early harvested production, the early harvested production will be counted but no adjustment will apply.

(ii) Does not accept the early harvested production, the production to count will be the production guarantee for the acreage harvested early.

* * * * *

Marcia Bunger,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 2023–25123 Filed 11–14–23; 8:45 am]

BILLING CODE 3410–08–P

CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Part 1022

Fair Credit Reporting Act Disclosures

AGENCY: Consumer Financial Protection Bureau.

ACTION: Final rule; official interpretation.

SUMMARY: The Consumer Financial Protection Bureau (CFPB) is issuing this final rule amending an appendix for Regulation V, which implements the Fair Credit Reporting Act (FCRA). The CFPB is required to calculate annually the dollar amount of the maximum allowable charge for disclosures by a consumer reporting agency to a consumer pursuant to section 609 of the FCRA; this final rule establishes the maximum allowable charge for the 2024 calendar year.

DATES: This final rule is effective January 1, 2024.

FOR FURTHER INFORMATION CONTACT: Anna Boadwee and Adrien Fernandez, Attorney-Advisors, Office of Regulations, at (202) 435–7700. If you require this document in an alternative electronic format, please contact CFPB_Accessibility@cfpb.gov.

SUPPLEMENTARY INFORMATION: The CFPB is amending Appendix O to Regulation V, which implements the FCRA, to establish the maximum allowable charge for disclosures by a consumer reporting agency to a consumer for 2024. The maximum allowable charge will be \$15.50 for 2024.

I. Background

Under section 609 of the FCRA, a consumer reporting agency must, upon a consumer's request, disclose to the consumer information in the consumer's file.¹ Section 612(a) of the FCRA gives consumers the right to a free file disclosure upon request once every 12 months from the nationwide consumer reporting agencies and nationwide specialty consumer reporting agencies.² Section 612 of the FCRA also gives consumers the right to a free file disclosure under certain other, specified circumstances.³ Where the consumer is not entitled to a free file disclosure, section 612(f)(1)(A) of the FCRA

provides that a consumer reporting agency may impose a reasonable charge on a consumer for making a file disclosure. Section 612(f)(1)(A) of the FCRA provides that the charge for such a disclosure shall not exceed \$8.00 and shall be indicated to the consumer before making the file disclosure.⁴

Section 612(f)(2) of the FCRA also states that the \$8.00 maximum amount shall increase on January 1 of each year, based proportionally on changes in the Consumer Price Index, with fractional changes rounded to the nearest fifty cents.⁵ Such increases are based on the Consumer Price Index for All Urban Consumers (CPI-U), which is the most general Consumer Price Index and covers all urban consumers and all items.

II. Adjustment

For 2024, the ceiling on allowable charges under section 612(f) of the FCRA will be \$15.50, an increase of one dollar from 2023. The CFPB is using the \$8.00 amount set forth in section 612(f)(1)(A)(i) of the FCRA as the baseline for its calculation of the increase in the ceiling on reasonable charges for certain disclosures made under section 609 of the FCRA. Since the effective date of section 612(a) was September 30, 1997, the CFPB calculated the proportional increase in the CPI-U from September 1997 to September 2023. The CFPB then determined what modification, if any, from the original base of \$8.00 should be made effective for 2024, given the requirement that fractional changes be rounded to the nearest fifty cents.

Between September 1997 and September 2023, the CPI-U increased by 90.936 percent from an index value of 161.2 in September 1997 to a value of 307.789 in September 2023.⁶ An increase of 90.936 percent in the \$8.00 base figure would lead to a figure of \$15.27. However, because the statute directs that the resulting figure be rounded to the nearest \$0.50, the maximum allowable charge is \$15.50. The CFPB therefore determines that the maximum allowable charge for the year 2024 will increase to \$15.50.

III. Procedural Requirements

A. Administrative Procedure Act

Under the Administrative Procedure Act (APA), notice and opportunity for public comment are not required if the CFPB finds that notice and public

¹ 15 U.S.C. 1681g.

² 15 U.S.C. 1681j(a).

³ 15 U.S.C. 1681j(b)–(d). The maximum allowable charge announced by the CFPB does not apply to requests made under section 612(a)–(d) of the FCRA. The charge does apply when a consumer who orders a file disclosure has already received a free annual file disclosure and does not otherwise qualify for an additional free file disclosure.

⁴ 15 U.S.C. 1681j(f)(1)(A).

⁵ 15 U.S.C. 1681j(f)(2).

⁶ The Bureau of Labor Statistics began reporting CPI-U with three decimal points instead of one decimal point in 2007.

comment are impracticable, unnecessary, or contrary to the public interest.⁷ Pursuant to this final rule, in Regulation V, Appendix O is amended to update the maximum allowable charge for 2024 under section 612(f). The amendments in this final rule are technical and non-discretionary, as they merely apply the method previously established in Regulation V for determining adjustments to the thresholds. For these reasons, the CFPB has determined that publishing a notice of proposed rulemaking and providing opportunity for public comment are unnecessary. The amendments therefore are adopted in final form.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) does not apply to a rulemaking where a general notice of proposed rulemaking is not required.⁸ As noted previously, the CFPB has determined that it is unnecessary to publish a general notice of proposed rulemaking for this final rule. Accordingly, the RFA's requirement relating to an initial and final regulatory flexibility analysis does not apply.

C. Paperwork Reduction Act

The information collections contained in Regulation V, which implements the FCRA, are approved by the Office of Management and Budget under Control number 3170-0002. The current approval for this control number expires on October 31, 2025. In accordance with the Paperwork Reduction Act of 1995,⁹ the CFPB reviewed this final rule. The CFPB has determined that this rule does not create any new information collections or substantially revise any existing collections.

D. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the CFPB will submit a report containing this rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to the rule taking effect. The Office of Information and Regulatory Affairs has designated this rule as not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 12 CFR Part 1022

Banks, banking, Consumer protection, Credit unions, Holding companies, National banks, Privacy, Reporting and recordkeeping requirements, Savings associations.

Authority and Issuance

For the reasons set forth in the preamble, the CFPB amends Regulation V, 12 CFR part 1022, as set forth below:

PART 1022—FAIR CREDIT REPORTING (REGULATION V)

- 1. The authority citation for part 1022 continues to read as follows:

Authority: 12 U.S.C. 5512, 5581; 15 U.S.C. 1681a, 1681b, 1681c, 1681c-1, 1681e, 1681g, 1681i, 1681j, 1681m, 1681s, 1681s-2, 1681s-3, and 1681t; Sec. 214, Pub. L. 108-159, 117 Stat. 1952.

- 2. Appendix O is revised to read as follows:

Appendix O to Part 1022—Reasonable Charges for Certain Disclosures

Section 612(f) of the FCRA, 15 U.S.C. 1681j(f), directs the Bureau to increase the maximum allowable charge a consumer reporting agency may impose for making a disclosure to the consumer pursuant to section 609 of the FCRA, 15 U.S.C. 1681g, on January 1 of each year, based proportionally on changes in the Consumer Price Index, with fractional changes rounded to the nearest fifty cents. The Bureau will publish notice of the maximum allowable charge each year by amending this appendix. For calendar year 2024, the maximum allowable charge is \$15.50. For historical purposes:

1. For calendar year 2012, the maximum allowable disclosure charge was \$11.50.
2. For calendar year 2013, the maximum allowable disclosure charge was \$11.50.
3. For calendar year 2014, the maximum allowable disclosure charge was \$11.50.
4. For calendar year 2015, the maximum allowable disclosure charge was \$12.00.
5. For calendar year 2016, the maximum allowable disclosure charge was \$12.00.
6. For calendar year 2017, the maximum allowable disclosure charge was \$12.00.
7. For calendar year 2018, the maximum allowable disclosure charge was \$12.00.
8. For calendar year 2019, the maximum allowable disclosure charge was \$12.50.
9. For calendar year 2020, the maximum allowable disclosure charge was \$12.50.
10. For calendar year 2021, the maximum allowable disclosure charge was \$13.00.
11. For calendar year 2022, the maximum allowable disclosure charge was \$13.50.
12. For calendar year 2023, the maximum allowable disclosure charge was \$14.50.
13. For calendar year 2024, the maximum allowable disclosure charge is \$15.50.

Brian Shearer,

Senior Advisor, Consumer Financial Protection Bureau.

[FR Doc. 2023-25172 Filed 11-14-23; 8:45 am]

BILLING CODE 4810-AM-P

DEPARTMENT OF STATE

22 CFR Part 171

[Public Notice: 12225]

RIN 1400-AF57

Privacy Act of 1974; STATE-60, Special Presidential Envoy for Hostage Affairs and Related Records

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is giving notice of a publication for a system of records pursuant to the Privacy Act of 1974 for the Special Presidential Envoy for Hostage Affairs and Related Records, STATE-60; and this final rule, which exempts portions of this system of records from one or more provisions of the Privacy Act of 1974.

DATES: This rule is effective December 15, 2023.

FOR FURTHER INFORMATION CONTACT: Eric F. Stein, Senior Agency Official for Privacy; U.S. Department of State; Office of Global Information Services, A/GIS; Room 4534, 2201 C St. NW; Washington, DC 20520 or by calling (202) 485-2051.

SUPPLEMENTARY INFORMATION: The Department of State maintains the Special Presidential Envoy for Hostage Affairs and Related Records system of records. The primary purpose of this system of records is to support diplomatic and consular efforts to secure the recovery of and provide assistance and support services to individuals taken hostage or wrongfully detained abroad.

The Department concurrently published a notice of a new system of records, Special Presidential Envoy for Hostage Affairs and Related Records, STATE-60, 88 FR 23487, April 17, 2023, and a proposed rule with a request for comments (88 FR 23368), amending 22 CFR part 171 to exempt portions of STATE-60 from subsections (c)(3); (d); (e)(1); (e)(4)(G), (H), and (I); and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(1) and (k)(2). STATE-60 is exempted under subsection (k)(1) to the extent that records within that system are subject to the provisions of 5 U.S.C. 552(b)(1). STATE-60 is exempted under subsection (k)(2) to the extent that records within that system are comprised of investigatory material compiled for law enforcement purposes, subject to the limitations set forth in that section. One public comment was received; however, it did not pertain to the subject of this rulemaking.

⁷ 5 U.S.C. 553(b)(B).

⁸ 5 U.S.C. 603(a), 604(a).

⁹ 44 U.S.C. 3506; 5 CFR part 1320.

The Department is now promulgating a final rule with no substantive changes from the proposed rule.

Regulatory Findings

Administrative Procedure Act

In accordance with the Administrative Procedure Act, this rule was published and 60 days provided for public comment.

Other Regulatory Analyses

This rule does not affect small businesses; is not subject to the Unfunded Mandates Act of 1995; is not a major rule within the meaning of the Congressional Review Act, or a significant rule within the meaning of Executive Order 12866; has no federalism or tribal implications; and will not create or modify any information collections subject to the Paperwork Reduction Act.

List of Subjects in 22 CFR Part 171

Administrative practice and procedure; Freedom of information; Privacy.

For the reasons discussed above, the Department revises 22 CFR part 171 to read as follows:

PART 171—PUBLIC ACCESS TO INFORMATION

■ 1. The authority citation for part 171 continues to read as follows:

Authority: 22 U.S.C. 2651a; 5 U.S.C. 552, 552a; 5 U.S.C. Ch. 131; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235; 5 CFR part 2634.

■ 2. Amend § 171.26 by:

■ a. Adding an entry, in alphabetical order, in Table 2 to Paragraph (b)(1) for “Special Presidential Envoy for Hostage Affairs and Related Records, State-60.”; and

■ b. Adding an entry, in alphabetical order, in Table 3 to Paragraph (b)(2) for “Special Presidential Envoy for Hostage Affairs and Related Records, State-60.”

■ 3. The additions read as follows:

§ 171.26 Exemptions.

* * * * *
(b) * * *
(1) * * *

TABLE 2 TO PARAGRAPH (b)(1)

Title	Number
* * * * *	
Special Presidential Envoy for Hostage Affairs	STATE-60
* * * * *	
(2) * * *	

TABLE 3 TO PARAGRAPH (b)(2)

Title	Number
* * * * *	
Special Presidential Envoy for Hostage Affairs	STATE-60
* * * * *	
* * * * *	

Kevin E. Bryant,
Deputy Director, Office of Directives Management, Department of State.
[FR Doc. 2023-25018 Filed 11-14-23; 8:45 am]
BILLING CODE 4710-05-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R04-OAR-2022-0409; FRL-8790-01-R4]

Air Plan Approval; Kentucky; Update to Materials Incorporated by Reference

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; notice of administrative change.

SUMMARY: The Environmental Protection Agency (EPA) is updating the materials that are incorporated by reference (IBR) into the Commonwealth of Kentucky’s (Commonwealth’s) State Implementation Plan (SIP). The regulations affected by this update have been previously submitted by the Commonwealth and approved by EPA. In this notice, EPA is also notifying the public of corrections and clarifying changes to the Code of Federal Regulations (CFR) tables that identify material incorporated by reference into the Commonwealth’s SIP. This update affects the materials that are available for public inspection at the National Archives and Records Administration (NARA) and the EPA Regional Office.

DATES: This rule is effective November 15, 2023.

ADDRESSES: The SIP materials whose incorporation by reference into 40 CFR part 52 is finalized through this action are available for inspection at the following locations: Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, GA 30303; and www.regulations.gov. To view the materials at the Region 4 Office, EPA requests that you email the contact listed in the FOR FURTHER INFORMATION CONTACT section to schedule your inspection. The Regional Office’s

official hours of business are Monday through Friday 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

FOR FURTHER INFORMATION CONTACT: Sarah LaRocca, Air Planning and Implementation Branch, Air and Radiation Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW, Atlanta, Georgia 30303-8960. Ms. LaRocca can be reached via telephone at (404) 562-8994 or via electronic mail at larocca.sarah@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Each State has a SIP containing the control measures and strategies used to attain and maintain the national ambient air quality standards (NAAQS). The SIP is extensive, containing such elements as air pollution control regulations, emission inventories, monitoring networks, attainment demonstrations, and enforcement mechanisms.

Each State must formally adopt the control measures and strategies in the SIP after the public has had an opportunity to comment on them and then submit the proposed SIP revisions to EPA. Once these control measures and strategies are approved by EPA, and after notice and comment, they are incorporated into the federally-approved SIP and are identified in part 52—“Approval and Promulgation of Implementation Plans,” Title 40 of the Code of Federal Regulations (40 CFR part 52). The full text of the State regulation approved by EPA is not reproduced in its entirety in 40 CFR part 52 but is “incorporated by reference.” This means that EPA has approved a given State regulation or specified changes to a given regulation with a specific effective date. The public is referred to the location of the full text version should they want to know which measures are contained in the SIP. The information provided allows EPA and the public to monitor the extent to which a State implements a SIP to attain and maintain the NAAQS and to take enforcement action for violations of the SIP.

The SIP is a living document which the State can revise as necessary to address the unique air pollution problems in the State. Therefore, EPA from time to time must take action on proposed revisions containing new or revised regulations. A submission from a State can revise one or more rules in their entirety or portions of rules. The State indicates the changes in the submission (such as by using redline/ strikethrough text), and EPA then takes

action on the requested changes. EPA establishes a docket for its actions using a unique Docket Identification Number, which is listed in each action. These dockets and the complete submission are available for viewing on www.regulations.gov.

On May 22, 1997 (62 FR 27968), EPA revised the procedures for incorporating by reference, into the Code of Federal Regulations, materials approved by EPA into each SIP. These changes revised the format for the identification of the SIP in 40 CFR part 52, streamlined the mechanisms for announcing EPA approval of revisions to a SIP, and streamlined the mechanisms for EPA's updating of the IBR information contained for each SIP in 40 CFR part 52. The revised procedures also called for EPA to maintain "SIP Compilations" that contain the federally approved regulations and source-specific permits submitted by each State agency. EPA generally updates these SIP Compilations on an annual basis. Under the revised procedures, EPA must periodically publish an informational document in the rules section of the **Federal Register** notifying the public that updates have been made to a SIP Compilation for a particular State. EPA began applying the 1997 revised procedures to the Commonwealth on May 27, 1999 (64 FR 28748), to Jefferson County, Kentucky, on October 23, 2001 (66 FR 53658), and to EPA-Approved Kentucky Source-Specific Requirements on May 27, 1999 (64 FR 28748) and is providing this notice in accordance with such procedures.

II. EPA Action

In this action, EPA is providing notice of an update to the materials incorporated by reference into the Commonwealth's SIP as of September 30, 2022, and identified in 40 CFR 52.920(c) and (d). This update includes SIP materials approved by EPA since the last IBR update. *See* 69 FR 1677 (January 12, 2004). In addition, EPA is providing notice of the following corrections and clarifying changes to 40 CFR 52.920(c) and (d):

Changes Applicable to Paragraph (c), Table 1—EPA-Approved Kentucky Laws and Regulations

A. Correcting Table (c)'s title, from "(c) EPA approved regulations" to "(c) EPA-approved laws and regulations".

B. Changing Table 1's header of paragraph (c) from "EPA-Approved Kentucky Regulations" to "EPA-Approved Kentucky Laws and Regulations".

C. Under the "State effective date" and "EPA approval date" removing the

leading zero from the month and day, changing the 2-digit year to reflect a 4-digit year (for consistency), and correcting **Federal Register** citations to reflect the beginning page of the preamble as opposed to that of the regulatory text.

D. Removing the period after all **Federal Register** citations (for consistency) under "EPA approval date".

E. Changing the EPA approval date under Chapter 50, 401 KAR 50:055, from "5/4/1989, 54 FR 19169" to "12/4/1986, 51 FR 43742", to accurately reflect revisions made to the respective rule.

F. Correcting a typographical error in the CFR under Chapter 50, 401 KAR 50:066, by changing the title from "Conformity of transportation plans, programs, and projects. (Amendment)" to "Conformity of transportation plans, programs, and projects (Amendment)".

G. Adding language "Except the phrase 'except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140' in 401 KAR 51:001 Section 1(118)(a)(2)(a) and the phrase 'except ethanol production facilities producing ethanol by natural fermentation under NAICS codes 325193 or 312140' in 401 KAR 51:001 Section 1(118)(c)(20)" into the "Explanation" for the entry under Chapter 51, 401 KAR 51:001, to better reflect the action described in 75 FR 55988.

H. Adding language "With the exception of the SILs and SMC provisions for PM_{2.5}, and except the phrase 'except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140' in 401 KAR 51:017 Section 7(1)(c)20" for the entry under Chapter 51, 401 KAR 51:017, to better reflect the action described in 75 FR 55988.

I. Adding language "With the exception of the SILs and SMC provisions for PM_{2.5} and except the phrase 'except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140' in 401 KAR 51:052 Section 2(3)(i)" for the entry under Chapter 51, 401 KAR 51:052, to better reflect the actions described in 79 FR 65143 and 75 FR 55988, respectively.

J. Correcting a typographical error in the CFR under Chapter 51, 401 KAR 51:052, by changing the title "Review of new sources in or impacting

nonattainment areas" to "Review of new sources in or impacting upon nonattainment areas".

K. Changing the effective date of 401 KAR 51:052 because Kentucky's September 23, 2011, SIP revision, with an effective date of August 4, 2011, is captured and superseded by Kentucky's January 31, 2013, SIP revision, state effective on December 7, 2012, which EPA previously approved on November 3, 2014.

L. Changing the State Citation title "*** 401 KAR 52:040" to "401 KAR 52:040".

M. Adding language "Except for references to hydrogen sulfide, fluorides, and odor" into the "Explanation" for the entry under Chapter 53, 401 KAR 53:010, to better reflect the action described in 82 FR 42746.

N. Correcting a typographical error for State citation 401 KAR 59:105 by changing the title, "New process gas streams" to "New process gas streams".

O. Correcting a typographical error in the CFR under Chapter 61, 401 KAR 61:001, changing the title "Definitions and abbreviations of terms used in the Title 401, Chapter 61" to "Definitions for 401 KAR Chapter 61".

P. Including an EPA approval date and a **Federal Register** citation for 401 KAR 61:001.

Changes Applicable to Paragraph (c), Table 2—EPA-Approved Jefferson County Regulations for Kentucky

A. Under the "State effective date" and "EPA approval date" removing the leading zero from the month and day, changing the 2-digit year to reflect a 4-digit year (for consistency), and correcting **Federal Register** citations to reflect the beginning page of the preamble as opposed to that of the regulatory text.

B. Adding the phrase "Except for paragraphs 1.3, 5.3 and 5.6 regarding asbestos demolition, which were removed from the federally approved SIP by EPA on 5/7/2021" into the "Explanation" for the entry under Reg 2, Reg 2.03 to reflect the action described in 86 FR 24505.

C. Reformatting Reg 6, specifically 6.44 and 6.45, to be in sequential order.

D. Removing the heading "Reg 8—Mobile Source Emissions Control".

Changes Applicable to Paragraph (d) EPA-Approved Kentucky Source-Specific Requirements

A. Under the "State effective date" and "EPA approval date" removing the leading zero from the month and day, changing the 2-digit year to reflect a 4-digit year (for consistency), correcting

various dates under “State effective date,” and correcting **Federal Register** citations to reflect the beginning page of the preamble as opposed to that of the regulatory text of the regulatory text.

B. Removing the period after all **Federal Register** citations (for consistency) under “EPA approval date”.

C. Rephrasing the “Explanation” for entry “Calgon Carbon Corporation”, specifically for emission points 32, 34, 39, 40, to be in sequential order.

D. Removing the duplicate “TVA Paradise Permit” entry with “Permit No.” “KDEPDAQ Permit 0–87–012”.

E. Correcting a typographical error in the “Explanation” column for the entry “Source-Specific SIP Revision for Avis Budget Car Rental Group” by adding a period to read as follows: “Removal of stage II requirements.”

F. Under “Variance for seven perchloroethylene dry cleaners”, the State effective date is revised from “8/4/1982” to “7/30/1982”.

G. Under “Variance for two dry cleaners”, the State effective date is revised from “1/27/1983” to “1/12/1983”.

H. Under “Variance for Jiffy and Hiland Dry Cleaners”, the State effective date is revised from “4/25/1984” to “3/30/1984”.

I. Correcting a typographical error in the CFR under “Opacity variance for boiler Units 1 and 2 of TVA’s Paradise Steam Plant” by changing the State effective date from “7/24/1996” to “7/24/1986”.

III. Good Cause Exemption

EPA has determined that this action falls under the “good cause” exemption in section 553(b)(3)(B) of the Administrative Procedure Act (APA) which, upon finding “good cause,” authorizes agencies to dispense with public participation and section 553(d)(3) which allows an agency to make an action effective immediately (thereby avoiding the 30-day delayed effective date otherwise provided for in the APA). This administrative action simply codifies provisions which are already in effect as a matter of law in Federal and approved State programs, makes typographical/ministerial revisions to the tables in the CFR, and makes ministerial changes to the prefatory heading to the tables in the CFR. Under section 553(b)(3)(B) of the APA, an agency may find good cause where procedures are “impracticable, unnecessary, or contrary to the public interest.” Public comment for this administrative action is “unnecessary” and “contrary to the public interest” since the codification (and corrections)

only reflect existing law and the changes to the prefatory heading to the tables are ministerial in nature. Immediate notice of this action in the **Federal Register** benefits the public by providing the public notice of the updated Kentucky SIP Compilation and notice of corrections and clarifications to the Commonwealth’s “Identification of Plan” portion of the CFR. Further, pursuant to section 553(d)(3), making this action immediately effective benefits the public by immediately updating both the SIP Compilation and the CFR “Identification of plan” section (which includes table entry corrections).

IV. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of regulations promulgated by Kentucky, previously approved by EPA and federally effective before to September 30, 2022, contained in “Kentucky, Volume 1, 40 CFR 52.920(c)(1), EPA-Approved Kentucky Laws and Regulations”, “Kentucky, Volume 2, 40 CFR 52.920(c)(2), EPA-Approved Jefferson County Regulations”, and “Kentucky, Volume 3, 40 CFR 52.920(d), EPA-Approved Kentucky Source-Specific Requirements”. EPA has made, and will continue to make, these materials generally available through www.regulations.gov and at the EPA Region 4 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. See 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA’s role is to approve State choices, provided that they meet the criteria of the CAA. Accordingly, this final rule and notification of administrative change does not impose additional requirements beyond those imposed by State law. For that reason, this action:

- Is not a “significant regulatory action” subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and

- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on Tribal governments or preempt Tribal law.

Executive Order 12898 (Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address

“disproportionately high and adverse human health or environmental effects” of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. EPA defines environmental justice (EJ) as “the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.” EPA further defines the term fair treatment to mean that “no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.” EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there

is no information in the record inconsistent with the stated goal of E.O. 12898 of achieving EJ for people of color, low-income populations, and Indigenous peoples.

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

EPA also believes that the provisions of section 307(b)(1) of the CAA pertaining to petitions for judicial review are not applicable to this action. This is because prior EPA rulemaking actions for each individual component of the Kentucky SIP compilation previously afforded interested parties the opportunity to file a petition for judicial review in the United States Court of Appeals for the appropriate circuit within 60 days of such rulemaking action. Thus, EPA believes judicial review of this action under section 307(b)(1) is not available.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: November 1, 2023.

Jeanne Gettle,

Acting Regional Administrator, Region 4.

40 CFR part 52, is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart S—Kentucky

■ 2. In § 52.920, paragraphs (b), (c), and (d) are revised as follows:

§ 52.920 Identification of plan.

* * * * *

(b) *Incorporation by reference.* (1) Material listed in paragraphs (c) and (d) of this section with an EPA approval date prior to September 30, 2022, for the Commonwealth of Kentucky and September 30, 2022, for Jefferson County, Kentucky, was approved for incorporation by reference by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1

CFR part 51. Material is incorporated as it exists on the date of the approval and notice of any change in the material will be published in the **Federal Register**. Entries in paragraph (c), Tables 1 and 2, and paragraph (d) of this section with EPA approval dates after September 30, 2022, for the Commonwealth of Kentucky and September 30, 2022, for Jefferson County, Kentucky, will be incorporated by reference in the next update to the SIP compilation.

(2) EPA Region 4 certifies that the rules/regulations provided by EPA in the SIP compilation at the addresses in paragraph (b)(3) of this section are an exact duplicate of the officially promulgated State rules/regulations which have been approved as part of the State Implementation Plan as of the dates referenced in paragraph (b)(1).

(3) Copies of the materials incorporated by reference may be inspected at the Region 4 EPA office at 61 Forsyth Street SW, Atlanta, GA 30303. To obtain the material, please call (404) 562–9022. You may also inspect the material with an EPA approval date prior to September 30, 2022, for the Commonwealth 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.

(c) *EPA-approved laws and regulations.*

TABLE 1 TO PARAGRAPH (c)—EPA-APPROVED KENTUCKY LAWS AND REGULATIONS

State citation	Title/subject	State effective date	EPA approval date	Explanation
Chapter 50 Division for Air Quality: General Administrative Procedures				
401 KAR 50:005	General application	6/6/1979	7/12/1982, 47 FR 30059	Except for Section 1(1) and 1(4), which were removed from the SIP by EPA on 8/11/2022.
401 KAR 50:010	Definitions and abbreviations of terms used in Title 401 Chapters 50, 51, 53, 55, 57, 59, 61, 63, and 65.	11/8/2006	9/13/2007, 72 FR 52282	
401 KAR 50:012	General application	11/12/1997	7/24/1998, 63 FR 39739	
401 KAR 50:015	Documents incorporated by reference.	4/14/1988	2/7/1990, 55 FR 4169	
401 KAR 50:020	Air quality control regions	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 50:025	Classification of counties	6/1/1983	4/2/1996, 61 FR 14489	
401 KAR 50:030	Registration of sources	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 50:040	Air quality models	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 50:042	Good engineering practice stack height.	6/10/1986	9/4/1987, 52 FR 33592	
401 KAR 50:045	Performance tests	7/13/2005	10/17/2007, 72 FR 58759	
401 KAR 50:047	Test procedures for capture efficiency.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 50:050	Monitoring	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 50:055	General compliance requirements ..	9/22/1982	12/4/1986, 51 FR 43742	
401 KAR 50:060	Enforcement	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 50:065	Conformity of general federal actions.	10/11/1995	7/27/1998, 63 FR 40044	
401 KAR 50:066	Conformity of transportation plans, programs, and projects (Amendment).	11/12/2008	4/21/2010, 75 FR 20780	

TABLE 1 TO PARAGRAPH (c)—EPA-APPROVED KENTUCKY LAWS AND REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
Chapter 51 Attainment and Maintenance of the National Ambient Air Quality Standards				
401 KAR 51:001	Definitions for 401 KAR Chapter 51	12/7/2012	11/3/2014, 79 FR 65143	Except the phrase “except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140” in 401 KAR 51:001 Section 1(118)(a)(2)(a) and the phrase “except ethanol production facilities producing ethanol by natural fermentation under NAICS codes 325193 or 312140” in 401 KAR 51:001 Section 1(118)(c)(20).
401 KAR 51:005	Purpose and general provisions	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 51:010	Attainment status Designations	11/19/2019	3/1/2021, 86 FR 11870	
401 KAR 51:017	Prevention of significant deterioration of air quality.	12/7/2012	11/3/2014, 79 FR 65143	With the exception of the SILs and SMC provisions for PM _{2.5} , and except the phrase “except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140” in 401 KAR 51:017 Section 7(1)(c)20. With the exception of the SILs and SMC provisions for PM _{2.5} , and except the phrase “except ethanol production facilities producing ethanol by natural fermentation under the North American Industry Classification System (NAICS) codes 325193 or 312140” in 401 KAR 51:052 Section 2(3)(t).
401 KAR 51:052	Review of new sources in or impacting upon nonattainment areas.	12/7/2012	10/8/2015, 80 FR 60805	
401 KAR 51:150	NO _x requirements for stationary internal combustion engines.	2/3/2006	10/23/2009, 74 FR 54755	
401 KAR 51:160	NO _x requirements for large utility and industrial boilers.	2/3/2006	10/23/2009, 74 FR 54755	
401 KAR 51:170	NO _x requirements for cement kilns	8/15/2001	4/11/2002, 67 FR 17624	
401 KAR 51:180	NO _x credits for early reduction and emergency.	8/15/2001	4/11/2002, 67 FR 17624	
401 KAR 51:190	Banking and trading NO _x allowances.	8/15/2001	4/11/2002, 67 FR 17624	
401 KAR 51:195	NO _x opt-in provisions	8/15/2001	4/11/2002, 67 FR 17624	
401 KAR 51:210	CAIR NO _x Annual Trading Program	2/2/2007	10/4/2007, 72 FR 56623	
401 KAR 51:220	CAIR NO _x Ozone Season Trading Program.	6/13/2007	10/4/2007, 72 FR 56623	
401 KAR 51:230	CAIR SO ₂ Trading Program	2/2/2007	10/4/2007, 72 FR 56623	
401 KAR 51:240	Cross-State Air Pollution Rule (CSAPR) NO _x annual trading program.	7/5/2018	2/10/2020, 85 FR 7449	
401 KAR 51:260	Cross-State Air Pollution Rule (CSAPR) SO ₂ group 1 trading program.	7/5/2018	2/10/2020, 85 FR 7449	
Chapter 52 Permits, Registrations, and Prohibitory Rules				
401 KAR 52:001	Definitions for 401 KAR Chapter 52	11/18/2006	9/13/2007, 72 FR 52282	Only adding the first sentence of Section 22 entitled “Annual Emissions Certification”, and introductory paragraph text and subsection (4) of Section 23 entitled “Certification by Responsible Official”.
401 KAR 52:020	Title V permits	1/15/2001	1/28/2016, 81 FR 4896	
401 KAR 52:030	Federally enforceable permits for non-major sources.	1/15/2001	9/6/2006, 71 FR 52460	Only adding subsection (2) introductory text, subsection (2)(c), and subsection (3) of Section 3 entitled “General Provisions”; subsection (1) of Section 20 entitled “Annual Emissions Certification for Specified Sources”; and introductory text and subsection (4) of Section 21 entitled “Certification by Responsible Official”. Only adding subsection (2) introductory text, subsection (2)(a)(1), and first sentence of subsection (2)(a)(2) of Section 3 entitled “General Provisions”.
401 KAR 52:040	State-origin permits	1/15/2001	1/28/2016, 81 FR 4896	
401 KAR 52:070	Registration of designated sources	1/15/2001	1/28/2016, 81 FR 4896	
401 KAR 52:090	Prohibitory rule for hot mix asphalt plants.	1/15/2001	9/6/2006, 71 FR 52460	
401 KAR 52:100	Public, affected state, and U.S. EPA review.	6/2/2020	10/1/2021, 86 FR 54379	
Chapter 53 Ambient Air Quality				
401 KAR 53:005	General provisions	4/14/1988	2/7/1990, 55 FR 4169	Except for references to hydrogen sulfide, fluorides, and odor.
401 KAR 53:010	Ambient air quality standards	7/19/2016	9/12/2017, 82 FR 42746	
Chapter 55 Emergency Episodes				
401 KAR 55:005	Significant harm criteria	4/14/1988	2/7/1990, 55 FR 4169	
401 KAR 55:010	Episode criteria	4/14/1988	2/7/1990, 55 FR 4169	

TABLE 1 TO PARAGRAPH (c)—EPA-APPROVED KENTUCKY LAWS AND REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
401 KAR 55:015	Episode declaration	6/6/1979	1/25/1980, 45 FR 6092	
401 KAR 55:020	Abatement strategies	6/6/1979	1/25/1980, 45 FR 6092	
Chapter 59 New Source Standards				
401 KAR 59:001	Definitions for abbreviations of terms used in the Title 401, Chapter 59.	11/18/2006	9/13/2007, 72 FR 52282	
401 KAR 59:005	General provisions	12/1/1982	12/4/1986, 51 FR 43742	
401 KAR 59:010	New process operations	4/14/1988	2/7/1990, 55 FR 4169	
401 KAR 59:015	New indirect heat exchangers	1/7/1981	3/22/1983, 48 FR 11945	
401 KAR 59:020	New incinerators	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 59:046	Selected new petroleum refining processes and equipment.	6/29/1979	8/7/1981, 46 FR 40188	
401 KAR 59:050	New storage vessels for petroleum liquids.	2/4/1981	3/30/1983, 48 FR 13168	
401 KAR 59:080	New kraft (sulfate) pulp mills	6/6/1979	1/25/1980, 45 FR 6092	
401 KAR 59:085	New sulfite pulp mills	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 59:090	New ethylene producing plants	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 59:095	New oil-effluent water separators	6/29/1979	8/7/1981, 46 FR 40188	
401 KAR 59:101	New bulk gasoline plants	9/28/1994	6/28/1996, 61 FR 33674	
401 KAR 59:105	New process gas streams	4/7/1982	3/22/1983, 48 FR 11945	
401 KAR 59:174	Stage II controls at gasoline dispensing facilities.	5/3/2016	10/14/2016, 81 FR 70966	
401 KAR 59:175	New service stations	2/8/1993	6/23/1994, 59 FR 32343	
401 KAR 59:185	New solvent metal cleaning equipment.	1/4/2005	10/4/2005, 70 FR 57750	
401 KAR 59:190	New insulation of magnet wire operations.	6/24/1992		
401 KAR 59:210	New fabric, vinyl and paper surface coating operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 59:212	New graphic arts facilities using rotogravure and flexography.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 59:214	New factory surface coating operations of flat wood paneling.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 59:225	New miscellaneous metal parts and products surface coating operation.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 59:230	New synthesized pharmaceutical product manufacturing operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 59:235	New pneumatic rubber tire manufacturing plants.	2/4/1981	3/30/1983, 48 FR 13168	
401 KAR 59:240	New perchloroethylene dry cleaning systems.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 59:315	Specific new sources	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 59:760	Commercial Motor Vehicle and Mobile Equipment Refinishing Operations.	3/11/2005	10/4/2005, 70 FR 57750	
Chapter 61 Existing Source Standards				
401 KAR 61:001	Definitions for 401 KAR Chapter 61	11/18/2006	9/13/2007, 72 FR 52282	
401 KAR 61:005	General provisions	12/1/1982	5/4/1989, 54 FR 19169	
401 KAR 61:010	Existing incinerators	6/6/1979	5/4/1989, 54 FR 19169	
401 KAR 61:015	Existing indirect heat exchangers	6/1/1983	4/2/1996, 61 FR 14489	
401 KAR 61:020	Existing process operations	4/14/1988	2/7/1990, 55 FR 4169	
401 KAR 61:025	Existing kraft (sulfate) pulp mills	6/6/1979	5/26/1982, 47 FR 22955	
401 KAR 61:030	Existing sulfuric acid plants	6/6/1979	3/22/1983, 48 FR 11945	
401 KAR 61:035	Existing process gas streams	4/7/1982	3/22/1983, 48 FR 11945	
401 KAR 61:040	Existing ethylene producing plants	6/6/1979	1/25/1980, 45 FR 6092	
401 KAR 61:045	Existing oil-effluent water separators.	6/29/1979	8/7/1981, 46 FR 40188	
401 KAR 61:050	Existing storage vessels for petroleum liquids.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:055	Existing loading facilities at bulk gasoline terminals.	8/24/1982	3/30/1983, 48 FR 13168	
401 KAR 61:056	Existing bulk gasoline plants	9/28/1994	6/28/1996, 61 FR 33674	
401 KAR 61:060	Existing sources using organic solvents.	6/29/1979	1/25/1980, 45 FR 6092	
401 KAR 61:065	Existing nitric acid plants	6/6/1979	7/12/1982, 47 FR 30059	
401 KAR 61:070	Existing ferroalloy production facilities.	6/6/1979	5/3/1984, 49 FR 18833	
401 KAR 61:075	Steel plants and foundries using existing electric arc furnaces.	12/1/1982	5/4/1989, 54 FR 19169	
401 KAR 61:080	Steel plants using existing basic oxygen process furnaces.	4/1/1984	5/4/1989, 54 FR 19169	
401 KAR 61:085	Existing service stations	2/8/1993	6/23/1994, 59 FR 32343	
401 KAR 61:090	Existing automobile and light-duty truck surface coating operations.	6/24/1992	6/23/1994, 59 FR 32343	

TABLE 1 TO PARAGRAPH (c)—EPA-APPROVED KENTUCKY LAWS AND REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
401 KAR 61:095	Existing solvent metal cleaning equipment.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:100	Existing insulation of magnet wire operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:105	Existing metal furniture surface coating operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:110	Existing large appliance surface coating operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:120	Existing fabric, vinyl and paper surface coating operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:122	Existing graphic arts facilities using rotogravure and flexography.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:124	Existing factory surface coating operations of flat wood paneling.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:125	Existing can surface coating operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:130	Existing coil surface coating operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:132	Existing miscellaneous metal parts and products surface coating operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:135	Selected existing petroleum refining processes and equipment.	6/29/1979	1/25/1980, 45 FR 6092	
401 KAR 61:137	Leaks from existing petroleum refinery equipment.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:140	Existing by-product coke manufacturing plants.	9/4/1986	5/4/1989, 54 FR 19169	
401 KAR 61:145	Existing petroleum refineries	1/7/1981	3/22/1983, 48 FR 11945	
401 KAR 61:150	Existing synthesized pharmaceutical product manufacturing operations.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:155	Existing pneumatic rubber tire manufacturing plants.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:160	Existing perchloroethylene dry cleaning systems.	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 61:165	Existing primary aluminum reduction plants.	6/4/1985	12/2/1986, 51 FR 43395	
401 KAR 61:170	Existing blast furnace casthouses ...	4/14/1988		
401 KAR 61:175	Leaks from existing synthetic organic chemical and polymer manufacturing equipment.	6/24/1992	6/23/1994, 59 FR 32343	
Chapter 63 General Standards of Performance				
401 KAR 63:001	Definitions and abbreviations of terms used in 401 KAR Chapter 63.	11/18/2006	9/13/2007, 72 FR 52282	Except for the nuisance provision found in Section 3, Paragraph (4).
401 KAR 63:005	Open burning	7/13/2005	10/17/2007, 72 FR 58759	
401 KAR 63:010	Fugitive emissions	6/30/2020	5/9/2022, 87 FR 27524	
401 KAR 63:015	Flares	6/6/1979	12/24/1980, 45 FR 84999	
401 KAR 63:025	Asphalt paving operations	6/24/1992	6/23/1994, 59 FR 32343	
401 KAR 63:031	Leaks from gasoline tank trunks	2/8/1993	6/23/1994, 59 FR 32343	
Chapter 65 Mobile Source-Related Emissions				
401 KAR 65:001	Definitions and abbreviations of terms used in 401 KAR Chapter 65.	11/18/2006	9/13/2007, 72 FR 52282	
401 KAR 65:005	Liquefied petroleum gas carburetion systems.	6/6/1979	1/25/1980, 45 FR 6092	
Kentucky Revised Statutes (KRS)				
KRS Chapter 11A.020	Public servant prohibited from certain conduct—Exception—Disclosure of personal or private interest.	7/15/1998	10/3/2012, 77 FR 60307	
KRS Chapter 11A.030	Considerations in determination to abstain from action on official decision—Advisory opinion.	7/14/1992	10/3/2012, 77 FR 60307	
KRS Chapter 11A.040	Acts prohibited for public servant or officer—exception.	7/16/2006	10/3/2012, 77 FR 60307	
KRS Chapter 224.10–020	Department within the cabinet—Offices and divisions within the departments—Appointments.	7/15/2010	10/3/2012, 77 FR 60307	
KRS Chapter 224.10–100	Powers and duties of cabinet	8/30/2007	10/3/2012, 77 FR 60307	

TABLE 2 TO PARAGRAPH (c)—EPA-APPROVED JEFFERSON COUNTY REGULATIONS FOR KENTUCKY

Reg	Title/subject	EPA approval date	Federal Register notice	District effective date	Explanation
Reg 1—General Provisions					
1.01	General Application of Regulations and Standards.	10/23/2001	66 FR 53658	3/17/1999	Except Section 5 and any references to Section 5 in this regulation.
1.02	Definitions	10/22/2020	85 FR 67282	6/19/2019	
1.03	Abbreviations and Acronyms	8/31/2017	82 FR 41335	1/16/2008	
1.04	Performance Tests	7/10/2020	85 FR 41399	6/19/2019	
1.05	Compliance with Emission Standards and Maintenance Requirements.	10/23/2001	66 FR 53658	11/18/1992	
1.06	Stationary Source Self-Monitoring, Emissions Inventory Development, and Reporting.	3/9/2022	87 FR 13177	5/20/2020	
1.07	Excess Emissions During Startups, Shutdowns, and Upset Conditions.	6/10/2014	79 FR 33101	7/21/2005	
1.08	Administrative Procedures	10/21/2020	85 FR 66876	11/20/2019	
1.09	Prohibition of Air Pollution	10/23/2001	66 FR 53658	11/16/1983	
1.10	Circumvention	10/23/2001	66 FR 53658	4/19/1972	
1.11	Control of Open Burning	8/31/2017	82 FR 41335	1/16/2008	
1.14	Control of Fugitive Particulate Emissions	10/23/2001	66 FR 53658	1/20/1988	
1.18	Rule Effectiveness	10/23/2001	66 FR 53686	9/21/1994	
1.19	Administrative Hearings	8/31/2017	82 FR 41335	1/16/2008	
Reg 2—Permit Requirements					
2.01	General Application	10/23/2001	66 FR 53658	4/21/1982	Except for paragraphs 1.3, 5.3 and 5.6 regarding asbestos demolition, which were removed from the federally approved SIP by EPA on 5/7/2021.
2.02	Air Pollution Regulation Requirements and Exemptions.	10/23/2001	66 FR 53658	6/21/1995	
2.03	Permit Requirements—Non-Title V Construction and Operating Permits and Demolition/Renovation Permits.	10/23/2001	66 FR 53658	12/15/1993	
2.04	Construction or Modification of Major Sources in or Impacting Upon Non-Attainment Areas (Emission Offset Requirements).	10/23/2001	66 FR 53658	3/17/1993	This approval does not include Jefferson County's revisions to incorporate by reference the Fugitive Emissions Rule (December 19, 2008).
2.05	Prevention of Significant Deterioration of Air Quality.	9/16/2020	85 FR 57707	1/17/2018	
2.06	Permit Requirements—Other Sources	10/23/2001	66 FR 53658	11/16/1983	
2.07	Public Notification for Title V, PSD, and Offset Permits; SIP Revisions; and Use of Emission Reduction Credits.	10/23/2001	66 FR 53658	6/21/1995	
2.09	Causes for Permit Suspension	11/3/2003	68 FR 62236	6/19/2002	
2.10	Stack Height Considerations	10/23/2001	66 FR 53658	7/19/1989	
2.11	Air Quality Model Usage	10/23/2001	66 FR 53658	5/19/1999	
2.17	Federally Enforceable District Origin Operating Permits.	3/1/2023	88 FR 12831	3/16/2022	
Reg 3—Ambient Air Quality Standards					
3.01	Ambient Air Quality Standards	5/11/2018	83 FR 21907	2/15/2017	
Reg 4—Emergency Episodes					
4.01	General Provisions for Emergency Episodes	10/23/2001	66 FR 53658	6/13/1979	
4.02	Episode Criteria	10/23/2001	66 FR 53658	4/20/1988	
4.03	General Abatement Requirements	10/23/2001	66 FR 53658	2/16/1983	
4.04	Particulate and Sulfur Dioxide Reduction Requirements.	10/23/2001	66 FR 53658	4/19/1972	
4.05	Hydrocarbon and Nitrogen Oxides Reduction Requirements.	10/23/2001	66 FR 53658	2/16/1983	
4.06	Carbon Monoxide Reduction Requirements	10/23/2001	66 FR 53658	2/16/1983	
4.07	Episode Reporting Requirements	10/23/2001	66 FR 53658	6/13/1979	
Reg 6—Standards of Performance for Existing Affected Facilities					
6.01	General Provisions	10/23/2001	66 FR 53658	11/16/1983	
6.02	Emission Monitoring for Existing Sources	10/23/2001	66 FR 53658	11/16/1983	
6.07	Standards of Performance for Existing Indirect Heat Exchangers.	10/1/2019	84 FR 52003	1/17/2018	
6.08	Standard of Performance for Existing Incinerators.	10/23/2001	66 FR 53658	6/13/1979	
6.09	Standards of Performance for Existing Process Operations.	5/21/2019	84 FR 22982	1/17/2018	
6.10	Standard of Performance for Existing Process Gas Streams.	10/23/2001	66 FR 53658	11/16/1983	
6.12	Standard of Performance for Existing Asphalt Paving Operations.	10/23/2001	66 FR 53658	5/15/1991	
6.13	Standard of Performance for Existing Storage Vessels for Volatile Organic Compounds.	3/10/2021	86 FR 13655	6/19/2019	
6.14	Standard of Performance for Selected Existing Petroleum Refining Processes and Equipment.	10/23/2001	66 FR 53658	4/21/1982	

TABLE 2 TO PARAGRAPH (c)—EPA-APPROVED JEFFERSON COUNTY REGULATIONS FOR KENTUCKY—Continued

Reg	Title/subject	EPA approval date	Federal Register notice	District effective date	Explanation
6.15	Standard of Performance for Gasoline Transfer to Existing Service Station Storage Tanks (Stage I Vapor Recovery).	1/25/1980	45 FR 6092	6/13/1979	Except for the phrase "or an alternate procedure approved by District" in subsection 3.6.4.2.
6.16	Standard of Performance for Existing Large Appliance Surface Coating Operations.	10/23/2001	66 FR 53658	5/15/1991	
6.17	Standard of Performance for Existing Automobile and Truck Surface Coating Operations.	10/23/2001	66 FR 53658	11/18/1992	
6.18	Standards of Performance for Existing Solvent Metal Cleaning Equipment.	8/31/2017	82 FR 41335	5/9/2003	
6.19	Standard of Performance for Existing Metal Furniture Surface Coating Operations.	10/23/2001	66 FR 53658	5/15/1991	
6.20	Standard of Performance for Existing Bulk Gasoline Plants.	10/23/2001	66 FR 53658	11/16/1983	
6.21	Standard of Performance for Existing Gasoline Loading Facilities at Bulk Terminals.	3/11/2021	86 FR 13816	6/19/2019	
6.22	Standard of Performance for Existing Volatile Organic Materials Loading Facilities.	10/23/2001	66 FR 53658	3/17/1993	
6.24	Standard of Performance for Existing Sources Using Organic Materials.	10/23/2001	66 FR 53658	3/17/1993	
6.26	Standards of Performance for Existing Volatile Organic Compound Water Separators.	7/11/2019	84 FR 33004	1/17/2018	
6.27	Standards of Performance for Existing Liquid Waste Incinerators.	10/23/2001	66 FR 53658	6/13/1979	
6.28	Standard of Performance for Existing Hot Air Aluminum Atomization Processes.	10/23/2001	66 FR 53658	3/18/1981	
6.29	Standards of Performance for Existing Graphic Arts Facilities Using Rotogravure and Flexography.	10/12/2017	82 FR 47376	8/21/2013	
6.30	Standard of Performance for Existing Factory Surface Coating Operations of Flat Wood Paneling.	10/23/2001	66 FR 53658	5/15/1991	
6.31	Standards of Performance for Existing Miscellaneous Metal Parts and Products Surface Coating Operations.	9/2/2020	85 FR 54510	6/19/2019	
6.32	Standard of Performance for Leaks from Existing Petroleum Refinery Equipment.	10/23/2001	66 FR 53658	5/15/1991	
6.33	Standard of Performance for Existing Synthesized Pharmaceutical Product Manufacturing Operations.	10/23/2001	66 FR 53658	5/15/1991	
6.34	Standard of Performance for Existing Pneumatic Rubber Tire Manufacturing Plants.	10/23/2001	66 FR 53658	5/15/1991	
6.35	Standard of Performance for Existing Fabric, Vinyl and Paper Surface Coating Operations.	10/23/2001	66 FR 53658	5/15/1991	
6.38	Standard of Performance for Existing Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industries.	10/23/2001	66 FR 53658	12/17/1986	
6.39	Standard of Performance for Equipment Leaks of Volatile Organic Compounds in Existing Synthetic Organic Chemical and Polymer Manufacturing Plants.	10/23/2001	66 FR 53658	7/17/1996	
6.40	Standards of Performance for Gasoline Transfer to Motor Vehicles (Stage II Vapor Recovery and Control System).	9/18/2017	82 FR 43489	11/10/2016	
6.42	Reasonably Available Control Technology Requirements for Major Volatile Organic Compound- and Nitrogen Oxides-Emitting Facilities.	10/23/2001	66 FR 53658	3/17/1999	
6.43	Volatile Organic Compound Reduction Requirements.	8/31/2017	82 FR 41335	2/15/2006	
6.44	Standards of Performance for Existing Commercial Motor Vehicle and Mobile Equipment Refinishing Operations.	10/23/2001	66 FR 53658	9/20/1995	
6.45	Standards of Performance for Existing Solid Waste Landfills.	10/23/2001	66 FR 53686	2/2/1994	
6.46	Standards of Performance for Existing Ferroalloy and Calcium Carbide Production Facilities.	10/23/2001	66 FR 53658	12/21/1994	
6.48	Standard of Performance for Existing Bakery Oven Operations.	10/23/2001	66 FR 53658	7/19/1995	
6.49	Standards of Performance for Reactor Processes and Distillation Operations Processes in the Synthetic Organic Chemical Manufacturing Industry.	10/23/2001	66 FR 53664	6/20/2001	
6.50	NO _x Requirements for Portland Cement Kilns	11/19/2002	67 FR 69688	3/20/2002	
Reg 7—Standards of Performance for New Affected Facilities					
7.01	General Provisions	10/23/2001	66 FR 53658	5/17/2000	
7.06	Standards of Performance for New Indirect Heat Exchangers.	10/23/2001	66 FR 53658	4/21/1982	
7.07	Standard of Performance for New Incinerators ...	10/23/2001	66 FR 53658	9/15/1993	

TABLE 2 TO PARAGRAPH (c)—EPA-APPROVED JEFFERSON COUNTY REGULATIONS FOR KENTUCKY—Continued

Reg	Title/subject	EPA approval date	Federal Register notice	District effective date	Explanation
7.08	Standards of Performance for New Process Operations.	5/21/2019	84 FR 22982	1/17/2018	Except for the phrase “or an alternate procedure approved by the District” in subsection 3.11.1.2.
7.09	Standards of Performance for New Process Gas Streams.	10/23/2001	66 FR 53658	6/18/1997	
7.11	Standard of Performance for New Asphalt Paving Operations.	10/23/2001	66 FR 53658	5/15/1991	
7.12	Standard of Performance for New Storage Vessels of Volatile Organic Compounds.	3/10/2021	86 FR 13655	6/19/2019	
7.14	Standard of Performance for Selected New Petroleum Refining Processes and Equipment.	10/23/2001	66 FR 53658	6/13/1979	
7.15	Standards of Performance for Gasoline Transfer to New Service Station Storage Tanks (Stage I Vapor Recovery).	10/23/2001	66 FR 53658	4/20/1988	
7.20	Standard of Performance for New Gasoline Loading Facilities at Bulk Plants.	3/11/2021	86 FR 13816	6/19/2019	
7.22	Standard of Performance for New Volatile Organic Materials Loading Facilities.	10/23/2001	66 FR 53658	3/17/1993	
7.25	Standard of Performance for New Sources Using Volatile Organic Compounds.	10/23/2001	66 FR 53658	3/17/1993	
7.34	Standard of Performance for New Sulfite Pulp Mills.	10/23/2001	66 FR 53658	6/13/1979	
7.35	Standard of Performance for New Ethylene Producing Plants.	10/23/2001	66 FR 53658	6/13/1979	
7.36	Standards of Performance for New Volatile Organic Compound Water Separators.	7/11/2019	84 FR 33004	1/17/2018	
7.51	Standard of Performance for New Liquid Waste Incinerators.	10/23/2001	66 FR 53658	1/20/1988	
7.52	Standard of Performance for New Fabric, Vinyl, and Paper Surface Coating Operations.	10/23/2001	66 FR 53658	5/15/1991	
7.55	Standard of Performance for New Insulation of Magnet Wire.	10/23/2001	66 FR 53658	3/17/1993	
7.56	Standard of Performance for Leaks from New Petroleum Refinery Equipment.	10/23/2001	66 FR 53658	5/15/1991	
7.58	Standard of Performance for New Factory Surface Coating Operations of Flat Wood Paneling.	10/23/2001	66 FR 53658	5/15/1991	
7.59	Standards of Performance for New Miscellaneous Metal Parts and Products Surface Coating Operations.	9/2/2020	85 FR 54510	6/19/2019	
7.60	Standard of Performance for New Synthesized Pharmaceutical Product Manufacturing Operations.	10/23/2001	66 FR 53658	5/15/1991	
7.77	Standards of Performance for New Blast Furnace Casthouses.	10/23/2001	66 FR 53658	10/20/1993	
7.79	Standards of Performance for New Commercial Motor Vehicles and Mobile Equipment Refinishing Operations.	10/23/2001	66 FR 53686	2/2/1994	
7.81	Standard of Performance for New or Modified Bakery Oven Operations.	10/23/2001	66 FR 53658	5/17/2000	

(d) *EPA-approved source-specific requirements.*

TABLE 3 TO PARAGRAPH (d)—EPA-APPROVED KENTUCKY SOURCE-SPECIFIC REQUIREMENTS

Name of source	Permit No.	State effective date	EPA approval date	Explanations
Bubble action at Kentucky Utilities Green River Plant.	N/A	12/1/1980	6/15/1981, 46 FR 31260	
Bubble action at Corning Glassworks.	N/A	5/18/1981	10/29/1981, 46 FR 53408	
Bubble action at National Distillers Company's, Old Crow Plant.	N/A	12/24/1980	9/14/1981, 46 FR 45610	
Bubble action at Borden Chemical CO in Jefferson CO.	N/A	3/5/1982	5/11/1982, 47 FR 20125	
Variance for seven perchloroethylene dry cleaners.	N/A	7/30/1982	5/2/1983, 48 FR 19716	
Variance for two dry cleaners	N/A	1/12/1983	5/5/1983, 48 FR 20233	
Variance for Jiffy and Hiland Dry Cleaners.	N/A	3/30/1984	4/18/1985, 50 FR 15421	
Opacity variance for boiler Units 1 and 2 of TVA's Paradise Steam Plant.	KDEPDAQ Permit 0–86–75	7/24/1986	8/17/1988, 53 FR 30998	

TABLE 3 TO PARAGRAPH (d)—EPA-APPROVED KENTUCKY SOURCE-SPECIFIC REQUIREMENTS—Continued

Name of source	Permit No.	State effective date	EPA approval date	Explanations
Operating Permit requiring VOC RACT for Calgon CO.	KDEPDAQ Permit 0–94–020.	11/17/1994	5/24/1995, 60 FR 27411	
Alternative Averaging Period for American Greetings Corporation.	KDEPDAQ Permit V–98–049.	7/7/1999	5/9/2001, 66 FR 23615	
Title V permit requiring VOC RACT for Publisher's Printing, Inc., Bullitt County.	KDEPDAQ Permit 21–029–00019.	7/20/2001	10/23/2001, 66 FR 53662	
Board Order E.I. du Pont de Nemours & Company.	NO _x RACT Plan 02/21/01 ..	3/1/2001	10/23/2001, 66 FR 53665	
Board Order Ford Louisville Assembly Plant.	NO _x RACT Plan 11/08/99 ..	1/1/2000	10/23/2001, 66 FR 53665	
Board Order General Electric Company.	NO _x RACT Plan 01/17/01 ..	3/1/2001	10/23/2001, 66 FR 53665	
Board Order Kosmos Cement Company.	NO _x RACT Plan 05/03/04 ..	5/3/2004	5/18/2005, 70 FR 28429	
Board Order Louisville Gas and Electric Company, Cane Run Generating Station.	NO _x RACT Plan 10/18/00 ..	1/1/2001	10/23/2001, 66 FR 53665	
Board Order Louisville Gas and Electric Company, Mill Creek Generating Station.	NO _x RACT Plan 10/18/00 ..	1/1/2001	10/23/2001, 66 FR 53665	
Board Order Louisville Medical Center Steam Plant.	NO _x RACT Plan 1/18/2017	1/18/2017	10/12/2017, 82 FR 47376	
Board Order Oxy Vinyls, LP	NO _x RACT Plan 12/20/00 ..	1/1/2001	10/23/2001, 66 FR 53665	
Board Order Rohm and Haas Company.	NO _x RACT Plan 12/20/00 ..	1/1/2001	10/23/2001, 66 FR 53665	
Board Order Texas Gas Transmission.	NO _x RACT Plan 5/18/2016	5/18/2016	10/12/2017, 82 FR 47376	
Lawson Mardon Packaging, USA, Inc.	N/A	8/11/2003	7/10/2003, 68 FR 41083	
Calgon Carbon Corporation	V–00–015	5/13/2005	5/24/2006, 71 FR 29786	The only parts of the permit being approved and incorporated are the SO ₂ emission limits from the following emissions points: 12, 14, 21, 31, 32, 34, 39, 40, 42, and 64.
TVA Paradise Permit	KDEPDAQ Permit 0–87–012.	10/19/2007	4/29/2008, 73 FR 23105	Emission Rates Units 1 and 2 are 1.2 lb/MMBTU and Unit 3 is 1.2 lb/MMBTU or * 3.1 lb/MMBTU.
Source-Specific SIP Revision for Avis Budget Car Rental Group.	N/A	8/9/2007	11/30/2009, 74 FR 62499	Removal of stage II requirements.
LG & E Cane Run Generating Station NO _x RACT Plan Amendment 2.	N/A	7/18/2012	8/30/2016, 81 FR 59488	
Louisville Gas and Electric Mill Creek Electric Generating Station.	145–97–TV(R3)	6/23/2017	6/28/2019, 84 FR 30920	Plant-wide Specific condition S1-Standards, S2-Monitoring and Record Keeping and S3-Reporting in title V permit 145–97–TV(R3) for EGU U1, U2, U3 and U4.
Board Order for the American Synthetic Rubber Company—Amendment 2.	N/A	11/17/2021	6/7/2022, 87 FR 34577	Including the attached VOC/NO _x RACT Plan.
Board Order for LL Flex, LLC	N/A	11/18/2020	9/30/2022, 87 FR 59309	

* Bypass of the scrubber shall be limited to 720 operating hours in any 12 consecutive months.

* * * * *

[FR Doc. 2023–24694 Filed 11–14–23; 8:45 am]

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Proposed Rules

Federal Register

Vol. 88, No. 219

Wednesday, November 15, 2023

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

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 575

[Docket ID: OPM–2023–0027]

RIN 3206–AO36

Recruitment and Relocation Incentive Waivers

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management (OPM) is issuing a proposed rule to expand the authority to approve waivers of the normal payment limitations on recruitment and relocation incentives. An expansion of the waiver approval authority would provide agencies with access to higher payment limitations for these flexibilities without requesting approval from OPM. Under this proposed rule, agencies would have the authority to approve a recruitment or relocation incentive of up to 50 percent of an employee's annual rate of basic pay multiplied by the number of years in a service agreement (not to exceed 100 percent of annual basic pay) based on a critical agency need. In addition, this proposed rule would give agencies flexibility to set the length of the required service period for recruitment incentives to a period less than 6 months but not more than 4 years, which would align the service requirements for recruitment incentives with those for relocation incentives and provide agencies with additional flexibility in taking advantage of this incentive as a recruitment tool.

DATES: Comments must be received on or before January 16, 2024.

ADDRESSES: You may submit comments, identified by the Regulation Identifier Number (RIN) number “3206–AO36” and title, using the following method:

- *Federal Rulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.

The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing at <https://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Gene Holson by telephone at (202) 606–2858 or by email at pay-leave-policy@opm.gov.

SUPPLEMENTARY INFORMATION:

Background

Section 101 of the Federal Workforce Flexibility Act of 2004 (Act) (Pub. L. 108–411, October 30, 2004) amended 5 U.S.C. 5753 and 5754 by providing enhanced authorities to pay recruitment, relocation, and retention incentives. Congress originally provided the authority to pay such incentives under the Federal Employees Pay Comparability Act of 1990 (Pub. L. 101–509, November 5, 1990). In the 2004 Act, Congress expanded the circumstances under which these flexibilities may be paid and enabled agencies to make the payments in more ways to enhance their desired effect in assisting Federal agencies' efforts to recruit and retain the kind of workforce needed in the 21st century. OPM's regulations at 5 CFR part 575, subparts A, B, and C, implement these authorities. This rulemaking proposes changes to the recruitment incentive regulations at 5 CFR part 575, subpart A, and relocation incentive regulations at 5 CFR part 575, subpart B, to provide agencies additional payment options. To differentiate these kinds of payments—which are designed to provide a monetary incentive for an individual to accept a new position, as opposed to rewarding an individual for quality of performance (the typical context in which the term “bonus” is used)—OPM's regulations use the term “incentive” in place of the term “bonus,” which is used in the statute.

Recruitment Incentives

Under 5 U.S.C. 5753 and 5 CFR part 575, subpart A, an agency may pay a recruitment incentive to an employee newly appointed to a General Schedule or other covered position in the Federal service when the agency determines the position is likely to be difficult to fill in the absence of an incentive. The

employee must sign an agreement to fulfill a period of service with the agency. A recruitment incentive may not exceed 25 percent of the employee's annual rate of basic pay in effect at the beginning of the service period, multiplied by the number of years (including fractions of a year) in the service period (not to exceed 4 years). Currently, this cap may be increased to up to 50 percent with OPM approval, based on a critical agency need, as long as the total incentive does not exceed 100 percent of the employee's annual rate of basic pay. A recruitment incentive may be paid as an initial lump-sum payment at the beginning of the service period, in installments throughout the service period, as a final lump-sum payment upon completion of the service period, or in a combination of these methods. (See 5 CFR 575.109.)

Before paying a recruitment incentive, an agency must establish a recruitment incentive plan. (See 5 CFR 575.107(a).) The plan must include the designation of officials with authority to review and approve the payment of recruitment incentives, the designation of officials with authority to waive the repayment of a recruitment incentive, the categories of employees who may not receive recruitment incentives, the required documentation for determining that a position is likely to be difficult to fill, requirements for determining the amount of a recruitment incentive, the payment methods that may be authorized, requirements governing service agreements (including criteria for determining the length of a service period, the conditions for terminating a service agreement, and the obligations of the agency and the employee if a service agreement is terminated), and documentation and recordkeeping requirements. Unless the head of the agency determines otherwise, an agency recruitment incentive plan must apply uniformly across the agency. (See 5 CFR 575.107(c).)

For each determination to pay a recruitment incentive, an agency must document, in writing, the basis for determining that the position is likely to be difficult to fill in the absence of a recruitment incentive, the amount and timing of the incentive payments, and the length of the service period. The determination to pay a recruitment incentive must be made before the prospective employee enters on duty in

the position for which they are recruited. The authorized agency official must review and approve the recruitment incentive determination before the agency pays the incentive to the employee. (See 5 CFR 575.107(b), 575.108.) Payment of a recruitment incentive is subject to the aggregate limitation on pay under 5 CFR part 530, subpart B. (See 5 CFR 575.109(f).)

An agency may determine that a position is likely to be difficult to fill if the agency is likely to have difficulty recruiting candidates with the competencies (*i.e.*, knowledge, skills, abilities, behaviors, and other characteristics) required for the position (or group of positions) in the absence of a recruitment incentive based on a consideration of the factors listed in 5 CFR 575.106(b). An agency also may determine that a position is likely to be difficult to fill if OPM has approved the use of a direct-hire authority applicable to the position. (See 5 CFR 575.106(c).) The use of recruitment incentives can help agencies expand applicant pools to include more diverse candidates.

Before receiving a recruitment incentive, an employee must sign a written agreement to complete a specified period of employment with the agency of not less than 6 months. The service agreement must specify the length, commencement date, and termination date of the service period; the total amount of the incentive; the method, timing, and amounts of incentive payments; the conditions under which an agreement will be terminated by the agency; any agency or employee obligations if a service agreement is terminated (including the conditions under which the employee must repay an incentive or under which the agency must make additional payments for partially completed service); and any other terms and conditions for receiving and retaining a recruitment incentive. (See 5 CFR 575.110.) OPM has provided a fact sheet with additional information on recruitment incentives.¹

Relocation Incentives

Under 5 U.S.C. 5753 and 5 CFR part 575, subpart B, an agency may pay a relocation incentive to a current employee who must relocate to accept a General Schedule or other covered position in a different geographic area (permanently or temporarily) if the agency determines that the position is likely be difficult to fill in the absence

of an incentive. (See 5 CFR 575.205(a).) A relocation incentive may be paid only when the employee's rating of record under an official performance appraisal or evaluation system is at least "Fully Successful" or equivalent. (See 5 CFR 575.205(c).) Like a recruitment incentive, a relocation incentive may not exceed 25 percent of the employee's annual rate of basic pay in effect at the beginning of the service period multiplied by the number of years (including fractions of a year) in the service period (not to exceed 4 years). With OPM approval, this cap may be raised to up to 50 percent (based on a critical agency need), as long as the total incentive does not exceed 100 percent of the employee's annual rate of basic pay at the beginning of the service period. The incentive may be paid as an initial lump-sum payment at the beginning of the service period, in installments throughout the service period, as a final lump-sum payment upon completion of the service period, or in a combination of these methods. (See 5 CFR 575.209.)

Before paying a relocation incentive, an agency must establish a relocation incentive plan. A relocation incentive plan must generally address the same information required in a recruitment incentive plan, as described above. (See 5 CFR 575.207.)

For each relocation incentive authorized, an agency must document in writing the justification for approving the incentive that addresses factors similar to those needed for recruitment incentive authorizations, as described above. The agency must also document that the worksite of the new position is in a different geographic area than the previous position. The determination to pay a relocation incentive must be made before the employee enters on duty in the position at the new duty station. The authorized agency official must review and approve the relocation incentive determination before the agency pays the incentive to the employee. (See 5 CFR 575.207(b), 575.208.) Agency determinations to pay a relocation incentive must generally be made on a case-by-case basis. (See 5 CFR 575.208.) Payment of a relocation incentive is subject to the aggregate limitation on pay under 5 CFR part 530, subpart B. (See 5 CFR 575.209(e).)

The factors an agency may consider in determining that the new position is likely to be difficult to fill in the absence of a relocation incentive are also similar to those that may be considered for recruitment incentives. (See 5 CFR 575.206(b).) The use of relocation incentives can help agencies expand applicant pools to include more

diverse candidates. Before receiving a relocation incentive, an employee must sign a written agreement to complete a specified period of employment with the agency at the new duty station (not to exceed 4 years). The relocation incentive service agreement requirements and payment termination provisions are consistent with those required for recruitment incentives, except there is no minimum service period required. (See 5 CFR 575.210 and 575.211.) OPM has provided a fact sheet with additional information on relocation incentives.²

Recruitment and Relocation Incentive Waivers

Agencies currently have the authority to approve a recruitment or relocation incentive without OPM approval for payments of up to 25 percent of an employee's annual rate of basic pay times the number of years in a service agreement (not to exceed 4 years or 100 percent of annual basic pay). However, OPM approval is required when an agency would like to exceed this payment limit to make larger payments over shorter service agreement lengths. Under a recruitment or relocation incentive waiver, agencies can approve a recruitment or relocation incentive of up to 50 percent of an employee's annual rate of basic pay times the number of years in a service agreement (not to exceed 100 percent of annual basic pay). (See 5 CFR 575.109(c) and 575.209(c).)

For example, an OPM waiver is not required for an agency to pay a recruitment or relocation incentive of up to 25 percent of annual basic pay for a 1-year service agreement, 50 percent of basic pay for a 2-year service agreement, or 100 percent of basic pay for a 4-year service agreement. An OPM waiver currently is required for an agency to pay a recruitment or relocation incentive of 50 percent of annual basic pay for a 1-year service agreement or 100 percent of annual basic pay for a 2-year service agreement. OPM has provided a fact sheet on calculating maximum recruitment and relocation incentives for service periods of various lengths.³

² Office of Personnel Management. "Fact Sheet: Relocation Incentives." <https://www.opm.gov/policy-data-oversight/pay-leave/recruitment-relocation-retention-incentives/fact-sheets/relocation-incentives/>.

³ Office of Personnel Management. "Fact Sheet: Calculating Maximum Recruitment and Relocation Incentives for Service Periods of Various Lengths." <https://www.opm.gov/policy-data-oversight/pay-leave/recruitment-relocation-retention-incentives/fact-sheets/calculating-maximum-recruitment-and-relocation-incentives-for-service-periods-of-various-lengths/>.

¹ Office of Personnel Management. "Fact Sheet: Recruitment Incentives." <https://www.opm.gov/policy-data-oversight/pay-leave/recruitment-relocation-retention-incentives/fact-sheets/recruitment-incentives/>.

A waiver request must include a description of the critical agency need the proposed recruitment or relocation incentive would address. The authorized agency official must determine that the competencies required for the position(s) are critical to the successful accomplishment of an important agency mission, project, or initiative (e.g., programs or projects related to a national emergency or implementing a new law or critical management initiative). To assist agencies in developing waiver requests, OPM has provided waiver request templates for recruitment incentives⁴ and relocation incentives.⁵

The law, 5 U.S.C. 5754, does not permit the expansion of the waiver authority for retention incentives found at 5 CFR part 575, subpart C. Therefore, retention incentives are not included in this proposed rule.

Proposed Changes to Recruitment Incentive Rules

In 5 CFR part 575, subpart A, OPM is proposing to amend the current regulations as follows:

- Revise 5 CFR 575.106(a)(4) to provide an authorized agency official with sole and exclusive discretion, subject only to OPM review and oversight, to waive the limitation on the maximum amount of a recruitment incentive under 5 CFR 575.109(c).
- Require agencies at proposed 5 CFR 575.107(a) to designate the officials with authority to waive the recruitment incentive payment limitation in their recruitment incentive plans.
- Amend the incentive approval level provisions in 5 CFR 575.107(b)(1) to state that if a determination to pay a recruitment incentive includes a waiver of the payment limitation under 5 CFR 575.109(c), the official who is designated in the agency's plan under 5 CFR 575.107(a) must approve the determination.
- Revise 5 CFR 575.107(b)(2) to state that when necessary to make a timely offer of employment, an authorized agency official may authorize an official who is not lower than a candidate's supervisor to offer a recruitment incentive to a candidate without further review or approval in any amount within a pre-established range up to the normal payment limitation in 5 CFR

575.109(b) or a higher cap if the agency has approved a waiver to the normal payment limitation under 5 CFR 575.109(c).

- Amend 5 CFR 575.109(c)(1) to provide the conditions under which an authorized agency official would be able to waive the payment limitation in 5 CFR 575.109(b) for an employee or group of employees based on a critical agency need.
- Require in proposed 5 CFR 575.109(c)(2) that waiver determinations be made in writing.
- Delete 5 CFR 575.109(c)(2)(iii)–(v) to eliminate redundancy because those requirements are covered by 5 CFR 575.109(c)(2)(ii).
- Amend 5 CFR 575.110(a) to remove the minimum 6-month required service period for recruitment incentives. Under the proposed rule, a recruitment incentive service agreement could be any length up to 4 years, consistent with the current allowable service agreement lengths for relocation incentives. For example, this would allow an agency to determine that a summer internship position is likely to be difficult to fill and authorize a recruitment incentive for an intern with a 3-month service agreement.

Proposed Changes to Relocation Incentive Rules

In 5 CFR part 575, subpart B, OPM is proposing to amend the current regulations as follows:

- Revise 5 CFR 575.206(a)(4) to provide an authorized agency official with sole and exclusive discretion, subject only to OPM review and oversight, to waive the limitation on the maximum amount of a relocation incentive under 5 CFR 575.209(c).
- Require agencies at proposed 5 CFR 575.207(a) to designate the officials with authority to waive the relocation incentive payment limitation in their relocation incentive plans.
- Amend 5 CFR 575.207(b)(1) to state that if a determination to pay a relocation incentive includes a waiver of the payment limitation under 5 CFR 575.209(c), the official who is designated in the agency's plan under 5 CFR 575.207(a) must approve the determination.
- Revise 5 CFR 575.209(c)(1) to provide the conditions under which an authorized agency official may waive the payment limitation in 5 CFR 575.209(b) for an individual or group of employees based on a critical agency need.
- Require in proposed 5 CFR 575.209(c)(2) that waiver determinations be made in writing.

- Delete 5 CFR 575.209(c)(2)(iii)–(v) to eliminate redundancy because those requirements are covered by 5 CFR 575.209(c)(2)(ii).

Other Changes

OPM is proposing to revise several sections to use gender neutral language. These changes are contained at 5 CFR 575.102, 5 CFR 575.110(f), 5 CFR 575.111(e), 5 CFR 575.111(f), 5 CFR 575.210(f), 5 CFR 575.211(e), and 5 CFR 575.211(f).

Expected Impact of This Proposed Rule

A. Statement of Need

OPM serves as the chief human resources agency and personnel policy manager for the Federal Government. OPM provides human resources leadership and support to Federal agencies and helps the Federal workforce achieve their goals as they serve the American people. OPM oversees merit-based and inclusive hiring into the civil service, directs human resources and employee management services, administers retirement benefits, manages health insurance and insurance programs, and manages personnel vetting policies and processes.

As noted in OPM's FY 2022–2026 Strategic Plan,⁶ “We will promote a diverse, equitable, inclusive, and accessible Federal workforce based on merit; develop a strategic vision for the Federal Government to prepare for the future of work; support Federal agencies to attract early career talent; and equip current and future Federal workers with the ability to build new skills over time to adapt to a rapidly changing world.”

In its March 2021 report,⁷ the National Academy of Public Administration (NAPA) recommended that OPM adopt a more decentralized and risk-based approach to executing its transactional approval and oversight responsibilities. Specifically, NAPA recommended that OPM delegate, to the maximum extent possible, decision-making authorities to agencies, and conduct cyclical reviews to verify that appropriate actions were taken. NAPA's Rec. 2.5 was incorporated into OPM's Strategic Plan as Objective 4.2, which reads as follows: “Increase focus on Governmentwide policy work by

⁴ Office of Personnel Management. “Recruitment Incentive Waiver Template.” <https://www.opm.gov/policy-data-oversight/pay-leave/recruitment-relocation-retention-incentives/fact-sheets/recruitment-incentive-waiver-template.pdf>.

⁵ Office of Personnel Management. “Relocation Incentive Waiver Template.” <https://www.opm.gov/policy-data-oversight/pay-leave/recruitment-relocation-retention-incentives/fact-sheets/relocation-incentive-waiver-template.pdf>.

⁶ Office of Personnel Management. “Strategic Plan Fiscal Years 2022–2026.” <https://www.opm.gov/about-us/strategic-plan/03454-fy2022-2026-strategicplan-lookbook-508pdf.pdf>.

⁷ National Academy of Public Administration. “Elevating Human Capital: Reframing the U.S. Office of Personnel Management's Leadership Imperative” <https://www.volckeralliance.org/sites/default/files/attachments/OPM-Final-Report-National-Academy-of-Public-Administration.pdf>.

shifting more low-risk delegations of authorities to agencies.” Further, Objective 4.6 is to streamline Federal human capital regulations and guidance to reduce administrative burden and promote innovation while upholding merit system principles.

Permitting agencies to review and approve payment limit waivers at the agency level will reduce administrative burden on agencies and increase the efficiency of using recruitment and relocation incentives. This will allow agencies to move more quickly in hiring new employees and relocating those who are moving into positions that are likely to be difficult to fill. Such efficiency could be especially helpful in emergency or other critical situations in which recruiting new employees or relocating current employees rapidly is necessary. Also, with increases in the number of retirement-eligible employees, recruiting early career and experienced talent to the Federal workforce is a high priority. Using recruitment incentives can be a useful tool in achieving this goal.

B. Impact

It is important to understand that waivers to the normal payment limitations do not alter the maximum total amount of a recruitment or relocation incentives that may be paid to an individual employee. Agencies have the authority to approve a recruitment or relocation incentive for payments of up to 25 percent of an employee’s annual rate of basic pay times the number of years in a service agreement, not to exceed 4 years or 100 percent of annual basic pay. With a waiver, agencies can approve a recruitment or relocation incentive of up to 50 percent of an employee’s annual rate of basic pay times the number of years in a service agreement, but still not to exceed 100 percent of annual basic pay. Therefore, the total incentive paid under a waiver continues to be limited to 100 percent of the employee’s annual basic pay, but the incentive may be paid over 2 years rather than 4 years.

Section 101(a) of the Federal Workforce Flexibility Act of 2004 (Pub. L. 108–411, October 30, 2004) established significantly enhanced recruitment, relocation, and retention incentive authorities that provided Federal agencies with the flexibility to use such incentives in more strategic ways to help the Federal Government improve its competitiveness in recruiting and maintaining a high quality workforce. The enhancements provided by the Act included the authority to waive the normal cap on

recruitment and relocation incentives because of a critical agency need and provided authority to pay higher amounts over shorter periods of time (not to exceed a total of 100 percent of the employee’s starting salary). The implementing regulations⁸ required OPM approval to waive the recruitment and relocation incentive limits.

Although this waiver authority was effective upon publication of the implementing regulations on May 13, 2005, OPM did not receive any agency requests for recruitment or relocation waivers until 2008. Since that time, OPM has approved 15 recruitment incentive waivers for 6 agencies and 11 relocation incentive waivers for 4 agencies. OPM has approved waivers for healthcare, cybersecurity, and other mission-critical occupations. OPM-approved waivers provide agencies the discretionary authority to use a higher recruitment or relocation incentive payment limit for the covered position(s) and employee(s). An agency with an OPM-approved incentive waiver is responsible for documenting in writing the justification for paying each incentive authorized for an employee under the waiver and obtaining approval from the appropriate authorized agency official.

OPM does not know how agencies would use the additional flexibility provided by this proposed change. It is possible that agencies would approve more recruitment and relocation incentive waivers if they are not required to go through the process of submitting a waiver request to OPM. However, the criteria for approval will not be changing, so agencies will still need to determine that the situation meets the critical need and other requirements for approving a waiver. In other words, approval of a waiver is not automatic and agencies will need to use discretion in granting waiver requests. In addition, agencies will need to make determinations about whether they have funds available in their budgets to provide waivers. The use of discretionary pay flexibilities such as recruitment and relocation incentives may be limited by agency budgets.

As with the waiver authority, OPM does not know how agencies would use the additional flexibility of utilizing recruitment incentive service agreements of less than 6 months. Agencies do not report data to OPM on the length of the service agreements they authorize. Since the amount of the maximum recruitment incentive is based on the length of the service period, an agency would be limited in

how much of an incentive they could authorize. For example, under the normal payment limitations, the maximum recruitment incentive that could be paid for a 3-month service period is 6.25 percent (.25 (25 percent) $\times$.25 (3 months or $\frac{1}{4}$ of 1 year) = 6.25 percent) of the employee’s annual rate of basic pay at the beginning of the service period. Under a waiver, the maximum recruitment incentive that could be paid for a 3-month service period is 12.5 percent (.50 (50 percent) $\times$.25 (3 months or $\frac{1}{4}$ of 1 year) = 12.5 percent) of the employee’s annual rate of basic pay at the beginning of the service period.

C. Regulatory Alternatives

An alternative to this proposed rule is to continue to require agencies to request approval from OPM when they seek waiver of the normal recruitment and relocation payment limitations. OPM would continue to review agency requests and grant waivers if the regulatory criteria are met. However, this slows down the approval process for agencies that have a critical need to recruit or relocate employees and need to act quickly.

Another alternative would be to expand the authority to waive the normal recruitment and relocation payment limitations, but require higher approval levels within the agency. OPM believes agencies are in the best position to decide at what level to delegate this authority within their agency.

Also, OPM could expand the agency waiver authority, but require additional approval criteria. Agencies may include additional approval criteria in their agency plan. OPM doesn’t believe it is necessary to require agencies to use additional approval criteria.

Finally, OPM could expand the agency waiver authority, but institute special reporting requirements for the use of the new waiver authority. Agencies are required to report to OPM’s central data system when they authorize a waiver of the normal recruitment or relocation incentive payment limitations using legal authority code VPO. OPM doesn’t believe additional reporting requirements are necessary.

Regarding the amendment of the service agreement requirement for recruitment incentives, possible alternatives include maintaining the current 6-month minimum service agreement or reducing it to a lesser amount (e.g., 3 months). OPM believes agencies are in the best position to decide the appropriate length for a recruitment incentive service agreement.

⁸ 70 FR 25732, May 13, 2005.

D. Costs

This proposed rule would affect the operations of more than 80 Federal agencies—ranging from cabinet-level departments to small independent agencies—that have employees covered by the recruitment and relocation incentive regulations. OPM estimates that this rule would require individuals employed by these agencies to spend time updating agency policies and procedures as a result of the proposed regulations. For this cost analysis, the assumed average salary rate of Federal employees performing this work will be the rate in 2023 for GS–14, step 5, from the Washington, DC, locality pay table (\$150,016 annual locality rate and \$71.88 hourly locality rate). OPM assumes the total dollar value of labor, which includes wages, benefits, and overhead, is equal to 200 percent of the wage rate, resulting in an assumed labor cost of \$143.76 per hour.

To comply with the regulatory changes in the proposed rule, affected agencies would need to review the rule and update their policies and procedures. OPM estimates that, in the first year following publication of a final rule, this would require an average of 160 hours of work by employees with an average hourly cost of \$143.76 per hour. This would result in estimated costs in that first year of implementation of about \$23,000 per agency, and about \$2.7 million Governmentwide. There are costs associated with administering recruitment and relocation incentives, but not necessarily an increase in administrative costs for agencies that are already using these pay flexibilities.

E. Benefits

Permitting agencies to review and approve waivers at the agency level will reduce administrative burden on agencies and increase the efficiency of using recruitment and relocation incentives. This will allow agencies to move more quickly in approving incentives when hiring new employees and relocating those who are moving into positions that are likely to be difficult to fill. Such efficiency could be especially helpful in emergency or other urgent situations in which recruiting new employees or relocating current employees rapidly is necessary. Also, with increases in the number of retirement-eligible employees, recruiting early career and experienced talent to the Federal workforce is a high priority. Providing agencies with more flexibility in implementing recruitment incentives by permitting greater latitude in determining service agreement

lengths and payment limits can be a useful tool in achieving this goal.

F. Request for Comments

OPM requests comments on the implementation and impacts of this proposed rule. Such information will be useful for better understanding the effect of these regulations on recruitment and relocation incentives. The type of information in which OPM is interested includes, but is not limited to, the following:

- Are there additional ways that the Federal Government can be a model employer with respect to recruitment and relocation incentives?
- How can the Federal Government use recruitment and relocation incentives more effectively and efficiently?
- OPM has provided a fact sheet addressing oversight and accountability for these incentives.⁹ Are there any additional ways in which the Federal Government can provide better oversight and accountability of recruitment and relocation incentives?

E.O. 12866, 13563, 14094, Regulatory Review

OPM has examined the impact of this rule as required by Executive Order 12866 and Executive Order 13563, and Executive Order 14094, which 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). A regulatory impact analysis must be prepared for major rules with economically significant effects of \$200 million or more in any one year. While this proposed rule does not reach the economic effect of \$200 million or more, OMB has designated this rule as a “significant regulatory action” under Executive Order 14094.

Regulatory Flexibility Act

The Director of OPM certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities because they will apply only to Federal agencies and employees.

E.O. 13132, Federalism

This proposed rule will not have substantial direct effects on the States,

⁹ Office of Personnel Management. “Fact Sheet: Oversight and Accountability.” <https://www.opm.gov/policy-data-oversight/pay-leave/recruitment-relocation-retention-incentives/fact-sheets/oversight-and-accountability/>.

on the relationship between the National Government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this proposed rule does not have sufficient federalism implications to warrant preparation of a Federalism Assessment.

E.O. 12988, Civil Justice Reform

This proposed rule meets the applicable standards set forth in section 3(a) and (b)(2) of Executive Order 12988.

Unfunded Mandates Reform Act of 1995

This proposed rule will not result in the expenditure by State, local or tribal governments, in the aggregate, or by the private sector, of more than \$100 million annually. Thus, no written assessment of unfunded mandates is required.

Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35)

This regulatory action will not impose any reporting or recordkeeping requirements under the Paperwork Reduction Act.

List of Subjects in Title 5 CFR Part 575

Government employees, Wages.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

Accordingly, OPM is proposing to amend 5 CFR part 575 as follows:

PART 575—RECRUITMENT, RELOCATION, AND RETENTION INCENTIVES; SUPERVISORY DIFFERENTIALS; AND EXTENDED ASSIGNMENT INCENTIVES

- 1. The authority citation for part 575 continues to read as follows:

Authority: 5 U.S.C. 1104(a)(2) and 5307; subparts A and B also issued under 5 U.S.C. 5753; subpart C also issued under 5 U.S.C. 5754; subpart D also issued under 5 U.S.C. 5755; subpart E also issued under 5 U.S.C. 5757 and sec. 207 of Public Law 107–273, 116 Stat. 1780.

Subpart A—Recruitment Incentives

- 2. In § 575.102, revise paragraph (3) of the definition “Newly appointed” to read as follows:

§ 575.102 Definitions.

* * * * *
Newly appointed * * *

(3) An appointment of an individual in the Federal Government when the individual’s service in the Federal Government during the 90-day period

immediately preceding the appointment was not in a position excluded by § 575.104 and was limited to one or more of the following:

* * * * *

■ 3. In § 575.106, revise paragraph (a)(4) to read as follows:

§ 575.106 Authorizing a recruitment incentive.

(a) * * *

(4) Waive the limitation on the maximum amount of a recruitment incentive under § 575.109(c); and

* * * * *

■ 4. In § 575.107, revise paragraphs (a)(1) and (b) to read as follows:

§ 575.107 Agency recruitment incentive plan and approval levels.

(a) * * *

(1) The designation of officials with authority to—

(i) Review and approve payment of recruitment incentives (subject to paragraph (b) of this section), including the circumstances under which an official has the authority to approve payment without higher-level approval under paragraph (b)(2) of this section;

(ii) Waive the recruitment incentive payment limitation under § 575.109(c) (subject to the approval requirements in paragraph (b) of this section); and

(iii) Waive the repayment of a recruitment incentive under § 575.111(h);

* * * * *

(b) (1) Except as provided in paragraph (b)(2) of this section, an authorized agency official who is at least one level higher than the employee's supervisor must review and approve each determination to pay a recruitment incentive to a newly appointed employee, unless there is no official at a higher level in the agency. If a determination includes a waiver of the payment limitation in § 575.109(c), the official who is designated in the agency's plan under § 575.107(a) to approve waivers must approve the determination. The authorized agency official must review and approve the recruitment incentive determination before the agency may pay the incentive to the employee.

(2) When necessary to make a timely offer of employment, an authorized agency official may establish criteria in advance for offering recruitment incentives to newly-appointed employees and may authorize an official who is not lower than a candidate's supervisor to use these criteria to offer a recruitment incentive to a candidate without further review or approval in any amount within a pre-established range up to—

(i) The normal payment limitation in § 575.109(b); or

(ii) A higher cap if the agency has approved a waiver to the normal payment limitation under § 575.109(c).

* * * * *

■ 5. In § 575.109, revise paragraph (c) to read as follows:

§ 575.109 Payment of recruitment incentives.

* * * * *

(c) (1) An authorized agency official may waive the limitation in paragraph (b)(1) of this section for an employee or group of employees based on a critical agency need. The authorized agency official must determine that the competencies required for the position(s) are critical to the successful accomplishment of an important agency mission, project, or initiative (e.g., programs or projects related to a national emergency or implementing a new law or critical management initiative). Under such a waiver, the total amount of recruitment incentive payments paid to an employee in a service period may not exceed 50 percent of the employee's annual rate of basic pay at the beginning of the service period multiplied by the number of years (including fractions of a year) in the service period. However, in no event may a waiver provide total recruitment incentive payments exceeding 100 percent of the employee's annual rate of basic pay at the beginning of the service period.

(2) Waiver determinations must be made in writing and include—

(i) A description of the critical agency need the recruitment incentive would address;

(ii) The documentation required by § 575.108; and

(iii) Any other information pertinent to the case at hand.

* * * * *

■ 6. In § 575.110, revise paragraphs (a) and (f) to read as follows:

§ 575.110 Service agreement requirements.

(a) Before paying a recruitment incentive, an agency must require the employee to sign a written service agreement to complete a specified period of employment with the agency (or successor agency in the event of a transfer of function). An authorized agency official must establish the criteria for determining the length of a service period. The service period may not exceed 4 years.

* * * * *

(f) The service agreement may include any other terms or conditions that, if violated, will result in termination of

the service agreement under § 575.111(b). For example, the service agreement may specify the employee's work schedule, type of position, and the duties the employee is expected to perform. In addition, the service agreement may address the extent to which periods of time on detail, in a nonpay status, or in a paid leave status are creditable towards the completion of the service period.

■ 7. In § 575.111, revise paragraphs (e) and (f) to read as follows:

§ 575.111 Termination of a service agreement.

* * * * *

(e) If an authorized agency official terminates a service agreement under paragraph (a) of this section, the employee is entitled to all recruitment incentive payments that are attributable to completed service and to retain any portion of a recruitment incentive payment the employee received that is attributable to uncompleted service.

(f) Except as provided in paragraph (j) of this section, if an authorized agency official terminates a service agreement under paragraph (b) of this section, the employee is entitled to retain recruitment incentive payments previously paid by the agency that are attributable to the completed portion of the service period. If the employee received recruitment incentive payments that are less than the amount that would be attributable to the completed portion of the service period, the agency is not obligated to pay the employee the amount attributable to completed service, unless the agency agreed to such payment under the terms of the recruitment incentive service agreement. If the employee received recruitment incentive payments in excess of the amount that would be attributable to the completed portion of the service period, the employee must repay the excess amount, except when an authorized agency official waives the requirement to repay the excess amount under paragraph (h) of this section.

* * * * *

Subpart B—Relocation Incentives

■ 8. In § 575.206, revise paragraph (a)(4) to read as follows:

§ 575.206 Authorizing a relocation incentive.

(a) * * *

(4) Waive the limitation on the maximum amount of a relocation incentive under § 575.209(c); and

* * * * *

■ 9. In § 575.207, revise paragraphs (a)(1) and (b)(1) to read as follows:

§ 575.207 Agency relocation incentive plan and approval levels.

(a) * * *

(1) The designation of officials with authority to—

(i) Review and approve payment of relocation incentives (subject to paragraph (b) of this section);

(ii) Waive the relocation incentive payment limitation under § 575.209(c) (subject to the approval requirements in paragraph (b) of this section); and

(iii) Waive the repayment of a relocation incentive under § 575.211(h);

* * * * *

(b) (1) Except as provided in paragraph (b)(2) of this section, an authorized agency official who is at least one level higher than the employee's supervisor must review and approve each determination to pay a relocation incentive, unless there is no official at a higher level in the agency. If a determination includes a waiver of the payment limitation in § 575.209(c), the official who is designated in the agency's plan under § 575.207(a) to approve waivers must approve the determination. The authorized agency official must review and approve the relocation incentive determination before the agency pays the incentive to the employee.

* * * * *

■ 10. In § 575.209, revise paragraph (c) to read as follows:

§ 575.209 Payment of relocation incentives.

* * * * *

(c) (1) An authorized agency official may waive the limitation in paragraph (b)(1) of this section for an employee (or group of employees, if the case-by-case determination is waived under the conditions in § 575.208(b)) based on a critical agency need. The authorized agency official must determine that the competencies required for the position are critical to the successful accomplishment of an important agency mission, project, or initiative (e.g., programs or projects related to a national emergency or implementing a new law or critical management initiative). Under such a waiver, the total amount of relocation incentive payments paid to an employee in a service period may not exceed 50 percent of the annual rate of basic pay of the employee at the beginning of the service period multiplied by the number of years (including fractions of a year) in the service period. However, in no event may a waiver provide total relocation incentive payments exceeding 100 percent of the employee's annual rate of basic pay at the beginning of the service period.

(2) Waiver determinations must be in writing and include—

(i) A description of the critical agency need the relocation incentive would address;

(ii) The documentation required by § 575.208;

and

(iii) Any other information pertinent to the case at hand.

* * * * *

■ 11. In § 575.210, revise paragraph (f) to read as follows:

§ 575.210 Service agreement requirements.

* * * * *

(f) The service agreement may include any other terms or conditions that, if violated, will result in termination of the service agreement. For example, the service agreement may specify the employee's work schedule, type of position, and the duties the employee is expected to perform. In addition, the service agreement may address the extent to which periods of time on detail, in a nonpay status, or in a paid leave status are creditable towards the completion of the service period.

■ 12. In § 575.211, revise paragraphs (e) and (f) to read as follows:

§ 575.211 Termination of a service agreement.

* * * * *

(e) If an authorized agency official terminates a service agreement under paragraph (a) of this section, the employee is entitled to all relocation incentive payments attributable to completed service and to retain any portion of a relocation incentive payment the employee received that is attributable to uncompleted service.

(f) If an authorized agency official terminates a service agreement under paragraph (b) of this section, the employee is entitled to retain relocation incentive payments previously paid by the agency that are attributable to the completed portion of the service period. If the employee received relocation incentive payments that are less than the amount that would be attributable to the completed portion of the service period, the agency is not obligated to pay the employee the amount attributable to completed service, unless the agency agreed to such payment under the terms of the relocation incentive service agreement. If the employee received relocation incentive payments in excess of the amount that would be attributable to the completed portion of the service period, the employee must repay the excess amount, except when an authorized agency official waives the requirement

to repay the excess amount under paragraph (h) of this section.

* * * * *

[FR Doc. 2023–25199 Filed 11–14–23; 8:45 am]

BILLING CODE 6325–39–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD**10 CFR Part 1703**

[Docket No. DNFSB–2024–01]

Freedom of Information Act Fee Schedule

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Defense Nuclear Facilities Safety Board (DNFSB or Board) is proposing to revise its Freedom of Information Act (FOIA) fee schedule and to make conforming amendments to two related provisions of its FOIA regulations.

DATES: To be considered, comments must be submitted by December 15, 2023.

ADDRESSES: You may submit written comments by either of the following methods:

- *Email:* Send comments to comment@dnfsb.gov. Please include “FOIA Fee Revision” in the subject line of your email.

- *Mail or Hand Delivery:* Send hard copy comments to the Defense Nuclear Facilities Safety Board, Attn: General Manager, 625 Indiana Avenue NW, Suite 700, Washington, DC 20004–2901.

FOR FURTHER INFORMATION CONTACT: Tayrn L. Gude, Director, Division of Operational Services, Office of the General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW, Suite 700, Washington, DC 20004–2901, (202) 694–7000 (Toll Free (800) 788–4016).

SUPPLEMENTARY INFORMATION:**I. Background**

The Freedom of Information Act requires Federal agencies to which it applies to publish a schedule of the costs that they may charge for the expenditures incurred in responding to requests for their records. Guidelines published by the Office of Management and Budget assist agencies in meeting that requirement and provide a structure for its consistent implementation across the Executive Branch, 5 U.S.C. 552(a)(4)(A)(i), and “Uniform Freedom of Information Act Fee Schedules and Guidelines,” 52 FR 10012 (March 27, 1987), Revised 85 FR 81955 (Dec. 17,

2020), respectively. In accordance with those authorities, the Board's FOIA regulations require it to publish and regularly update a schedule identifying the expenditures it might seek to recover and the cost associated with each request. 10 CFR 1703.107(b)(6).

Since implementing its FOIA program, 56 FR 21261, May 8, 1991, DNFSB has calculated the fees charged for document search and review time based on the average hourly pay rate of its employees, plus the average hourly projected benefit cost. DNFSB has charged the costs of reproducing records directly to the requester either at the actual cost to the agency, or the amount charged by a commercial service. As of its most recent update, 80 FR 52174, Aug. 28, 2015, DNFSB's schedule of fees is as follows:

Search or Review Charge: \$85.00 per hour

Copy Charge:

Paper: \$.05 per page, if done in-house, or generally available commercial rate, approximately \$0.10 per page

Electronic Media: \$5.00 per electronic media

Audio and Video Cassettes: Actual commercial rates

Duplication CD or DVD: \$25.00 for each individual DVD; \$16.50 for each duplicate DVD

Large Documents, e.g., maps or diagrams: Actual commercial rates

II. Overview of Proposed Rule

In this action, DNFSB is proposing the following changes to the FOIA fee schedule:

1. Incorporating a schedule of fees in DNFSB's FOIA fee regulation (at 10 CFR 1703.107(b)(6)), rather than publishing the fees in a separate, non-codified **Federal Register** publication;

2. Separating the fee schedule for both manual and electronic record searches; and

3. Including the direct cost of computer time into the cost of electronic record searches; and,

4. Changing the basis used for calculating the cost of the time spent by employees searching for and/or reviewing records in response to FOIA requests.

Pursuant to this proposal, those costs will be calculated using the actual salary rate(s) (*i.e.*, basic hourly rate of pay plus an additional 16 percent for benefit costs) of the employee(s) performing the work. DNFSB currently uses the average of all employees' hourly pay rates plus average projected benefit costs as the basis for determining fees. DNFSB finds that the methodology should be changed for several reasons. First, basing costs on the salary of the

employee performing the work is more precise than basing them on an agency-wide average pay rate. Second, basing costs on the salary of the employee accurately reflects the actual costs incurred by the agency in searching for and reviewing responsive documents. Finally, it will eliminate the need to annually *republish* the FOIA fee schedule to account for the changed amount of the average employee salary resulting from Congressional changes to rates of pay, the number of agency employees, and their job classifications.

In this action, DNFSB is also announcing a proposal to amend the following four subsections of its FOIA fee regulation, 10 CFR 1703.107, to reflect the agency's adoption of actual salary cost(s) of the employee(s) performing document search and review activities for calculating response costs to be charged to requesters:

1. § 1703.107(b)(1) "*Direct Costs*"
2. § 1703.107(b)(2)(i) "*Fees*" (commercial use requests)
3. § 1703.107(b)(2)(iii) "*Fees*" ("other" requesters)
4. § 1703.107(b)(6) "*Annual adjustment of fees*"

II. Regulatory Analysis

Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 601–612, agencies must consider the impact of their rulemakings on "small entities" (small businesses, small organizations, and local governments) when publishing regulations subject to the notice and comment requirements of the Administrative Procedure Act. These proposed regulations pertain to the Board's policies and practices for processing FOIA requests, and do not impose any new requirements on small entities. Therefore, no analysis is required by the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in aggregate, or by the private sector, of \$100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions are deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996, as amended, 5

U.S.C. 804. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Paperwork Reduction Act

This rule contains no new reporting or recordkeeping requirements under the Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. 3501 *et seq.* This update to the Board's FOIA regulations does not require or request information from members of the public. Therefore, this rulemaking is not covered by the restrictions of the PRA.

Executive Order 12988—Civil Justice Reform

These proposed regulations meet the applicable standards set forth in Executive Order 12988.

Executive Order 13132—Federalism

According to Executive Order 13132, agencies must state in clear language the preemptive effect, if any, of new regulations. The amendments to the Board's FOIA regulations affect only how the Board responds to requests for information and have no effect on preemption of State, tribal, or local government laws or otherwise have federalism implications.

Congressional Review Act

This is a rule under the Congressional Review Act. The Board will send a copy of this rulemaking to Congress and the Government Accountability Office pursuant to 5 U.S.C. 801(a)(1)(A).

List of Subjects in 10 CFR Part 1703

Freedom of Information.

For the reasons discussed in the preamble, the Defense Nuclear Facilities Safety Board proposes to amend 10 CFR part 1703 as follows:

■ 1. The authority citation for part 1703 continues to read:

Authority: 5 U.S.C. 301, 552; 31 U.S.C. 9701; 42 U.S.C. 2286b.

■ 2. Amend § 1703.107 by revising paragraphs (b)(1), (b)(2)(i), (ii), (iii), and (b)(6) to read as follows:

§ 1703.107 Fees for record requests.

*	*	*	*	*	*
(b)	*	*	*		
(1)	*	*	*		
*	*	*	*	*	*

Direct costs mean those expenditures which DNFSB incurs in search, review,

and duplication, as applicable to different categories of requesters, to respond to requests under § 1703.105. Direct costs include, for example, the hourly salary and projected benefits costs of agency employees who search for, review, or duplicate records in response to a request. Overhead expenses such as cost of space, and heating or lighting the facility in which DNFSB records are stored are not included in direct costs.

* * * * *

(2) *Fees.* (i) If documents are requested for commercial use, DNFSB shall charge the hourly salary and projected benefits costs of agency employees who search for and review records in response to a request, and for the costs of duplication as set out in subsection (b)(6) of this section.

(ii) If documents are not sought for commercial use and the request is made by an educational or noncommercial scientific institution, whose purpose is scholarly or scientific research, or a representative of the news media, DNFSB's charges shall be limited to the direct costs of duplication as set out in subsection (b)(6) of this section.

(iii) For a request not described in paragraphs (b)(2) (i) or (ii) of this section, DNFSB shall charge the hourly salary and projected benefits costs of the agency's employee(s) who search for records in response to a request and the direct costs of duplication as set out in subsection (b)(6) of this section. There shall be no charge for document review time, and the first 100 pages of reproduction and the first two hours of search time will be provided without charge.

* * * * *

(6) *Schedule of Fees.* (1) To the extent authorized by these regulations, DNFSB is authorized to seek the following fees to recover costs incurred in responding to FOIA requests:

(i) Document Search Charges

(A) *Manual:* Salary rate(s) (basic hourly pay plus 16 percent) of employee(s) performing records search or review.

(B) *Electronic:* Salary rate(s) (basic hourly pay plus 16 percent) of employee(s) performing search or review.

(ii) *Document Review Charges:* Salary rate(s) (basic hourly pay plus 16 percent) of employee(s) performing search or review.

(2) DNFSB will charge requesters who seek records for commercial purposes for the cost of reviewing them to determine whether they are exempt from mandatory disclosure. The agency will assess these charges only when the

records are first analyzed to determine the applicability of a specific exemption to a record or portion thereof. DNFSB will not charge for the review of an exemption previously applied at the administrative review level. If a record or portion thereof was withheld in full under an exemption that is subsequently found inapplicable, it may be reviewed again to determine the applicability of other exemptions not previously considered. DNFSB may charge for the cost of such review.

(3) Copying Charges

(i) *Paper:* \$.05 per page, if done in-house, or generally available commercial rate, approximately \$0.10 per page.

(ii) *Electronic Media:* Direct cost, including operator time (employee's basic hourly pay plus 16 percent).

(iii) *Audio and Video Cassette:* Actual commercial rates.

(iv) *Duplication of CD or DVD:* Direct cost, including operator time (employee's basic hourly pay plus 16 percent).

(v) *Large Documents, e.g., maps or diagrams:* Actual commercial rates.

Dated: November 8, 2023.

Joyce Connery,
Chair.

[FR Doc. 2023–25074 Filed 11–14–23; 8:45 am]

BILLING CODE 3670–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–2000; Project Identifier MCAI–2023–00415–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., 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 Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. This proposed AD was prompted by reports that some overheat detection sensing elements of the bleed air leak detection system were manufactured with insufficient salt fill, which can result in an inability to detect hot bleed air leaks. This proposed AD would require maintenance records verification, and if an affected part is installed, would prohibit the use of certain Master Minimum Equipment

List (MMEL) items under certain conditions by requiring revising the operator's existing MEL. This proposed AD would also require testing the overheat detection sensing elements, marking each serviceable sensing element with a witness mark, and replacing each non-serviceable part with a serviceable part. This proposed AD would also prohibit the installation of affected parts under certain conditions. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by January 2, 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](https://www.regulations.gov). Follow the instructions for submitting comments.

- *Fax:* 202–493–2251.

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

- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

AD Docket: You may examine the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA–2023–2000; 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 Bombardier service information identified in this NPRM, 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](https://www.bombardier.com).

- For Liebherr-Aerospace Toulouse SAS service information identified in this NPRM, contact Liebherr-Aerospace Toulouse SAS, 408, Avenue des Etats-Unis—B.P.52010, 31016 Toulouse Cedex, France; telephone +33 (0)5.61.35.28.28; fax +33 (0)5.61.35.29.29; email: techpub.toulouse@liebherr.com; website: www.liebherr.aero.

- You may view this service information 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: 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:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include “Docket No. FAA–2023–2000; Project Identifier MCAI–2023–00415–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 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*. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2023–17, dated March 8, 2023 (Transport Canada AD CF–2023–17) (also referred to after this as the MCAI), to correct an unsafe condition on certain Bombardier, Inc., Model BD–700–1A10 and BD–700–1A11 airplanes. The MCAI states that Bombardier received reports from the supplier of the overheat detection sensing elements of a manufacturing quality escape. Some of the sensing elements of the bleed air leak detection system were manufactured with insufficient salt fill. This condition can result in an inability to detect hot bleed air leaks, which can cause damage to surrounding structures and systems and prevent continued safe flight and landing.

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–2023–2000.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Liebherr Service Bulletin CFD–F1958–26–01, dated May 6, 2022, which specifies part numbers for affected sensing elements.

The FAA reviewed the following Bombardier service bulletins, which specify procedures for testing each leak detection loop (LDL) sensing element installed on the airplane, marking each serviceable sensing element with a witness mark, and replacing each non-serviceable part with a serviceable part. These documents are distinct since they apply to different airplane models and configurations:

- Bombardier Service Bulletin 700–1A11–36–005 Basic Issue, dated December 23, 2022;
- Bombardier Service Bulletin 700–36–026 Basic Issue, dated December 23, 2022;
- Bombardier Service Bulletin 700–36–5002 Basic Issue, dated December 23, 2022;

- Bombardier Service Bulletin 700–36–5501 Basic Issue, dated December 23, 2022;

- Bombardier Service Bulletin 700–36–6002 Basic Issue, dated December 23, 2022; and

- Bombardier Service Bulletin 700–36–6501 Basic Issue, dated December 23, 2022.

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.

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

Proposed AD Requirements in This NPRM

This proposed AD would require maintenance records verification. If an affected part is installed, this proposed AD would prohibit the use of certain MMEL items unless specific dispatch instructions are followed by revising the operator’s existing MEL and accomplishing the actions specified in the service information already described. For certain airplanes, this proposed AD would also require testing each LDL sensing element installed on the airplane, marking each serviceable sensing element with a witness mark, and replacing each non-serviceable part with a serviceable part. This proposed AD would also prohibit the installation of affected parts under certain conditions.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 160 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 140 work-hours × \$85 per hour = Up to \$11,900.	\$0	Up to \$11,900	Up to \$1,904,000.

The FAA has received no definitive data on which to base the cost estimates for the on-condition actions specified in this proposed AD. The FAA estimates it would take up to 1.5 hours to replace a sensing element.

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:

Bombardier, Inc.: Docket No. FAA-2023-2000; Project Identifier MCAI-2023-00415-T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by January 2, 2024.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD-700-1A10 and BD-700-1A11 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code: 36, Pneumatic.

(e) Unsafe Condition

This AD was prompted by reports that some overheat detection sensing elements of the bleed air leak detection system were manufactured with insufficient salt fill. The FAA is issuing this AD to address non-conforming sensing elements of the bleed air leak detection system. The unsafe condition, if not addressed, could result in an inability to detect hot bleed air leaks and consequent

damage to surrounding structures and systems, which could prevent continued safe flight and landing.

(f) Compliance

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

(g) Definitions

For the purpose of this AD, the definitions specified in paragraphs (g)(1) through (3) of this AD apply.

(1) The following Model BD-700-1A10 and BD-700-1A11 airplane groups are identified in (g)(1)(i) through (iv) of this AD:

(i) Group A airplanes: serial numbers (S/N) 9002 through 9151 inclusive, and 9153.

(ii) Group B airplanes: S/N 9152, 9154 through 9879 inclusive, 9998, 60001 through 60041 inclusive, 60043, 60044, 60045, and 60051.

(iii) Group C airplanes: S/N 60042, 60046, 60047, 60049, 60053, and subsequent.

(iv) Group D airplanes: S/N 60048, 60050, and 60052.

(2) An affected part is a sensing element marked with a date code A0448 through A2104 inclusive and having an LTS/Kidde part number specified in Liebherr Service Bulletin CFD-F1958-26-01, dated May 6, 2022, unless that sensing element meets the criteria specified in paragraph (g)(2)(i) or (ii) of this AD.

(i) The sensing element has been tested as specified in Section 3 of the Accomplishment Instructions of Kidde Aerospace and Defense Service Bulletin CFD-26-1, Revision 6, dated February 28, 2022, or earlier revisions, and has been found to be serviceable; and the sensing element has been marked on one face of its connector hex nut and packaged as specified in Section 3.C. of the Accomplishment Instructions of Kidde Aerospace and Defense Service Bulletin CFD-26-1, Revision 6, dated February 28, 2022, or earlier revisions.

(ii) The sensing element has been tested and found to be serviceable as specified in paragraph (j) of this AD; and the sensing element has been marked on one face of one connector hex nut with one green mark, as specified in Figure 4 (the figure is representative for all sensing elements) in the Accomplishment Instructions of the applicable Bombardier service bulletin (BA SB) in figure 1 to paragraph (g)(2)(ii) of this AD.

Figure 1 to paragraph (g)(2)(ii)—Applicable service information

BILLING CODE 4910-12-P

Aeroplane Model (Marketing Designation)	Applicable BA SB
BD-700-1A10 (Global Express & Global Express XRS)	SB 700-36-026 Basic Issue, dated 23 December 2022, or later revisions approved by the Chief, Continuing Airworthiness, Transport Canada
BD-700-1A11 (Global 5000)	SB 700-1A11-36-005 Basic Issue, dated 23 December 2022, or later revisions approved by the Chief, Continuing Airworthiness, Transport Canada
BD-700-1A11 (Global 5000 featuring Global Vision Flight Deck)	SB 700-36-5002 Basic Issue, dated 23 December 2022, or later revisions approved by the Chief, Continuing Airworthiness, Transport Canada
BD-700-1A10 (Global 6000)	SB 700-36-6002 Basic Issue, dated 23 December 2022, or later revisions approved by the Chief, Continuing Airworthiness, Transport Canada
BD-700-1A11 (Global 5500)	SB 700-36-5501 Basic Issue, dated 23 December 2022, or later revisions approved by the Chief, Continuing Airworthiness, Transport Canada
BD-700-1A10 (Global 6500)	SB 700-36-6501 Basic Issue, dated 23 December 2022, or later revisions approved by the Chief, Continuing Airworthiness, Transport Canada

(3) A serviceable part is a sensing element that is not an affected part.

(h) Maintenance Records Verification

For Groups A and C whose airplane date of manufacture, as identified on the identification plate of the airplane, is on or before July 27, 2022 (the effective date of Transport Canada AD CF-2022-38): Within 60 days after the effective date of this AD, examine the airplane maintenance records to verify whether any affected part has been installed since the airplane date of

manufacture, as identified on the identification plate of the airplane.

(1) If the maintenance records confirm that an affected part has been installed, or if it cannot be confirmed that an affected part has not been installed, paragraphs (i) and (j) of this AD must be complied with within the applicable compliance times specified in paragraphs (i) and (j) of this AD.

(2) For Groups A and C airplanes: if the maintenance records confirm that no affected parts have been installed since airplane date

of manufacture, then paragraphs (i) and (j) of this AD are not applicable.

(i) Minimum Equipment List (MEL) Revision

For Groups B and D airplanes, and Groups A and C airplanes required by paragraph (h) of this AD: Within 90 days after the effective date of this AD, revise the operator's existing MEL by incorporating the information specified in figures 2 through 8 to paragraph (i) of this AD, as applicable. This may be done by inserting a copy of this information into the operator's existing MEL.

Figure 2 to paragraph (i) – MMEL Item 36-12-01

MMEL Item 36-12-01			
1. System & Sequence N° Item N° de système/série article	2. Number Installed Nombre d'article installés	3. Number Required For Dispatch Nombre d'articles à expédier	4. Remarks or Exceptions
36 - <u>PNEUMATICS</u> 12-01 Bleed Leak Detection Loops C	18	9	(O) Either loop A or loop B may be inoperative provided redundant loop in the same zone is operative.

1. PLACARD

(1) Put a BLEED LEAK DETECTION LOOPS INOPERATIVE placard on the instrument panel.

2. OPERATIONS (O)

Before each flight:

(1) Make sure that the aeroplane is not powered on and that engines and APU are OFF.

a. Connect electrical power to the aeroplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

i. Connect external AC power, OR

ii. Start the APU as follows:

- On the ELECTRICAL control panel, set the BATT MASTER switch to ON.
- On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.
- On the APU control panel, turn the APU switch to START.

b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

c. After 6 minutes, make sure that the EICAS primary display shows as follows:

i. If the Advisory L BLEED FAULT or R BLEED FAULT shows, DISPATCH IS PERMITTED.

Note: If the Advisory L BLEED FAULT or R BLEED FAULT shows, it confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

ii. If the Advisory L BLEED FAULT or R BLEED FAULT does not show, DISPATCH IS NOT PERMITTED.

Note: If the Advisory L BLEED FAULT or R BLEED FAULT does not show, it confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

d. If required, remove external AC power from the aeroplane.

e. If required, set APU BLEED to AUTO.

Figure 3 to paragraph (i) – MMEL Item 36-12-01-1**MMEL Item 36-12-01-1**

1. System & Sequence No Item	2. Number Installed	3. Number Required For Dispatch	4. Remarks or Exceptions
Nº de système/série article	Nombre d'article installés	Nombre d'articles à expédier	
36 - <u>PNEUMATICS</u> 12-01 Bleed Leak Detection Loops C	18	9	(O) Either loop A or loop B may be inoperative provided redundant loop in the same zone is operative.
1) Wing Anti-Ice Leak C	12	6	(M) (O) One loop in each section may be inoperative provided: a) Power-up BIT test is performed on system prior to each dispatch into icing, and b) Cause of WING ANTI-ICE FAULT Advisory message is confirmed by maintenance.

1. PLACARD

- (1) Put a WING ANTI-ICE LEAK INOPERATIVE placard on the instrument panel.

2. OPERATIONS (O)

Before each flight:

- (1) Make sure that the aeroplane is not powered on and that engines and APU are OFF.

- a. Connect electrical power to the aeroplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

- i. Connect external AC power, OR

- ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the BATT MASTER switch to ON.
2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.
3. On the APU control panel, turn the APU switch to START.

- b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

- c. After 6 minutes, make sure that the EICAS primary display shows as follows:

- i. If the Advisory WING A/ICE FAULT shows, DISPATCH IS PERMITTED unless step (2) of the Maintenance (M) procedure under (3) below does not pass, in which case DISPATCH IS NOT PERMITTED.

Note: If the Advisory WING A/ICE FAULT shows, it confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

- ii. If the Advisory WING A/ICE FAULT does not show, DISPATCH IS NOT PERMITTED.

Note: If the Advisory WING A/ICE FAULT does not show, it confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

- d. If required, remove external AC power from the aeroplane.
- e. If required, set APU BLEED to AUTO.

3. MAINTENANCE (M)

The requirement to perform this section is conditional on (1)(c)(i) under the Operations (O) procedure above.

- (1) Power-up BIT test is performed on system prior to each dispatch into icing.
- (2) The cause of the WING ANTI-ICE FAULT Advisory message is to be confirmed by maintenance personnel to make sure that no section has encountered a dual loop failure.

Figure 4 to paragraph (i) – MMEL Item 36-12-01-2**MMEL Item 36-12-01-2**

1. System & Sequence No Item	2. Number Installed	3. Number Required For Dispatch	4. Remarks or Exceptions
No de système/série article	Nombre d'article installés	Nombre d'articles à expédier	
36 - <u>PNEUMATICS</u> 12-01 Bleed Leak Detection Loops C	18	9	(O) Either loop A or loop B may be inoperative provided redundant loop in the same zone is operative.
2) Trim Air Leak C	2	1	(O) Except for ER operations, one loop may be inoperative.

1. PLACARD

- (1) Put a TRIM AIR LEAK INOPERATIVE placard on the instrument panel.

2. OPERATIONS (O)

Before each flight:

- (1) Make sure that the aeroplane is not powered on and that engines and APU are OFF.

- a. Connect electrical power to the aeroplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

- i. Connect external AC power, OR

- ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the BATT MASTER switch to ON.
2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.
3. On the APU control panel, turn the APU switch to START.

- b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

- c. After 6 minutes, make sure that the EICAS primary display shows as follows:

- i. If the Advisory TRIM AIR FAULT shows, DISPATCH IS PERMITTED.

Note: If the Advisory TRIM AIR FAULT shows, it confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

- ii. If the Advisory TRIM AIR FAULT does not show, DISPATCH IS NOT PERMITTED.

Note: If the Advisory TRIM AIR FAULT does not show, it confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

- d. If required, remove external AC power from the aeroplane.

- e. If required, set APU BLEED to AUTO.

Figure 5 to paragraph (i) – L BLEED FAULT

L BLEED FAULT		
CAS Indication	1.	2. Dispatch Consideration
L BLEED FAULT (Advisory)	C	(O) Aircraft may be dispatched provided, prior to each flight: - None of the following messages are also posted: – R BLEED SYS FAIL Caution; – R WING ANTI-ICE FAIL Caution; – XBLEED FAIL Caution; – R BLEED FAULT Advisory; – WING ANTI-ICE FAULT Advisory; - Left PRV and left HPSOV open and close correctly in response to L BLEED OFF switch selection, as indicated on Synoptic Page; - Left HPSOV is open at engine idle and closed at high thrust settings, as indicated on Synoptic Page; - WING XBLEED FROM R is selected and remains open; and - Operations are not conducted in known or forecast icing conditions.

1. OPERATIONS (O)

Before each flight:

- Make sure that the aeroplane is not powered on and that engines and APU are OFF.
 - Connect electrical power to the aeroplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

 - Connect external AC power, OR
 - Start the APU as follows:
 - On the ELECTRICAL control panel, set the BATT MASTER switch to ON.
 - On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.
 - On the APU control panel, turn the APU switch to START.
 - When external AC power is on or APU is running, wait a minimum of 6 minutes.

c. After 6 minutes, make sure that the EICAS primary display shows as follows:

i. If the Advisory L BLEED FAULT shows, DISPATCH IS PERMITTED.

Note: If the Advisory L BLEED FAULT shows, it confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

ii. If the Advisory L BLEED FAULT does not show, DISPATCH IS NOT PERMITTED.

Note: If the Advisory L BLEED FAULT does not show, it confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

d. If required, remove external AC power from the aeroplane.

e. If required, set APU BLEED to AUTO.

2. OPERATIONS (O)

Before each flight and after engine start:

(1) On the EICAS primary display, make sure that the messages that follow do not show:

- R BLEED SYS FAIL (Caution)
- R WING ANTI-ICE FAIL (Caution)
- XBLEED FAIL (Caution)
- R BLEED FAULT (Advisory)
- WING ANTI-ICE FAULT (Advisory)

(2) Make sure that the left Pressure Regulator Valve (PRV) and left High Pressure Shut Off Valve (HPSOV) open and close as follows:

- a. On the BLEED/AIR COND control panel, set the L ENG BLEED switch to OFF.
- b. On the BLEED/ANTI-ICE synoptic page, make sure that the left PRV and left HPSOV show closed.
- c. On the BLEED/AIR COND control panel, set the L ENG BLEED switch to AUTO.
- d. On the BLEED/ANTI-ICE synoptic page, make sure that the left PRV and left HPSOV show open.

(3) Make sure that the left High Pressure Shut Off Valve (HPSOV) switching operates as follows:

- a. Slowly advance the left throttle to high thrust setting.
- b. On the BLEED/ANTI-ICE synoptic page, make sure that the left HPSOV shows closed.
- c. Slowly retard the left throttle to engine idle.
- d. On the BLEED/ANTI-ICE synoptic page, make sure that the left HPSOV shows open.

(4) On the ANTI-ICE control panel, set the WING XBLEED to FROM R for the rest of the flight.

(5) Operations are not conducted in known or forecast icing conditions.

Figure 6 to paragraph (i) – R BLEED FAULT**R BLEED FAULT**

CAS Indication	1.	2. Dispatch Consideration
R BLEED FAULT (Advisory)	C	(O) Aircraft may be dispatched provided, prior to each flight: a) None of the following messages are also posted: – L BLEED SYS FAIL Caution; – L WING ANTI-ICE FAIL Caution; – XBLEED FAIL Caution; – L BLEED FAULT Advisory; – WING ANTI-ICE FAULT Advisory; b) Right PRV and right HPSOV open and close correctly in response to R BLEED OFF switch selection, as indicated on Synoptic Page; c) Right HPSOV is open at engine idle and closed at high thrust settings, as indicated on Synoptic Page; d) WING XBLEED FROM L is selected and remains open; and e) Operations are not conducted in known or forecast icing conditions.

1. OPERATIONS (O)

Before each flight:

- (1) Make sure that the aeroplane is not powered on and that engines and APU are OFF.
 - a. Connect electrical power to the aeroplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

 - i. Connect external AC power, OR
 - ii. Start the APU as follows:
 1. On the ELECTRICAL control panel, set the BATT MASTER switch to ON.
 2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.
 3. On the APU control panel, turn the APU switch to START.
 - b. When external AC power is on or APU is running, wait a minimum of 6 minutes.
 - c. After 6 minutes, make sure that the EICAS primary display shows as follows:
 - i. If the Advisory R BLEED FAULT shows, DISPATCH IS PERMITTED.

Note: If the Advisory R BLEED FAULT shows, it confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.
 - ii. If the Advisory R BLEED FAULT does not show, DISPATCH IS NOT PERMITTED.

Note: If the Advisory R BLEED FAULT does not show, it confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.
 - d. If required, remove external AC power from the aeroplane.
 - e. If required, set APU BLEED to AUTO.

2. OPERATIONS (O)

Before each flight and after engine start:

- (1) On the EICAS primary display, make sure that the messages that follow do not show:

- L BLEED SYS FAIL (Caution)
 - L WING ANTI-ICE FAIL (Caution)
 - XBLEED FAIL (Caution)
 - L BLEED FAULT (Advisory)
 - WING ANTI-ICE FAULT (Advisory)
- (2) Make sure that the right Pressure Regulator Valve (PRV) and right High Pressure Shut Off Valve (HPSOV) open and close as follows:
- a. On the BLEED/AIR COND control panel, set the R ENG BLEED switch to OFF.
 - b. On the BLEED/ANTI-ICE synoptic page, make sure that the right PRV and right HPSOV show closed.
 - c. On the BLEED/AIR COND control panel, set the R ENG BLEED switch to AUTO.
 - d. On the BLEED/ANTI-ICE synoptic page, make sure that the right PRV and right HPSOV show open.
- (3) Make sure that the right High Pressure Shut Off Valve (HPSOV) switching operates as follows:
- a. Slowly advance the right throttle to high thrust setting.
 - b. On the BLEED/ANTI-ICE synoptic page, make sure that the right HPSOV shows closed.
 - c. Slowly retard the right throttle to engine idle.
 - d. On the BLEED/ANTI-ICE synoptic page, make sure that the right HPSOV shows open.
- (4) On the ANTI-ICE control panel, set the WING XBLEED to FROM L for the rest of the flight.
- (5) Operations are not conducted in known or forecast icing conditions.

Figure 7 to paragraph (i) – WING A/ICE FAULT**WING A/ICE FAULT**

CAS Indication	1.	2. Dispatch Consideration
WING A/ICE FAULT (Advisory)	C	(O) Aircraft may be dispatched provided, prior to each departure: a) Flight is not conducted in known or forecast icing conditions; b) A power-up test is performed by cycling WING A/ICE switch from OFF to ON; and c) None of the following CAS messages are also posted: – ICE DETECT FAIL Caution; – L BLEED SYS FAIL Caution; – R BLEED SYS FAIL Caution; – ICE DETECT FAULT Advisory; – L BLEED FAULT Advisory; – R BLEED FAULT Advisory.

1. OPERATIONS (O)

Before each flight:

- (1) Make sure that the aeroplane is not powered on and that engines and APU are OFF.

- a. Connect electrical power to the aeroplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

- i. Connect external AC power, OR

- ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the BATT MASTER switch to ON.
2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.
3. On the APU control panel, turn the APU switch to START.

- b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

- c. After 6 minutes, make sure that the EICAS primary display shows as follows:

- i. If the Advisory WING A/ICE FAULT shows, DISPATCH IS PERMITTED.

Note: If the Advisory WING A/ICE FAULT shows, it confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

- ii. If the Advisory WING A/ICE FAULT does not show, DISPATCH IS NOT PERMITTED.

Note: If the Advisory WING A/ICE FAULT does not show, it confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

- d. If required, remove external AC power from the aeroplane.

- e. If required, set APU BLEED to AUTO.

2. OPERATIONS (O)

Before each flight and after engine start:

- (1) Perform a power-up test as follows:

- a. On the ANTI-ICE control panel, cycle the WING switch from OFF to ON.
- b. On the EICAS primary display, make sure that the following CAS status message is shown:
– WING A/ICE ON.
- c. On the EICAS primary display, make sure that the following CAS messages are not shown:
– L WING A/ICE FAIL (Caution)
– R WING A/ICE FAIL (Caution)

- (2) On the EICAS primary display, make sure that the following CAS messages are not shown:

- ICE DETECT FAIL (Caution)
- L BLEED SYS FAIL (Caution)
- R BLEED SYS FAIL (Caution)
- ICE DETECT FAULT (Advisory)
- L BLEED FAULT (Advisory)
- R BLEED FAULT (Advisory)

- (3) Operations are not conducted in known or forecast icing conditions.

Figure 8 to paragraph (i) – TRIM AIR FAULT**TRIM AIR FAULT**

CAS Indication	1.	2. Dispatch Consideration
TRIM AIR FAULT (Advisory)	C	(O) Aircraft may be dispatched provided: a) Duct temperature indications are operative for all three ducts; b) Either HASOV showing incorrect indication on Synoptic page is verified CLOSED; and c) L PACK FAIL or R PACK FAIL Caution messages are not displayed.

1. OPERATIONS (O)

Before each flight:

- (1) Make sure that the aeroplane is not powered on and that engines and APU are OFF.

- a. Connect electrical power to the aeroplane as follows:

Note: Do not use a Jet Airstart Cart or High Pressure Ground Cart.

- i. Connect external AC power, OR

- ii. Start the APU as follows:

1. On the ELECTRICAL control panel, set the BATT MASTER switch to ON.

2. On the BLEED/AIR COND control panel, make sure that the APU BLEED switch is set to OFF.

3. On the APU control panel, turn the APU switch to START.

- b. When external AC power is on or APU is running, wait a minimum of 6 minutes.

- c. After 6 minutes, make sure that the EICAS primary display shows as follows:

- i. If the Advisory TRIM AIR FAULT shows, DISPATCH IS PERMITTED.

Note: If the Advisory TRIM AIR FAULT shows, it confirms it is not heat related and therefore cannot be a potential leak in the presence of an affected part.

- ii. If the Advisory TRIM AIR FAULT does not show, DISPATCH IS NOT PERMITTED.

Note: If the Advisory TRIM AIR FAULT does not show, it confirms that it is heat related and therefore could be a potential leak in the presence of an affected part.

- d. If required, remove external AC power from the aeroplane.

- e. If required, set APU BLEED to AUTO.

2. OPERATIONS (O)

Before each flight and after engine start:

- (1) On the AIR CONDITIONING synoptic page, make sure that the duct temperature indications are operative for all three ducts.

- (2) Make sure that either HASOV that shows incorrect indication on the AIR CONDITIONING synoptic page is verified CLOSED as follows:

- a. On the BLEED/AIR COND control panel, alternate the TRIM AIR switch from ON to OFF to ON.

- b. At the same time, on the AIR CONDITIONING synoptic page, identify the HASOV that shows incorrect indication.

- c. In the flight compartment, on the EMS CDU, open the applicable circuit breaker as follows:

SYSTEM NAME	CIRCUIT BREAKER NAME	BUS NAME
AIR COND/PRESS	L ECS HASOV	DC ESS
AIR COND/PRESS	R ECS HASOV	DC ESS

- d. In the aft equipment compartment, make sure that any identified HASOV is in the CLOSED position.

- (3) On the EICAS primary display, make sure that the following CAS messages are not shown:

- L PACK FAIL (Caution)
– R PACK FAIL (Caution)

(j) Testing and Replacement of Affected Overheat Detection Sensing Elements

(1) For Group B and D airplanes, and Group A and C airplanes required by paragraph (h) of this AD: Within 2,000 flight hours or 120 months, whichever occurs first, from the effective date of this AD, test the overheat detection sensing elements to determine if they are serviceable, in accordance with the Accomplishment Instructions of the applicable Bombardier service bulletin in paragraphs (j)(1)(i) through (vi) of this AD.

(i) For Model BD-700-1A11 (Global 5000) airplanes: Bombardier Service Bulletin 700-1A11-36-005 Basic Issue, dated December 23, 2022.

(ii) For Model BD-700-1A10 (Global Express and Global Express XRS) airplanes: Bombardier Service Bulletin 700-36-026 Basic Issue, dated December 23, 2022.

(iii) For Model BD-700-1A11 (Global 5000 featuring Global Vision Flight Deck) airplanes: Bombardier Service Bulletin 700-36-5002 Basic Issue, dated December 23, 2022.

(iv) For Model BD-700-1A11 (Global 5500) airplanes: Bombardier Service Bulletin 700-36-5501 Basic Issue, dated December 23, 2022.

(v) For Model BD-700-1A10 (Global 6000) airplanes: Bombardier Service Bulletin 700-36-6002 Basic Issue, dated December 23, 2022.

(vi) For Model BD-700-1A10 (Global 6500) airplanes: Bombardier Service Bulletin 700-36-6501 Basic Issue, dated December 23, 2022.

(2) For each sensing element that is serviceable, as determined by paragraph (j)(1) of this AD, before further flight, mark the sensing element with a witness mark in accordance with the Accomplishment Instructions in the applicable Bombardier service bulletin in paragraphs (j)(1)(i) through (vi) of this AD.

(3) For each sensing element that is not serviceable, as determined by paragraph (j)(1) of this AD, before further flight, replace the sensing element with a serviceable part in accordance with the Accomplishment Instructions in the applicable Bombardier Service Bulletin in paragraphs (j)(1)(i) through (vi) of this AD.

(k) Parts Installation Prohibition

As of the effective date of this AD, no person may install, on any airplane, any affected part unless it is a serviceable part.

(l) No Reporting Requirement

Although Bombardier service bulletins in figure 1 to paragraph (g)(2)(ii) of this AD specify to submit certain information to the manufacturer, this AD does not include that requirement.

(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 ATTN: Program Manager, Continuing Operational Safety, at the address identified in paragraph (n)(2) of this AD or email to: 9-avs-nyaco-cos@faa.gov. If mailing information, also submit information by email. 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.

(n) Additional Information

(1) Refer to Transport Canada AD CF-2023-17, dated March 8, 2023, for related information. This Transport Canada AD may be found in the AD docket at [regulations.gov](https://www.regulations.gov) under Docket No. FAA-2023-2000.

(2) 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.

(o) Material Incorporated by Reference

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

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

(i) Bombardier Service Bulletin 700-1A11-36-005 Basic Issue, dated December 23, 2022.

(ii) Bombardier Service Bulletin 700-36-026 Basic Issue, dated December 23, 2022.

(iii) Bombardier Service Bulletin 700-36-5002 Basic Issue, dated December 23, 2022.

(iv) Bombardier Service Bulletin 700-36-5501 Basic Issue, dated December 23, 2022.

(v) Bombardier Service Bulletin 700-36-6002 Basic Issue, dated December 23, 2022.

(vi) Bombardier Service Bulletin 700-36-6501 Basic Issue, dated December 23, 2022.

(vii) Liebherr Service Bulletin CFD-F1958-26-01, dated May 6, 2022.

(3) For Bombardier service information 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](https://www.bombardier.com).

(4) For Liebherr-Aerospace Toulouse SAS service information identified in this AD, contact Liebherr-Aerospace Toulouse SAS, 408, Avenue des Etats-Unis—B.P.52010, 31016 Toulouse Cedex, France; telephone +33 (0)5.61.35.28.28; fax +33 (0)5.61.35.29.29; email: techpub.toulouse@liebherr.com; website: www.liebherr.aero.

(5) You may view this service information 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.

(6) 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 26, 2023.

Caitlin Locke,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023-24007 Filed 11-14-23; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[[Docket No. FAA-2023-2247; Airspace Docket No. 23-ACE-4]

RIN 2120-AA66

Amendment of VOR Federal Airway V-132 and Revocation of VOR Federal Airways V-131, V-307, and V-350 in the Vicinity of Chanute, KS

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Very High Frequency Omnidirectional Range (VOR) Federal airway V-132 and revoke VOR Federal airways V-131, V-307, and V-350. The FAA is proposing this action due to the planned decommissioning of the VOR portion of the Chanute, KS (CNU), VOR/Distance Measuring Equipment (VOR/DME) navigational aid (NAVAID). The Chanute VOR is being decommissioned in support of the FAA's VOR Minimum Operational Network (MON) program.

DATES: Comments must be received on or before January 2, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA-2023-2247 and Airspace Docket No. 23-ACE-4 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:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12-140 of the West Building

Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except 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 Federal holidays.

FAA Order JO 7400.11H, 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: Colby Abbott, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 modify the National Airspace System (NAS) as necessary to preserve the safe and efficient flow of air traffic.

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 edit, 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 normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Parkway, Fort Worth, TX 76177.

Incorporation by Reference

VOR Federal airways are published in paragraph 6010(a) 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 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published in the next update to FAA Order JO 7400.11. That order is

publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

Background

The FAA is planning to decommission the VOR portion of the Chanute, KS, VOR/DME in July 2024. The Chanute VOR is one of the candidate VORs identified for discontinuance by the FAA's VOR MON program and listed in the Final policy statement notice, "Provision of Navigation Services for the Next Generation Air Transportation System (NextGen) Transition to Performance-Based Navigation (PBN) (Plan for Establishing a VOR Minimum Operational Network)," published in the **Federal Register** on July 26, 2016 (81 FR 48694), Docket No. FAA–2011–1082.

Although the VOR portion of the Chanute VOR/DME is planned for decommissioning, the co-located DME portion of the NAVAID is being retained to support current and future NextGen PBN flight procedure requirements.

The VOR Federal airways affected by the planned decommissioning of the Chanute VOR are V–131, V–132, V–307, and V–350. With the planned decommissioning of the Chanute VOR, the remaining ground-based NAVAID coverage in the area is insufficient to enable the continuity of the affected airways. As such, the FAA proposes modifications would result in a gap in airway V–132 and in a revocation of airways V–131, V–307, and V–350.

To address the affected VOR Federal airway proposed amendment and revocations, instrument flight rules (IFR) traffic could use portions of adjacent VOR Federal airways V–73 and V–88 between Wichita, KS, and Springfield, MO; V–71 and V–234 between Hutchinson, KS, and Springfield, MO; and V–77 and V–532 between Okmulgee, OK, and Topeka, KS, for conventional navigation or RNAV routes T–312 and T–413 for global positioning system-equipped aircraft. Additionally, IFR pilots equipped with RNAV capabilities could also navigate point-to-point using the existing NAVAIDs, Fixes, and waypoints (WP) that would remain in place to support continued operations through the affected area or receive air traffic control (ATC) radar vectors to fly around or through the affected area, upon request. Visual flight rules (VFR) pilots who elect to navigate via the affected VOR Federal airways could also take advantage of the adjacent airways or ATC services listed previously.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to amend VOR Federal airway V-132 and revoke VOR Federal airways V-131, V-307, and V-350 due to the planned decommissioning of the VOR portion of the Chanute, KS, VOR/DME NAVAID. The proposed airway actions are described below.

V-131: V-131 currently extends between the Okmulgee, OK, VOR/DME and the Topeka, KS, VOR/Tactical Air Navigation (VORTAC). The FAA proposes to remove the airway segment between the Tulsa, OK, VORTAC and the Topeka VORTAC due to the planned decommissioning of the Chanute VOR. Additionally, the FAA proposes to remove the airway segment between the Okmulgee VOR/DME and the Tulsa VORTAC also since that airway segment overlaps V-161 which will remain charted and provide navigational guidance between the two NAVAIDs. As a result, the airway would be removed in its entirety.

V-132: V-132 currently extends between the Medicine Bow, WY, VOR/DME and the intersection of the Forney, MO, VOR 086° and Vichy, MO, VOR/DME 156° radials (LENEX Fix), excluding that portion within restricted areas R-4501A, R-4501B, R-4501C, and R-4501D during their time of activation. The FAA proposes to remove the airway segment between the Hutchinson, KS, VOR/DME and the Springfield, MO, VORTAC. Additionally, the FAA proposes to exclude the airway portion within restricted areas R-4501E, R-4501F, and R-4501H during their times of activation since those restricted areas also fall within 4 nautical miles of the airway. As amended, the airway would be changed to extend between the Medicine Bow VOR/DME and the Hutchinson VOR/DME and between the Springfield VORTAC and the intersection of the Forney VOR 086° and Vichy VOR/DME 156° radials (LENEX Fix), excluding the portion within all 7 restricted areas of the R-4501 restricted area complex.

V-307: V-307 currently extends between the Chanute, KS, VOR/DME and the Emporia, KS, VORTAC. The FAA proposes to remove the airway in its entirety.

V-350: V-350 currently extends between the Wichita, KS, VORTAC and the Chanute, KS, VOR/DME. The FAA proposes to remove the airway in its entirety.

The NAVAID radials listed in the V-132 description in The Proposed Amendment section are unchanged and stated in degrees True north.

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 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 FAA final regulatory action.

List 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 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

- 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6010(a) Domestic VOR Federal Airways.

* * * * *

V-131 [Removed]

* * * * *

V-132 [Amended]

From Medicine Bow, WY; INT Medicine Bow 106° and Cheyenne, WY, 330° radials;

Cheyenne; Akron, CO; 17 miles, 49 miles, 59 MSL, Goodland, KS; 50 miles, 97 miles, 65 MSL, to Hutchinson, KS. From Springfield, MO; INT Springfield 058° and Forney, MO, 266° radials; Forney; to INT Forney 086° and Vichy, MO, 156° radials, excluding that portion within R-4501A, R-4501B, R-4501C, R-4501D, R-4501E, R-4501F, and R-4501H during their time of activation.

* * * * *

V-307 [Removed]

* * * * *

V-350 [Removed]

* * * * *

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

Karen L. Chiodini,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–25182 Filed 11–14–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2023–2195; Airspace Docket No. 23–ASO–48]

RIN 2120–AA66

Revocation of Colored Federal Airway Blue 9 (B–9); Eastern United States

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to revoke Colored Federal airway Blue 9 (B–9) in the Eastern United States. The FAA is taking this action due to the pending decommissioning of the Marathon, FL (MTH), Nondirectional Radio Beacon (NDB).

DATES: Comments must be received on or before January 2, 2024.

ADDRESSES: Send comments identified by FAA Docket No. FAA–2023–2195 and Airspace Docket No. 23–ASO–48 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:* Send comments to Docket Operations, M–30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12–140, West Building Ground Floor, Washington, DC 20590–0001.

* *Hand Delivery or Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey

Avenue SE, Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except 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 Federal holidays.

FAA Order JO 7400.11H, 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: Brian Vidis, Rules and Regulations Group, Office of Policy, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; telephone: (202) 267–8783.

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 the 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 amends the route structure to maintain the efficient flow of air traffic within the National Airspace System.

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 edit, 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 normal business hours at the office of the Eastern Service Center, Federal Aviation Administration, Room 210, 1701 Columbia Avenue, College Park, GA 30337.

Incorporation by Reference

Colored Federal airways are published in paragraph 6009 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 7400.11H, dated August 11, 2023, and effective September 15, 2023. These updates would be published in the next update to FAA Order JO 7400.11. That

order is publicly available as listed in the **ADDRESSES** section of this document.

FAA Order JO 7400.11H lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 by revoking Colored Federal Airway B–9. The proposed changes are described below.

B–9: B–9 currently extends between the DEEDS, FL, Fix and the Marathon, FL (MTH), NDB. The route is dependent on the Marathon NDB which is scheduled to be decommissioned. Without this navigation facility B–9 is no longer viable, so the FAA is proposing to revoke B–9 in its entirety.

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 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 FAA final regulatory action.

List 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 14 CFR part 71 continues to read as follows:

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11H, Airspace Designations and Reporting Points, dated August 11, 2023, and effective September 15, 2023, is amended as follows:

Paragraph 6009 Colored Federal Airways
* * * * *

B–9 [Removed]

* * * * *

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

Karen L. Chiodini,

Acting Manager, Rules and Regulations Group.

[FR Doc. 2023–25166 Filed 11–14–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

49 CFR Part 674

[Docket No. FTA–2023–0008]

RIN 2132–AB42

State Safety Oversight

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The Federal Transit Administration (FTA) is proposing revisions to the State Safety Oversight (SSO) regulation to implement new requirements of the Bipartisan Infrastructure Law (enacted as the Infrastructure Investment and Jobs Act (IIJA)), remove outdated references, and simplify notification requirements.

DATES: Comments should be filed by January 16, 2024. FTA will consider comments received after that date to the extent practicable.

ADDRESSES: You may send comments, identified by docket number FTA–2023–0008, by any of the following methods:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for sending comments.
- *Fax:* (202) 493–2251.
- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery/Courier:* West Building Ground Floor, Room W12–140,

1200 New Jersey Avenue SE, Washington, DC, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the “Public Participation” heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: To access the docket and read background documents or comments received, go to: <https://www.regulations.gov>. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Ave. SE, Docket Operations, M–30, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. EST, Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: For program matters, contact Loretta Bomgardner, Office of Transit Safety and Oversight, FTA, telephone (202) 577–5896 or loretta.bomgardner@dot.gov. For legal matters, contact Richard Wong, Office of the Chief Counsel, telephone (202) 366–4011 or richard.wong@dot.gov. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

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- Executive Summary
 - Purpose of Regulatory Action
 - Statutory Authority
 - Summary of Major Provisions
 - Benefits and Costs
- Section-by-Section Analysis
- Regulatory Analyses and Notices

1. Executive Summary

A. Purpose of Regulatory Action

This proposed rulemaking will update the existing regulations for state safety oversight of rail fixed guideway public transportation systems. In the Moving Ahead for Progress in the 21st Century Act (MAP–21) (Pub. L. 112–141, July 6, 2012), Congress directed FTA to establish a comprehensive public transportation safety program, one element of which is the State Safety Oversight (SSO) Program. (See 49 U.S.C. 5329). Section 30012 of the Bipartisan Infrastructure Law (BIL), enacted as the Infrastructure Investment and Jobs Act (IIJA), established new requirements for

FTA’s Public Transportation Safety Program. FTA is proposing revisions to 49 CFR part 674 to address requirements related to the BIL, remove requirements related to the initial establishment of this part, and clarify requirements of the existing part.

B. Statutory Authority

Section 5329 of Title 49, United States Code, includes several provisions that require FTA to establish a comprehensive public transportation safety program, the elements of which include a National Public Transportation Safety Plan; a training and certification program for Federal, state, and local transportation agency employees with safety responsibilities; Public Transportation Agency Safety Plans; and a strengthened State Safety Oversight Program.

C. Summary of Major Provisions

This NPRM proposes to make the following changes to strengthen the existing SSO program:

- Updating terminology to reflect current use across programs.
- Clarifying existing requirements consistent with FTA expectations.
- Removing language relating to the period of transition from 49 CFR part 659, FTA’s previous SSO regulation, to 49 CFR part 674, the current SSO regulation.
- Addressing BIL requirements.

D. Benefits and Costs

The proposed rule would result in additional oversight of safety-related activities of rail transit agencies (RTAs) by state safety oversight agencies (SSOAs). The effects of the increased oversight are unknown and unquantified. The proposed rule also would result in additional costs for SSOAs and RTAs to comply with the requirements. The requirements of the proposed rule have estimated costs of \$12.6 million (in 2022 dollars) for the first year and annual costs of \$10.7 million for later years. The largest annual costs are for SSOA oversight (\$7.9 million), which includes new risk-based inspection activities, and RTA activities (\$2.0 million), which include investigations and reporting for a larger number of safety events.

Table 1 summarizes the economic effects of the proposed rule over the first ten years of the proposed rule from 2023—the assumed effective date of the rule—to 2033 in 2022 dollars. On an annualized basis, the proposed rule would have costs of \$11.7 million at a 7 percent discount rate (discounted to 2023) and \$11.3 million at 3 percent.

TABLE 1—SUMMARY OF ECONOMIC EFFECTS, 2023–2033
[\$2022, discounted to 2023]

Item	Total, 2023–2033	Annualized (7%)	Annualized (3%)
Benefits	Unquantified		
Costs:			
SSOA documentation of enforcement authority	\$118,140	\$16,820	\$13,850
SSOA oversight	80,338,058	8,659,910	8,300,458
SSOA safety event tracking	183,879	19,675	18,940
SSOA investigations	7,355,168	787,003	757,582
SSOA annual reporting to FTA	609,755	65,244	62,805
RTA investigations and reporting	20,456,560	2,188,852	2,107,026
Total costs	109,061,560	11,737,504	11,260,660
Net benefits	Unquantified		

Totals may not sum due to rounding.

II. Section-by-Section Analysis

Subpart A—General Provisions

Section 674.1 Purpose

This section explains that the purpose of these regulations is to carry out the mandate of 49 U.S.C. 5329 for States to perform oversight of rail fixed guideway public transportation systems within their jurisdictions. This represents an expansion from the purpose stated in the existing § 674.1, “this part carries out the mandate of 49 U.S.C. 5329(e).” The removal of “(e)” acknowledges the additional obligations for inspections and data collection required by SSO Agencies in section 5329(k), as amended by the BIL, and better reflects the connection among all elements of the FTA’s public transportation safety program.

Section 674.3 Applicability

FTA is not proposing changes to this section.

Section 674.5 Policy

This section proposes removing the term “sufficient” in paragraph (a) to eliminate subjectivity regarding the requirements for SSOA authorities. FTA is also proposing to remove the first sentence in paragraph (b), as the availability of funding is addressed in the existing language in § 674.17(a).

Section 674.7 Definitions

This section proposes replacing the terms “accident,” “incident,” “occurrence,” and “event” with the inclusive term “safety event,” which includes events such as collisions, derailments, fires, and unintended train movements for purposes of meeting the two-hour notification requirement in § 674.33. The definition of “safety event” excludes general criminal actions but includes intentional events that result in a collision with a transit

vehicle, such as an assault, homicide, or suicide.

FTA also proposes removing the definition of “serious injury.” These revisions are consistent with changes that FTA proposed in the PTASP NPRM (88 FR 25336) and are intended to simplify requirements related to safety event notifications and investigations.

This section proposes new terms and definitions for “collision,” “derailment,” “evacuation for life safety reasons,” “fatality,” “injury,” “public transportation,” “rail transit vehicle,” “revenue vehicle,” and “unintended train movement,” and the removal of the general term “vehicle” in recognition of these new definitions, which will be consistent with FTA’s NTD reporting manuals and support the notification and investigation thresholds FTA is proposing in sections 674.33 and 674.35. FTA’s proposed definition of “injury” restores the threshold under FTA’s previous part 659 regulation and is consistent with the aforementioned NTD reporting manuals. The definition of “injury” includes damage or harm to persons that requires immediate medical attention away from the scene. An individual who declines transportation away from the scene for medical attention should not be counted as an “injury” for two-hour notification purposes. This proposed definition allows for an immediate, on scene determination of injuries by the RTA without the need to await a formal diagnosis or determination from an off-site medical professional.

FTA also proposes a new definition for “disabling damage” to support the proposed notification and investigation thresholds. “Disabling damage” is limited to damage resulting from a collision that physically prevents a vehicle or train from operating under its own power. Disabling damage does not include mechanical failures or other

malfunctions that may impact operations.

FTA proposes new terms and definitions for “potential consequence,” “safety committee,” “safety risk,” and “safety risk mitigation” as well as revised definitions of “Accountable Executive” and “safety risk management” for consistency with definitions proposed in the PTASP NPRM.

This section proposes revising the definition of “investigation” to reflect the replacement of the terms “accident” and “incident” with “safety event” as described above.

This section proposes new terms and definitions for “inspection” and “risk-based inspection program” to support new SSOA requirements mandated by the BIL.

This section proposes revising the definition of “Public Transportation Agency Safety Plan” to remove reference to the transition from the requirements under 49 CFR part 659, the previous State Safety Oversight regulation, to the present requirements under 49 CFR part 674. This revision is consistent with the end of the transition period, which occurred in early 2019, and FTA’s subsequent rescission of part 659 (87 FR 6783).

This section proposes revising the definition of “Public Transportation Safety Certification Training Program” to remove reference to the interim provisions for this program. This section also proposes adding a new term and definition for “designated personnel” to recognize individuals subject to the Public Transportation Safety Certification Training Program regulation (49 CFR 672).

This section proposes reordering the clauses in the definition of “rail fixed guideway public transportation system” for clarity. This change aligns with the definition that FTA proposed in the PTASP NPRM and does not reflect a

change in FTA's implementation or interpretation.

FTA proposes a minor revision to the definition of "State Safety Oversight Agency" to add a citation referencing the SSOA inspection requirement in 49 U.S.C. 5329(k), which was added by the BIL.

Section 674.9 Reserved

FTA proposes removing and reserving this section. Previously, this section provided requirements for the transition from 49 CFR part 659, the previous State Safety Oversight regulation, to part 674. This removal acknowledges the end of the transition period, which occurred in early 2019, and FTA's subsequent rescission of part 659.

Subpart B—Role of the State

Section 674.11 State Safety Oversight Program

FTA proposes eliminating the deadlines established for States' initial compliance with the requirement, as all States must have an FTA-approved SSO program for rail transit agencies in their State to be eligible for FTA financial assistance. This initial compliance date, which was three years of April 15, 2016," has already passed. FTA is also making a minor technical correction to the statutory citation regarding FTA triennial audits of SSO programs.

Section 674.13 Designation of Oversight Agency

FTA proposes revising the statutory citation in § 674.13(a) to reflect new statutory requirements. In § 674.13(a)(5), FTA proposes including inspection authorities to the list of authorities an SSOA must have, reflecting the new requirements in 49 U.S.C. 5329(k) that SSOAs must conduct risk-based inspections of the rail fixed guideway public transportation systems that the SSOA oversees.

In §§ 674.13(a)(4) and (a)(6), FTA proposes a new reference to 49 CFR part 673, Public Transportation Agency Safety Plans, which did not exist when FTA published the current part 674 in 2016.

Section 674.15 Designation of Oversight Agency for Multi-State System

FTA is not proposing changes to this section.

Section 674.17 Use of Federal Financial Assistance

FTA is proposing to delete the term "parts" as superfluous.

Section 674.19 Certification of a State Safety Oversight Program

FTA proposes removing "(e)" from "5329(e)" in this section for the reasons mentioned above and adding language in § 674.19(d) to clarify the Administrator's determination to issue a certification or a denial of certification for an SSO program. This does not reflect a change in FTA's application of the statutory and regulatory criteria.

Section 674.21 Withholding of Federal Financial Assistance for Noncompliance

When FTA published its final rule in 2016, States with existing rail fixed guideway public transportation systems were provided a three-year transition period. Now that the transition period has expired, FTA proposes updating § 674.21(b) to adopt FTA current practice, which is to require a State to establish an SSO program and have that program approved by the FTA Administrator prior to a new rail fixed guideway public transportation system entering the engineering or construction phase of development. FTA also proposes replacing the word "apportioned" with "authorized" for accuracy.

Section 674.23 Confidentiality of Information

FTA is not proposing changes to this section.

Subpart C—State Safety Oversight Agencies

Section 674.25 Role of the State Safety Oversight Agency

In § 674.25, FTA proposes to add a new paragraph (c) to explicitly acknowledge an SSOA's authority to provide safety oversight of projects in the engineering or construction phase of development. This parallels the statutory language in 49 U.S.C. 5329(e)(2)(B) and clarifies FTA's intent that SSOAs take an active oversight role during a project's pre-revenue phases. FTA also proposes to move from the current paragraph (b) into a new paragraph (d) the requirement that SSOAs ensure that a PTASP meets the requirements of 49 U.S.C. 5329(d) and part 673, a non-substantive change that will provide clarity and improve readability. Consequently, FTA proposes to redesignate existing paragraphs 674.24(c) through (f) as paragraphs (e) through (h).

In addition, FTA is proposing minor conforming edits in these paragraphs to reflect the proposed definitions in § 674.7 as discussed above and to

remove references to 49 U.S.C. 5330, which has been repealed.

Section 674.27 State Safety Oversight Program Standards

In § 674.27, FTA proposes a new paragraph (a)(3) to require an SSOA to develop a process to address comments from an RTA regarding an SSO program standard. This reflects industry concerns that some SSOAs do not formally respond to RTA comments. This addition requires SSOs to establish a process by which SSOAs will address RTA comments regarding the program standard. Because of the proposed addition of paragraph (a)(3), the remaining paragraphs are being renumbered.

FTA proposes expanding the renumbered § 674.27(a)(5) to include specific requirements for SSOA oversight of RTA internal safety reviews. Internal safety reviews are distinct from the existing annual review and update requirement in 49 CFR 673.11(a)(5). Internal safety reviews monitor the actual implementation of the PTASP. However, the results of the internal safety reviews may inform the RTA's annual PTASP document review and update process. The previous 49 CFR 659.19 included explicit requirements for these internal safety reviews; however, Part 674 removed the prescriptive requirements in § 659.19 with the expectation that they would be addressed in the PTASP final rule. The PTASP final rule did not address internal safety reviews, prompting some RTAs to ask whether they were no longer required by FTA, even though SSOAs continued to require them under their State program standards. To provide clarity, the proposed language confirms the requirement that the State's program standard must define internal safety review requirements, which are addressed in § 673.27(d)(iii) of the PTASP NPRM (88 FR 25336, at 25351). The proposed language establishes minimum requirements for internal safety reviews, including the requirement that RTAs must verify the implementation of all elements of the PTASP over a three-year period, with the expectation that RTAs will be conducting internal safety reviews on an ongoing basis. Further, the RTA must notify the SSOA thirty days before it conducts an internal safety review of any aspect of the rail fixed guideway public transportation system and provide any checklists or procedures it will use during the review. Finally, the RTA must submit a report to the SSOA annually documenting the internal safety review activities and the status of

subsequent findings and corrective actions.

A new § 674.27(a)(6) relating to the oversight of safety risk mitigations proposes requirements for the SSOA to define the process it will use to oversee an RTA's development, implementation, and monitoring of safety risk mitigations. The program standard must specify the frequency and format for how the SSOA will receive and review information about an RTA's safety risk mitigation status and effectiveness. Although 49 CFR part 673 established specific requirements for safety management, including the development, implementation and monitoring of safety risk mitigations, part 674 was published prior to part 673 and did not include specific oversight requirements related to safety risk mitigation. Therefore, FTA is proposing these requirements to ensure that SSOAs have a documented process to oversee the safety risk mitigation processes required of RTAs.

A new § 674.27(a)(7) regarding oversight of the safety certification training program proposes that the SSOA will review and approve RTA designations of individuals directly responsible for safety oversight and the RTA's identification of refresher training as required under the Public Safety Certification Training Program regulation (49 CFR 672). This role was not made explicit in the current part 674 and this new language clarifies FTA's expectation that SSOAs oversee RTA compliance with 49 CFR 672 requirements.

The renumbered § 674.27(a)(9) is also renamed from "Accident notification" to "Safety event notification," consistent with the discussion above in § 674.7, where FTA proposes replacing the term "accident" with the term "safety event" and proposes conforming edits in the renumbered § 674.27(a)(10). FTA also proposes requiring the SSO program standard to establish requirements for RTAs to notify the SSOA and FTA of safety events to ensure that the notification requirement in § 674.33 is addressed in an RTA's PTASP, as the current paragraph omitted any reference to FTA.

In the renumbered § 674.27(a)(11), FTA is inserting the term "SSO" before "program standard" for consistency with the rest of this section.

FTA proposes adding a new § 674.27(a)(12), "Inspections," to incorporate the requirement that SSOAs conduct risk-based inspections of the RTAs they oversee. On October 21, 2022, FTA issued Special Directives to each SSOA directing them to develop and implement a risk-based inspection

program as required by the BIL. The Special Directives require SSOAs to include policies and procedures for Risk-Based Inspection in their Program Standards and develop and begin implementing their Risk-Based Inspection program by October 21, 2024.

FTA proposes adding a new § 674.27(a)(13), "Vehicle maintenance and testing," requiring SSOAs to amend their program standard to include a new requirement that SSOAs ensure that rail transit agencies conduct maintenance and testing procedures of braking systems, consistent with NTSB Recommendation R-17-004 (<https://data.nts.gov/carol-main-public/sr-details/R-17-004>).

Finally, a new § 674.27(a)(14), "Data collection," proposes specific data collection requirements for collecting data that the RTA uses when identifying hazards and assessing safety risk. This responds to industry feedback regarding the role of the SSOA in overseeing safety risk management of the RTAs under their jurisdiction.

Section 674.29 Public Transportation Agency Safety Plans: General Requirements

In § 674.29, FTA proposes the addition of a reference to 49 U.S.C. 5329(d) and 49 CFR part 673 in paragraph (a) for clarity and the removal of paragraph (b). Because part 674 was published prior to part 673, FTA provided a list of the expected PTASP elements in paragraph (b) as an interim measure to guide SSOAs. With the publication of part 673 in 2018, the list is no longer necessary. Consistent with the removal of the current paragraph (b), FTA proposes to renumber paragraph (c) as paragraph (b).

Section 674.31 Triennial Audits: General Requirements

In § 674.31, FTA proposes to clarify that SSOAs which elect to audit an RTA's compliance with its Public Transportation Agency Safety Plan on an ongoing basis must issue interim audit reports at least annually. This clarification does not reflect a change in FTA's current implementation of this requirement.

Section 674.33 Notifications of Safety Events

In § 674.33, FTA proposes to replace the term "accident" with "safety event." This replacement streamlines definitions used in requirements related to event notification and investigation.

This section proposes specific notification criteria that replace the Appendix in the current part 674. This replacement text clarifies FTA's

minimum requirements for two-hour notifications to FTA and SSOAs and reflects changes to reporting thresholds suggested by SSOAs and RTAs, who found it difficult to quickly determine the scope of one's "serious injuries" as defined in the Appendix within two hours of a safety event, specifically, injuries resulting in bone fractures, nerve or muscle damage, injuries to internal organs, or hospitalizations exceeding 48 hours. The proposed notification requirements exclude general crimes but include intentional events resulting in a collision with a transit vehicle, such as an assault, homicide, or suicide. Additionally, FTA proposes to remove paragraph (b) that requires RTAs to notify FTA and SSOAs of safety events triggering FRA's notification requirements under 49 CFR part 225, as notification on FRA-regulated trackage is already reported to the USDOT and received by FTA via the National Response Center.

Section 674.35 Investigations

In § 674.35, FTA proposes replacing the term "accident" with "safety event," and clarifying that this includes any safety event that meets one or more thresholds in § 674.33. FTA also proposes dividing the requirements in § 674.35(a) into a new § 674.35(a) and § 674.35(b) for clarity. These changes do not reflect a change in the implementation of the current requirements.

Section 674.37 Corrective Action Plans

In § 674.37, FTA proposes a new paragraph (a) and redesignating paragraphs (a) through (c) as paragraphs (b) through (d).

The new paragraph (a) proposes language clarifying the basis for the development of a corrective action plan (CAP). The proposed language requires the development of a CAP to address investigations that determined causal or contributing factors require corrective actions, findings of non-compliance from safety reviews and inspections performed by the SSOA, or findings of non-compliance from internal safety reviews performed by the RTA. These proposals do not reflect a change in current practice.

In the renumbered § 674.37(c), FTA proposes language clarifying CAP requirements to ensure alignment with Safety Management System terminology. In the renumbered 674.37(d), FTA proposes adding "FTA" as an agency authorized to conduct investigations, reflecting FTA's authority to investigate public transportation accidents and incidents under 49 U.S.C. 5329(f)(5), with the

SSOA expected to evaluate whether the findings or recommendations by FTA or the NTSB require a CAP by the RTA.

Section 674.39 State Safety Oversight Agency Annual Reporting to FTA

In § 674.39(a)(2), FTA proposes clarifying language regarding “designated personnel” for consistency with the Public Transportation Safety Certification Training Program in 49 CFR part 672 and does not reflect a change in purpose or intent.

In § 674.39(a)(3), FTA proposes replacing the term “accident” with “safety event,” consistent with the explanation provided above. Section 674.39(a)(4) proposes specifying that SSOAs must submit final investigation reports as part of their annual reporting to FTA. This reporting is already required through the current reporting process and this language does not reflect a change in FTA’s practice.

In § 674.39(a)(5), FTA proposes specifying that SSOAs must provide a summary of the internal safety reviews conducted by RTAs during the previous 12 months and RTA progress in carrying out CAPs arising from the SSOA’s oversight of RTA ASPs and any related safety reviews. This reporting is already required through the current reporting process and this language does not reflect a change in FTA’s practice.

Section 674.41 Conflicts of Interest

FTA is not proposing changes to this section.

Removed: Appendix to Part 674—Notification and Reporting of Accidents, Incidents, and Occurrences

FTA proposes removing the table addressing the notification and reporting requirements for accidents, incidents, and occurrences, as FTA is proposing to address this requirement in § 674.33.

III. Regulatory Analyses and Notices

Executive Order 12866 (Regulatory Planning and Review), Executive Order 13563 (Improving Regulation and Regulatory Review), and Department of Transportation (DOT) Regulatory Policies and Procedures

Executive Order 12866 (“Regulatory Planning and Review”), as supplemented by Executive Order 13563 (“Improving Regulation and Regulatory Review”), directs Federal agencies to assess the benefits and costs of regulations, to select regulatory approaches that maximize net benefits when possible, and to consider economic, environmental, and distributional effects. It also directs the Office of Management and Budget (OMB) to review significant regulatory actions, including regulations with annual economic effects of \$100 million or more. OMB has determined that the proposed rule is not significant within the meaning of Executive Order 12866 and has not reviewed it under that order.

Overview

The proposed rule, which implements amendments made by the Bipartisan

Infrastructure Law, would add requirements for state safety oversight agencies (SSOAs) and the rail transit agencies (RTAs) they oversee. The proposed rule will require SSOAs to conduct risk-based inspections, oversee safety risk mitigations, and investigate a larger number of safety events than they currently investigate. The proposed rule will also require RTAs to conduct additional accident investigations and prepare additional reports. Finally, the proposed rule will clarify existing requirements, update terminology, and remove interim provisions that no longer apply.

Benefits

The proposed rule would lead to increased oversight of RTA safety-related activities, although the effects of the oversight are unknown and unquantified in the analysis. The proposed rule may also benefit SSOAs and rail transit agencies by clarifying requirements and reducing costs to ensure compliance.

Costs

SSOAs and RTAs would incur economic costs to meet the new oversight and increased reporting requirements of the proposed rule. To estimate the costs of meeting the new requirements, FTA estimated the number of entities affected, the number and type of staff involved, and the time needed. The new oversight requirements would affect 31 SSOAs in operation as of March 1, 2023 (table 2).¹

TABLE 2—STAFF AND HOURS NEEDED FOR SSOAS TO MEET NEW OVERSIGHT REQUIREMENTS

Requirement	Staff	Annual hours	Total hours
SSOA documentation of enforcement authority (first year only)	31 SSOA staff	40	1,240
SSOA oversight (first year):			
Establish disposition process	31 SSOA staff	80	2,480
Define requirements for internal safety reviews	31 SSOA staff	80	2,480
Document oversight of safety risk mitigations	31 SSOA staff	80	2,480
Document oversight of RTA training compliance	31 SSOA staff	20	620
Develop risk-based inspection programs	62 SSOA staff (2 staff per SSOA)	160	9,920
Establish thresholds for safety event notifications	31 SSOA staff	10	310
Document data collection procedures with RTAs	31 SSOA staff	20	620
SSOA oversight (annual):			
Oversee safety risk mitigations	31 SSOA staff	500	15,500
Oversee RTA training compliance	31 SSOA staff	20	620

Source: FTA analysis.

Under the current thresholds for reporting safety events, RTAs had an average of 618 reportable events per

year from 2017 to 2021.² Under the proposed thresholds, the number would increase to 811 reportable events per

year (an increase of 193 reports) and result in additional reporting costs for SSOA and RTA employees (table 3).

¹ Federal Transit Administration. August 3, 2022. “State Safety Oversight Contacts.” [https://](https://www.transit.dot.gov/regulations-and-guidance/safety/state-safety-oversight-contacts)

www.transit.dot.gov/regulations-and-guidance/safety/state-safety-oversight-contacts.

² Average events calculated using FTA’s State Safety Oversight Reporting system.

TABLE 3—STAFF AND HOURS NEEDED FOR SSOAs AND RTAs TO MEET REPORTING REQUIREMENTS

Requirement	Staff	Annual hours	Total hours
SSOA safety event tracking (annual)	SSOA staff; 193 reports	1	193
SSOA safety event investigations (annual):			
Prepare investigation reports	SSOA safety event investigators; 193 reports	22	4,246
Review and approve reports	SSOA safety event investigators; 193 reports	10	1,930
SSOA reporting to FTA (annual):			
Submit investigation reports	SSOA staff; 193 reports	5	320
Submit summary of internal safety reviews	SSOA staff; 193 reports	5	320
Investigation and reporting (annual):			
Conduct accident investigations	RTA safety event investigators; 193 reports	47	9,071
Prepare event investigation reports	RTA safety event investigators; 193 reports	30	5,790
Make submissions to SSOA	RTA safety event investigators; 193 reports	12	2,316

Source: FTA analysis.

To estimate the value of staff time spent on the requirements, FTA used occupational wage data from the Bureau of Labor Statistics as of May 2022 (table 2).³ For general SSOA and trail transit agency staff, the closest occupational category is “General and Operations

Managers” (code 11–1021) in the “Transit and Ground Passenger Transportation” industry (North American Industry Classification System code 485000). FTA used median hourly wages as a basis for the estimates, multiplied by 1.62 to account

for employer benefits, for a cost estimate of \$95.27 per hour.⁴ For safety event investigators, who do not have a close analogue in the occupational wage data, FTA assumed a 25 percent wage and benefit premium for a cost estimate of \$119.09 per hour.

TABLE 4—OCCUPATIONAL CATEGORIES AND WAGES USED TO VALUE STAFF TIME
[2022]

Staff	Occupational category	Code	Median hourly wage	Wage with benefits
SSOA and RTA general staff	General and Operations Managers	11–1021	\$59.07	\$95.27
SSOA and RTA safety event investigators	N/A		73.84	119.09

Source: Bureau of Labor Statistics, May 2022 National Occupational Employment and Wage Estimates.

The requirements of the proposed rule have estimated costs of \$12.6 million (in 2022 dollars) for the first year and annual costs of \$10.7 million for later

years (table 5). The largest annual costs are for SSOA oversight (\$7.9 million), which includes risk-based inspection activities, and RTA activities (\$2.0

million), which include investigations and reporting for a larger number of safety events.

TABLE 5—FIRST-YEAR AND ANNUAL COSTS FOR PROPOSED RULE REQUIREMENTS
[2022]

Requirement	First-year costs	Annual costs
SSOA documentation of enforcement authority	\$118,140	
SSOA oversight	9,655,277	\$7,853,642
SSOA safety event tracking	18,388	18,388
SSOA investigations	735,517	735,517
SSOA annual reporting to FTA	60,975	60,975
RTA investigations and reporting	2,045,656	2,045,656
Total	12,633,954	10,714,179

Totals may not sum due to rounding.

Summary

Table 6 summarizes the economic effects of the proposed rule over the first

ten years of the proposed rule from 2023—the assumed effective date of the rule—to 2032 in 2022 dollars. On an annualized basis, the proposed rule

would have net costs of \$11.7 million at a 7 percent discount rate (discounted to 2023) and \$11.3 million at 3 percent.

³ Bureau of Labor Statistics. 2023. “May 2022 National Occupational Employment and Wage Estimates: United States.” https://www.bls.gov/oes/2022/may/oes_nat.htm.

⁴ Multiplier derived using Bureau of Labor Statistics data on employer costs for employee compensation in December 22 (<https://www.bls.gov/news.release/ecec.htm>). Employer costs for state

and local government workers averaged \$57.60 an hour, with \$35.69 for wages and \$21.95 for benefit costs. To estimate full costs from wages, one would use a multiplier of \$57.60/\$21.95, or 1.62.

TABLE 6—SUMMARY OF ECONOMIC EFFECTS, 2023–2033
[\$2022, discounted to 2023]

Item	Total, 2023–2033	Annualized (7%)	Annualized (3%)
Benefits	Unquantified ...		
Costs:			
SSOA documentation of enforcement authority	\$118,140	\$16,820	\$13,850
SSOA oversight	80,338,058	8,659,910	8,300,458
SSOA safety event tracking	183,879	19,675	18,940
SSOA investigations	7,355,168	787,003	757,582
SSOA annual reporting to FTA	609,755	65,244	62,805
RTA investigations and reporting	20,456,560	2,188,852	2,107,026
Total costs	109,061,560 ...	11,737,504	11,260,660
Net benefits	Unquantified ...		

Totals may not sum due to rounding.

Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980 (RFA) (5 U.S.C. 601 *et seq.*) requires Federal agencies to assess the impact of a regulation on small entities unless the agency determines that the regulation is not expected to have a significant economic impact on a substantial number of small entities.

The proposed rule would require state safety oversight agencies to meet additional reporting and administrative requirements. Under the Regulatory Flexibility Act, governments and other public-sector organizations qualify as small entities if they serve a population of less than 50,000. State agencies do not qualify because they serve populations greater than 50,000. FTA has therefore determined that the proposed rule would not have a significant effect on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

FTA has determined that this rulemaking does not require a written statement under the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) because it does not impose a Federal mandate that may result in the expenditure of \$100 million or more in any 1 year (when adjusted annually for inflation using the base year of 1995) for either State, local, and tribal governments in the aggregate, or by the private sector.

Executive Order 13132 (Federalism Assessment)

Executive Order 13132 requires agencies to assure meaningful and timely input by State and local officials in the development of regulatory policies that may 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. This action has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (August 4, 1999), and FTA determined this action will not have a substantial direct effect or sufficient federalism implications on the States. FTA also determined this action will not preempt any State law or regulation or affect the States' ability to discharge traditional State governmental functions.

Executive Order 12372 (Intergovernmental Review)

The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.

Paperwork Reduction Act

In compliance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), and the White House Office of Management and Budget's (OMB) implementing regulation at 5 CFR 1320.8(d), FTA is seeking approval from OMB for a currently approved information collection (OMB Control Number 2132–0558) that is associated with this Notice of Proposed Rulemaking. The information collection (IC) was previously approved on April 7, 2023. However, this submission includes changes in requirements applicable to the SSO program affecting various respondents.

National Environmental Policy Act

Federal agencies are required to adopt implementing procedures for the National Environmental Policy Act (NEPA) that establish specific criteria for, and identification of, three classes of actions: (1) Those that normally require preparation of an Environmental Impact Statement, (2) those that normally require preparation of an

Environmental Assessment, and (3) those that are categorically excluded from further NEPA review (40 CFR 1507.3(b)). This rulemaking qualifies for categorical exclusions under 23 CFR 771.118(c)(4) (planning and administrative activities that do not involve or lead directly to construction). FTA has evaluated whether the rulemaking will involve unusual or extraordinary circumstances and has determined that it will not.

Executive Order 12630 (Taking of Private Property)

FTA has analyzed this rulemaking under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. FTA does not believe this rulemaking affects a taking of private property or otherwise has taking implications under Executive Order 12630.

Executive Order 12988 (Civil Justice Reform)

This rulemaking meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Executive Order 13045 (Protection of Children)

FTA has analyzed this rulemaking under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. FTA certifies that this action will not cause an environmental risk to health or safety that might disproportionately affect children.

Executive Order 13175 (Tribal Consultation)

FTA has analyzed this rulemaking under Executive Order 13175, dated November 6, 2000, and believes that it

will not have substantial direct effects on one or more Indian tribes; will not impose substantial direct compliance costs on Indian tribal governments; and will not preempt tribal laws. Therefore, a tribal summary impact statement is not required.

Executive Order 13211 (Energy Effects)

FTA has analyzed this rulemaking under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. FTA has determined that this action is not a significant energy action under that order and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. Therefore, a Statement of Energy Effects is not required.

Executive Order 12898 (Environmental Justice)

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations) and DOT Order 5610.2(a) (<https://www.transportation.gov/transportation-policy/environmental-justice/departments-transportation-order-56102a>) require DOT agencies to achieve Environmental Justice (EJ) as part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects, including interrelated social and economic effects, of their programs, policies, and activities on minority and low-income populations. All DOT agencies must address compliance with Executive Order 12898 and the DOT Order in all rulemaking activities. On August 15, 2012, FTA's Circular 4703.1 became effective, which contains guidance for recipients of FTA financial assistance to incorporate EJ principles into plans, projects, and activities (http://www.fta.dot.gov/documents/FTA_EJ_Circular_7.14-12_FINAL.pdf).

FTA has evaluated this rulemaking under Executive Order 12898, the DOT Order, and the FTA Circular, and FTA has determined that this action will not cause disproportionately high and adverse human health and environmental effects on minority or low-income populations.

Regulation Identifier Number

A Regulation Identifier Number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN number contained in the

heading of this document can be used to cross-reference this rulemaking with the Unified Agenda.

List of Subjects in 49 CFR Part 674

Grant program—transportation, Mass transportation, Reporting and recordkeeping requirements, Safety.

Nuria I. Fernandez,
Administrator.

■ For the reasons stated in the preamble, and under the authority of 49 U.S.C. 5329 and the delegation of authority at 49 CFR 1.91, the Federal Transit Administration proposes to revise 49 CFR part 674 to read as follows:

Title 49—Transportation

PART 674—STATE SAFETY OVERSIGHT

Sec.

Subpart A—General Provisions

- 674.1 Purpose.
- 674.3 Applicability.
- 674.5 Policy.
- 674.7 Definitions.
- 674.9 [Reserved]

Subpart B—Role of the State

- 674.11 State Safety Oversight Program.
- 674.13 Designation of oversight agency.
- 674.15 Designation of oversight agency for multi-state system.
- 674.17 Use of Federal financial assistance.
- 674.19 Certification of a State Safety Oversight Program.
- 674.21 Withholding of Federal financial assistance for noncompliance.
- 674.23 Confidentiality of information.

Subpart C—State Safety Oversight Agencies

- 674.25 Role of the State safety oversight agency.
- 674.27 State safety oversight program standards.
- 674.29 Public Transportation Agency Safety Plans: General requirements.
- 674.31 Triennial audits: General requirements.
- 674.33 Notification of safety events.
- 674.35 Investigations.
- 674.37 Corrective action plans.
- 674.39 State Safety Oversight Agency annual reporting to FTA.
- 674.41 Conflicts of interest.

Authority: 49 U.S.C. 5329; 49 CFR 1.91.

49 CFR Part 674

Subpart A—General Provisions

§ 674.1 Purpose.

This part carries out the mandate of 49 U.S.C. 5329 for State safety oversight of rail fixed guideway public transportation systems.

§ 674.3 Applicability.

This part applies to States with rail fixed guideway public transportation systems; State safety oversight agencies that oversee the safety of rail fixed guideway public transportation systems; and entities that own or operate rail fixed guideway public transportation systems with Federal financial assistance authorized under 49 U.S.C. Chapter 53.

§ 674.5 Policy.

(a) In accordance with 49 U.S.C. 5329, a State that has a rail fixed guideway public transportation system within the State has primary responsibility for overseeing the safety of that rail fixed guideway public transportation system. A State safety oversight agency must have the authority, resources, and qualified personnel to oversee the number, size, and complexity of rail fixed guideway public transportation systems that operate within a State.

(b) FTA will certify whether a State safety oversight program meets the requirements of 49 U.S.C. 5329 and is adequate to promote the purposes of the public transportation safety programs codified at 49 U.S.C. 5329.

§ 674.7 Definitions.

As used in this part:

Accountable Executive means a single, identifiable person who has ultimate responsibility for carrying out the Public Transportation Agency Safety Plan of a transit agency; responsibility for carrying out the transit agency's Transit Asset Management Plan; and control or direction over the human and capital resources needed to develop and maintain both the transit agency's Public Transportation Agency Safety Plan, in accordance with 49 U.S.C. 5329(d), and the transit agency's Transit Asset Management Plan in accordance with 49 U.S.C. 5326.

Administrator means the Federal Transit Administrator or the Administrator's designee.

Collision means any impact between a rail transit vehicle and any other vehicle, object, or any person.

Contractor means an entity that performs tasks on behalf of FTA, a State Safety Oversight Agency, or a Rail Transit Agency, through contract or other agreement.

Corrective action plan means a plan developed by a Rail Transit Agency that describes the actions the Rail Transit Agency will take to minimize, control, correct, or eliminate risks and hazards, and the schedule for taking those actions. Either a State Safety Oversight Agency or FTA may require a Rail

Transit Agency to develop and carry out a corrective action plan.

Derailment for the purposes of this part means an event in which one or more wheels of a rail transit vehicle unintentionally leaves the rails.

Designated personnel means:

(1) Employees and contractors identified by a recipient whose job functions are directly responsible for safety oversight of the public transportation system of the public transportation agency; or

(2) Employees and contractors of a State Safety Oversight Agency whose job functions require them to conduct reviews, inspections, examinations, and other safety oversight activities of the rail fixed guideway public transportation systems subject to the jurisdiction of the agency.

Disabling Damage means damage to a rail transit vehicle resulting from a collision and preventing the vehicle from operating under its own power.

Evacuation for Life Safety Reasons means a condition that occurs when persons depart from transit vehicles or facilities for life safety reasons, including self-evacuation. A life safety reason may include a situation such as a fire, the presence of smoke or noxious fumes, a fuel leak from any source, an electrical hazard, or other hazard to any person. An evacuation of passengers into the rail right of way (not at a platform or station) for any reason is presumed to be an evacuation for life safety reasons.

Fatality means a death confirmed within 30 days of an event. Fatalities include suicides, but do not include deaths in or on transit property that are a result of drug overdose, exposure to the elements, illness, or natural causes.

FRA means the Federal Railroad Administration, an operating administration within the United States Department of Transportation.

FTA means the Federal Transit Administration, an operating administration within the United States Department of Transportation.

Hazard means any real or potential condition that can cause injury, illness, or death; damage to or loss of the facilities, equipment, rolling stock, or infrastructure; or damage to the environment.

Injury means any harm to persons as a result of an event that requires immediate medical attention away from the scene. Does not include harm resulting from a drug overdose, exposure to the elements, illness, natural causes, or occupational safety events occurring in administrative buildings.

Inspection means a physical observation of equipment, facilities, rolling stock, operations, or records for the purpose of gathering or analyzing facts or information.

Investigation means the process of determining the causal and contributing factors of a safety event or hazard, for the purpose of preventing recurrence and mitigating safety risk.

National Public Transportation Safety Plan means the plan to improve the safety of all public transportation systems that receive Federal financial assistance under 49 U.S.C. Chapter 53.

NTSB means the National Transportation Safety Board, an independent Federal agency.

Person means a passenger, employee, contractor, volunteer, official worker, pedestrian, trespasser, or any other individual on the property of a rail fixed guideway public transportation system or associated infrastructure.

Potential Consequence means the effect of a hazard.

Public transportation has the meaning found in 49 U.S.C. 5302.

Public Transportation Agency Safety Plan (PTASP) means the documented comprehensive agency safety plan for a transit agency that is required by 49 U.S.C. 5329 and part 673 of this chapter.

Public Transportation Safety Certification Training Program (PTSCTP) means the certification training program that is required by 49 U.S.C. 5329(c) and part 672 of this chapter.

Rail fixed guideway public transportation system means any fixed guideway system, or any such system in engineering or construction, that uses rail, is operated for public transportation, is within the jurisdiction of a State, and is not subject to the jurisdiction of the Federal Railroad Administration. These include but are not limited to rapid rail, heavy rail, light rail, monorail, trolley, inclined plane, funicular, and automated guideway.

Rail Transit Agency (RTA) means any entity that provides services on a rail fixed guideway public transportation system.

Rail transit vehicle means any rolling stock used on a rail fixed guideway public transportation system, including but not limited to passenger and maintenance vehicles.

Revenue vehicle means a rail transit vehicle used to provide revenue service for passengers. This includes providing fare free service.

Risk-based inspection program means an inspection program that uses qualitative and quantitative data analysis to inform ongoing inspection activities. Risk-based inspection

programs are designed to prioritize inspections to address safety concerns and hazards associated with the highest levels of safety risk.

Safety Committee means the formal joint labor-management committee on issues related to safety that is required by 49 U.S.C. 5329 and part 673 of this chapter.

Safety event means an unexpected outcome resulting in injury or death; damage to or loss of the facilities, equipment, rolling stock, or infrastructure of a public transportation system; or damage to the environment.

Safety risk means the composite of predicted severity and likelihood of a potential consequence of a hazard.

Safety Risk Management means a process within a transit agency's Public Transportation Agency Safety Plan for identifying hazards and analyzing, assessing, and mitigating the safety risk of their potential consequences.

Safety risk mitigation means a method or methods to eliminate or reduce the severity and/or likelihood of a potential consequence of a hazard.

State means a State of the United States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, Guam, American Samoa, and the Virgin Islands.

State Safety Oversight Agency (SSOA) means an agency established by a State that meets the requirements and performs the functions specified by 49 U.S.C. 5329(e) and (k) and the regulations set forth in this part.

Unintended train movement means any instance where a revenue vehicle is moving and is not under the control of a driver (whether or not the operator is physically on the vehicle at the time). This applies regardless of whether the event occurred in revenue service.

§ 674.9 [Reserved]

Subpart B—Role of the State

§ 674.11 State Safety Oversight Program.

Every State that has a rail fixed guideway public transportation system must have a State Safety Oversight (SSO) program that has been approved by the Administrator. FTA will audit each State's compliance at least triennially, consistent with 49 U.S.C. 5329(e)(10). At minimum, an SSO program must:

(a) Explicitly acknowledge the State's responsibility for overseeing the safety of the rail fixed guideway public transportation systems within the State;

(b) Demonstrate the State's ability to adopt and enforce Federal and relevant State law for safety in rail fixed guideway public transportation systems;

(c) Establish a State safety oversight agency, by State law, in accordance with the requirements of 49 U.S.C. 5329 and this part;

(d) Demonstrate that the State has determined an appropriate staffing level for the State safety oversight agency commensurate with the number, size, and complexity of the rail fixed guideway public transportation systems in the State, and that the State has consulted with the Administrator for that purpose;

(e) Demonstrate that the employees and other personnel of the State safety oversight agency who are responsible for the oversight of rail fixed guideway public transportation systems are qualified to perform their functions, based on appropriate training, including substantial progress toward or completion of the Public Transportation Safety Certification Training Program; and

(f) Demonstrate that by law, the State prohibits any public transportation agency in the State from providing funds to the SSOA.

§ 674.13 Designation of oversight agency.

(a) Every State that must establish a State Safety Oversight program in accordance with 49 U.S.C. 5329 must also establish a SSOA for the purpose of overseeing the safety of rail fixed guideway public transportation systems within that State. Further, the State must ensure that:

(1) The SSOA is financially and legally independent from any public transportation agency the SSOA is obliged to oversee;

(2) The SSOA does not directly provide public transportation services in an area with a rail fixed guideway public transportation system the SSOA is obliged to oversee;

(3) The SSOA does not employ any individual who is also responsible for administering a rail fixed guideway public transportation system the SSOA is obliged to oversee;

(4) The SSOA has authority to review, approve, oversee, and enforce the Public Transportation Agency Safety Plan for a rail fixed guideway public transportation system required by 49 U.S.C. 5329(d) and part 673 of this chapter;

(5) The SSOA has investigative, inspection, and enforcement authority with respect to the safety of all rail fixed guideway public transportation systems within the State;

(6) At least once every three years, the SSOA audits every rail fixed guideway public transportation system's compliance with the Public Transportation Agency Safety Plan

required by 49 U.S.C. 5329(d) and part 673 of this chapter; and

(7) At least once a year, the SSOA reports the status of the safety of each rail fixed guideway public transportation system to the Governor, the FTA, and the board of directors, or equivalent entity, of the rail fixed guideway public transportation system.

(b) At the request of the Governor of a State, the Administrator may waive the requirements for financial and legal independence and the prohibitions on employee conflicts of interest under paragraphs (a)(1) and (3) of this section, if the rail fixed guideway public transportation systems in design, construction, or revenue operations in the State have fewer than one million combined actual and projected rail fixed guideway revenue miles per year or provide fewer than ten million combined actual and projected unlinked passenger trips per year. However:

(1) If a State shares jurisdiction over one or more rail fixed guideway public transportation systems with another State, and has one or more rail fixed guideway public transportation systems that are not shared with another State, the revenue miles and unlinked passenger trips of the rail fixed guideway public transportation system under shared jurisdiction will not be counted in the Administrator's decision whether to issue a waiver.

(2) The Administrator will rescind a waiver issued under this subsection if the number of revenue miles per year or unlinked passenger trips per year increases beyond the thresholds specified in this subsection.

§ 674.15 Designation of oversight agency for multi-state system.

In an instance of a rail fixed guideway public transportation system that operates in more than one State, all States in which that rail fixed guideway public transportation system operates must either:

(a) Ensure that uniform safety standards and procedures in compliance with 49 U.S.C. 5329 are applied to that rail fixed guideway public transportation system, through an SSO program that has been approved by the Administrator; or

(b) Designate a single entity that meets the requirements for an SSOA to serve as the SSOA for that rail fixed guideway public transportation system, through an SSO program that has been approved by the Administrator.

§ 674.17 Use of Federal financial assistance.

(a) In accordance with 49 U.S.C. 5329(e)(6), FTA will make grants of

Federal financial assistance to eligible States to help the States develop and carry out their SSO programs. This Federal financial assistance may be used for reimbursement of both the operational and administrative expenses of SSO programs, consistent with the uniform administrative requirements for grants to States under 2 CFR parts 200 and 1201. The expenses eligible for reimbursement include, specifically, the expense of employee training and the expense of establishing and maintaining a SSOA in compliance with 49 U.S.C. 5329.

(b) The apportionments of available Federal financial assistance to eligible States will be made in accordance with a formula, established by the Administrator, following opportunity for public notice and comment. The formula will take into account fixed guideway vehicle revenue miles, fixed guideway route miles, and fixed guideway vehicle passenger miles attributable to all rail fixed guideway systems within each eligible State not subject to the jurisdiction of the FRA.

(c) The grants of Federal financial assistance for State safety oversight shall be subject to terms and conditions as the Administrator deems appropriate.

(d) The Federal share of the expenses eligible for reimbursement under a grant for State safety oversight activities shall be eighty percent of the reasonable costs incurred under that grant.

(e) The non-Federal share of the expenses eligible for reimbursement under a grant for State safety oversight activities may not be comprised of Federal funds, any funds received from a public transportation agency, or any revenues earned by a public transportation agency.

§ 674.19 Certification of a State Safety Oversight Program.

(a) The Administrator must determine whether a State's SSO program meets the requirements of 49 U.S.C. 5329. Also, the Administrator must determine whether a SSO program is adequate to promote the purposes of 49 U.S.C. 5329, including, but not limited to, the National Public Transportation Safety Plan, the Public Transportation Safety Certification Training Program, and the Public Transportation Agency Safety Plans.

(b) The Administrator must issue a certification to a State whose SSO program meets the requirements of 49 U.S.C. 5329. The Administrator must issue a denial of certification to a State whose SSO program does not meet the requirements of 49 U.S.C. 5329.

(c) In an instance in which the Administrator issues a denial of

certification to a State whose SSO program does not meet the requirements of 49 U.S.C. 5329, the Administrator must provide a written explanation, and allow the State an opportunity to modify and resubmit its SSO program for the Administrator's approval. In the event the State is unable to modify its SSO program to merit the Administrator's issuance of a certification, the Administrator must notify the Governor of that fact, and must ask the Governor to take all possible actions to correct the deficiencies that are precluding the issuance of a certification for the SSO program. In his or her discretion, the Administrator may also impose financial penalties as authorized by 49 U.S.C. 5329(e), which may include:

(1) Withholding SSO grant funds from the State;

(2) Withholding up to five percent of the 49 U.S.C. 5307 Urbanized Area formula funds appropriated for use in the State or urbanized area in the State, until such time as the SSO program can be certified; or

(3) Requiring all rail fixed guideway public transportation systems governed by the SSO program to spend up to 100 percent of their Federal funding under 49 U.S.C. chapter 53 only for safety-related improvements on their systems, until such time as the SSO program can be certified.

(d) When determining whether to issue a certification or a denial of certification for a SSO program, the Administrator must evaluate whether the cognizant SSOA has the authority, resources, and expertise to oversee the number, size, and complexity of the rail fixed guideway public transportation systems that operate within the State, or will attain the necessary authority, resources, and expertise in accordance with a developmental plan and schedule.

§ 674.21 Withholding of Federal financial assistance for noncompliance.

(a) In making a decision to impose financial penalties as authorized by 49 U.S.C. 5329(e) and determining the nature and amount of the financial penalties, the Administrator shall consider the extent and circumstances of the noncompliance; the operating budgets of the SSOA and the rail fixed guideway public transportation systems that will be affected by the financial penalties; and such other matters as justice may require.

(b) If a State fails to establish an SSO program that has been approved by the Administrator prior to a rail fixed guideway public transportation system entering the engineering or construction

phase of development, FTA will be prohibited from obligating Federal financial assistance authorized under 49 U.S.C. 5338 to any entity in the State that is otherwise eligible to receive that Federal financial assistance, in accordance with 49 U.S.C. 5329(e)(3).

§ 674.23 Confidentiality of information.

(a) A State, an SSOA, or an RTA may withhold an investigation report prepared or adopted in accordance with these regulations from being admitted as evidence or used in a civil action for damages resulting from a matter mentioned in the report.

(b) This part does not require public availability of any data, information, or procedures pertaining to the security of a rail fixed guideway public transportation system or its passenger operations.

Subpart C—State Safety Oversight Agencies

§ 674.25 Role of the State safety oversight agency.

(a) An SSOA must establish minimum standards for the safety of all rail fixed guideway public transportation systems within its oversight. These minimum standards must be consistent with the National Public Transportation Safety Plan, the Public Transportation Safety Certification Training Program, the rules for Public Transportation Agency Safety Plans and all applicable Federal and State law.

(b) An SSOA must review and approve the Public Transportation Agency Safety Plan for every rail fixed guideway public transportation system within its oversight. An SSOA must oversee an RTA's execution of its Public Transportation Agency Safety Plan. An SSOA must enforce the execution of a Public Transportation Agency Safety Plan, through an order of a corrective action plan or any other means, as necessary or appropriate.

(c) An SSOA has the responsibility to provide safety oversight of an RTA's project(s) in the engineering or construction phase to verify compliance with all applicable Federal and State safety requirements.

(d) An SSOA must ensure that a Public Transportation Agency Safety Plan meets the requirements at 49 U.S.C. 5329(d) and part 673 of this chapter.

(e) An SSOA has primary responsibility for the investigation of any allegation of noncompliance with a Public Transportation Agency Safety Plan. These responsibilities do not preclude the Administrator from exercising their authority under 49 U.S.C. 5329(f).

(f) An SSOA has primary responsibility for the investigation of a safety event on a rail fixed guideway public transportation system. This responsibility does not preclude the Administrator from exercising his or her authority under 49 U.S.C. 5329(f).

(g) An SSOA may enter into an agreement with a contractor for assistance in overseeing safety event investigations and performing independent safety event investigations; and for expertise the SSOA does not have within its own organization.

(h) All personnel and contractors employed by an SSOA must comply with the requirements of the Public Transportation Safety Certification Training Program as applicable.

§ 674.27 State safety oversight program standards.

(a) An SSOA must adopt and distribute a written SSO program standard, consistent with the National Public Transportation Safety Plan and the rules for Public Transportation Agency Safety Plans. This SSO program standard must identify the processes and procedures that govern the activities of the SSOA. Also, the SSO program standard must identify the processes and procedures an RTA must have in place to comply with the standard. At minimum, the program standard must meet the following requirements:

(1) *Program management.* The SSO program standard must explain the authority of the SSOA to oversee the safety of rail fixed guideway public transportation systems; the policies that govern the activities of the SSOA; the reporting requirements that govern both the SSOA and the rail fixed guideway public transportation systems; and the steps the SSOA will take to ensure open, on-going communication between the SSOA and every rail fixed guideway public transportation system within its oversight.

(2) *Program standard development.* The SSO program standard must explain the SSOA's process for developing, reviewing, adopting, and revising its minimum standards for safety, and distributing those standards to the rail fixed guideway public transportation systems.

(3) *Disposition of RTA comments.* The SSO program standard must establish a disposition process that defines how the SSOA will address any comments the RTA makes with respect to the SSO program standard.

(4) *Program policy and objectives.* The SSO program standard must set an explicit policy and objectives for safety

in rail fixed guideway public transportation throughout the State.

(5) *Oversight of RTA Public Transportation Agency Safety Plans and internal safety reviews.* The SSO program standard must explain the role of the SSOA in overseeing an RTA's execution of its Public Transportation Agency Safety Plan and any related safety reviews of the RTA's fixed guideway public transportation system. The SSO program standard must describe the process whereby the SSOA will receive and evaluate all material submitted under the signature of an RTA's accountable executive. The SSO program standard must define baseline RTA internal safety review requirements including, at a minimum, the following requirements:

(i) The RTA must develop and document an ongoing internal safety review process to ensure that all elements of an RTA's Public Transportation Agency Safety Plan are performing and being implemented as intended.

(ii) The RTA's internal safety review process must ensure that the implementation of all elements of its Public Transportation Agency Safety Plan are reviewed within a three-year period.

(iii) The RTA must notify the SSOA at least thirty (30) days before the RTA conducts an internal safety review of any aspect of the rail fixed guideway public transportation system and provide any checklists or procedures it will use during the review.

(iv) The RTA must submit a report to the SSOA annually documenting the internal safety review activities and the status of subsequent findings and corrective actions.

(6) *Oversight of safety risk mitigations.* The SSO program standard must explain the role of the SSOA in overseeing an RTA's development, implementation, and monitoring of safety risk mitigations related to rail fixed guideway transportation, including how the SSOA will track RTA safety risk mitigations. The SSO program standard must specify the frequency and format whereby the SSOA will receive and review information on RTA safety risk mitigation status and effectiveness.

(7) *Oversight of RTA compliance with the Public Transportation Safety Certification Training Program.* The SSOA must review and approve the RTA's designated personnel. The SSOA must review and approve the refresher training defined by the RTA to satisfy the requirements of the *Public Transportation Safety Certification Training Program*.

(8) *Triennial SSOA audits of RTA Public Transportation Agency Safety Plans.* The SSO program standard must explain the process the SSOA will follow and the criteria the SSOA will apply in conducting a complete audit of the RTA's compliance with its Public Transportation Agency Safety Plan at least once every three years, in accordance with 49 U.S.C. 5329. Alternatively, the SSOA and RTA may agree that the SSOA will conduct its audit on an on-going basis over the three-year timeframe. The program standard must establish a procedure the SSOA and RTA will follow to manage findings and recommendations arising from the triennial audit.

(9) *Safety event notifications.* The SSO program standard must establish requirements for RTA notifications of safety events occurring on the RTA's rail fixed guideway public transportation system, including notifications to the SSOA and to FTA. SSOA safety event notification requirements must address, specifically, the time limits for notification, methods of notification, and the nature of the information the RTA must submit to the SSOA.

(10) *Investigations.* The SSO program standard must identify safety events that require an RTA to conduct an investigation. Also, the program standard must address how the SSOA will oversee an RTA's own internal investigation; the role of the SSOA in supporting any investigation conducted or findings and recommendations made by the NTSB or FTA; and procedures for protecting the confidentiality of the investigation reports.

(11) *Corrective actions.* The program standard must explain the process and criteria by which the SSOA may order an RTA to develop and carry out a corrective action plan (CAP), and a procedure for the SSOA to review and approve a CAP. Also, the program standard must explain the SSOA's policy and practice for tracking and verifying an RTA's compliance with the CAP and managing any conflicts between the SSOA and RTA relating either to the development or execution of the CAP or the findings of an investigation.

(12) *Inspections.* The SSO program standard must include or incorporate by reference a risk-based inspection program that:

(i) is commensurate with the number, size, and complexity of the rail fixed guideway public transportation systems that the State safety oversight agency oversees;

(ii) provides the SSOA with the authority and capability to enter the facilities of each rail fixed guideway

public transportation system that the SSOA oversees to inspect infrastructure, equipment, records, personnel, and data, including the data that the RTA collects when identifying and evaluating safety risks; and

(iii) include policies and procedures regarding the access of the SSOA to conduct inspections of the rail fixed guideway public transportation system, including access for inspections that occur without advance notice to the RTA.

(13) *Vehicle maintenance and testing.* The SSO program standard must include the process by which the SSOA will review an RTA's rail transit vehicle maintenance program, including periodic testing of rail transit vehicle braking systems, to ensure performance, and to detect potential latent system failures.

(14) *Data collection.* The program standard must include policies and procedures for collecting and reviewing data that the RTA uses when identifying hazards and assessing safety risk. The frequency of collection shall be commensurate with the size and complexity of the rail fixed guideway public transportation system.

(b) At least once a year an SSOA must submit its SSO program standard and any referenced program procedures to FTA, with an indication of any revisions made to the program standard since the last annual submittal. FTA will evaluate the SSOA's program standard as part of its continuous evaluation of the State Safety Oversight Program, and in preparing FTA's report to Congress on the certification status of that State Safety Oversight Program, in accordance with 49 U.S.C. 5329.

§ 674.29 Public Transportation Agency Safety Plans: General requirements.

(a) In determining whether to approve a Public Transportation Agency Safety Plan for a rail fixed guideway public transportation system, an SSOA must evaluate whether the Public Transportation Agency Safety Plan is compliant with 49 U.S.C. 5329(d) and part 673 of this chapter; is consistent with the National Public Transportation Safety Plan; and is in compliance with the SSO program standard set by the SSOA.

(b) In an instance in which an SSOA does not approve a Public Transportation Agency Safety Plan, the SSOA must provide a written explanation and allow the RTA an opportunity to modify and resubmit its Public Transportation Agency Safety Plan for the SSOA's approval.

§ 674.31 Triennial audits: General requirements.

At least once every three years, an SSOA must conduct a complete audit of an RTA's compliance with its Public Transportation Agency Safety Plan. Alternatively, an SSOA may conduct the audit on an on-going basis over the three-year timeframe. If an SSOA audits an RTA's compliance on an ongoing basis, the SSOA shall issue interim audit reports at least annually. At the conclusion of the three-year audit cycle, the SSOA shall issue a report with findings and recommendations arising from the triennial or ongoing audit, which must include, at minimum, an analysis of the effectiveness of the Public Transportation Agency Safety Plan, recommendations for improvements, and a corrective action plan, if necessary or appropriate. The RTA must be given an opportunity to comment on the findings and recommendations.

§ 674.33 Notifications of safety events.

An RTA must notify FTA and the SSOA within two hours of any safety event occurring on a rail fixed guideway public transportation system that results in one or more of the following:

- (a) Fatality
- (b) Two or more injuries
- (c) Derailment
- (d) Collision resulting in one or more injuries
- (e) Collision between two rail transit vehicles
- (f) Collision resulting in disabling damage to a rail transit vehicle
- (g) Evacuation for life safety reasons
- (h) Unintended train movement.

§ 674.35 Investigations.

(a) An SSOA must investigate or require an investigation of any safety event that requires notification under § 674.33.

(b) The SSOA is ultimately responsible for the sufficiency and thoroughness of all investigations, whether conducted by the SSOA or RTA. If an SSOA requires an RTA to investigate a safety event, the SSOA must conduct an independent review of the RTA's findings of causation. In any instance in which an RTA is conducting its own internal investigation of the safety event, the SSOA and the RTA must coordinate their investigations in accordance with the SSO program standard and any agreements in effect.

(c) Within a reasonable time, an SSOA must issue a written report on its investigation of a safety event or review of an RTA's safety event investigation in accordance with the reporting requirements established by the SSOA.

The report must describe the investigation activities; identify the factors that caused or contributed to the safety event; and set forth a corrective action plan, as necessary or appropriate. The SSOA must formally adopt the report of a safety event and transmit that report to the RTA for review and concurrence. If the RTA does not concur with an SSOA's report, the SSOA may allow the RTA to submit a written dissent from the report, which may be included in the report, at the discretion of the SSOA.

(d) All personnel and contractors that conduct investigations on behalf of an SSOA must be trained to perform their functions in accordance with the Public Transportation Safety Certification Training Program.

(e) The Administrator may conduct an independent investigation of any safety event or an independent review of an SSOA's or an RTA's findings of causation of a safety event.

§ 674.37 Corrective action plans.

(a) The SSOA must, at a minimum, require the development of a CAP for the following:

- (1) Results from investigations, in which the RTA or SSOA determined that causal or contributing factors require corrective action;
- (2) Findings of non-compliance from safety reviews and inspections performed by the SSOA; or
- (3) Findings of non-compliance from internal safety reviews performed by the RTA.

(b) In any instance in which an RTA must develop and carry out a CAP, the SSOA must review and approve the CAP before the RTA carries out the plan. However, an exception may be made for immediate or emergency corrective actions that must be taken to ensure immediate safety, provided that the SSOA has been given timely notification, and the SSOA provides subsequent review and approval.

(c) A CAP must describe, specifically, the actions the RTA will take to correct the deficiency identified by the CAP, the schedule for taking those actions, and the individuals responsible for taking those actions. The RTA must periodically report to the SSOA on its progress in carrying out the CAP. The SSOA may monitor the RTA's progress in carrying out the CAP through unannounced, on-site inspections, or any other means the SSOA deems necessary or appropriate.

(d) In any instance in which a safety event on the RTA's rail fixed guideway public transportation system is the subject of an investigation by the NTSB or FTA, the SSOA must evaluate

whether the findings or recommendations by the NTSB or FTA require a CAP by the RTA, and if so, the SSOA must order the RTA to develop and carry out a CAP.

§ 674.39 State Safety Oversight Agency annual reporting to FTA.

(a) On or before March 15 of each year, an SSOA must submit the following material to FTA:

(1) The SSO program standard adopted in accordance with § 674.27, with an indication of any changes to the SSO program standard during the preceding twelve months;

(2) Evidence that its designated personnel have completed the requirements of the Public Transportation Safety Certification Training Program, or, if in progress, the anticipated completion date of the training;

(3) A publicly available report that summarizes its oversight activities for the preceding twelve months, describes the causal factors of safety events identified through investigation, and identifies the status of corrective actions, changes to Public Transportation Agency Safety Plans, and the level of effort by the SSOA in carrying out its oversight activities;

(4) Final investigation reports for all safety events meeting one or more of the criteria specified at § 674.33;

(5) A summary of the internal safety reviews conducted by RTAs during the previous twelve months, and the RTA's progress in carrying out CAPs arising under § 674.37(a)(3);

(6) A summary of the triennial audits completed during the preceding twelve months, and the RTAs' progress in carrying out CAPs arising from triennial audits conducted in accordance with § 674.31;

(7) Evidence that the SSOA has reviewed and approved any changes to the Public Transportation Agency Safety Plans during the preceding twelve months; and

(8) A certification that the SSOA is in compliance with the requirements of this part.

(b) These materials must be submitted electronically through a reporting system specified by FTA.

§ 674.41 Conflicts of interest.

(a) An SSOA must be financially and legally independent from any rail fixed guideway public transportation system under the oversight of the SSOA, unless the Administrator has issued a waiver of this requirement in accordance with § 674.13(b).

(b) An SSOA may not employ any individual who provides services to a

rail fixed guideway public transportation system under the oversight of the SSOA, unless the Administrator has issued a waiver of	this requirement in accordance with § 674.13(b). (c) A contractor may not provide services to both an SSOA and a rail fixed guideway public transportation	system under the oversight of that SSOA, unless the Administrator has issued a waiver of this prohibition. [FR Doc. 2023–25186 Filed 11–14–23; 8:45 am] BILLING CODE 4910–57–P

Notices

Federal Register

Vol. 88, No. 219

Wednesday, November 15, 2023

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS-FGIS-23-0051]

Opportunity To Comment on Applicants for the Texas Central U.S. Grain Standards Act Designation Area

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: Plainview Grain Inspection and Weighing Service, Inc. (Plainview) and Grain Inspection Services of Texas, LLC (Texas Grain) have applied for designation to provide official U.S. Grain Standards Act services in the Texas Central designation area. The Agricultural Marketing Service (AMS) is asking for comments on these applicants.

DATES: Comments must be received before December 15, 2023 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments concerning this notice and view the applications.

To Submit Comments: All comments must be submitted through the Federal e-rulemaking portal at <https://www.regulations.gov> and should reference the document number and the date and page number of this issue of the **Federal Register**. Instructions for submitting and reading comments are detailed on the site. All comments submitted in response to this notice will be included in the record and will be made available for public inspection. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

To Read Applications and Comments: If you would like to view the applications, please contact us at FGISQACD@usda.gov. All comments

will be available for public inspection online at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: J. Ricardo Espitia, Compliance Officer, Federal Grain Inspection Service, AMS, USDA; Telephone: (202) 699-0246; or Email: FGISQACD@usda.gov.

SUPPLEMENTARY INFORMATION: In the April 3, 2023, **Federal Register** (88 FR 19605), AMS asked persons interested in providing official U.S. Grain Standards Act services in the Texas Central designation area to submit an application. There are two applicants for the Texas Central area: Plainview Grain Inspection and Weighing Service, Inc. (Plainview) and Grain Inspection Services of Texas, LLC (Texas Grain). Plainview is currently a designated official agency, and Texas Grain is a new business requesting designation. Plainview applied for designation to provide official services for part of the unassigned Texas Central area, specifically, Coke, Coleman, Ector, Glasscock, Midland, Runnels, Sterling, and Winkler counties. Texas Grain applied for the entire unassigned area.

The unassigned area in the state of Texas includes the counties of: Anderson, Angelina, Atascosa, Austin, Bandera, Bastrop, Bell, Bexar, Blanco, Bosque, Brazos, Brewster, Brown, Burleson, Burnet, Caldwell, Camp, Cherokee, Coke, Coleman, Collin, Comal, Comanche, Concho, Cooke, Coryell, Crane, Crockett, Culberson, Dallas, Delta, Denton, DeWitt, Eastland, Ector, Edwards, Ellis, El Paso, Erath, Falls, Fannin, Fayette, Franklin, Freestone, Frio, Gillespie, Glasscock, Gonzales, Grayson, Gregg, Grimes, Guadalupe, Hamilton, Hardin, Harrison, Hays, Henderson, Hill, Hood, Hopkins, Houston, Hudspeth, Hunt, Irion, Jack, Jasper, Jeff Davis, Johnson, Karnes, Kaufman, Kendall, Kerr, Kimble, Kinney, Lamar, Lampasas, Lavaca, Lee, Leon, Liberty, Limestone, Llano, Loving, McCulloch, McLennan, Madison, Marion, Mason, Maverick, Medina, Menard, Midland, Milam, Mills, Montague, Montgomery, Morris, Nacogdoches, Navarro, Newton, Orange, Palo Pinto, Panola, Parker, Pecos, Polk, Presidio, Rans, Reagan, Real, Red River, Reeves, Robertson, Rockwall, Runnels, Risk, Sabine, San Augustine, San Jacinto, San Saba, Schleicher, Shelby, Smith, Somervell, Stephens, Sterling, Sutton, Tarrant, Terrell, Titus, Tom Green, Travis, Trinity, Tyler, Upshur,

Upton, Uvalde, Val Verde, Van Zandt, Walker, Ward, Washington, Williamson, Wilson, Winkler, Wise, Wood, Young, and Zavala. This area excludes any established or future export port locations, which are serviced by FGIS.

AMS is publishing this notice to provide interested persons the opportunity to comment on the quality of services provided by Plainview and Texas Grain. In the designation process, comments citing reasons and pertinent data supporting or objecting to the designation of the applicant(s) are particularly helpful. All comments will also become a matter of public record and made available for public inspection at <https://www.regulations.gov>.

AMS considers applications, comments, and other available information, such as audit reports, when determining which applicants will be designated.

Authority: 7 U.S.C. 71-87k.

Melissa Bailey,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023-25144 Filed 11-14-23; 8:45 am]

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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS-FGIS-23-0029]

Opportunity for United States Grain Standards Act Designation in Decatur, IN and Marshall, MI

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice; request for comments.

SUMMARY: The Agricultural Marketing Service (AMS) is seeking persons or governmental agencies interested in providing official services in the areas noted below to submit an application for designation. Designation provides for private entities or State governmental agencies to be an integral part of the official grain inspection system (<https://www.ams.usda.gov/services/fgis/official-grain-inspection-weighing-system>). Designated agencies work under the supervision of the Federal Grain Inspection Service (FGIS) and are authorized to provide official inspection and weighing services in a defined geographic area, as appropriate.

In addition, we request comments on the quality of services provided by designated agency Michigan Grain Inspection Services, Inc. (Michigan Grain Inspection). AMS encourages submissions from traditionally underrepresented individuals, organizations, and businesses to reflect the diversity of this industry. AMS encourages submissions from qualified applicants, regardless of race, color, age, sex, sexual orientation, gender identity, national origin, religion, disability status, protected veteran status, or any other characteristic protected by law.

DATES: Applications for the Decatur, IN, designation area must be received by 11:59 p.m. eastern time on December 15, 2023.

Applications and comments for the Marshall, MI, designation area, which is currently operated by Michigan Grain Inspection, must be received between January 1, 2024, and January 31, 2024.

ADDRESSES: Submit applications and comments concerning this notice using the following methods:

To apply for USGSA designation: You will need to obtain an FGISonline customer number (CIM) and create a USDA eAuthentication account at [https://www.eauth.usda.gov/eauth/b/](https://www.eauth.usda.gov/eauth/b/usda/home)

[usda/home](https://www.eauth.usda.gov/eauth/b/usda/home) prior to applying. Then go to FGISonline at <https://fgisonline.ams.usda.gov/> and click on the Delegations/Designations and Export Registrations (DDR) link. Applicants are encouraged to begin the designation application process early and allow time for system authentication.

To submit comments regarding current designated official agencies: Go to [Regulations.gov](https://www.regulations.gov) (<https://www.regulations.gov>). Instructions for submitting and reading comments are detailed on the site.

Interested persons are invited to submit written comments concerning this notice. All comments must be submitted through the Federal e-rulemaking portal at <https://www.regulations.gov> and should reference the document number and the date and page number of this issue of the **Federal Register**. All comments submitted in response to this notice will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting comments will be made public on the internet at the address provided above.

To read applications and comments: If you would like to view the

applications, please contact FGISQACD@usda.gov. All comments will be available for public viewing online at <https://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: J. Ricardo Espitia, Compliance Officer, Federal Grain Inspection Service, AMS, USDA; Telephone: (202) 699-0246; or Email: Jose.Espitia@usda.gov or FGISQACD@usda.gov.

SUPPLEMENTARY INFORMATION: The U. S. Department of Agriculture (USDA) revoked Northeast Indiana Grain Inspection Inc.'s designation as an agency that may perform official grain inspection and weighing services on August 21, 2023, due to its failure to comply with requirements of the United States Grain Standards Act (USGSA). Further information and documentation on this legal matter can be received by contacting the USDA Hearing Clerk's office at 202.720.4443 or via email at SM.OHA.hearingclerks@usda.gov. Due to the designation revocation in this territory, USDA seeks new applicants for the Decatur, IN, designation area. Applications must be received by December 15, 2023.

Additionally, the designation of the official agency listed below will end on the prescribed date:

Official agency	Headquarters location and telephone	Designation End	Applications/comments open period
Michigan Grain Inspection Services, Inc	Marshall, MI, 269-781-2711	3/31/2024	01/01/2024-01/31/2024

Section 7(f) of the United States Grain Standards Act (USGSA) authorizes the Secretary to designate a qualified applicant to provide official services in a specified area after determining that the applicant is better able than any other applicant to provide such official services (7 U.S.C. 79(f)). A designated agency may provide official inspection service and/or Class X or Class Y weighing services at locations other than port locations. Under section 7(g) of the USGSA, designations of official agencies are effective for no longer than five years, unless terminated by the Secretary, and may be renewed according to the criteria and procedures prescribed in section 7(f) of the USGSA. Please see the regulation at 7 CFR 800.196 for further information and guidance.

Designation Application Locations

The following identifies the specific areas of operation for designation applications.

Decatur, Indiana: The designation area includes parts of Indiana. Please see the December 12, 2016, issue of the

Federal Register (81 FR 89428) for a description of the area open for designation. The designation area is listed under the subheading titled "IN INDIANA."

Marshall, Michigan: The designation area includes parts of Michigan and Ohio. Please see the March 29, 2016, issue of the **Federal Register** (81 FR 17428-17431) for a description of the area open for designation. The designation area is listed under the subheading titled "Marshall, MI."

Opportunity for Designation

Interested persons or governmental agencies may apply for designation to provide official services in the geographic areas of the official agencies specified above under the provisions of section 7(f) of the USGSA and 7 CFR 800.196. Designation in the specified geographic area in the Decatur, IN, area will begin after a designation decision is issued by the Agricultural Marketing Service. The designation in the specified geographic area for Michigan is expected to begin no sooner than April 1, 2024. If you have questions

about how to apply for designation or wish to request more information on the geographic areas open for designation, please contact FGISQACD@usda.gov.

Please note that sampling, weighing, and inspection services may be offered by designated agencies under the Agricultural Marketing Act of 1946 for other commodities under the auspices of FGIS through separate cooperative service agreements with AMS. The service area for such cooperative agreements mirrors the USGSA designation area. For further information, see 7 U.S.C. 1621 *et seq.* or contact FGISQACD@usda.gov.

Authority: 7 U.S.C. 71-87k.

Melissa Bailey,
Associate Administrator, Agricultural Marketing Service.
[FR Doc. 2023-25145 Filed 11-14-23; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE**Animal and Plant Health Inspection Service****[Docket No. APHIS–2023–0022]****Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Proposed Exemptions****AGENCY:** Animal and Plant Health Inspection Service, USDA.**ACTION:** Notice.

SUMMARY: We are advising the public that we are proposing to add five new types of genetic modifications a plant can contain and be exempt from the regulations for the movement of organisms modified or produced through genetic engineering because such modifications could otherwise be achieved through conventional breeding methods. First, we propose any diploid or autopolyploid plant with any combination of loss of function modifications (*i.e.*, a modification that eliminates a gene's function) in one to all alleles of a single genetic locus, or any allopolyploid plant with any combination of loss of function modifications in one or both alleles of a single genetic locus on up to four pairs of homoeologous chromosomes, without the insertion of exogenous DNA, would qualify for exemption. Second, we propose that any diploid or autopolyploid plant in which the genetic modification is a single contiguous deletion of any size, resulting from cellular repair of one or two targeted DNA breaks on a single chromosome or at the same location(s) on two or more homologous chromosomes, without insertion of DNA, or with insertion of DNA in the absence of a repair template, would qualify for exemption. Third, we propose to extend the modifications described in certain existing exemptions in the regulations to all alleles of a genetic locus on the homologous chromosomes of an autopolyploid plant. Fourth, we propose that plants with up to four modifications that individually qualify for exemption and are made simultaneously or sequentially would be exempt from regulation, provided that each modification is at a different genetic locus. Fifth, we propose that plants that have previously completed a voluntary review confirming exempt status and that have subsequently been produced, grown, and observed consistent with conventional breeding methods appropriate for the plant species, could be successively modified in accordance with the exemptions.

This action would reduce the regulatory burden for developers of certain plants modified using genetic engineering that are not expected to pose plant pest risks greater than the plant pest risks posed by plants modified by conventional breeding methods.

DATES: We will consider all comments that we receive on or before December 15, 2023.

ADDRESSES: You may submit comments by either of the following methods:

- **Federal eRulemaking Portal:** Go to <http://www.regulations.gov>. Enter APHIS–2023–0022 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.

- **Postal Mail/Commercial Delivery:** Send your comment to Docket No. APHIS–2023–0022, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at [regulations.gov](https://www.regulations.gov) or in our reading room, which is located in room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Neil Hoffman, Science Advisor, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 98, Riverdale, MD 20737–1238; Neil.E.Hoffman@usda.gov; (301) 851–3947.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 govern the movement (importation, interstate movement, or release into the environment) of certain organisms modified or produced through genetic engineering. The Animal and Plant Health Inspection Service (APHIS) first issued these regulations in 1987 under the authority of the Federal Plant Pest Act of 1957 and the Plant Quarantine Act of 1912, two acts that were subsumed into the Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) in 2000, along with other provisions. Since 1987, APHIS has amended the regulations seven times, in 1988, 1990, 1993, 1994, 1997, 2005, and 2020.

On May 18, 2020, we published in the **Federal Register** (85 FR 29790–29838, Docket No. APHIS–2018–0034) a final

rule¹ that marked the first comprehensive revision of the regulations since they were established in 1987. The final rule provided a clear, predictable, and efficient regulatory pathway for innovators, facilitating the development of organisms developed using genetic engineering that are unlikely to pose plant pest risks.

The May 2020 final rule included regulatory exemptions for certain categories of modified plants. Specifically, § 340.1(b) exempted plants that contain a single modification of one of the following types, specified in § 340.1(b)(1) through (3):

- The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or
- The genetic modification is a targeted single base pair substitution; or
- The genetic modification introduces a gene known to occur in the plant's gene pool or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.

In addition to the modifications listed above, § 340.1(b)(4) provides that the Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may either be APHIS-initiated or may be initiated via a request that is accompanied by adequate supporting information and submitted by another party. In either case, APHIS will publish a notice in the **Federal Register** of the proposal, along with the supporting documentation, and will request public comments. After reviewing the comments, APHIS will publish a subsequent notice in the **Federal Register** announcing its final determination. A list specifying modifications a plant can contain and be exempt pursuant to paragraph (b)(4) is available on the APHIS website at <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>.

On July 19, 2021, we published a notice in the **Federal Register** (86 FR 37988–37989, Docket No. APHIS–2020–0072) proposing to exempt plants with any of the following additional modifications:

- Cellular repair of a targeted DNA break in the same location on two homologous chromosomes, in the absence of a repair template, resulting in homozygous or heterozygous biallelic

¹ To view the final rule and supporting documents, go to <https://www.regulations.gov/docket/APHIS-2018-0034>.

mutations, each of which is a loss of function mutation;

- Contiguous deletion of any size resulting from cellular repair of a targeted DNA break in the presence of an externally supplied repair template; or

- Cellular repair of two targeted DNA breaks on a single chromosome or at the same location on two homologous chromosomes, when the repair results in a contiguous deletion of any size in the presence or absence of a repair template, or in a contiguous deletion of any size combined with an insertion of DNA in the absence of a repair template.

We received comments on that notice that suggested these exemptions were piecemeal and could be replaced with an overarching exemption. Furthermore, comments included additional exemptions beyond those that we proposed.

Based on the comments that we received and our own subsequent review and analysis of conventional breeding techniques that are currently employed, we are withdrawing the original three proposed exemptions and are proposing five new types of modifications a plant can contain and qualify for exemption from regulation pursuant to paragraph (b)(4) of § 340.1.

First, we propose that a diploid or autopolyploid plant with any combination of loss of function modifications in one to all alleles of a single genetic locus, or an allopolyploid plant with any combination of loss of function modifications in one or both alleles of a single genetic locus on up to four pairs of homoeologous chromosomes, without the insertion of exogenous DNA, would qualify for exemption (proposed exemption 340.1(b)(4)(vi)(Additional Modification (AM)1)). (Because this exemption would be found solely on the internet, and not in the regulations themselves, the “AM” nomenclature would be used to identify the method by which it and the other exemptions proposed in this notice were added.) This category would apply to scenarios that might not be expressly described in the exemptions codified in the May 2020 final rule (namely, paragraphs (b)(1) and (2) of § 340.1) but would achieve an end result that can also be accomplished by those exemptions. In addition, it more broadly extends, compared to the 2020 rule, loss of function mutations without the insertion of exogenous DNA to polyploid plants.

Second, we propose that any diploid or autopolyploid plant in which the genetic modification is a single contiguous deletion of any size, resulting from cellular repair of one or

two targeted DNA breaks on a single chromosome or at the same location(s) on two or more homologous chromosomes, without insertion of DNA, or with insertion of DNA in the absence of a repair template, would qualify for exemption (proposed exemption 340.1(b)(4)(vi)(AM2)). As proposed, additional modifications to homoeologous loci of homoeologous chromosomes of allopolyploids would not qualify for this exemption.

Third, we propose to extend the modifications described in the exemptions found at § 340.1(b)(2) and (3) to all alleles of a genetic locus on the homologous chromosomes of autopolyploids (proposed exemption 340.1(b)(4)(vi)(AM3)). As proposed, additional modifications to homoeologous loci of homoeologous chromosomes of allopolyploids would not qualify for this exemption.

Fourth, we propose that plants with up to four modifications of a certain type, made simultaneously or sequentially, that individually qualify for exemption, and provided each modification is at a different genetic locus, would be exempt from regulation because such modifications are achievable through conventional breeding methods (proposed exemption 340.1(b)(4)(vi)(AM4)). Allopolyploid plants could contain up to four of the proposed loss of function modifications described herein or four modifications described under § 340.1(b)(2) and (3) or a combination thereof, provided each modification is introduced into just one allele; however, allopolyploid plants would not be exempt if they contain a modification that is allowable only in diploid and autopolyploid plants.

Fifth, we propose that plants that have previously completed voluntary reviews confirming the plants’ exempt status as described in § 340.1(e), which provides the process by which developers can request such a confirmation of exempt status, and that have been produced, grown, and observed consistent with conventional breeding methods appropriate for the plant species, could be successively modified in accordance with any exemption under § 340.1(b) of the regulations (proposed exemption 340.1(b)(4)(vi)(AM5)).

We are also making available for public review scientific literature that we considered prior to initiating this notice, which demonstrates that in polyploid plants (such as wheat, potato, tobacco, and canola), all alleles of a single genetic locus can be modified by conventional breeding to generate loss of function mutations. This notice provides scientific literature supporting

our rationale for why the proposed modifications could extend to any autopolyploid species and our rationale for why some of the proposed modifications could extend to any allopolyploid species. This notice includes examples of conventional breeding programs in sterile crops such as banana, long cycle crops such as forest trees, crops with complex genomes such as strawberry and sugarcane, and highly heterozygous crops such as potato and apple. This notice discusses literature describing the approach of pyramiding genes (*i.e.*, the simultaneous selection for and/or introduction of multiple genes during plant breeding) to create multiplex edits and provide examples in soybean, coffee, tobacco, tomato, potato, corn, and rice where four to seven traits are pyramided by conventional breeding methods. We also provide references to literature describing how homozygous autopolyploids can be created through conventional breeding methods in autopolyploid plants that are not applicable to allopolyploids plants. We also explain how the categories for loss of function modifications, and successive modifications for plants that have completed the voluntary confirmation process and that have been produced, grown, and observed are consistent with conventional breeding methods for the appropriate plant species. This action would reduce the regulatory burden for developers of certain plants modified using genetic engineering that are not expected to pose plant pest risks greater than the plant pest risks posed by plants modified by conventional breeding methods and, thus, should not be subjected to regulation under part 340.

First Proposed Exemption

Commenters to the previous July 2021 notice suggested that we “establish a single exemption category for indel modifications resulting from modifications to the alleles of a single gene on homologous chromosomes.” We recognize that as new tools emerge, there may be DNA modifications that are not expressly covered by the three exemptions described in the July 2021 notice. For example, base editing and prime editing involve nicking a single strand rather than making double strand breaks. In the case of base editing, a deaminase further modifies the DNA before the changes are resolved by natural repair. In prime editing, prime-editing guide RNA contains an internal template and further uses reverse transcriptase to incorporate the edit. When base editing is used to introduce a loss of function (“LOF”) mutation to

a single genetic locus, multiple changes may occur within the single genetic locus. The fact that multiple changes occur is irrelevant if one or more of the changes leads to a loss of function. Both base-editing and prime-editing can be used to make modifications that conform to the spirit of the modifications codified in § 340.1(b)(1) that are exempt from regulation, but they are not expressly described in the modifications. Creating a category for any DNA modification that leads to LOF of a single gene on homologous chromosomes would cover scenarios we did not specifically describe that are nevertheless consistent with our intent for modifications that would qualify for exemption in § 340.1(b)(1) because they are achievable through conventional breeding methods.

Accordingly, in this notice, we propose that diploid or autopolyploid plants with any combination of loss of function modifications in one to all alleles of a single genetic locus, or allopolyploid plants with any combination of loss of function modifications in one or both alleles of a single genetic locus on up to four homoeologous chromosomes, without the insertion of exogenous DNA, would be exempt from regulation. In the comment period for the previous notice, several papers were brought to our attention describing the successful breeding of tetraploid (AABB genomes) and hexaploid (AABBDD genomes) wheat lines with loss of function alleles for all four or six homoeologous alleles, respectively. In one case,² homologous null mutations in starch synthase from both the A and B genomes were isolated from the M2 generation of ethyl methanesulfonate (EMS) mutagenized tetraploid wheat lines. Both null mutants were crossed to generate the null lacking all 4-functioning starch synthase alleles. In a second case,³ the exomes of 2735 EMS mutagenized lines were sequenced, and more than 10 million mutations were identified covering about 90 percent of the three wheat genomes. The authors explained how loss of function homozygous mutants could be successfully isolated

from both genomes in the third generation of tetraploid wheat and homozygous mutants across all three genomes in the fourth generation of a hexaploid wheat. The literature contains several additional cases of double and triple null mutants successfully created by conventional breeding (naturally occurring transposon induced mutation/ems mutagenesis, tilling, and marker assisted breeding) in the polyploids, wheat, tobacco, potato and canola.⁴ The combination of mutagenesis and exome-sequencing described by Krasileva et al. 2017, has also been applied in tetraploid tobacco.⁵ Based on these examples, it appears this methodology can be used to create the modifications captured by the exemption in any species that can be bred conventionally. Breeding programs exist for crops that are challenging to breed, such as the largely sterile triploid bananas,⁶ forest trees with long generation times,⁷ and crops with complex genomes such as strawberry⁸ and sugarcane,⁹ or highly heterozygous

genomes such as potato¹⁰ or apple.¹¹ We propose that any diploid or autopolyploid plant that contains any combination of loss of function modifications in one to all alleles of a single genetic locus without the insertion of exogenous DNA, or any allopolyploid plant with any combination of loss of function modifications in one or both alleles of a single genetic locus on up to four homoeologous chromosomes, would qualify for exemption because such modifications are achievable through conventional breeding methods. The limitation to four homoeologous chromosomes in polyploid plants is explained further below.

Modifications resulting from insertions of exogenous DNA do not currently qualify for exemption and, likewise, LOF mutations created through insertion of exogenous DNA such as T-DNA (the transferred DNA of the (Ti) plasmid of *Agrobacterium* used in the transformation of plant cells) or transposons (DNA sequences that can move and integrate to different locations within the genome), would not qualify for exemption as proposed. LOF mutations could qualify for more than one exemption. For example, LOF mutations may still qualify for exemption § 340.1(b)(3), if they are already known to occur in the gene pool of the plant species.

By loss of function, we mean a mutation in which the altered gene product prevents the normal gene product from being produced or renders it inactive.¹² By gain of function (GOF) mutation, we mean a mutation that alters the properties of the protein product so that it has novel properties or has greater activity because a regulatory site has been lost¹³ and is

⁴ Pearce, S., L.M. Shaw, H. Lin, J.D. Cotter, C. Li and J. Dubcovsky (2017). "Night-Break Experiments Shed Light on the Photoperiod1-Mediated Flowering." *Plant Physiology* 174(2): 1139–1150; Karunaratna, N.L., H. Wang, H.-J. Harloff, L. Jiang and C. Jung (2020). "Elevating seed oil content in a polyploid crop by induced mutations in SEED FATTY ACID REDUCER genes." *Plant Biotechnology Journal* 18(11): 2251–2266; Kippes, N., Chen, A., Zhang, X., Lukaszewski, A.J., and Dubcovsky, J. (2016). Development and characterization of a spring hexaploid wheat line with no functional VRN2 genes. *Theor Appl Genet* 129, 1417–1428. Lewis, R.S., Lopez, H.O., Bowen, SW, Andres, K.R., Steede, W.T., and Dewey, R.E. (2015). Transgenic and Mutation-Based Suppression of a Berberine Bridge Enzyme-Like (BBL) Gene Family Reduces Alkaloid Content in Field-Grown Tobacco. *PLOS ONE* 10, e0117273. Mccord, P., Zhang, L., and Brown, C. (2012). The Incidence and Effect on Total Tuber Carotenoids of a Recessive Zeaxanthin Epoxidase Allele (Zep1) in Yellow-fleshed Potatoes. *American Journal of Potato Research* 89, 262–268.

⁵ Udagawa, H., Ichida, H., Takeuchi, T., Abe, T., and Takakura, Y. (2021). Highly Efficient and Comprehensive Identification of Ethyl Methanesulfonate-Induced Mutations in *Nicotiana tabacum* L. by Whole-Genome and Whole-Exome Sequencing. *Front Plant Sci* 12, 671598.

⁶ Jenny, C., Tomekpe, K., Bakry, F., and Escalent, J.V. (2002). "Conventional Breeding of Bananas", in: *Mycosphaerella leaf spot diseases of bananas: present status and outlook*. (eds.) L. Jacome, P. Lepoivre, D. Marin, R. Ortiz, R. Romero & J.V. Escalent. (San Jose Costa Rica: INIBAP).

⁷ Harfouche, A., Meilan, R., Kirst, M., Morgante, M., Boerjan, W., Sabatti, M., and Scarascia Mugnozza, G. (2012). Accelerating the domestication of forest trees in a changing world. *Trends in Plant Science* 17, 64–72.

⁸ Hummer, K.E., and Hancock, J. (2009). Strawberry genomics: botanical history, cultivation, traditional breeding, and new technologies. *Genetics and genomics of Rosaceae*, 413–435.

⁹ Kumar, U., Priyanka, and Kumar, S. (2016). "Genetic Improvement of Sugarcane Through Conventional and Molecular Approaches", 325–342.

¹⁰ Bonierbale, M.W., Amoroso, W.R., Salas, E., and De Jong, W. (2020). "Potato Breeding", in *The Potato Crop: Its Agricultural, Nutritional and Social Contribution to Humankind*, eds. H. Campos & O. Ortiz. (Cham: Springer International Publishing), 163–217; Bethke, P.C., Halterman, D.A., Francis, D.M., Jiang, J., Douches, D.S., Charkowski, A.O., and Parsons, J. (2022). Diploid Potatoes as a Catalyst for Change in the Potato Industry. *American Journal of Potato Research* 99, 337–357.

¹¹ Sedov, E.N. (2014). Apple breeding programs and methods, their development and improvement. *Russian Journal of Genetics: Applied Research* 4, 43–51.

¹² King, R., Stansfield, W., & Mulligan, P. (2007). loss of function mutation. In *A Dictionary of Genetics*. Oxford University Press. Retrieved 6 Jun. 2023, from <https://www.oxfordreference.com/view/10.1093/acref/9780195307610.001.0001/acref-9780195307610-e-3651>.

¹³ Lackie, J. gain-of-function mutation. In Nation, B. (Ed.), *A Dictionary of Biomedicine*. Oxford University Press. Retrieved 6 Jun. 2023, from <https://www.oxfordreference.com/view/10.1093/acref/9780191829116.001.0001/acref-9780191829116-e-3735>.

² Li, S., X. Zhong, X. Zhang, M. M. Rahman, J. Lan, H. Tang, P. Qi, J. Ma, J. Wang, G. Chen, X. Lan, M. Deng, Z. Li, W. Harwood, Z. Lu, Y. Wei, Y. Zheng and Q. Jiang (2020). "Production of waxy tetraploid wheat (*Triticum turgidum durum* L.) by EMS mutagenesis." *Genetic Resources and Crop Evolution* 67(2): 433–443).

³ Krasileva, K. V., H. A. Vasquez-Gross, T. Howell, P. Bailey, F. Paraiso, L. Clissold, J. Simmonds, R. H. Ramirez-Gonzalez, X. Wang, P. Borrill, C. Fosker, S. Ayling, A. L. Phillips, C. Uauy and J. Dubcovsky (2017). "Uncovering hidden variation in polyploid wheat." *Proc Natl Acad Sci U S A* 114(6): E913–e921).

usually dominant, semidominant, or codominant. In some cases, a mutation can render a protein to be non-functioning but lead to a new phenotype. For example, mutations that knockout the repressor protein CLV3 (CLAVATA 3) result in larger sized fruit.¹⁴ These mutations are a LOF modification that would qualify for exemption. In cases where a deletion or frameshift mutation leads to a new molecular function or increased expression of the altered gene product, the modification would not qualify for the new exemption. For example, a codon deletion in protoporphyrinogen oxidase conferred resistance to PPO type herbicide inhibitors.¹⁵ This deletion results in a protein with a new molecular function, is dominant, and does not lack the molecular function of the wild type (it is still able to convert protoporphyrinogen IX to protoporphyrin IX). This particular example is a naturally occurring mutation described in *Amaranthus tuberculatus*. If genome editing were used to confer herbicide tolerance to a crop plant by deleting the corresponding codon by DNA break and repair, the modified plant would likely qualify for the exemption found at § 340.1(b)(1). Thus, although GOF mutations will not qualify for the proposed exemption 340.1(b)(4)(vi)(AM4) as listed in the above-mentioned exemptions-confirmations website, there are some GOF mutations that could meet the criteria for exemptions at § 340.1(b)(1) through (3). For example, promoter deletions can result in either LOF or GOF. If a promoter deletion eliminates or greatly decreases expression of the downstream gene, that would be a LOF modification and would qualify for this exemption or the § 340.1(b)(1) exemption. If the promoter deletion results in an increase of expression of the downstream gene, that would be a GOF modification and it would not

qualify for this exemption but would qualify for the § 340.1(b)(1) exemption. In any plant, GOF modifications from faulty DNA repair qualify under exemptions § 340.1(b)(1) for a DNA break on a single chromosome or at the same location on two homologous chromosomes. In addition, GOF modifications from faulty repair could qualify for exemption under 340.1(b)(4)(vi) AM2 for one or two DNA breaks to the same location in the absence of an external template on all homologous chromosomes in autopolyploids (see below). In short, our proposal does not extend to all modifications that involve the insertion or deletion of bases (“indel”) because GOF modifications are statistically less common than LOF mutations and the same GOF mutation would not be expected to occur across multiple alleles in allopolyploids by conventional breeding.

We welcome comments from the public on the scope of this proposed exemption.

Second Proposed Exemption

In the published notice of July 2021, we proposed that plants with a modification that results in a single contiguous deletion of any size using an external repair template or using two targeted DNA breaks on a single chromosome would be exempt from regulation because they are achievable through conventional breeding methods. This type of modification allows deletions to contain more than one genetic locus. Based on the comments and information we received in response to the July 2021 notice, we are clarifying how the contiguous deletion of any size would apply to polyploids. Based on examples and methods described above, we propose that any diploid or autopolyploid plant with a genetic modification that is a single contiguous deletion of any size, resulting from cellular repair of one or two targeted DNA breaks on a single chromosome or at the corresponding location(s) on two or more homologous chromosomes, without insertion of DNA, or with the insertion of DNA in the absence of a repair template, would be exempt because these modifications are achievable through conventional breeding methods. This proposed modification allows for multiple modifications in autopolyploids, but not allopolyploids. This is because the literature indicates this type of modification can be achieved through conventional breeding in autopolyploids to produce the same deletion throughout the genome. For example, though potato is highly

heterozygous, a highly homozygous line was established from a doubled monoploid derived by another culture of a heterozygous diploid¹⁶ and this line in turn was used to create homozygous tetraploid lines by another round of whole genome doubling.¹⁷ In this way, conventional breeding was used to produce homozygous autopolyploids from allele variants in the haploid genome. Additionally, through random assortment of homologous chromosomes in autopolyploids, it is possible to achieve homozygosity of a modification across all chromosomes, while maintaining a high degree of heterozygosity across a genome, particularly when double reduction progeny are selected.¹⁸ Based on our review of the literature, we believe that this type of modification is not possible through conventional breeding methods for allopolyploids, which is why the proposed modification applies only to autopolyploids.

Third Proposed Exemption

We propose to extend the modifications described in § 340.1(b)(2) and (3) to all alleles of a genetic locus on the homologous chromosomes of autopolyploids. This would allow the following modifications to all alleles of a single gene on all homologous chromosomes in autopolyploids:

¹⁶ Xu, X., Pan, S., Cheng, S., Zhang, B., Mu, D., Ni, P., Zhang, G., Yang, S., Li, R., Orjeda, G., Guzman, F., Torres, M., Lozano, R., Ponce, O., Martinez, D., De La Cruz, G., Chakrabarti, S.K., Patil, V.U., Skryabin, K.G., Kuznetsov, B.B., Ravin, N.V., Kolganova, T.V., Beletsky, A.V., Mardanov, A.V., Di Genova, A., Bolser, D.M., Martin, D.M.A., Li, G., Yang, Y., Kuang, H., Hu, Q., Xiong, X., Bishop, G.J., Sagredo, B., Mejía, N., Zagorski, W., Gromadka, R., Gawor, J., Szczesny, P., Huang, S., Zhang, Z., Liang, C., He, J., Li, Y., He, Y., Xu, J., Zhang, Y., Xie, B., Du, Y., Qu, D., Bonierbale, M., Ghislain, M., Del Rosario Herrera, M., Giuliano, G., Pietrella, M., Perrotta, G., Facella, P., O'Brien, K., Feingold, S.E., Barreiro, L.E., Massa, G.A., Diambra, L., Whitty, B.R., Vaillancourt, B., Lin, H., Massa, A.N., Geoffroy, M., Lundback, S., Dellapenna, D., Robin Buell, C., Sharma, S.K., Marshall, D.F., Waugh, R., Bryan, G.J., Destefanis, M., Nagy, I., Milbourne, D., Thomson, S.J., Fiers, M., Jacobs, J.M.E., Nielsen, K.L., Sønderkær, M., Iovene, M., Torres, G.A., Jiang, J., Veilleux, R.E., Bachem, C.W.B., De Boer, J., Borm, T., Kloosterman, B., Van Eck, H., Datema, E., Te Lintel Hekkert, B., Goverse, A., Van Ham, R.C.H.J., Visser, R.G.F., The Potato Genome Sequencing, C., The Potato Genome, C., Shenzhen, B.G.I., et al. (2011). Genome sequence and analysis of the tuber crop potato. *Nature* 475, 189–195.

¹⁷ Guo, H., Zhou, M., Zhang, G., He, L., Yan, C., Wan, M., Hu, J., He, W., Zeng, D., Zhu, B., and Zeng, Z. (2023). Development of homozygous tetraploid potato and whole genome doubling-induced the enrichment of H3K27ac and potentially enhanced resistance to cold-induced sweetening in tubers. *Horticulture Research* 10.

¹⁸ Bourke, P.M., Voorrips, R.E., Visser, R.G., and Maliepaard, C. (2015). The Double-Reduction Landscape in Tetraploid Potato as Revealed by a High-Density Linkage Map. *Genetics* 201, 853–863.

¹⁴ Rodríguez-Leal, D., Lemmon, Z.H., Man, J., Bartlett, M.E., and Lippman, Z.B. (2017). Engineering Quantitative Trait Variation for Crop Improvement by Genome Editing. *Cell* 171, 470–480.e478.

Rönspies, M., Schindele, P., and Puchta, H. (2021). CRISPR/Cas-mediated chromosome engineering: opening up a new avenue for plant breeding. *J Exp Bot* 72, 177–183. Xu, C., Liberatore, K.L., Macalister, C.A., Huang, Z., Chu, Y.-H., Jiang, K., Brooks, C., Ogawa-Ohnishi, M., Xiong, G., Pauly, M., Van Eck, J., Matsubayashi, Y., Van Der Knaap, E., and Lippman, Z.B. (2015). A cascade of arabinosyltransferases controls shoot meristem size in tomato. *Nature Genetics* 47, 784–792.

¹⁵ Patzoldt, W.L., Hager, A.G., McCormick, J.S., and Tranel, P.J. (2006). A codon deletion confers resistance to herbicides inhibiting protoporphyrinogen oxidase. *Proceedings of the National Academy of Sciences* 103, 12329–12334.

- a targeted single base pair substitution, or
- introduction of a gene known to occur in the plant's gene pool or make changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.

For the reasons discussed above, the modifications described in § 340.1(b)(2) and (3) would only extend to all loci on the homologous chromosomes in autopolyploids plants and not to all homoeologous loci in allopolyploids plants.

Fourth Proposed Exemption

We have received several comments that multiplexing genome edits that individually qualify for exemption should qualify for exemption when achieved simultaneously or sequentially because conventional breeding allows the combination of multiple desired traits. In the 2020 preamble, APHIS noted, “[i]nitially, the exemptions will apply only to plants containing a single targeted modification in one of the categories listed. APHIS anticipates scientific information and/or experience may, over time, allow APHIS to list additional modifications that plants can contain and still be exempted from the regulations so that the regulatory system stays up to date and keeps pace with advances in scientific knowledge, evidence, and experience. This may include multiple simultaneous genomic changes.” 85 FR 29790, 29794. We have verified that there is literature on this topic, including literature describing gene pyramiding.¹⁹ One commenter provided us with a patent for a tobacco plant made homozygous in five separate loci through conventional breeding.²⁰

¹⁹ Majhi, P. (2020). “GENE PYRAMIDING.”, 3–16; Chapagain, S., Pruthi, R., and Subudhi, P.K. (2023). Pyramiding QTLs using multiparental advanced generation introgression lines enhances salinity tolerance in rice. *Acta Physiologiae Plantarum* 45, 59.; Dormatey, R., Sun, C., Ali, K., Coulter, J.A., Bi, Z., and Bai, J. (2020). Gene Pyramiding for Sustainable Crop Improvement against Biotic and Abiotic Stresses. *Agronomy* 10, 1255.; Malav, A.K., Indu, and Chandrawat, K.S. (2016). Gene Pyramiding: An Overview. *International Journal of Current Research in Biosciences and Plant Biology* 3, 22–28; Muthurajan, R., and Balasubramanian, P. (2009). “Pyramiding Genes for Enhancing Tolerance to Abiotic and Biotic Stresses,” in *Molecular Techniques in Crop Improvement: 2nd Edition*, eds. S.M. Jain & D.S. Brar. (Dordrecht: Springer Netherlands), 163–184; Servin, B., Martin, O., Mezard, M., and Hospital, F. (2004). Toward a Theory of Marker-Assisted Gene Pyramiding. *Genetics* 168, 513–523.

²⁰ Lewis, R.S., Dewey, R.E., and Tamburrino, J.S. (2023). US Patent Application for GENETIC APPROACH FOR ACHIEVING ULTRA LOW NICOTINE CONTENT IN TOBACCO Patent Application (#20230029171 issued January 26, 2023)—Justia Patents Search.

Additionally, we observed cases where four to seven traits were combined in soybean,²¹ potato,²² coffee,²³ corn,²⁴ tomato,²⁵ and rice²⁶ suggesting that pyramiding genes is becoming a standard practice in conventional breeding and four traits are conservatively within the norm. The examples provided include four different diploid species, an autopolyploid species (potato), an allopolyploid species (coffee), which is also a tree, suggesting that gene pyramiding is widely applicable to crop plants. When discussing the first proposed exemption, we noted new techniques that created DNA modifications using chemical mutagenesis while characterizing the genome using molecular analysis both of which are applicable to any species. We also provide examples of crops that have active breeding programs even though they are challenging to breed. Based on feedback during the comment period of the 2021 notice and our own review of the literature, it is our current view that a single targeted modification is more conservative than what can be achieved by conventional breeding in all species.

Accordingly, we propose that plants with up to four modifications of a certain type that individually qualify for exemption and that are made simultaneously or sequentially would be exempt from regulation, provided that that each modification is at a different genetic locus. This is because

²¹ Singh, Y., Shrivastava, M., and Banerjee, J. (2021). “Chapter –3 Gene Pyramiding in Soybean.”.

²² Rogozina, E.V., Beketova, M.P., Muratova, O.A., Kuznetsova, M.A., and Khavkin, E.E. (2021). Stacking Resistance Genes in Multiparental Interspecific Potato Hybrids to Anticipate Late Blight Outbreaks. *Agronomy* 11, 115.

²³ Saavedra, L.M., Caixeta, E.T., Barka, G.D., Borém, A., Zambolim, L., Nascimento, M., Cruz, C.D., Oliveira, A.C.B.D., and Pereira, A.A. (2023). Marker-Assisted Recurrent Selection for Pyramiding Leaf Rust and Coffee Berry Disease Resistance Alleles in *Coffea arabica* L. *Genes* 14, 189.

²⁴ Zambrano, J.L., Jones, M.W., Brenner, E., Francis, D.M., Tomas, A., and Redinbaugh, M.G. (2014). Genetic analysis of resistance to six virus diseases in a multiple virus-resistant maize inbred line. *Theoretical and Applied Genetics* 127, 867–880.

²⁵ Hanson, P., Lu, S.-F., Wang, J.-F., Chen, W., Kenyon, L., Tan, C.-W., Tee, K.L., Wang, Y.-Y., Hsu, Y.-C., Schafleitner, R., Ledesma, D., and Yang, R.-Y. (2016). Conventional and molecular marker-assisted selection and pyramiding of genes for multiple disease resistance in tomato. *Scientia Horticulturae* 201, 346–354.

²⁶ Ramalingam, J., Raveendra, C., Savitha, P., Vidya, V., Chaithra, T.L., Velprabakaran, S., Saraswathi, R., Ramanathan, A., Arumugam Pillai, M.P., Arumugachamy, S., and Vanniarajan, C. (2020). Gene Pyramiding for Achieving Enhanced Resistance to Bacterial Blight, Blast, and Sheath Blight Diseases in Rice. *Frontiers in Plant Science* 11.

such modifications are achievable through conventional breeding methods. For the reasons discussed above, allopolyploid plants could contain up to four of the proposed loss of function modifications described herein. Allopolyploid plants would also qualify for exemption with the following changes to a single pair of homologous chromosomes:

- § 340.1(b)(2)—a genetic modification is a targeted single base pair substitution; and
- § 340.1(b)(3)—the introduction of a gene known to occur in the plant's gene pool or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.

We propose that up to four such modifications would qualify for exemption in allopolyploids provided that each change is heterozygous. We note that the introduction of multiple dominant resistance traits has been accomplished by conventional breeding in both allopolyploid coffee (see footnote 23) and autopolyploid potato (see footnote 22). However, we are not aware of multiple homologous traits pyramided in allopolyploids.

Modifications would be counted based on loci modified. For an autopolyploid, such as potato, which has four alleles of the same genetic locus, a change to make four homozygous copies of an allele would count as one multiplex modification. However, in an allopolyploid, such as canola, which has two pairs of homoeologous chromosomes, LOF edits to all alleles (two loci and four alleles) would count as two multiplex modifications. We welcome comments from the public on the number of individual modifications that are achievable simultaneously or sequentially in plants based on conventional breeding methods, and comments on the reasons for or against allowing for simultaneous or sequential modifications in all plants. We emphasize that multiplexed or sequential modifications must be made to distinct loci; multiple modifications to a single gene would not qualify for exemption except in the cases where the gene is known to occur in the plant's gene pool.

Fifth Proposed Exemption

We have also received questions on whether a modified plant that meets the criteria for exemption from the regulations at part 340, may undergo successive or further modification. In the preamble that accompanied the final rule, we noted that we would address

the possibility for sequential modification (*i.e.*, subsequent or further modification to an exempt plant) in a future notice using the process described in § 340.1(b)(4). In conventional breeding, it is standard practice to introduce new traits through successive crosses. Conventional breeding affords the opportunity to evaluate and select the progeny of a cross that will be advanced in the breeding program. Along these lines, we

propose that plants that have previously completed the voluntary confirmation process (also called the “CR” process) found at § 340.1(e) and that have been produced, grown, and observed consistent with conventional breeding methods for the appropriate plant species, may be successively modified in accordance with the exemptions because allowing for such successive modification is consistent with plant development in conventional breeding

programs. Plants that are merely hypothetical in nature would not be eligible for subsequent hypothetical modifications because they have not yet been produced, grown, and observed consistent with conventional breeding methods for the appropriate plant species.

The following table summarizes the proposed exemptions and their applicability to polyploids:

TABLE 1—SUMMARY OF PROPOSED EXEMPTION CHANGES AND APPLICABILITY TO POLYPLOIDS.

Notes	Designation	Exemption	Diploids	Autoploids	Allopolyploids	GOF
	§ 340.1(b)(1)	The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template.	1 pair of homologous chromosomes			Yes.
	§ 340.1(b)(2)	The genetic modification is a targeted single base pair substitution.	1 pair of homologous chromosomes			Yes.
	§ 340.1(b)(3)	The genetic modification introduces a gene known to occur in the plant's gene pool or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.	1 pair of homologous chromosomes			Yes.
	340.1(b)(4)(vi)(AM1) on the exemptions-confirmations website.	Any diploid or autopolyploid plant that contains any combination of loss of function modifications in one to all alleles of a single genetic locus, or any allopolyploid plant with any combination or loss of function modification in one or both alleles of a single genetic locus on up to four pairs of homoeologous chromosomes, without the insertion of exogenous DNA.	All alleles of a single genetic locus on homologous chromosomes.	All alleles of a single genetic locus on homologous chromosomes.	Any combination of loss of function modifications in one or both alleles of a single genetic locus on up to four pairs of homoeologous chromosomes.	No.
Deletion of any size; one or two cuts; external repair template for deletion diploids and autopolyploids.	340.1(b)(4)(vi)(AM2) as listed in the exemptions-confirmations website.	A single contiguous deletion of any size, resulting from cellular repair of one or two targeted DNA breaks on a single chromosome or at the same location(s) on two or more homologous chromosomes, without insertion of DNA, or with insertion of DNA in the absence of a repair template.	Applicable	Applicable	Does not apply	Yes.

TABLE 1—SUMMARY OF PROPOSED EXEMPTION CHANGES AND APPLICABILITY TO POLYPOIDS.—Continued

Notes	Designation	Exemption	Diploids	Autoploids	Allopoloids	GOF
Expand § 340.1(b)(2) and (3) to auto-polyploids.	340.1(b)(4)(vi)(AM3) as listed in the exemptions-confirmations website.	The genetic modification is a targeted single base pair substitution or the genetic modification introduces a gene known to occur in the plant's gene pool or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.	Not relevant	Applicable	Does not apply	Yes.
Allow up to 4 multiplex or sequential modifications.	340.1(b)(4)(vi)(AM4) as listed in the exemptions-confirmations website.	Any combination of up to 4 multiplexed or sequentially made modifications provided that each edit is at a different genetic locus and would individually qualify for an existing exemption.	Applicable	Applicable	Applicable	For allopolyploids, multiple heterozygous modifications are Applicable.
Process for further modification of exempt plants.	340.1(b)(4)(vi)(AM5) in the exemptions-confirmations website.	Plants that have previously completed voluntary confirmation process and have been produced, grown, and observed consistent with conventional breeding methods for the appropriate plant species, could be further modified in accordance with the exemptions.	Applicable	Applicable	Applicable	For allopolyploids, multiple heterozygous modifications are applicable.

After reviewing any comments we receive, we will announce in a future notice our decision regarding any modifications that plants can contain and qualify for exemption.

Authority: 7 U.S.C. 7701–7772 and 7781–7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 7th day of November 2023.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2023–25122 Filed 11–14–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Forest Service

Black Hills National Forest Advisory Board

AGENCY: Forest Service, Agriculture USDA.

ACTION: Notice of meeting.

SUMMARY: The Black Hills National Forest Advisory Board will hold a public meeting according to the details shown below. The Board is authorized under the Forest and Rangeland Renewable Resources Planning Act of 1974, the National Forest Management Act of 1976, the Federal Lands Recreation Enhancement Act, and

operates in compliance with the Federal Advisory Committee Act (FACA). The purpose of the Board is to provide advice and recommendations on a broad range of forest issues such as forest plan revisions or amendments, forest health including fire, insect and disease, travel management, forest monitoring and evaluation, recreation fees, and site-specific projects having forest-wide implications.

DATES: An in-person meeting will be held on December 6, 2023, 1 p.m.–4:30 p.m. mountain standard time (MST).

Written and Oral Comments: Anyone wishing to provide in-person oral comments must pre-register by 11:59 p.m. MST on December 1, 2023. Written public comments will be accepted up to 11:59 p.m. MST on December 1, 2023. Comments submitted after this date will be provided to the Forest Service, but the Committee may not have adequate time to consider those comments prior to the meeting.

All board meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: This meeting will be held in person at the U.S. Forest Service Mystic Ranger District Office, 8221 Mount Rushmore Road, Rapid City, South Dakota 57702. Board information and meeting details can be found at the

following website: <https://www.fs.usda.gov/main/blackhills/workingtogether/advisorycommittees> or by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**.

Written Comments: Written comments must be sent by email to scott.j.jacobson@usda.gov or via mail (*i.e.*, postmarked) to Scott Jacobson, 8221 Mount Rushmore Road, Rapid City, South Dakota 57702. The Forest Service strongly prefers comments be submitted electronically.

Oral Comments: Persons or organizations wishing to make oral comments must pre-register by 11:59 p.m. MST, December 1, 2023, and speakers can only register for one speaking slot. Oral comments must be sent by email to scott.j.jacobson@usda.gov or via mail (*i.e.*, postmarked) to Scott Jacobson, 8221 Mount Rushmore Road, Rapid City, South Dakota 57702.

FOR FURTHER INFORMATION CONTACT: Ivan Green, Designated Federal Officer (DFO), by phone at 605–673–9201, or email at ivan.green@usda.gov or Scott Jacobson, Committee Coordinator, at 605–440–1409 or email at scott.j.jacobson@usda.gov.

SUPPLEMENTARY INFORMATION: The meeting agenda will include:

1. Off-Highway Vehicle (OHV) discussion;
2. Mitchell Lake discussion;

3. Forest Plan Revision update;
 4. New membership outreach update;
- and
5. Elect Vice-Chair.

The agenda will include time for individuals to make oral statements of three minutes or less. Individuals wishing to make an oral statement should make a request in writing at least three days prior to the meeting date to be scheduled on the agenda. Written comments may be submitted to the Forest Service up to 7 days after the meeting date listed under **DATES**.

Please contact the person listed under **FOR FURTHER INFORMATION CONTACT**, by or before the deadline, for all questions related to the meeting. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

Meeting Accommodations: The meeting location is compliant with the Americans with Disabilities Act, and the USDA provides reasonable accommodation to individuals with disabilities where appropriate. If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpretation, assistive listening devices, or other reasonable accommodation to the person listed under the **FOR FURTHER INFORMATION CONTACT** section or contact USDA's TARGET Center at (202) 720-2600 (voice and TTY) or USDA through the Federal Relay Service at (800) 877-8339. Additionally, program information may be made available in languages other than English.

USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Equal opportunity practices in accordance with USDA's policies will be followed in all appointments to the Board. To ensure that the recommendations of the Board have taken into account the needs of the diverse groups served by USDA, membership shall include to the extent possible, individuals with demonstrated ability to represent minorities, women, and persons with disabilities. USDA is

an equal opportunity provider, employer, and lender.

Dated: November 9, 2023.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2023-25235 Filed 11-14-23; 8:45 am]

BILLING CODE 3411-15-P

ARCHITECTURAL AND TRANSPORTATION BARRIERS COMPLIANCE BOARD

Privacy Act of 1974; System of Records

AGENCY: Architectural and Transportation Barriers Compliance Board.

ACTION: Notice; proposed new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, as amended, the Architectural and Transportation Barriers Compliance Board (Access Board or Board) gives notice of the establishment of a new Privacy Act System of Records, entitled, "USAB.002—Complaint Tracking System". This system of records covers records related to the investigation and adjudication of complaints filed with the agency alleging violations of the Architectural Barriers Act.

DATES: This Notice is effective on publication, with the exception of the routine uses. The routine uses will be effective 30 days after publication, unless comments are received that dictate otherwise. Written comments should be submitted December 15, 2023.

ADDRESSES: You may submit comments on this notice by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Email:* privacy@access-board.gov.
- *Mail:* Office of General Counsel, U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004-1111.

Instructions: All comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Wendy Marshall, Attorney-Advisor and Privacy Officer, (202) 272-0043, marshall@access-board.gov.

SUPPLEMENTARY INFORMATION: The Access Board is publishing this notice to inform the public of the creation of a new system of records relating to the investigation and adjudication of complaints filed with the agency alleging violations of the Architectural

Barriers Act of 1968 (ABA). The ABA requires that buildings or facilities that were constructed or altered by or on behalf of the United States, or leased or financed in whole or in part by the United States, after August 12, 1968, be accessible to individuals with disabilities. The Access Board enforces the ABA through the investigation of complaints filed by members of the public or federal employees. See 29 U.S.C. 792(b)(1). Complaints may be submitted by any person and may be filed anonymously. Once a complaint is filed, it is electronically entered into the agency's complaint tracking system and the Board investigates the complaint according to the procedures in 36 CFR part 1150. Complainants who choose to provide their contact information (name, phone number, email address, and/or physical mailing address), will be kept up to date on the status of the investigation and any corrective action taken by the agency or department in question. In the past, this information was not considered to be kept in a system of records, because while the contact information was contained within the complaint system, individual complaints were not pulled by an identifier related to the complainant. The Board recently updated to a new platform for this system and now believes it necessary to establish this system as a system of records, so that on occasion the compliance specialist can pull specific complaints by complainant name or email address. This will not change the processing of the complaint and complaints can still be filed anonymously or complainants can choose which personally identifying information to provide, such as just their name and email.

SYSTEM NAME:

USAB.002—Complaint Tracking System.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004.

SYSTEM MANAGER:

Senior Compliance Specialist, U.S. Access Board, 1331 F Street NW, Suite 1000, Washington, DC 20004.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

29 U.S.C. 792(b)(1); 42 U.S.C. 4151 *et seq.*; 36 CFR 1150; and 36 CFR 1191.

PURPOSE(S) OF THE SYSTEM:

This system of records supports the receipt and investigation of complaints alleging violations of the ABA, to

monitor the progress of any corrective action in response to such complaints, and to ensure the Access Board can communicate with complainants throughout the investigative process who choose to provide identifying information. Additionally, this record system tracks and reports the number of complaints received, the current status of active complaints, and the disposition of complaints. However, these reports do not include any personally identifiable information.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individuals covered by this system include any individual that chooses to file a complaint alleging a violation of the ABA with the Board and to provide personally identifiable information with that complaint.

CATEGORIES OF RECORDS IN THE SYSTEM:

Name, email address, physical address, and phone number of individual filing complaint; any additional information about the complainant, including potentially the nature of the individual's disability, provided by the complainant relating to the filing of the complaint; communications between the complainant and the compliance specialist regarding the complaint; communications between the compliance specialist and the agency in charge of the facility or building regarding the complaint and any corrective action to be taken.

RECORD SOURCE CATEGORIES:

Records in the system are obtained from individual members of the public or employees of federal agencies who file a complaint, agency officials from the Federal agency that manages the building or facility named in the complaint, and the compliance specialist who processes and investigates the complaint.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

The identity of the complainant may only be disclosed with written authorization, as required in 36 CFR 1150.12(b). The routine uses of the records maintained in the Complaint Tracking System include, in addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, disclosures outside the agency as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

1. Disclosure to a Federal Agency—To disclose information to a Federal agency for the purpose of investigation and informal or formal resolution of the

alleged violation of the ABA or if requested by another Federal agency pursuant to an administrative, civil, or criminal legal proceeding in which the Federal agency is a party.

2. Contractors, Experts, and Consultants—To contractors, experts, consultants, and the agents thereof, and others performing or working on a contract, service, cooperative agreement, or other assignment for the Access Board when necessary to accomplish an agency function. Individuals provided information under this routine use are subject to the same Privacy Act requirements and limitations on disclosure as Access Board employees.

3. Congressional Inquiries—A record from this system of records may be disclosed to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of the individual.

4. Law Enforcement—In the event that a system of records maintained by the Access Board to carry out its functions indicates a violation or potential violation of law, whether criminal, civil, or regulatory in nature, and whether arising by general statute or particular program pursuant thereto, the relevant records in the system of records may be disclosed to the appropriate agency, whether Federal, state, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto.

5. Disclosure in Litigation—A record from this system of records may be disclosed in a proceeding before a court or other adjudicative body in which the Access Board, an employee of the Access Board in his or her official capacity, or an employee of the Access Board in his or her individual capacity if the Access Board (or the Department of Justice ("DOJ")) has agreed to represent him or her is a party, or the United States or any other Federal agency is a party and the Access Board determines that it has an interest in the proceeding, if the Access Board determines that the record is relevant to the proceeding and that the use is compatible with the purpose for which the Access Board collected the information.

6. Disclosure to the Department of Justice in Litigation—When the Access Board, an employee of the Access Board in his or her official capacity, or an employee of the Access Board in his or her individual capacity whom the Access Board has agreed to represent is a party to a proceeding before a court or

other adjudicative body, or the United States or any other Federal agency is a party and the Access Board determines that it has an interest in the proceeding, a record from this system of records may be disclosed to the DOJ if the Access Board is consulting with the DOJ regarding the proceeding or has decided that the DOJ will represent the Access Board, or its interest, in the proceeding and the Access Board determines that the record is relevant to the proceeding and that the use is compatible with the purpose for which the Access Board collected the information.

7. Disclosure in Response to a Federal Data Breach—A record from this system of records may be disclosed to appropriate agencies, entities, and persons when (1) the Access Board suspects or has confirmed that there has been a breach of the system of records; (2) the Access Board has determined that, as a result of the suspected or confirmed breach, there is a risk of harm to individuals, the Board (including its information systems, operations, and programs), the Federal government or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Access Board's efforts to respond to the suspected or confirmed breach or to prevent, minimize, or remedy such harm.

8. Records Management—To the National Archives and Records Administration or to the General Services Administration for records management inspections conducted under 44 U.S.C. 2904 and 2906.

9. Assistance to Federal Agencies and Entities—To another Federal agency or Federal entity, when the Board determines that information from this system is reasonably necessary to assist the recipient agency or entity in: (a) Responding to a suspected or confirmed breach or (b) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, program, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system consist of electronic records. Electronic records are maintained within a restricted access system, namely the Board's Complaint Tracking System. Access is limited to the system owner(s) and other agency personnel who have an official need for access to perform their duties (e.g., contractor who manages the system and compliance staff). Access

Board policy requires new employees to read and acknowledge the rules of behavior applicable to all agency information technology systems (including appropriate protection and handling of personally identifiable information) before getting access to these systems and complete annual cybersecurity awareness training.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Records are routinely retrieved by Access Board complaint number or the name of the facility to which a complaint relates. Records can also be retrieved by a variety of other fields, including the name and/or email address of the complainant, while this is not the routine method of retrieval, it is available for use by the compliance specialist, when needed.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Electronic records are retained in accordance with the Access Board File Plan 500- Complaint Files, which prescribes a three-year retention period. For administrative program files, the retention period dates from file supersession. For these records, five years after the closure of the complaint the files are transferred to Washington National Records Center (WNRC). Ten years after closure, these records are eligible for destruction, electronic records are securely destroyed or erased using methods prescribed by the National Institute of Standards and Technology.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Access to system records is restricted to authorized Access Board personnel who are system owners or have an official need to access such records to perform their duties. Electronic records are stored in a restricted-access separate system. Access to electronic records is controlled by technical safeguards through assignment of system roles and permissions, secure log-ins, multi-factor authentication, time-out features, firewalls, and cybersecurity monitoring systems. Access Board policy also requires all emails, email strings, and attachments that contain sensitive personally identifiable information to be protected by encryption or password protection before transmission, absent express waiver from an agency privacy officer.

RECORD ACCESS PROCEDURES:

Individuals seeking access to, or notification of, any record contained in this system of records, or seeking to contest its content, may inquire in

writing in accordance with instructions appearing in the Access Board's Privacy Act Implementation rule, 36 CFR part 1121, which also appear on the Access Board's website at www.access-board.gov/privacy.

CONTESTING RECORD PROCEDURES:

See "Record Access Procedures," above.

NOTIFICATION PROCEDURE:

See "Record Access Procedures," above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Christopher Kuczynski,

Senior Agency Official for Privacy, General Counsel.

[FR Doc. 2023-25194 Filed 11-14-23; 8:45 am]

BILLING CODE 8150-01-P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of commission public briefing, *Racial Disparities in Violent Crime Victimization in the United States*, notice of commission business meeting, and call for public comments.

DATES: Friday, November 17, 2023, 9 a.m. ET.

ADDRESSES: The briefing is open to the public and can be attended via live stream on the Commission's YouTube page at: <https://www.youtube.com/usccr>.

FOR FURTHER INFORMATION CONTACT:

Angelia Rorison (202) 376-8359; publicaffairs@usccr.gov.

SUPPLEMENTARY INFORMATION: The U.S. Commission on Civil Rights will hold a briefing on November 17, 2023, on the federal government's response to anti-Asian racism in the United States. The Commission's investigation seeks to examine the federal government's role in documenting, prosecuting, and preventing hate crimes against persons of Asian descent.

This briefing is open to the public and is accessible via live stream at <https://www.youtube.com/usccr>. (* Streaming information subject to change.)

Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, November 17, 2023, is <https://www.streamtext.net/>

player?event=USCCR. Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

To request additional accommodations, persons with disabilities should email access@usccr.gov by Thursday, November 16, 2023, indicating "accommodations" in the subject line.

Briefing Agenda for the Federal Response to Anti-Asian Racism in the United States

9:00 a.m.–6:00 p.m. * All times Eastern Standard Time

I. Introductory Remarks: 9:00 a.m.–9:15 a.m.

II. *Panel 1:* Current & Former Government Officials: 9:15 a.m.–10:25 a.m.

III. Break: 10:25 a.m.–10:35 a.m.

IV. *Panel 2:* Community Stakeholders & Advocates: 10:35 a.m.–11:45 a.m.

V. Lunch Break: 11:45 a.m.–12:45 p.m.

VI. *Panel 3:* Impacted Persons: 12:45 p.m.–1:55 p.m.

VII. Break: 1:55 p.m.–2:05 p.m.

VIII. *Panel 4:* Researcher & Policy Experts: 2:05 p.m.–3:15 p.m.

IX. Break: 3:15 p.m.–4:25 p.m.

X. Open Public Comment Session: 4:25 p.m.–5:55 p.m.

XI. Closing Remarks: 5:55 p.m.–6:00 p.m.

VI. Adjourn Meeting

** Public Comments will also be accepted through written testimony.

* Schedule is subject to change.

Call for Public Comments

In addition to the testimony collected on Friday, November 17, 2023, via public briefing, the Commission welcomes the submission of material for consideration as we prepare our report. Please submit such information to victimsofcrime@usccr.gov no later than December 15, 2023, or by mail to OCRE/ Public Comments, ATTN: Anti-Asian Discrimination, U.S. Commission on Civil Rights, 1331 Pennsylvania Ave. NW, Suite 1150, Washington, DC 20425. The Commission encourages the use of email to provide public comments due to the current COVID-19 pandemic.

Dated: November 13, 2023.

Angelia Rorison,

USCCR Media and Communications Director.

[FR Doc. 2023-25320 Filed 11-13-23; 11:15 am]

BILLING CODE 6335-01-P

COMMISSION ON CIVIL RIGHTS**Notice of Public Briefing of the Commonwealth of the Northern Mariana Islands Advisory Committee to the U.S. Commission on Civil Rights****AGENCY:** Commission on Civil Rights.**ACTION:** Notice of public briefing.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Commonwealth of the Northern Mariana Islands Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public briefing via Zoom at 9:00 a.m. ChST on Wednesday, January 17, 2024 (6:00 p.m. ET on Tuesday, January 16, 2024). The purpose of the briefing is to collect additional testimony on healthcare in the CNMI judicial system.

DATES: Wednesday, January 17, 2024, 9:00 a.m.–11:00 a.m. Chamorro Standard Time (Tuesday, January 16, 2024, 6:00 p.m.–8:00 p.m. Eastern Time)

ADDRESSES: The meeting will be held via Zoom.

Registration Link (Audio/Visual):
<https://www.zoomgov.com/j/1611838906>.

Join by Phone (Audio Only): (833) 435–1820 USA Toll-Free; Meeting ID: 161 183 8906.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, Designated Federal Officer, at kfajota@usccr.gov or (434) 515–2395.

SUPPLEMENTARY INFORMATION: This committee meeting is available to the public through the registration link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Liliana Schiller, Support Services Specialist, at lschiller@usccr.gov at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the meeting. Written comments may be emailed to Kayla Fajota at kfajota@usccr.gov. Persons who desire additional information may contact the Regional Programs Coordination Unit at (312) 353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via www.facadatabase.gov under the Commission on Civil Rights, Commonwealth of the Northern Mariana Islands Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, <http://www.usccr.gov>, or may contact the Regional Programs Coordination Unit at lschiller@usccr.gov.

Agenda

- I. Welcome & Roll Call
- II. Introductory Remarks
- III. Panelist Presentations & Committee Q&A
- IV. Public Comment
- V. Closing Remarks
- VI. Adjournment

Dated: November 9, 2023.

David Mussatt,
Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–25226 Filed 11–14–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS**Sunshine Act Meeting; Commission on the Social Status of Black Men and Boys (CSSBMB)**

AGENCY: Commission on the Social Status of Black Men and Boys (CSSBMB), U.S. Commission on Civil Rights.

ACTION: Notice of CSSBMB public business meeting.

DATES: Friday, November 17, 2023, from 11:00 a.m.–12:00 p.m. EDT.

ADDRESSES: The briefing will take place virtually via YouTube: <https://www.youtube.com/user/USCCR/videos>.

FOR FURTHER INFORMATION CONTACT: Diamond Newman, 202–339–2371, dnewman@usccr.gov.

SUPPLEMENTARY INFORMATION: In accordance with Public Law 116–156, 1134 Stat. 700 (2020), the Commission on the Social Status of Black Men and Boys (CSSBMB) will hold its First

Quarter Business Meeting exploring CSSBMB business items, operations, and next steps.

This business meeting is open to the public via livestream on the Commission on Civil Rights' YouTube Page at <https://www.youtube.com/user/USCCR/videos>. (Streaming information subject to change.) Public participation is available for the event with view access, along with an audio option for listening. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, November 17 is <https://www.steamtext.net/player?event=USCCR> (*subject to change, please visit usccr.gov for updates). Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

* Date and meeting details are subject to change. For more information on the CSSBMB or the upcoming public briefing, please visit www.usccr.gov/CSSBMB and CSSBMB's Instagram, Facebook, and X.

Briefing Agenda

- I. Opening Remarks by CSSBMB Chair, Frederica S. Wilson
- II. Call to Order and Quorum
- III. Approval of Agenda
- IV. New Order of Business
- V. Adjourn Briefing

Dated: November 13, 2023.

Angelia Rorison,
Director of Media and Communications, United States Commission on Civil Rights.

[FR Doc. 2023–25321 Filed 11–13–23; 4:15 pm]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE**International Trade Administration****Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty**

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable November 15, 2023.

FOR FURTHER INFORMATION CONTACT: Jonathan Hall-Eastman, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Ave. NW, Washington, DC 20230, telephone: (202) 482–1468.

SUPPLEMENTARY INFORMATION: On August 15, 2023, the U.S. Department of Commerce (Commerce), pursuant to

section 702(h) of the Trade Agreements Act of 1979 (as amended) (the Act), published the quarterly update to the annual listing of foreign government subsidies on articles of cheese subject to an in-quota rate of duty covering the period January 1, 2023, through March 31, 2023.¹ In the *First Quarter 2023 Update*, we requested that any party that had information on foreign government subsidy programs that benefited articles of cheese subject to an in-quota rate of duty submit such information to Commerce.² We received no comments, information, or requests for consultation from any party.

Pursuant to section 702(h) of the Act, we hereby provide Commerce's update of subsidies on articles of cheese that were imported during the period April 1, 2023, through June 30, 2023. The appendix to this notice lists the country,

the subsidy program or programs, and the gross and net amounts of each subsidy for which information is currently available.

Commerce will incorporate additional programs which are found to constitute subsidies, and additional information on the subsidy programs listed, as the information is developed. Commerce encourages any person having information on foreign government subsidy programs which benefit articles of cheese subject to an in-quota rate of duty to submit such information in writing through the Federal eRulemaking Portal at <https://www.regulations.gov>, Docket No. ITA-2020-0005, "Quarterly Update to Cheese Subject to an In-Quota Rate of Duty." The materials in the docket will not be edited to remove identifying or contact information, and Commerce

cautions against including any information in an electronic submission that the submitter does not want publicly disclosed. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF formats only. All comments should be addressed to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

This determination and notice are in accordance with section 702(a) of the Act.

Dated: November 8, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

SUBSIDY PROGRAMS ON CHEESE SUBJECT TO AN IN-QUOTA RATE OF DUTY

Country	Program(s)	Gross ³ subsidy (\$/lb)	Net ⁴ subsidy(\$/lb)
27 European Union Member States ⁵	European Union Restitution Payments	\$ 0.00	\$0.00
Canada	Export Assistance on	0.47	0.47
	Certain Types of Cheese		
Norway	Indirect (Milk) Subsidy	0.00	0.00
	Consumer Subsidy	0.00	0.00
	Total	0.00	0.00
Switzerland	Deficiency Payments	0.00	0.00

[FR Doc. 2023-25202 Filed 11-14-23; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-570-970]

Multilayered Wood Flooring From the People's Republic of China: Notice of Court Decision Not in Harmony With the Results of Antidumping Administrative Review; Notice of Amended Final Results

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On October 30, 2023, the U.S. Court of International Trade (CIT) issued its final judgment in *American Manufacturers of Multilayered Wood*

Flooring v. United States, Court No. 20-03948, Slip Op. 23-70 (CIT May 5, 2023), sustaining the U.S. Department of Commerce (Commerce)'s remand results pertaining to the administrative review of the antidumping duty (AD) order on multilayered wood flooring (MLWF) from the People's Republic of China (China) covering the period of review (POR) December 1, 2017, through November 30, 2018. Commerce is notifying the public that the CIT's final judgment is not in harmony with Commerce's final results of the administrative review, and that Commerce is amending the final results with respect to the dumping margin assigned to Dalian Qianqiu Wooden Product Co., Ltd., Fusong Jinlong Wooden Group Co., Ltd., Fusong Jinqiu Wooden Product Co., Ltd., and Fusong Qianqiu Wooden Product Co., Ltd. (collectively, Jinlong); Jiangsu Guyu

International Trading Co., Ltd. (Guyu); and certain non-individually examined respondents.

DATES: Applicable November 9, 2023.

FOR FURTHER INFORMATION CONTACT: Alexis Cherry, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482-0607.

SUPPLEMENTARY INFORMATION:

Background

On December 3, 2020, Commerce published its *Final Results* in the 2017-2018 AD administrative review of MLWF from China.¹ Commerce determined that mandatory respondents Jinlong and Guyu did not make sales of MLWF from China at prices below normal value (NV) during the POR.²

¹ See *Quarterly Update to Annual Listing of Foreign Government Subsidies on Articles of Cheese Subject to an In-Quota Rate of Duty*, 88 FR 55438 (August 15, 2023) (*First Quarter 2023 Update*).

² *Id.*

³ Defined in 19 U.S.C. 1677(5).

⁴ Defined in 19 U.S.C. 1677(6).

⁵ The 27 member states of the European Union are: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, and Sweden.

¹ See *Multilayered Wood Flooring from the People's Republic of China: Final Results of Antidumping Duty Administrative Review and New Shipper Review and Final Determination of No Shipments*, 2017-2018, 85 FR 78118 (December 3, 2020) (*Final Results*), and accompanying Issues and Decision Memorandum (IDM).

² *Id.*

Thus, Commerce calculated an estimated weighted-average dumping margin and cash deposit rate (adjusted for subsidy offsets) of 0.00 percent for Jinlong and Guyu, which it applied to the non-individually-examined companies that were found to be eligible for a separate rate.³

The American Manufacturers of Multilayered Wood Flooring (the petitioner) appealed Commerce's *Final Results*. On May 5, 2023, the CIT remanded the *Final Results* to Commerce.⁴ In the *Remand Order*, the CIT directed Commerce to revise the surrogate manufacturing overhead (MOH) ratio calculation by including the entire amount of indirect production expenses stated in the surrogate financial statement in the numerator, or otherwise explain why it cannot do so.⁵ The CIT held that Commerce's determination of the MOH ratio was not supported by substantial evidence because: (1) limiting overhead expenses in the numerator to depreciation, other materials, and third party service expenses is unreasonable in light of the universe of expenses normally considered to make up overhead; and (2) Commerce's claim that using the indirect production expenses entry in the numerator of the MOH ratio may be distortive is a speculative conclusion.⁶ Additionally, the CIT remanded the *Final Results* to Commerce to reconsider its application of its Labor Rate Policy, which assumes 24 working days per month, 5.5 working days per week, and eight working hours per day, to calculate a surrogate hourly labor rate.⁷ If Commerce continued to use this policy, the CIT directed Commerce to explain: (1) the source for the assumptions; (2) why it is a reasonable basis on which to calculate the surrogate labor rate; and (3) how it is more specific to Romania than information provided by the petitioner.⁸

In its remand redetermination, issued on August 24, 2023, Commerce revised the surrogate MOH ratio, explained the assumptions underlying its Labor Rate Policy, and revised the surrogate hourly

labor rate.⁹ On October 30, 2023, the CIT sustained Commerce's final redetermination.¹⁰

Timken Notice

In its decision in *Timken*,¹¹ as clarified by *Diamond Sawblades*,¹² the U.S. Court of Appeals for the Federal Circuit held that, pursuant to section 516A(c) and (e) of the Tariff Act of 1930, as amended (the Act), Commerce must publish a notice of court decision that is not "in harmony" with a Commerce determination and must suspend liquidation of entries pending a "conclusive" court decision. The CIT's October 30, 2023, judgment constitutes a final decision of the CIT that is not in harmony with Commerce's *Final Results*. Thus, this notice is published in fulfillment of the publication requirements of *Timken*.

Amended Final Results

Because there is now a final court judgment, Commerce is amending its *Final Results* with respect to Jinlong, Guyu, and the non-individually-examined separate rate companies, as follows:

Exporter	Weighted-average dumping margin (percent)
Dalian Qianqiu Wooden Product Co., Ltd.; Fusong Jinlong Wooden Group Co., Ltd.; Fusong Jinqiu Wooden Product Co., Ltd.; and Fusong Qianqiu Wooden Product Co., Ltd. (collectively, Jinlong)	2.05
Jiangsu Guyu International Trading Co., Ltd	0.00
Non-Selected Companies Under Review Receiving a Separate Rate ¹³	¹⁴ 2.05

Cash Deposit Requirements

For seven separate rate respondents that do not have a superseding cash

deposit rate,¹⁵ Commerce will issue revised cash deposit instructions to U.S. Customs and Border Protection (CBP). Because Jinlong, Guyu, and the remaining separate rate respondents have a superseding cash deposit rate, *i.e.*, there have been final results published in a subsequent administrative review, we will not issue revised cash deposit instructions to CBP. This notice will not affect the current cash deposit rate for these companies.

Liquidation of Suspended Entries

At this time, Commerce remains enjoined by CIT order from liquidating entries that: were exported by Jinlong, Guyu, and the non-individually-examined separate rate respondents listed in the Appendix, and were entered, or withdrawn from warehouse, for consumption during the period December 1, 2017, through November 30, 2018. These entries will remain enjoined pursuant to the terms of the injunction during the pendency of any appeals process.

In the event the CIT's ruling is not appealed, or, if appealed, upheld by a final and conclusive court decision, Commerce intends to instruct CBP to assess antidumping duties on unliquidated entries of subject merchandise exported by Jinlong, Guyu, and the non-individually-examined separate rate respondents in accordance with 19 CFR 351.212(b), where appropriate. We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the weighted-average dumping margin or an importer-specific *ad valorem* assessment rate is not zero or *de minimis*. Where the weighted-average dumping margin or an importer-specific *ad valorem* assessment rate is zero or *de minimis*,¹⁶ we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Notification to Interested Parties

This notice is issued and published in accordance with sections 516A(c) and (e) and 777(i)(1) of the Act.

examined separate rate companies, consistent with the guidance provided in section 735(c)(5) of the Act.

¹⁵ These companies are Anhui Longhua Bamboo Product Co., Ltd.; Dalian Deerfu Wooden Product Co., Ltd.; Dalian Shengyu Science And Technology Development Co., Ltd.; Dunhua City Wanrong Wood Industry Co., Ltd.; Power Dekor Group Co., Ltd.; Yekalon Industry Inc.; and Zhejiang Shiyou Timber Co., Ltd.

¹⁶ See 19 CFR 351.106(c)(2).

³ *Id.*, 85 FR at 78119.

⁴ See *American Manufacturers of Multilayered Wood Flooring v. United States*, Court No. 20–03948, Slip Op. 23–70 (CIT May 5, 2023) (*Remand Order*).

⁵ *Id.* at 33.

⁶ See *Final Results* IDM at 17–20; see also *Remand Order* at 19–20.

⁷ See *Remand Order* at 33; see also *Antidumping Methodologies in Proceedings Involving Non-Market Economies: Valuing the Factor of Production: Labor*, 76 FR 36092, 36093 (June 21, 2011) (*Labor Rate Policy*).

⁸ See *Remand Order* at 33.

⁹ See *Final Results of Redetermination Pursuant to Court Remand, American Manufacturers of Multilayered Wood Flooring v. United States*, Court No. 20–3948, dated August 24, 2023 (*Final Remand*), available at <https://access.trade.gov/resources/remands/23-70.pdf>.

¹⁰ See *American Manufacturers of Multilayered Wood Flooring v. United States*, Court No. 20–03948, Slip Op. 23–156 (CIT October 30, 2023).

¹¹ See *Timken Co. v. United States*, 893 F.2d 337 (Fed. Cir. 1990) (*Timken*).

¹² See *Diamond Sawblades Manufacturers Coalition v. United States*, 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*).

¹³ See Appendix.

¹⁴ As the recalculated margin for Jinlong is the only margin that is not zero, *de minimis*, or determined entirely under section 776 of the Act, we assigned this margin to the non-individually-

Dated: November 8, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

Non-Individually Examined Companies Eligible for a Separate Rate

A&W (Shanghai) Woods Co., Ltd.
 Anhui Longhua Bamboo Product Co., Ltd.
 Benxi Wood Company
 Dalian Dajen Wood Co., Ltd.
 Dalian Deerfu Wooden Product Co., Ltd.
 Dalian Jiahong Wood Industry Co., Ltd.
 Dalian Kemian Wood Industry Co., Ltd.
 Dalian Penghong Floor Products Co., Ltd./
 Dalian Shumaike Floor Manufacturing Co., Ltd.
 Dalian Shengyu Science And Technology Development Co., Ltd.
 Dalian T-Boom Wood Products Co., Ltd.
 Dongtai Fuan Universal Dynamics, LLC
 Dunhua City Dexin Wood Industry Co., Ltd.
 Dunhua City Hongyuan Wood Industry Co., Ltd.
 Dunhua City Wanrong Wood Industry Co., Ltd.
 Dun Hua Sen Tai Wood Co., Ltd.
 Dunhua Shengda Wood Industry Co., Ltd.
 Guangzhou Panyu Southern Star Co., Ltd.
 HaiLin LinJing Wooden Products, Ltd.
 Hangzhou Hanje Tec Company Limited
 Hunchun Xingjia Wooden Flooring Inc.
 Huzhou Chenghang Wood Co., Ltd.
 Huzhou Fulinmen Imp. & Exp. Co., Ltd.
 Huzhou Sunergy World Trade Co., Ltd.
 Jiangsu Keri Wood Co., Ltd.
 Jiangsu Mingle Flooring Co., Ltd.
 Jiangsu Senmao Bamboo and Wood Industry Co., Ltd.
 Jiangsu Simba Flooring Co., Ltd.
 Jiashan HuiJiaLe Decoration Material Co., Ltd.
 Jiaxing Hengtong Wood Co., Ltd.
 Jilin Xinyuan Wooden Industry Co., Ltd.
 Karly Wood Product Limited
 Kember Flooring, Inc.
 Kemian Wood Industry (Kunshan) Co., Ltd.
 Lauzon Distinctive Hardwood Flooring, Inc.
 Linyi Youyou Wood Co., Ltd.
 Metropolitan Hardwood Floors, Inc.
 Mudanjiang Bosen Wood Industry Co., Ltd.
 Nakahiro Jyou Sei Furniture (Dalian) Co., Ltd.
 Omni Arbor Solution Co., Ltd.
 Pingte Timber Manufacturing (Zhejiang) Co., Ltd.
 Power Dekor Group Co., Ltd.
 Scholar Home (Shanghai) New Material Co., Ltd.
 Shenyang Haobainian Wooden Co., Ltd.
 Sino-Maple (Jiangsu) Co., Ltd.
 Suzhou Dongda Wood Co., Ltd.
 Tongxiang Jisheng Import and Export Co., Ltd.
 Xuzhou Shenghe Wood Co., Ltd.
 Yekalon Industry Inc.
 Yihua Lifestyle Technology Co., Ltd.
 (successor-in-interest to Guangdong Yihua Timber Industry Co., Ltd.)
 Zhejiang Dadongwu Green Home Wood Co., Ltd.
 Zhejiang Fuerjia Wooden Co., Ltd.
 Zhejiang Longsen Lumbering Co., Ltd.

Zhejiang Shiyou Timber Co., Ltd.

[FR Doc. 2023-25200 Filed 11-14-23; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Antidumping and Countervailing Duty Administrative Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) has received requests to conduct administrative reviews of various antidumping duty (AD) and countervailing duty (CVD) orders with September anniversary dates. In accordance with Commerce's regulations, we are initiating those administrative reviews.

DATES: Applicable November 15, 2023.

FOR FURTHER INFORMATION CONTACT:

Brenda E. Brown, AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482-4735.

SUPPLEMENTARY INFORMATION:

Background

Commerce has received timely requests, in accordance with 19 CFR 351.213(b), for administrative reviews of various AD and CVD orders with September anniversary dates.

All deadlines for the submission of various types of information, certifications, or comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting time.

Notice of No Sales

With respect to AD administrative reviews, if a producer or exporter named in this notice of initiation had no exports, sales, or entries during the period of review (POR), it must notify Commerce within 30 days of publication of this notice in the **Federal Register**. All submissions must be filed electronically at <https://access.trade.gov>, in accordance with 19 CFR 351.303.¹ Such submissions are subject to verification, in accordance with section 782(i) of the Tariff Act of 1930, as amended (the Act). Further, in accordance with 19 CFR 351.303(f)(1)(i),

¹ See *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures*, 76 FR 39263 (July 6, 2011).

a copy must be served on every party on Commerce's service list.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the POR. We intend to place the CBP data on the record within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Comments regarding the CBP data and respondent selection should be submitted within seven days after the placement of the CBP data on the record of this review. Parties wishing to submit rebuttal comments should submit those comments within five days after the deadline for the initial comments.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act, the following guidelines regarding collapsing of companies for purposes of respondent selection will apply. In general, Commerce has found that determinations concerning whether particular companies should be "collapsed" (e.g., treated as a single entity for purposes of calculating AD rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of the review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of the AD proceeding (e.g., investigation, administrative review, new shipper review, or changed circumstances review). For any company subject to the review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection.

Parties are requested to (a) identify which companies subject to review previously were collapsed, and (b) provide a citation to the proceeding in which they were collapsed. Further, if

companies are requested to complete the quantity and value (Q&V) questionnaire for purposes of respondent selection, in general, each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of the proceeding where Commerce considered collapsing that entity, complete Q&V data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that has requested a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of a particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.² Section 773(e) of the Act states that “if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.” When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a

PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial responses to section D of the questionnaire.

Separate Rates

In proceedings involving non-market economy (NME) countries, Commerce begins with a rebuttable presumption that all companies within the country are subject to government control and, thus, should be assigned a single AD deposit rate. It is Commerce’s policy to assign all exporters of merchandise subject to an administrative review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.

To establish whether a firm is sufficiently independent from government control of its export activities to be entitled to a separate rate, Commerce analyzes each entity exporting the subject merchandise. In accordance with the separate rates criteria, Commerce assigns separate rates to companies in NME cases only if respondents can demonstrate the absence of both *de jure* and *de facto* government control over export activities.

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. For these administrative reviews, in order to demonstrate separate rate eligibility, Commerce requires entities for whom a review was requested, that were assigned a separate rate in the most recent segment of this proceeding in which they participated, to certify that they continue to meet the criteria for obtaining a separate rate. The Separate Rate Certification form will be available on Commerce’s website at <https://access.trade.gov/Resources/nme/nme-sep-rate.html> on the date of publication of this **Federal Register** notice. In responding to the certification, please follow the “Instructions for Filing the Certification” in the Separate Rate Certification. Separate Rate Certifications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Certification applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers who purchase and export subject merchandise to the United States.

Entities that currently do not have a separate rate from a completed segment of the proceeding³ should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. In addition, companies that received a separate rate in a completed segment of the proceeding that have subsequently made changes, including, but not limited to, changes to corporate structure, acquisitions of new companies or facilities, or changes to their official company name,⁴ should timely file a Separate Rate Application to demonstrate eligibility for a separate rate in this proceeding. The Separate Rate Application will be available on Commerce’s website at <https://access.trade.gov/Resources/nme/nme-sep-rate.html> on the date of publication of this **Federal Register** notice. In responding to the Separate Rate Application, refer to the instructions contained in the application. Separate Rate Applications are due to Commerce no later than 30 calendar days after publication of this **Federal Register** notice. The deadline and requirement for submitting a Separate Rate Application applies equally to NME-owned firms, wholly foreign-owned firms, and foreign sellers that purchase and export subject merchandise to the United States.

Exporters and producers must file a timely Separate Rate Application or Certification if they want to be considered for individual examination. Furthermore, exporters and producers who submit a Separate Rate Application or Certification and subsequently are selected as mandatory respondents will no longer be eligible for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents.

Initiation of Reviews

In accordance with 19 CFR 351.221(c)(1)(i), we are initiating administrative reviews of the following AD and CVD orders and findings. We intend to issue the final results of these reviews not later than September 30, 2024.

³ Such entities include entities that have not participated in the proceeding, entities that were preliminarily granted a separate rate in any currently incomplete segment of the proceeding (e.g., an ongoing administrative review, new shipper review, etc.) and entities that lost their separate rate in the most recently completed segment of the proceeding in which they participated.

⁴ Only changes to the official company name, rather than trade names, need to be addressed via a Separate Rate Application. Information regarding new trade names may be submitted via a Separate Rate Certification.

² See Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

	Period to be reviewed
AD Proceedings	
India: Lined Paper Products, A-533-843	9/1/22-8/31/23
Cellpage Ventures Private Limited	
Dinakar Process Private Limited	
ITC Limited-Education and Stationery Products Business	
JC Stationery (P) Ltd	
Lotus Global Private Limited	
M/s. Bhaskar Paper Products	
Magic International Pvt. Ltd.	
Navneet Education Ltd.	
Pioneer Stationery Private Limited	
PP Bafna Ventures Private Limited	
SGM Paper Products	
India: Oil Country Tubular Goods, A-533-857	9/1/22-8/31/23
Surya Roshni Limited	
Mexico: Emulsion Styrene-Butadiene Rubber, A-201-848	9/1/22-8/31/23
Industrias Negromex, S.A. de C.V.	
Mexico: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes, A-201-847	9/1/22-8/31/23
Aceros del Toro S.A. de C.V.	
Aceros El Fraile S.A. de C.V.	
Arco Metal S.A. de C.V.	
Border Assembly S. de R.L. de C.V.	
Buffalo Tube S.A. de C.V.	
Fortacero S.A. de C.V.	
Forza Steel S.A. de C.V.	
Grupo Collado S.A. de C.V.	
Industrias Monterrey S.A. de C.V.	
Maquilacero S.A. de C.V.	
Perfiles y Herrajes L.M. S.A. de C.V.	
P.J. Trailers Company S.A. de C.V.	
Placa y Fierro de Monterrey S.A. de C.V.	
Productos Laminados de Monterrey S.A. de C.V.	
PYTCO S.A. de C.V.	
Regiomontana de Perfiles y Tubos S.A. de C.V.	
Ternium S.A. de C.V.	
Tuberia Nacional S.A. de C.V.	
Tuberias Procarsa S.A. de C.V.	
Republic of Korea: Cold-Rolled Steel Flat Products, A-580-881	9/1/22-8/31/23
Hyundai Steel Company	
KG Dongbu Steel Co., Ltd.	
POSCO; POSCO International Corporation	
Republic of Korea: Heavy Walled Rectangular Welded Carbon Pipes and Tubes, A-580-880	9/1/22-8/31/23
Dong-A Steel Co., Ltd.	
HiSteel Co., Ltd.	
NEXTEEL Co., Ltd.	
Republic of Korea: Oil Country Tubular Goods, A-580-870	9/1/22-8/31/23
AJU Besteel Co., Ltd.	
Husteel Co., Ltd.	
Hyundai Steel Company	
ILJIN Steel Corporation	
NEXTEEL Co., Ltd.	
SeAH Steel Corporation	
Socialist Republic of Vietnam: Oil Country Tubular Goods, A-552-817	9/1/22-8/31/23
Pusan Pipe America, Inc.	
SeAH Steel VINA Corporation	
Spain: Methionine, A-469-822	9/1/22-8/31/23
Adisseo Espana S.A.	
Taiwan: Forged Steel Fittings, A-583-863	9/1/22-8/31/23
Both-Well Steel Fittings, Co., Ltd.	
Taiwan: Narrow Woven Ribbons With Woven Selvedge, A-583-844	9/1/22-8/31/23
A-MADEUS TEXTILE LTD.	
A-MEN Ribbons Co., Ltd.	
Antonio Proietti Int. Inc.	
Apex Trimmings	
Banduoo Ltd.	
Bon-Mar Textiles	
Chang Store Co. Ltd	
Cheng Hsing Ribbon Factory	
Cheng Mei Label Mfg. Corp.	
Christmas Castle International Ltd.	
Dear Year Brothers Mfg. Co., Ltd	
Dearcobber International Co Ltd	
Ethel Enterprise Co., Ltd.; Glory Young Enterprise Co., Ltd.; King Young Enterprises Co., Ltd.	

	Period to be reviewed
Everwin Textile Corp. Fist Labeling Corp. Friend Chiu Co., Ltd. Fujian Rongshu Industry Co., Ltd. Golden State Industrial Co. Ltd. Great Texture Int'l Co., Ltd. Guangzhou Complacent Weaving Co., Ltd. Gyrostate Corp. Hao Shyang Ind. Co. Ltd. Hen Hao Trading Co. Ltd; Taiwan Tulip Ribbons and Braids Co. Ltd. Hsien Chan Enterprise Co., Ltd.; Novelty Handicrafts Co., Ltd.; Shienq Huong Enterprise Co., Ltd. Hubscher Ribbon Corp., Ltd.; Hubschercorp Imprimerie Mikan Inc. J.S. (Just Splendid) Co., Ltd. JCben Enterprises Co. Ltd. Junmay Label Mfg Corp. L'Emballage Tout Lace Fashions Industrial Co. Ltd. Linset Enterprises Co., Ltd. Lung Che Ribbons Enterprises Co. Ltd. Maple Ribbon Co., Ltd. Maxtend Industry Corporation May Favor Enterprise Co., Ltd Ming Wei Co., Ltd. Multicolor N.K. Galleria Inc. Nien Chow Industrial Co. Pansy Weaving Co/Ltd Papillon Ribbon & Bow (Canada) Papillon Ribbon & Bow (H.K.) Ltd. Papillon Ribbon & Bow (Shanghai) Ltd. Pearl Ribbons and Trims, Inc. Ren Her Industry Co. Ltd. Ribbon City Company Rong Shu Industry Corporation Rubans G A R Inc. (Les) Trio Co., Ltd Trydent Co. Ltd. Tse Tien Shin Enterprise Co Ltd Tsong Jiaw Enterprise Co., Ltd. Wing Hung (Tw) Co Ltd Xiamen Especial Industrial Co., Ltd. Xiamen Yi-He Textile Co., Ltd. Yanzhou Bepak Gifts & Crafts Co. Yih Jenq Textile Co. Ltd. Yu Shin Development Co. Ltd.	
Taiwan: Stainless Steel Wire Rod, A-583-828 Kuang Tai Metal Industrial Co., Ltd. Walsin Lihwa Corporation	9/1/22-8/31/23
The People's Republic of China: Certain Magnesite Carbon Bricks, A-570-954 Autong Industry Co., Ltd. Dandong Xinxing Carbon Co., Ltd. Fedmet Resources Corporation Fengchi Imp. and Exp. Co., Ltd. Fengchi Imp. and Exp. Co., Ltd. of Haicheng City Fengchi Mining Co., Ltd. of Haicheng City Fengchi Refractories Co., of Haicheng City FRC Global Inc. Haicheng Donghe Taidi Refractory Co., Ltd. Henan Xintuo Refractory Co., Ltd. Liaoning Fucheng Refractories Liaoning Zhongmei High Temperature Material Co., Ltd. Liaoning Zhongmei Holding Co., Ltd. Luoyang Dayang High-Performance Material Co., Ltd. PRCO America Inc. Puyang Refractories Co., Ltd. Puyang Refractories Group Co., Ltd. Qingdao Wonjin Special Refractory Material Co., Ltd. RHI Refractories Liaoning Co., Ltd. Shandong Minye Refractory Fibre Co., Ltd. Shanxi Xinrong International Trade Co., Ltd. Shenglong Refractories Co., Ltd. SL Refractories LLC	9/1/22-8/31/23

	Period to be reviewed
Tangshan Strong Refractories Co., Ltd. The Economic Trading Group Of Haicheng Houying Corp. Ltd. Thermstrong Corporation Tianjin New Century Refractories Co., Ltd. Wonjin Refractory Co., Ltd. Xinyi New Century Refractories Co., Ltd. Yingkou Baolong Industrial Co., Ltd. Yingkou Guangyang Refractories Co., Ltd. Yingkou Heping Samwha Minerals, Co., Ltd. Yingkou Heping Sanhua Materials Co., Ltd. Yingkou Hongyu Wonjin Refractory Material Co., Ltd. Yingkou Jiamei Refractories Co., Ltd. Yingkou Mei'ao Mining Product Co., Ltd. Zhengzhou Rongsheng Refractory Co., Ltd. Zibo Fubang Wonjin Refractory Technology Co., Ltd. Zibo Hengsen Refractory Co., Ltd. Zibo Hitech Material Co., Ltd. Zibo Jiuqiang Refractory Co., Ltd. Zibo Soaring Refractory & Insulation Materials Co., Ltd. The People's Republic of China: Kitchen Appliance Shelving and Racks, A-570-941 Asber Enterprises Co., Ltd. (China) Guangdong Wireking Housewares & Hardware Co., Ltd. (a/k/a Foshan Shunde Wireking Housewares & Hardware Co., Ltd.) Hangzhou Dunli Import & Export Co., Ltd. Hangzhou Dunli Industry Co., Ltd. Jiangsu Weixi Group Co. Leader Metal Industry Co., Ltd. (a/k/a Marmon Retail Services Asia) Marmon Retail Services Asia Ltd New King Shan (Zhu Hai) Co., Ltd Suzhou Huidou Imp. & Exp. Co., Ltd The People's Republic of China: Narrow Woven Ribbons With Woven Selvedge, A-570-952 Amadeus Textile Ltd. Amsun Industrial Co., Ltd. Apex Trimmings (d/b/a Papillon Ribbon & Bow (Canada)) Bestpak Gifts and Crafts Co., Ltd. Billion Trend International Ltd. Changle Huanyu Ribbon Weaving Co., Ltd Changle Ruixiang Webbing Co., Ltd. Cheng Hsing Ribbon Factory Cheng Xeng Label Mfg. Co. Complacent Industrial Co. Ltd. (HK) Creative Design Ltd. Dongguan Qaotou Sheng Feng Decoration Factory Dragon Max Weaving & Accessories Company East Sun Gift & Crafts Factory Fasheen Accessories Co. Ltd. Fly Dragon (Guang zhou) Imports & Exports trading co., Ltd Fuhua Industrial Co., Ltd Fujian Shi Lian Da Garment Accessories Co., Ltd. Fujian Xin Sheng Da Weaving Ribbons Co., Ltd Fujian Xinshengda Weaving Ribbons Co., Ltd Goodyear Webbing Products Co., Ltd Guangzhou Complacent Weaving Co Ltd Guangzhou Leiyu Trade Co., Ltd Guangzhou Liman Ribbon Factory Guangzhou String Textile Accessories Co., Ltd. Hen Hao Trading Co. Ltd. a.k.a. Taiwan Tulip Ribbons and Braids Co. Ltd. Hsien Chan Enterprise Co., Ltd. Huian Huida Webbing Co., Ltd. Huizhou Weiyi Gifts Co., Ltd. Huzhou Linghu Tianyi Tape Co., Ltd. Huzhou Lingxian Silk Ribbon Co., Ltd. Huzhou Unifull Label Fabric Co., Ltd. Intercontinental Skyline Jian Chang Ind. Co., Ltd. Jiangyin Lilai Tape Co., Ltd. Jufeng Ribbon Co.Ltd. Kaiping Qifan Weaving Co., Ltd. King Young Enterprises Co., Ltd. King's Pipe Cleaner's Ind. Inc aka King's Crafts (China) Ltd (aka King's Pipe Cleaner's, Ind. Inc) Kinstarlance & Embroidery Co. Kunshan Dah Mei Weaving Co. Ltd.	9/1/22-8/31/23 9/1/22-8/31/23

	Period to be reviewed
Lace Fashions Industrial Co. Ltd. Multicolor Nan Mei Decorative Ribbons Co., Ltd. Ningbo Bofa Co., Ltd Ningbo Hongshine Decorative Packing Industrial Co. Ltd. aka Ningbo Hongrun Craft and Ornament Factory Ningbo Jinfeng Thread & Ribbon Co. Ltd. Ningbo MH Industry Co., Ltd. Ningbo R&D Ind Company Ningbo Sunshine Import & Export Co. Ltd. Ningbo Wanhe Industry Co., Ltd. Ningbo XWZ Ribbon Manufactory Ningbo Yinzhou Hengcheng Ribbon Factory Novelty Handicrafts Co., Ltd. Papillon Ribbon & Bow (H.K.) Ltd. Papillon Ribbon & Bow (Shanghai) Ltd. Precious Planet Ribbons & Bows Co. Ltd. PROTEX Co., Ltd. Qingdao Cuifengyuan Industrial and Trading Co., Ltd. Qingdao Haili Lace & Ribbon Co., Ltd. Qingdao Hileaders Co., Ltd. RizeStar Weaving Ribbon Factory Roung Shu Industry Corporation a.k.a. Cheng Hsing Ribbon Factory Shanghai Dae Textile International Co., Ltd. Shanghai E & T Jawa Import & Export Co. Ltd. ShaoXing Haiyue Gifts Co. Ltd. Sheinq Huong Enterprise Co., Ltd. Shenq Sin Company Ltd. Shenzhen Bostrip Crafts Co. Ltd. Shenzhen Candour Belt & Tape Co., Ltd. Shenzhen Jinpin Gifts & Crafts Factory Shenzhen Lucky Star Craft Co., Ltd. Shenzhen Weiyi Crafts Technology Co., Ltd. Shenzhen Yibao Gifts Co. Ltd. Shishi Lifa Computer Woven Label Co., Ltd. Shuanglin Label Sinopak Gifts & Crafts Co., Ltd Stribbons (Guang Zhou) Ltd. Stribbons (Guangzhou) Ltd Aka MNC Stribbons String Textile Accessories Co., Ltd. String Textile Accessories Co., Ltd. Success Charter Enterprise Limited Sungai Garment Accessories Co., Ltd. Tianjin Sun Ribbon Company Ltd aka Tian Jin Sun Ribbon Company Ltd. Weifang Aofulun Weaving Company, Ltd. Weifang Chenrui Textile Co., Ltd. Weifang Dongfang Ribbon Weaving Co., Ltd. Weifang Jiacheng Webbing Co., Ltd. Weifang Yuyuan Textile Co., Ltd. Wenzhou Chuntian Ribbon Manufacturing Co., Ltd. Wenzhou GED Industrial Co., Ltd. Wiefang Shicheng Ribbon Factory Wing Tat Haberdashery Co., Ltd aka Wing Hiang Belt Weaving Ltd. Xiamen Bailuu Thread Manufacture Co., Ltd. Xiamen Daiyuan Ribbons & Printing Co., Ltd. Xiamen Egret Thread Manufacturing Co., Ltd. Xiamen Especial Industrial Co., Ltd. Xiamen LA Ribbons Crafts Co., Ltd. Xiamen Lude Ribbons And Bows Co., Ltd. Xiamen Sanling Ribbon Packing Co., Ltd. Xiamen ShangPeng Weaving Ribbon Factory Xiamen Sling Ribbon & Bows Co., Ltd. Yangzhou Bestpak Gifts and Crafts Co., Ltd. Yi Jia Trimmings Accessories & Supplies/Dong Guan WSJ Weaving Factory Limited Yiwu Baijin Belt Co., Ltd Yiwu City Pingzhan Weaving Ribbon Factory Yiwu Ruitai Webbing Factory Yiwu Yunli Tape Co., Ltd. Yu Shin Development Co. Ltd. Yuanhong Garment Accessory Co., Ltd. Yuyao Warp & Weft Tape Weaving Co., Ltd. Zenith Garment Accessories Co., Ltd. Zhejiang Chengxin Weaving Co., Ltd Zhejiang Sanding Weaving Co., Ltd.	

	Period to be reviewed
Zibo All Webbing Co., Ltd.	
The People's Republic of China: Polyethylene Retail Carrier Bags, ⁵ A-570-886	8/1/22-7/31/23
Dongguan Nozawa Plastics Products Co., Ltd. and United Power Packaging, Ltd. (collectively Nozawa)	
Crown Polyethylene Products (International) Ltd.	
The People's Republic of China: Steel Racks and Parts Thereof, A-570-088	9/1/22-8/31/23
Hebei Minmetals Co., Ltd.	
Jiangsu JISE Intelligent Storage Equipment Co., Ltd.	
Jiangsu Nova Intelligent Logistics Equipment Co., Ltd.	
Jiangsu Starshine Industry Equipment Co., Ltd.	
Nanjing Dongsheng Shelf Manufacturing Co., Ltd.	
Nanjing Ironstone Storage Equipment Co., Ltd.	
Nanjing Kingmore Logistics Equipment Manufacturing Co., Ltd.	
Ningbo Xinguang Rack Co., Ltd.	
Xiamen Luckyroc Industry Co., Ltd.	
CVD Proceedings	
India: Lined Paper Products, C-533-844	1/1/22-12/31/22
Navneet Education Ltd.	
India: Oil Country Tubular Goods, C-533-858	1/1/22-12/31/22
Surya Roshni Limited	
Republic of Korea: Cold-Rolled Steel Flat Products, C-580-882	1/1/22-12/31/22
AJU Steel Co., Ltd.	
Amerisource Korea	
Amerisource International	
BC Trade	
Busung Steel Co., Ltd.	
Cenit Co., Ltd.	
Daewoo Logistics Corp.	
Dai Yang Metal Co., Ltd.	
DK GNS Co., Ltd.	
Dongbu Incheon Steel Co., Ltd.	
Dongbu Steel Co., Ltd.	
Dong Jin Machinery	
Dongkuk Industries Co., Ltd.	
Dongkuk Steel Mill Co., Ltd.	
Eunsan Shipping and Air Cargo Co., Ltd.	
Euro Line Global Co., Ltd	
Golden State Corp.	
GS Global Corp.	
Hanawell Co., Ltd.	
Hankum Co., Ltd.	
Hyosung TNC Corp.	
Hyuk San Profile Co., Ltd.	
Hyundai Group	
Hyundai Steel Company	
Iljin NTS Co., Ltd.	
Iljin Steel Corp.	
Jeen Pung Industrial Co., Ltd.	
JS Steel Co., Ltd.	
JT Solution	
KG Dongbu Steel Co., Ltd.	
Kolon Global Corporation	
Nauri Logistics Co., Ltd.	
Okaya (Korea) Co., Ltd.	
PL Special Steel Co., Ltd.	
POSCO; POSCO International Corporation	
POSCO C&C Co., Ltd.	
POSCO Daewoo Corp.	
Samsung C&T Corp.	
Samsung STS Co., Ltd.	
SeAH Steel Corp.	
SM Automotive Ltd.	
SK Networks Co., Ltd.	
Taihan Electric Wire Co., Ltd.	
TGS Pipe Co., Ltd.	
TI Automotive Ltd.	
Topco Global Co., Ltd.	
Xeno Energy	
Young Steel Co., Ltd.	
The People's Republic of China: Narrow Woven Ribbons With Woven Selvedge, C-570-953	1/1/22-12/31/22
Amadeus Textile Ltd.	
Amsun Industrial Co., Ltd.	
Apex Ribbon	

	Period to be reviewed
Apex Trimmings (d/b/a Papillon Ribbon & Bow (Canada)) Beauty Horn Investment Limited Bestpak Gifts and Crafts Co., Ltd. Billion Trend International Ltd. Changle Huanyu Ribbon Weaving Co., Ltd. Changle Ruixiang Webbing Co., Ltd. Changtai Rongshu Textile Co., Ltd. Cheng Xeng Label Mfg. Co. Complacent Industrial Co., Ltd. (HK) Creative Design Ltd. Dongguan Qaotou Sheng Feng Decoration Factory Dongguan Yi Sheng Decoration Co., Ltd. Dragon Max Weaving & Accessories Company East Sun Gift & Crafts Factory Fasheen Accessories Co. Ltd. Fly Dragon (Guang zhou) Imports & Exports trading Co., Ltd. Fuhua Industrial Co., Ltd. Fujian Rongshu Industry Co., Ltd. Fujian Shi Lian Da Garment Accessories Co., Ltd. Fujian Xin Sheng Da Weaving Ribbons Co., Ltd. Fujian Xinshengda Weaving Ribbons Co., Ltd. Fung Ming Ribbon Ind., Ltd. Goodyear Webbing Products Co., Ltd. Gordon Ribbons & Trimmings Co., Ltd. Guangzhou Complacent Weaving Co., Ltd. Guangzhou Leiyu Trade Co., Ltd. Guangzhou Liman Ribbon Factory Guangzhou Mafolen Ribbons & Bows Ltd. Guangzhou String Textile Accessories Co., Ltd. Hen Hao Trading Co. Ltd.; Taiwan Tulip Ribbons and Braids Co., Ltd. Hubscher Ribbon Corp., Ltd. (d/b/a Hubschercorp) Huian Huida Webbing Co., Ltd. Huizhou Weiyi Gifts Co., Ltd. Huzhou Linghu Tianyi Tape Co., Ltd. Huzhou Lingxian Silk Ribbon Co., Ltd. Huzhou Unifull Label Fabric Co., Ltd. Intercontinental Skyline Jian Chang Ind. Co., Ltd. Jiangyin Lilai Tape Co., Ltd. Jufeng Ribbon Co., Ltd. Kaiping Qifan Weaving Co., Ltd. King Young Enterprises Co., Ltd. King's Pipe Cleaner's Ind. Inc; King's Crafts (China) Ltd; King's Pipe Cleaner's, Ind. Inc. Kinstarlace & Embroidery Co. Kunshan Dah Mei Weaving Co., Ltd. Lace Fashions Industrial Co., Ltd. Linghu Jiacheng Silk Ribbon Co., Ltd. Multicolor Nan Mei Decorative Ribbons Co., Ltd. Ningbo Bofa Co., Ltd. Ningbo Flowering Crafts Co., Ltd. Ningbo Hongshine Decorative Packing Industrial Co., Ltd.; Ningbo Hongrun Craft and Ornament Factory Ningbo Jinfeng Thread & Ribbon Co., Ltd. Ningbo MH Industry Co., Ltd. Ningbo R&D Ind. Company Ningbo Sunshine Import & Export Co., Ltd. Ningbo V.K. Industry and Trading Co., Ltd. Ningbo Wanhe Industry Co., Ltd. Ningbo XWZ Ribbon Manufactory Ningbo Yinzhou Jinfeng Knitting Factory Ningbo Yinzhou Hengcheng Ribbon Factory Pacific Imports Papillon Ribbon & Bow (H.K.) Ltd. Papillon Ribbon & Bow (Shanghai) Ltd. Precious Planet Ribbons & Bows Co., Ltd. PROTEX Co., Ltd. Qingdao Cuifengyuan Industrial and Trading Co., Ltd. Qingdao Haili Lace & Ribbon Co., Ltd. Qingdao Hileaders Co., Ltd. RizeStar Weaving Ribbon Factory Roung Shu Industry Corporation; Cheng Hsing Ribbon Factory Shandong Hileaders Industrial Co., Ltd. Shanghai Dae Textile International Co., Ltd.	

	Period to be reviewed
Shanghai E & T Jawa Import & Export Co., Ltd. ShaoXing Haiyue Gifts Co., Ltd. Sheing Huong Enterprise Co., Ltd.; Hsien Chan Enterprise Co., Ltd.; Novelty Handicrafts Co., Ltd. Sheng Sin Company Ltd. Shenzhen Bostrap Crafts Co., Ltd. Shenzhen Candour Belt & Tape Co., Ltd. Shenzhen Jinpin Gifts & Crafts Factory Shenzhen Lucky Star Craft Co., Ltd. Shenzhen Weiye Crafts Technology Co., Ltd. Shenzhen Yibao Gifts Co., Ltd. Shishi Lifa Computer Woven Label Co., Ltd. Shuanglin Label Sinopak Gifts & Crafts Co., Ltd. Stribbons (Guangzhou) Ltd; MNC Stribbons Stribbons (Nanyang) MNC Ltd. String Textile Accessories Co., Ltd. Success Charter Enterprise Limited Sungai Garment Accessories Co., Ltd. Sun Rich (Asia) Limited Supreme Laces Inc. Tianjin Sun Ribbon Company Ltd; Tian Jin Sun Ribbon Company Ltd. Weifang Aofulon Weaving Company Ltd. Weifang Chenrui Textile Co., Ltd. Weifang Dongfang Ribbon Weaving Co., Ltd. Weifang Jiacheng Webbing Co., Ltd. Weifang Jinqi Textile Co., Ltd. Weifang Yuyuan Textile Co., Ltd. Wenzhou Chuntian Ribbon Manufacturing Co., Ltd. Wenzhou GED Industrial Co., Ltd. Wiefang Shicheng Ribbon Factory Wing Tat Haberdashery Co., Ltd; Wing Hiang Belt Weaving Ltd. Xiamen Bailuu Thread Manufacture Co., Ltd. Xiamen Bethel Ribbon & Trims Co., Ltd. Xiamen Boca Ribbons & Crafts Co., Ltd. Xiamen Daiyuan Ribbons & Printing Co., Ltd. Xiamen Egret Thread Manufacturing Co., Ltd. Xiamen Especial Industrial Co., Ltd. Xiamen LA Ribbons Crafts Co., Ltd. Xiamen Lianglian Ribbons & Bows Co., Ltd. Xiamen Linji Ribbons & Bows Co., Ltd. Xiamen Lude Ribbons and Bows Co., Ltd. Xiamen Midi Ribbons & Crafts Co., Ltd. Xiamen Rainbow Gifts & Packs Co., Ltd. Xiamen Sanling Ribbon Packing Co., Ltd. Xiamen ShangPeng Weaving Ribbon Factory Xiamen Sling Ribbon & Bows Co., Ltd. Xiamen Yi He Textile Co., Ltd. (d/b/a Rongshu Ribbon) Yama Ribbons and Bows Co., Ltd. Yangzhou Bestpak Gifts and Crafts Co., Ltd. Yi Jia Trimmings Accessories & Supplies; Dong Guan WSJ Weaving Factory Limited Yiwu Baijin Belt Co., Ltd. Yiwu City Pingzhan Weaving Ribbon Factory Yiwu Dong Ding Ribbons Co., Ltd. Yiwu Ruitai Webbing Factory Yiwu Yunli Tape Co., Ltd. Yu Shin Development Co., Ltd. Yuanhong Garment Accessory Co., Ltd. Yuyao Warp & Weft Tape Weaving Co., Ltd. Zenith Garment Accessories Co., Ltd. Zhejiang Chengxin Weaving Co., Ltd Zhejiang Sanding Weaving Co., Ltd. Zibo All Webbing Co., Ltd.	
The People's Republic of China: Steel Racks, C-570-089 Jiangsu JISE Intelligent Storage Equipment Co., Ltd. Jiangsu Nova Intelligent Logistics Equipment Co., Ltd Jiangsu Starshine Industry Equipment Co., Ltd. Nanjing Dongsheng Shelf Manufacturing Co., Ltd. Nanjing Ironstone Storage Equipment Co., Ltd. Ningbo Xinguang Rack Co., Ltd. Xiamen Luckyroc Industry Co., Ltd.	1/1/22-12/31/22
Turkey: Oil Country Tubular Goods, C-489-817 Bakir Grup Makine Imalat Bakim Montaj Demontaj Sanayi ve Ticaret Ltd. Sti. Borusan Lojistik Dag. Deg. Tas Ve	1/1/22-12/31/22

	Period to be reviewed
Borusan Mannesmann Boru Sanayi ve Ticaret A.S. Borusan Istikbal Ticaret Borusan Mannesmann Boru Yatirim Holding Cayirova Boru Sanayi ve Ticaret A.S. Hatboru San ve Tic A.S. Hydra Insaat Sanayi ve Ticaret Anonim Sirketi Kalibre Boru Sanayi ve Ticaret KALTEK Machinery & Trading Ltd. Co. Milfit Boru ve Baglanti Elemenlari Sanayi ve Tic. A.S. NETBORU San. Ve Dis. Tic. Koll. Sti. Organize Sanayi Bolgesi Umransel Celik Boru Sanayi A.S. Yilmaz Pipo Yucel Boru Ithalat-Ihracat ve Pazarlama A.S. Suspension Agreements Mexico: Fresh Tomatoes, A-201-820	9/1/22-8/31/23

Duty Absorption Reviews

During any administrative review covering all or part of a period falling between the first and second or third and fourth anniversary of the publication of an AD order under 19 CFR 351.211 or a determination under 19 CFR 351.218(f)(4) to continue an order or suspended investigation (after sunset review), Commerce, if requested by a domestic interested party within 30 days of the date of publication of the notice of initiation of the review, will determine whether AD duties have been absorbed by an exporter or producer subject to the review if the subject merchandise is sold in the United States through an importer that is affiliated with such exporter or producer. The request must include the name(s) of the exporter or producer for which the inquiry is requested.

Gap Period Liquidation

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant "gap" period of the order (*i.e.*, the period following the expiry of provisional measures and before definitive measures were put into place), if such a gap period is applicable to the POR.

Administrative Protective Orders and Letters of Appearance

Interested parties must submit applications for disclosure under administrative protective orders in

⁵ In the initiation notice that was published on October 18, 2023 (88 FR 71829) Commerce listed the incorrect company names of companies under review. The correct company names of the two companies for which a review was requested are listed in this notice.

accordance with the procedures outlined in Commerce's regulations at 19 CFR 351.305. Those procedures apply to administrative reviews included in this notice of initiation. Parties wishing to participate in any of these administrative reviews should ensure that they meet the requirements of these procedures (*e.g.*, the filing of separate letters of appearance as discussed at 19 CFR 351.103(d)).

Factual Information Requirements

Commerce's regulations identify five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by Commerce; and (v) evidence other than factual information described in (i)–(iv). These regulations require any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The regulations, at 19 CFR 351.301, also provide specific time limits for such factual submissions based on the type of factual information being submitted. Please review the *Final Rule*,⁶ available

⁶ See *Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings*, 78 FR 42678 (July 17, 2013) (*Final Rule*); see also the frequently asked questions regarding the *Final Rule*, available at

at www.govinfo.gov/content/pkg/FR-2013-07-17/pdf/2013-17045.pdf, prior to submitting factual information in this segment. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).⁷

Any party submitting factual information in an AD or CVD proceeding must certify to the accuracy and completeness of that information using the formats provided at the end of the *Final Rule*.⁸ Commerce intends to reject factual submissions in any proceeding segments if the submitting party does not comply with applicable certification requirements.

Extension of Time Limits Regulation

Parties may request an extension of time limits before a time limit established under Part 351 expires, or as otherwise specified by Commerce.⁹ In general, an extension request will be considered untimely if it is filed after the time limit established under Part 351 expires. For submissions which are due from multiple parties simultaneously, an extension request will be considered untimely if it is filed after 10:00 a.m. on the due date. Examples include, but are not limited to: (1) case and rebuttal briefs, filed pursuant to 19 CFR 351.309; (2) factual information to value factors under 19 CFR 351.408(c), or to measure the adequacy of remuneration under 19 CFR

https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.

⁷ See *Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings; Final Rule*, 88 FR 67069 (September 29, 2023).

⁸ See section 782(b) of the Act; see also *Final Rule*; and the frequently asked questions regarding the *Final Rule*, available at https://enforcement.trade.gov/tlei/notices/factual_info_final_rule_FAQ_07172013.pdf.

⁹ See 19 CFR 351.302.

351.511(a)(2), filed pursuant to 19 CFR 351.301(c)(3) and rebuttal, clarification and correction filed pursuant to 19 CFR 351.301(c)(3)(iv); (3) comments concerning the selection of a surrogate country and surrogate values and rebuttal; (4) comments concerning CBP data; and (5) Q&V questionnaires. Under certain circumstances, Commerce may elect to specify a different time limit by which extension requests will be considered untimely for submissions which are due from multiple parties simultaneously. In such a case, Commerce will inform parties in the letter or memorandum setting forth the deadline (including a specified time) by which extension requests must be filed to be considered timely. This policy also requires that an extension request must be made in a separate, stand-alone submission, and clarifies the circumstances under which Commerce will grant untimely-filed requests for the extension of time limits. Please review the *Final Rule*, available at <https://www.gpo.gov/fdsys/pkg/FR-2013-09-20/html/2013-22853.htm>, prior to submitting factual information in these segments.

Notification to Interested Parties

These initiations and this notice are in accordance with section 751(a) of the Act (19 U.S.C. 1675(a)) and 19 CFR 351.221(c)(1)(i).

Dated: November 7, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2023–25138 Filed 11–14–23; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–857]

Certain Freight Rail Couplers and Parts Thereof From Mexico: Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on affirmative final determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC), Commerce is issuing an antidumping duty order on certain freight rail couplers and parts thereof (freight rail couplers) from Mexico.

DATES: Applicable November 15, 2023.

FOR FURTHER INFORMATION CONTACT:

Jonathan Hall-Eastman, 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) 482–1468

SUPPLEMENTARY INFORMATION:

Background

In accordance with sections 735(d) and 777(i) of the Tariff Act of 1930, as amended (the Act), on September 21, 2023, Commerce published its affirmative final determination in the less-than-fair-value (LTFV) investigation of freight rail couplers from Mexico.¹ On November 6, 2023, the ITC notified Commerce of its final determination, pursuant to section 735(d) of the Act, that an industry in the United States is materially injured within the meaning of section 735(b)(1)(A)(i) of the Act by reason of LTFV imports of freight rail couplers from Mexico.²

Scope of the Order

The products covered by this order are freight rail couplers from Mexico. For a complete description of the scope of the order, see the appendix to this notice.

Antidumping Duty Order

On November 6, 2023, in accordance with sections 735(b)(1)(A)(i) and 735(d) of the Act, the ITC notified Commerce of its final determination that an industry in the United States is materially injured by reason of imports of freight rail couplers from Mexico. Therefore, Commerce is issuing this antidumping duty order in accordance with sections 735(c)(2) and 736 of the Act. Because the ITC determined that imports of freight rail couplers from Mexico are materially injuring a U.S. industry, unliquidated entries of such merchandise from Mexico, entered or withdrawn from warehouse for consumption, are subject to the assessment of antidumping duties.

Therefore, in accordance with section 736(a)(1) of the Act, Commerce will direct U.S. Customs and Border Protection (CBP) to assess, upon further instruction by Commerce, antidumping duties equal to the amount by which the normal value of the merchandise exceeds the export price (or constructed export price) of the merchandise, for all relevant entries of freight rail couplers from Mexico. With the exception of

¹ See *Certain Freight Rail Couplers and Parts Thereof from Mexico: Final Affirmative Determination of Sales at Less Than Fair Value and Final Negative Determination of Critical Circumstances*, 88 FR 61653 (September 21, 2023) (*Final Determination*).

² See ITC's Letter, Investigation No. 731–TA–1593 (Final), dated November 6, 2023.

entries occurring after the expiration of the provisional measures period and before publication of the ITC's final affirmative injury determination, as further described below, antidumping duties will be assessed on unliquidated entries of freight rail couplers from Mexico, entered, or withdrawn from warehouse, for consumption, on or after May 3, 2023, the date of publication of the *Preliminary Determination*.³

Continuation of Suspension of Liquidation and Cash Deposits

Except as noted in the “Provisional Measures” section of this notice, in accordance with section 736 of the Act, Commerce will instruct CBP to continue to suspend liquidation on all relevant entries of freight rail couplers from Mexico. These instructions suspending liquidation will remain in effect until further notice.

Commerce will also instruct CBP to require cash deposits equal to the amounts indicated below. Accordingly, effective on the date of publication in the **Federal Register** of the notice of the ITC's final affirmative injury determination, CBP will require, at the same time as importers would normally deposit estimated duties on this subject merchandise, a cash deposit equal to the cash deposit rates listed in the table below. The all-others rate applies to all producers or exporters not specifically listed, as appropriate.

Estimated Weighted-Average Dumping Margins

The estimated weighted-average dumping margins for this antidumping order are as follows:

Exporter/producer	Weighted-average dumping margin (percent)
ASF–K de Mexico S. de R.L. de C.V	48.10
All Others	48.10

Provisional Measures

Section 733(d) of the Act states that suspension of liquidation pursuant to an affirmative preliminary determination may not remain in effect for more than four months, except where exporters representing a significant proportion of exports of the subject merchandise

³ See *Certain Freight Rail Couplers and Parts Thereof from Mexico: Preliminary Affirmative Determination of Sales at Less Than Fair Value Preliminary Negative Determination of Critical Circumstances, Postponement of Final Determination, and Extension of Provisional Measures*, 88 FR 27864 (May 3, 2023) (*Preliminary Determination*).

request that Commerce extend the four-month period to no more than six months. At the request of exporters that account for a significant proportion of freight rail couplers from Mexico, Commerce extended the four-month period to six months. Commerce's *Preliminary Determination* was published on May 3, 2023.⁴ Commerce's *Final Determination* was extended and was published on September 15, 2023.⁵

The extended provisional measures period, beginning on the date of publication of the *Preliminary Determination*, ended on October 29, 2023. Therefore, in accordance with section 733(d) of the Act and our practice,⁶ Commerce will instruct CBP to terminate the suspension of liquidation and to liquidate, without regard to antidumping duties, unliquidated entries of freight rail couplers from Mexico entered or withdrawn from warehouse, for consumption after October 29, 2023, the final day on which the provisional measures were in effect, until and through the day preceding the date of publication of the ITC's final affirmative injury determination in the **Federal Register**. Suspension of liquidation and the collection of cash deposits will resume on the date of publication of the ITC's final determination in the **Federal Register**.

Establishment of the Annual Inquiry Service Lists

On September 20, 2021, Commerce published the final rule titled “*Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*” in the **Federal Register**.⁷ On September 27, 2021, Commerce also published the notice titled “*Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*” in the **Federal Register**.⁸ The *Final Rule* and *Procedural Guidance* provide that Commerce will maintain an annual inquiry service list for each order or suspended investigation, and any interested party submitting a scope

ruling application or request for circumvention inquiry shall serve a copy of the application or request on the persons on the annual inquiry service list for that order, as well as any companion order covering the same merchandise from the same country of origin.⁹

In accordance with the *Procedural Guidance*, for orders published in the **Federal Register** after November 4, 2021, Commerce will create an annual inquiry service list segment in Commerce's online e-filing and document management system, Antidumping and Countervailing Duty Electronic Service System (ACCESS), available at <https://access.trade.gov>, within five business days of publication of the notice of the order. Each annual inquiry service list will be saved in ACCESS, under each case number, and under a specific segment type called “AISL-Annual Inquiry Service List.”¹⁰

Interested parties who wish to be added to the annual inquiry service list for an order must submit an entry of appearance to the annual inquiry service list segment for the order in ACCESS within 30 days after the date of publication of the order. For ease of administration, Commerce requests that law firms with more than one attorney representing interested parties in an order designate a lead attorney to be included on the annual inquiry service list. Commerce will finalize the annual inquiry service list within five business days thereafter. As mentioned in the *Procedural Guidance*, the new annual inquiry service list will be in place until the following year, when the *Opportunity Notice* for the anniversary month of the order is published.

Commerce may update an annual inquiry service list at any time as needed based on interested parties' amendments to their entries of appearance to remove or otherwise modify their list of members and representatives, or to update contact information. Any changes or announcements pertaining to these procedures will be posted to the ACCESS website at <https://access.trade.gov>.

Special Instructions for Petitioners and Foreign Governments

In the *Final Rule*, Commerce stated that, “after an initial request and placement on the annual inquiry service list, both petitioners and foreign governments will automatically be placed on the annual inquiry service list in the years that follow.”¹¹

Accordingly, as stated above, the petitioners and foreign governments should submit their initial entry of appearance after publication of this notice in order to appear in the first annual inquiry service list. Pursuant to 19 CFR 351.225(n)(3), the petitioners and foreign governments will not need to resubmit their entries of appearance each year to continue to be included on the annual inquiry service list. However, the petitioners and foreign governments are responsible for making amendments to their entries of appearance during the annual update to the annual inquiry service list in accordance with the procedures described above.

Notification to Interested Parties

This notice constitutes the antidumping duty order with respect to freight rail couplers from Mexico pursuant to section 736(a) of the Act. Interested parties can find a list of antidumping duty orders currently in effect at <https://www.trade.gov/data-visualization/adcvd-proceedings>.

This order is published in accordance with section 736(a) of the Act and 19 CFR 351.211(b).

Dated: November 8, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

Scope of the Order

The scope of this order covers certain freight railcar couplers (also known as “fits” or “assemblies”) and parts thereof. Freight railcar couplers are composed of two main parts, namely knuckles and coupler bodies but may also include other items (e.g., coupler locks, lock lift assemblies, knuckle pins, knuckle throwers, and rotors). The parts of couplers that are covered by the order include: (1) E coupler bodies, (2) E/F coupler bodies, (3) F coupler bodies, (4) E knuckles, and (5) F knuckles, as set forth by the Association of American Railroads (AAR). The freight rail coupler parts (*i.e.*, knuckles and coupler bodies) are included within the scope of the order when imported separately. Coupler locks, lock lift assemblies, knuckle pins, knuckle throwers, and rotors are covered merchandise when imported in an assembly but are not covered by the scope when imported separately.

¹¹ See *Final Rule*, 86 FR at 52335.

⁴ *Id.*

⁵ See *Final Determination*.

⁶ See, e.g., *Certain Corrosion-Resistant Steel Products from India, India, the People's Republic of China, the Republic of Korea and Taiwan: Amended Final Affirmative Antidumping Determination for India and Taiwan, and Antidumping Duty Orders*, 81 FR 48390, 48392 (July 25, 2016).

⁷ See *Regulations to Improve Administration and Enforcement of Antidumping and Countervailing Duty Laws*, 86 FR 52300 (September 20, 2021) (*Final Rule*).

⁸ See *Scope Ruling Application; Annual Inquiry Service List; and Informational Sessions*, 86 FR 53205 (September 27, 2021) (*Procedural Guidance*).

⁹ *Id.*

¹⁰ This segment will be combined with the ACCESS Segment Specific Information (SSI) field, which will display the month in which the notice of the order or suspended investigation was published in the **Federal Register**, also known as the anniversary month. For example, for an order under case number A-000-000 that published in the **Federal Register** in January, the relevant segment and SSI combination will appear in ACCESS as “AISL-January Anniversary.” Note that there will be only one annual inquiry service list segment per case number, and the anniversary month will be pre-populated in ACCESS.

Subject freight railcar couplers and parts are included within the scope whether finished or unfinished, whether imported individually or with other subject or non-subject parts, whether assembled or unassembled, whether mounted or unmounted, or if joined with non-subject merchandise, such as other non-subject parts or a completed railcar. Finishing includes, but is not limited to, arc washing, welding, grinding, shot blasting, heat treatment, machining, and assembly of various parts. When a subject coupler or subject parts are mounted on or to other non-subject merchandise, such as a railcar, only the coupler or subject parts are covered by the scope.

The finished products covered by the scope of this order meet or exceed the AAR specifications of M-211, "Foundry and Product Approval Requirements for the Manufacture of Couplers, Coupler Yokes, Knuckles, Follower Blocks, and Coupler Parts" and/or AAR M-215 "Coupling Systems," or other equivalent domestic or international standards (including any revisions to the standard(s)).

The country of origin for subject couplers and parts thereof, whether fully assembled, unfinished or finished, or attached to a railcar, is the country where the subject coupler parts were cast or forged. Subject merchandise includes coupler parts as defined above that have been further processed or further assembled, including those coupler parts attached to a railcar in third countries. Further processing includes, but is not limited to, arc washing, welding, grinding, shot blasting, heat treatment, painting, coating, priming, machining, and assembly of various parts. The inclusion, attachment, joining, or assembly of non-subject parts with subject parts or couplers either in the country of manufacture of the in-scope product or in a third country does not remove the subject parts or couplers from the scope.

The couplers that are the subject of this order are currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) statistical reporting number 8607.30.1000. Unfinished subject merchandise may also enter under HTSUS statistical reporting number 7326.90.8688. Subject merchandise attached to finished railcars may also enter under HTSUS statistical reporting numbers 8606.10.0000, 8606.30.0000, 8606.91.0000, 8606.92.0000, 8606.99.0130, 8606.99.0160, or under subheading 9803.00.50. Subject merchandise may also be imported under HTSUS statistical reporting number 7325.99.5000. These HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of this order is dispositive.

[FR Doc. 2023-25201 Filed 11-14-23; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XD521]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a meeting of its Scallop Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate. **DATES:** This meeting will be held on Wednesday, November 29, 2023, at 1 p.m.

ADDRESSES:

Webinar registration URL information: <https://attendee.gotowebinar.com/register/4699670473411333979>.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Ph.D., Executive Director, New England Fishery Management Council; telephone: (978) 465-0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Committee will review Framework 38 (FW38): review specifications alternatives in FW38 and select final preferred alternatives. FW38 will set specifications including the overfishing limit (OFL), acceptable biological catch/annual catch limit (ABC/ACLs), days-at-sea (DAS), access area allocations for Limited Access (LA) vessels, quota and access area trip allocation to the Limited Access General Category (LAGC) Individual Fishing Quota (IFQ) component, Total Allowable Landings (TAL) for Northern Gulf of Maine (NGOM) management area, a target-TAC for LAGC incidental catch and set-asides for the observer and research programs for fishing year 2024, and default specifications for fishing year 2025. This action also considers increasing VMS ping rates for scallop vessels to improve enforcement in the scallop fishery. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come

before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Ph.D., Executive Director, at (978) 465-0492, at least 5 days prior to the meeting date.

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

Dated: November 9, 2023.

Key Israel Marquez,

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

[FR Doc. 2023-25225 Filed 11-14-23; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XD361]

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to the Lutak Dock Replacement Project, Haines Borough, Alaska

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

ACTION: Notice; proposed incidental harassment authorization; request for comments on proposed authorization and possible renewal.

SUMMARY: NMFS has received a request from Haines Borough for authorization to take marine mammals incidental to the Lutak dock replacement project in Lutak, Alaska. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an incidental harassment authorization (IHA) to incidentally take marine mammals during the specified activities. NMFS is also requesting comments on a possible one-time, 1-year renewal that could be issued under certain circumstances and if all

requirements are met, as described in Request for Public Comments at the end of this notice. NMFS will consider public comments prior to making any final decision on the issuance of the requested MMPA authorization and agency responses will be summarized in the final notice of our decision.

DATES: Comments and information must be received no later than December 15, 2023.

ADDRESSES: Comments should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, NMFS and should be submitted via email to ITP.cockrell@noaa.gov. Electronic copies of the application and supporting documents, as well as a list of the references cited in this document, may be obtained online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>. In case of problems accessing these documents, please call the contact listed above.

Instructions: NMFS is not responsible for comments sent by any other method, to any other address or individual, or received after the end of the comment period. Comments, including all attachments, must not exceed a 25-megabyte file size. All comments received are a part of the public record and will generally be posted online at <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities> without change. All personal identifying information (e.g., name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit confidential business information or otherwise sensitive or protected information.

FOR FURTHER INFORMATION CONTACT: Craig Cockrell, Office of Protected Resources, NMFS, (301) 427-8401.

SUPPLEMENTARY INFORMATION:

Background

The MMPA prohibits the “take” of marine mammals, with certain exceptions. Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce (as delegated to NMFS) to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are proposed or, if the taking is limited to

harassment, a notice of a proposed IHA is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s) and will not have an unmitigable adverse impact on the availability of the species or stock(s) for taking for subsistence uses (where relevant). Further, NMFS must prescribe the permissible methods of taking and other “means of effecting the least practicable adverse impact” on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of the species or stocks for taking for certain subsistence uses (referred to in shorthand as “mitigation”); and requirements pertaining to the mitigation, monitoring and reporting of the takings are set forth. The definitions of all applicable MMPA statutory terms cited above are included in the relevant sections below.

National Environmental Policy Act

To comply with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) and NOAA Administrative Order (NAO) 216-6A, NMFS must review our proposed action (*i.e.*, the issuance of an IHA) with respect to potential impacts on the human environment.

This action is consistent with categories of activities identified in Categorical Exclusion B4 (IHAs with no anticipated serious injury or mortality) of the Companion Manual for NAO 216-6A, which do not individually or cumulatively have the potential for significant impacts on the quality of the human environment and for which we have not identified any extraordinary circumstances that would preclude this categorical exclusion. Accordingly, NMFS has preliminarily determined that the issuance of the proposed IHA qualifies to be categorically excluded from further NEPA review.

We will review all comments submitted in response to this notice prior to concluding our NEPA process or making a final decision on the IHA request.

Summary of Request

On July 10, 2023, NMFS received a request from the Haines Borough for an IHA to take marine mammals incidental to pile driving involving impact, vibratory, and down-the-hole (DTH) drilling to replace the Lutak Dock. Following NMFS’ review of the application, Haines Borough submitted a revised version on October 11, 2023. The application was deemed adequate

and complete October 16, 2023. Haines Borough’s request is for take of six species of marine mammals by Level B harassment and, for a subset of three of these species, Level A harassment. Neither Haines Borough nor NMFS expect serious injury or mortality to result from this activity and, therefore, an IHA is appropriate.

Description of Proposed Activity

Overview

The purpose of the project is to replace the dock facility, constructed in 1953, that has reached the end of its 60-year service life and has experienced local structural failures. The Lutak Dock is an important maritime shipping link that is connected by road to the mainland of Alaska and Canada and is an important connection for the Alaska Marine Highway System to many other Alaskan ports. Takes of marine mammals by Level A and Level B harassment are expected to occur due to impact, DTH, and vibratory pile driving and removal. The project would occur in Lutak inlet which is located in Haines Borough in southeast Alaska. It is expected to take up to 234 non-consecutive days to complete the pile driving and removal activities.

Dates and Duration

Construction activities are expected to over a 1-year period from winter 2023 to winter of 2024. It is expected to take up to 234 non-consecutive days of in water work over a 1-year work window to complete the pile driving activities. Pile driving would be completed intermittently throughout daylight hours. All pile driving is expected to be completed during one phase of construction.

Specific Geographic Region

The project area is in the Haines Borough on the southern shore of Lutak Inlet, at the upper reaches of Lynn Canal in southeast Alaska. Lutak Dock is located approximately 6 kilometers (km) (4 miles (mi)) northwest of downtown Haines. Lutak Inlet is approximately 9 km (6 mi)-long and measures less than 2 km (1 mi) across from shore to shore at its widest point and is about 110 meters (m) (360 feet (ft)) deep at its entrance between Tanani Point and Taiya Point. Depths at the proposed action area are shallower, approximately 8 m (25 ft) to 30 m (100 ft). To the north of the proposed action area, the Ferebee River empties into the Taiyasanka Harbor and then into Lutak Inlet; to the west of the proposed action area, Chilkoot Lake empties into Lutak Inlet

via the Chilkoot River (see Figure 7 in Haines Borough's application).

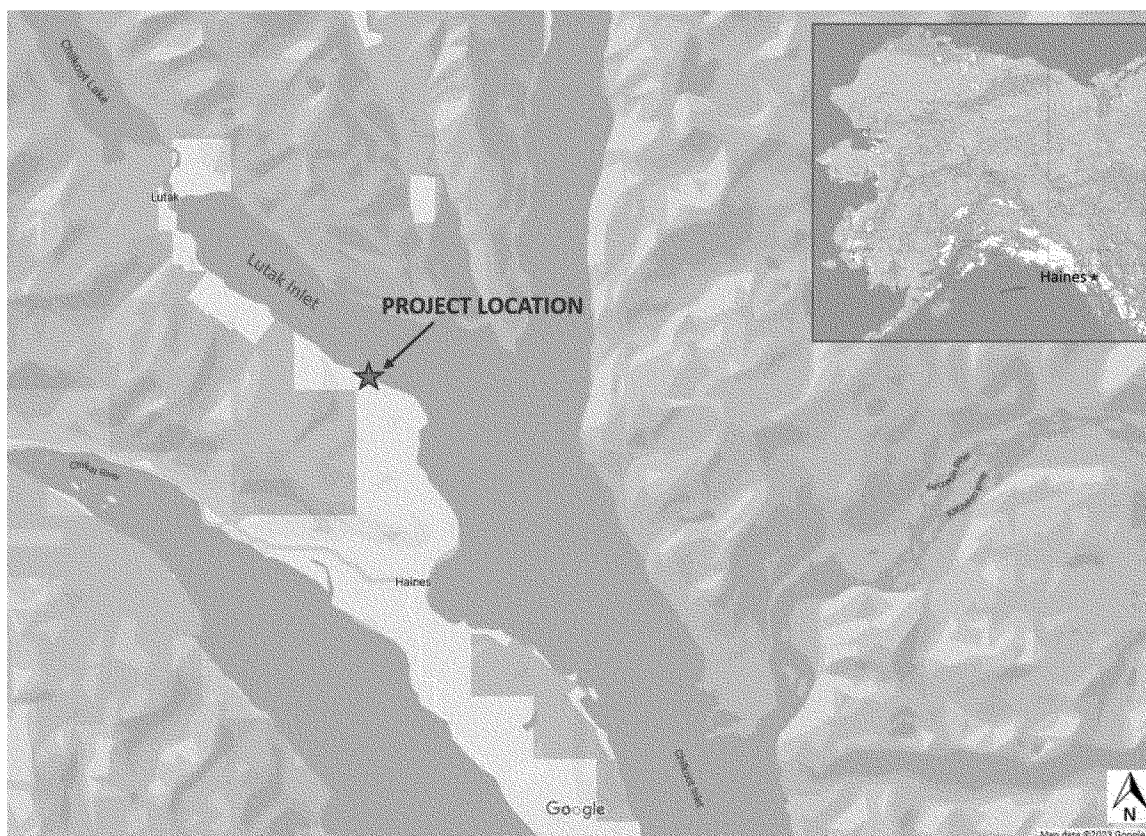


Figure 1. Project location of the Lutak Dock Replacement project

Figure 1. Project location of the Lutak Dock Replacement project

Detailed Description of the Specified Activity

The Haines Borough proposes to encapsulate the existing Lutak Dock structure with a new dock structure of similar design. In-water construction activities associated with the project would include impact pile driving, vibratory pile driving and removal, and DTH installation. Pile removal may also be completed using a “dead pull” method, where a pile is tethered to a crane and is removed directly. Impact hammers operate by repeatedly dropping a heavy piston onto a pile to drive the pile into the substrate. Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the

sediment. A DTH hammer is essentially a drill bit that drills through the bedrock using a rotating function like a normal drill, in concert with a hammering mechanism operated by a pneumatic (or sometimes hydraulic) component integrated into the DTH hammer to increase speed of progress through the substrate.

Pile removal would consist of 24 16 inches (in) steel pipe piles (41 centimeters (cm)) that make up the 4 mooring dolphins and 1 24-in (61-cm) steel guide pile. These piles would all be removed using dead pull or vibratory removal methods. Dead pull methods would not have impacts on marine mammals; however, we assume that all pile removal is conducted using vibratory hammer. A template frame would then be welded to 42 36-in (91-cm) temporary piles that is capable of

holding 10 permanent piles in each section. The temporary piles would be set in place using vibratory and impact hammers (as needed). The template frame would be used to position the 180 42-in (107-cm) permanent piles across the length of the dock. Up to 10 permanent piles would be set at a time, before moving the template to the next position to install the next 10 piles. Permanent piles would be set with vibratory hammers and if required, impact hammers would be used to drive the pile past any overburden to the bedrock. Once the pile reaches bedrock DTH systems would socket the pile approximately 10-ft into the bedrock. A permanent 55.5-in (140-cm) sheet pile would be installed using vibratory and impact hammers and attached to the permanent piles to make up the new dock return wall.

TABLE 1—NUMBER AND TYPES OF PILES TO BE INSTALLED AND REMOVED

	Guide pile removal (steel)	Dolphin pile removal (steel)	Temporary pile (steel)	Temporary pile removal (steel)	Permanent pile installation (steel)	Sheet pile installation (steel)
Pile Diameter size (in)	24	16	36	36	42	55.5
Vibratory Pile Driv- ing/Removal:						
Total Quantity	1	24	42	42	180	40
Max # of Piles per day	1	4	4	4	4	6
Vibratory time per pile (min)	45	45	15	15	45	30
Number of Days	1	6	11	11	45	7
Impact Pile Driv- ing:						
Total Quantity	N/A	N/A	42	N/A	180	40
Piles per day	N/A	N/A	4	N/A	4	6
Strikes per pile	N/A	N/A	900	N/A	1,500	900
Number of Days	N/A	N/A	11	N/A	45	7
Down the Hole Drilling:						
Total Quantity	N/A	N/A	N/A	N/A	180	N/A
Piles per day	N/A	N/A	N/A	N/A	2	N/A
Duration time per pile (min)	N/A	N/A	N/A	N/A	300	N/A
Strikes per pile	N/A	N/A	N/A	N/A	324,000	N/A
Number of Days	N/A	N/A	N/A	N/A	90	N/A

Above-water construction would include replacement of the dock surface and fill material placement. This above-water work is not expected to result in any take of marine mammals, as there are no pinniped haulouts close enough to be affected by airborne noise.

Proposed mitigation, monitoring, and reporting measures are described in detail later in this document (see Proposed Mitigation and Proposed Monitoring and Reporting).

Description of Marine Mammals in the Area of Specified Activities

Sections 3 and 4 of the application summarize available information regarding status and trends, distribution and habitat preferences, and behavior and life history of the potentially affected species. NMFS fully considered all of this information, and we refer the reader to these descriptions, instead of reprinting the information. Additional information regarding population trends and threats may be found in NMFS'

Stock Assessment Reports (SARs; <http://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>) and more general information about these species (e.g., physical and behavioral descriptions) may be found on NMFS' website (<https://www.fisheries.noaa.gov/find-species>).

Table 2 lists all species or stocks for which take is expected and proposed to be authorized for this activity, and summarizes information related to the population or stock, including regulatory status under the MMPA and Endangered Species Act (ESA) and potential biological removal (PBR), where known. PBR is defined by the MMPA as the maximum number of animals, not including natural mortalities, that may be removed from a marine mammal stock while allowing that stock to reach or maintain its optimum sustainable population (as described in NMFS' SARs). While no serious injury or mortality is anticipated

or proposed to be authorized here, PBR and annual serious injury and mortality from anthropogenic sources are included here as gross indicators of the status of the species or stocks and other threats.

Marine mammal abundance estimates presented in this document represent the total number of individuals that make up a given stock or the total number estimated within a particular study or survey area. NMFS' stock abundance estimates for most species represent the total estimate of individuals within the geographic area, if known, that comprises that stock. For some species, this geographic area may extend beyond U.S. waters. All managed stocks in this region are assessed in NMFS' Alaska SARs (Young *et al.*, 2023). All values presented in table 2 are the most recent available at the time of publication and are available online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessments>.

TABLE 2—SPECIES LIKELY IMPACTED BY THE SPECIFIED ACTIVITIES ¹

Common name	Scientific name	Stock	ESA/ MMPA status; strategic (Y/N) ²	Stock abundance (CV, N _{min} , most recent abundance survey) ³	PBR	Annual M/SI ⁴
Order Artiodactyla—Infraorder Cetacea—Mysticeti (baleen whales)						
<i>Family Balaenopteridae</i> (rorquals): Humpback whale	<i>Megaptera novaeangliae</i>	Hawai'i Mexico-North Pacific	-,-, N T, D, Y	11,278 (0.56, 7,265, 2020) N/A (N/A, N/A, 2006)	127 UND	27.09 0.57
Odontoceti (toothed whales, dolphins, and porpoises)						
<i>Family Delphinidae:</i> Killer whale	<i>Orcinus orca</i>	Eastern North Pacific Alaska Resident. Eastern Northern Pacific Northern Resident. West Coast Transient	-,-, N -,-, N -,-, N	1,920 (N/A, 1,920, 2019) 302 (N/A, 302, 2018) 349 (N/A, 349, 2018)	19 2.2 3.5	1.3 0.2 0.4
<i>Family Phocoenidae (porpoises):</i> Harbor porpoise	<i>Phocoena phocoena</i>	Northern Southeast Alaska In- land Waters.	-,-, N	1,619 (0.26, 1,250, 2019)	13	5.6
Dall's Porpoise	<i>Phocoenoides dalli</i>	Alaska	-,-, N	UND (UND, UND, 2015)	UND	37
Order Carnivora—Pinnipedia						
<i>Family Otariidae (eared seals and sea lions):</i> Steller sea lion	<i>Eumetopias jubatus</i>	Eastern DPS Western DPS	-,-, N E, D, Y	43,201 (N/A, 43,201, 2017) ... 52,932 (N/A, 52,932, 2019) ...	2,592 318	112 254
<i>Family Phocidae (earless seals)</i> Harbor Seal	<i>Phoca vitulina</i>	Lynn Canal/Stephens Pas- sage.	-,-, N	13,388 (N/A, 11,867, 2016) ...	214	50

¹ Information on the classification of marine mammal species can be found on the web page for The Society for Marine Mammalogy's Committee on Taxonomy (<https://www.marinemammalscience.org/science-and-publications/list-marine-mammal-species-subspecies/>; Committee on Taxonomy (2022)).

² ESA status: Endangered (E), Threatened (T)/MMPA status: Depleted (D). A dash (-) indicates that the species is not listed under the ESA or designated as depleted under the MMPA. Under the MMPA, a strategic stock is one for which the level of direct human-caused mortality exceeds PBR or which is determined to be declining and likely to be listed under the ESA within the foreseeable future. Any species or stock listed under the ESA is automatically designated under the MMPA as depleted and as a strategic stock.

³ NMFS marine mammal stock assessment reports online at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-stock-assessment-reports/>. CV is coefficient of variation; Nmin is the minimum estimate of stock abundance. In some cases, CV is not applicable.

⁴ These values, found in NMFS's SARs, represent annual levels of human-caused mortality plus serious injury from all sources combined (e.g., commercial fisheries, vessel strike). Annual M/SI often cannot be determined precisely and is in some cases presented as a minimum value or range. A CV associated with estimated mortality due to commercial fisheries is presented in some cases.

As indicated above, all six species (with 10 managed stocks) in table 2 temporally and/or spatially co-occur with the activity to the degree that take is reasonably likely to occur. While minke whales (*Balaenoptera acutorostrata*) and Pacific white-sided dolphins (*Lagenorhynchus obliquidens*) have been sighted in the area, the temporal and spatial occurrence of these species is such that take is not expected to occur, and they are not discussed further beyond the explanation provided here. A construction project to improve the Alaska Marine Lines, Inc. dock in Lutak, AK authorized the take of two minke whales by Level B harassment (85 FR 22139, April 21, 2020). A similar project in Skagway, AK to install dolphins on the Railroad Dock also authorized the take of two minke whales by Level B harassment (84 FR 4777, February 19, 2019). Pacific white-sided dolphins were not authorized for take in either project due to their extremely rare occurrence in the project areas (Dahlheim *et al.*, 2009). There

were no sightings by monitors of minke whales or Pacific white-sided dolphins during either construction project (Tom Mortensen Associates, LLC, 2021; Owl Ridge Natural Resource Consultants, 2019). Therefore, take is not expected for these species and they are not discussed further in this document.

Humpback Whale

On September 8, 2016, NMFS divided the once single species into 14 distinct population segments (DPS) under the ESA, removed the species-level listing as endangered, and, in its place, listed four DPSs as endangered and one DPS as threatened (81 FR 62259; September 8, 2016). The remaining nine DPSs were not listed. There are four DPSs in the North Pacific, including Western North Pacific and Central America, which are listed as endangered, Mexico, which is listed as threatened, and Hawaii, which is not listed.

The 2022 Alaska and Pacific SARs described a revised stock structure for humpback whales which modifies the

previous stocks designated under the MMPA to align more closely with the ESA-designated DPSs (Caretta *et al.*, 2023; Young *et al.*, 2023). Specifically, the three previous North Pacific humpback whale stocks (Central and western North Pacific stocks and a CA/OR/WA stock) were replaced by five stocks, largely corresponding with the ESA-designated DPSs. These include Western North Pacific and Hawaii stocks and a Central America/Southern Mexico-CA/OR/WA stock (which corresponds with the Central America DPS). The remaining two stocks, corresponding with the Mexico DPS, are the Mainland Mexico-CA/OR/WA and Mexico-North Pacific stocks (Caretta *et al.*, 2023; Young *et al.*, 2023). The former stock is expected to occur along the west coast from California to southern British Columbia, while the latter stock may occur across the Pacific, from northern British Columbia through the Gulf of Alaska and Aleutian Islands/Bering Sea region to Russia.

The Hawai'i stock consists of one demographically independent population (DIP)—Hawai'i—southeast Alaska/northern British Columbia DIP and one unit—Hawai'i—north Pacific unit, which may or may not be composed of multiple DIPs (Wade *et al.*, 2021). The DIP and unit are managed as a single stock at this time, due to the lack of data available to separately assess them and lack of compelling conservation benefit to managing them separately (NMFS, 2023; NMFS, 2019; NMFS, 2022b). The DIP is delineated based on two strong lines of evidence: genetics and movement data (Wade *et al.*, 2021). Whales in the Hawai'i—southeast Alaska/northern British Columbia DIP winter off Hawai'i and largely summer in southeast Alaska and northern British Columbia (Wade *et al.*, 2021). The group of whales that migrate from Russia, western Alaska (Bering Sea and Aleutian Islands), and central Alaska (Gulf of Alaska excluding southeast Alaska) to Hawai'i have been delineated as the Hawai'i-North Pacific unit (Wade *et al.*, 2021). There are a small number of whales that migrate between Hawai'i and southern British Columbia/Washington, but current data and analyses do not provide a clear understanding of which unit these whales belong to (Wade *et al.*, 2021; Carretta *et al.*, 2023; Young *et al.*, 2023).

The Mexico–North Pacific unit is likely composed of multiple DIPs, based on movement data (Martien *et al.*, 2021; Wade, 2021, Wade *et al.*, 2021). However, because currently available data and analyses are not sufficient to delineate or assess DIPs within the unit, it was designated as a single stock (NMFS, 2023a; NMFS, 2019; NMFS, 2022c). Whales in this stock winter off Mexico and the Revillagigedo Archipelago and summer primarily in Alaska waters (Martien *et al.*, 2021; Carretta *et al.*, 2023; Young *et al.*, 2023).

NMFS identified most of southeast Alaska, including Lynn Canal, as a Biologically Important Area (BIA) for humpback whales for feeding during the months of June through August; however, the proposed action area is northwest of and outside the boundaries of the BIA (Wild *et al.*, 2023). No humpback whales were observed in Lutak Inlet during monitoring for the Alaska Marine Lines, Inc. dock improvement project in Lutak in November 2020 (Tom Mortensen Associates, LLC, 2021). However, sightings of humpbacks are common in southeast Alaska (Dahlheim *et al.*, 2009). In Lynn Canal and Lutak Inlet, humpback whales are traditionally observed during seasons of high prey concentration, May through September

(Witteveen *et al.*, 2011; SolsticeAK, 2023).

Group sizes of humpback whales vary depending on the season, but based on sightings from local charter captains a group size of two can be expected from May through September and from October through April a group size of one can be expected (SolsticeAK, 2023; Straley *et al.*, 2018; Happywhale, 2023).

Killer Whale

Based on data regarding association patterns, acoustics, movements, and genetic differences, eight killer whale stocks are now recognized within the Pacific U.S. Exclusive Economic Zone, seven of which occur in Alaska. Of these eight stocks the three stocks most likely to occur in Lynn Canal are (1) the Alaska Resident stock which ranges from southeastern Alaska to the Aleutian Islands and Bering Sea; (2) the Northern Resident stock which occurs from Washington State through part of southeastern Alaska; and (3) the West Coast Transient stock which ranges from California through southeastern Alaska (Muto *et al.*, 2022).

Transient killer whales hunt and feed primarily on marine mammals, while residents forage primarily on fish. Transient killer whales feed primarily on harbor seals, Dall's porpoises, harbor porpoises, and sea lions. Resident killer whale populations in the eastern North Pacific feed mainly on salmonids, showing a strong preference for Chinook salmon (NMFS, 2016a).

Killer whales are common near the project area. During the monitoring of the White Pass and Yukon Railroad dock dolphin project groups of killer whales from one to nine individuals were observed from March through April (Owl Ridge Natural Resource Consultants, 2019). Group sizes of up to 15 may be expected during the project based on surveys conducted in southeast Alaska conducted by Witteveen *et al.* (2011).

Harbor Porpoise

The 2022 Alaska SARs described a revised stock structure for southeast Alaska harbor porpoise, which were split from one stock into three: the Northern Southeast Alaska Inland Waters, Southern Southeast Alaska Inland Waters, and Yakutat/Southeast Alaska Offshore Waters harbor porpoise stocks. This update better aligns harbor porpoise stock structure with genetics, trends in abundance, and information regarding discontinuous distribution trends (Young *et al.*, 2023). Harbor porpoises found in Lutak are assumed to be members of the northern southeast Alaska Inland Waters stock, which

encompasses Cross Sound, Glacier Bay, Icy Strait, Chatham Strait, Frederick Sound, Stephens Passage, Lynn Canal, and adjacent inlets.

Harbor porpoise are expected to be infrequent visitors to the upper portions of the Lynn Canal (Dahlheim *et al.*, 2009). Recent monitoring from the Alaska Marine Lines, Inc. dock improvement project in Lutak and the White Pass and Yukon Railroad dock dolphin project did not observe any harbor porpoises in the project areas during construction (Tom Mortensen Associates, LLC, 2021; Owl Ridge Natural Resource Consultants, 2019). A group size of two harbor porpoise is expected during the project based on survey data from Dahlheim *et al.* (2009).

Dall's Porpoise

Dall's porpoises are found throughout the North Pacific, from southern Japan to southern California and north to the Bering Sea. All Dall's porpoises in Alaska are members of the Alaska stock, and those off California, Oregon, and Washington are part of a separate stock. This species can be found in offshore, inshore, and nearshore habitat, but prefers waters more than 600 ft (183 m) deep (Dahlheim *et al.* 2009; Jefferson, 2009).

Dall's porpoises have been consistently observed in Lynn Canal, Stephens Passage, upper Chatham Strait, Frederick Sound, and Clarence Strait (Dahlheim *et al.*, 2000). The species is generally found in waters deeper than Lutak Inlet. However, despite generalized water depth preferences, Dall's porpoises may occur in shallower waters. Moran *et al.* (2018a) recently mapped Dall's porpoise distributions in bays, shallow water, and nearshore areas of Prince William Sound, habitats not typically utilized by this species. No Dall's porpoises were observed in Lutak Inlet during monitoring for the Alaska Marine Lines, Inc. dock improvement project in Lutak and the White Pass and Yukon Railroad dock dolphin project did not observe any Dall's porpoises in the project areas during construction (Tom Mortensen Associates, LLC, 2021; Owl Ridge Natural Resource Consultants, 2019). Although sightings near the project area are infrequent, a local tour boat captain confirmed there are occasional sightings of Dall's porpoises in Taiya Inlet, but most often they are seen farther south near Mud Bay, 15 km (9 mi) south of the project area (SolsticeAK 2023). It is expected that groups of two Dall's porpoise would be present in the project area based on survey data from Dahlheim *et al.* (2009) and on sighting data from above.

Steller Sea Lion

Steller sea lions were listed as threatened range-wide under the ESA on November 26, 1990 (55 FR 49204). Steller sea lions were subsequently partitioned into the western and eastern DPSs in 1997 (62 FR 24345, May 5, 1997). The eastern DPS remained classified as threatened until it was delisted on November 4, 2013 (78 FR 66140). The western DPS (those individuals west of the 144° W longitude or Cape Suckling, Alaska) was upgraded to endangered status following separation of the DPSs on May 5, 1997 (62 FR 24345). Both stocks of Steller sea lions are found in southeast Alaska and have the potential to occur in the project area, however it is more likely they would be from the eastern stock.

The majority of Steller sea lions that inhabit southeast Alaska are part of the eastern DPS; however, branded individuals from the western DPS make regular movements across the 144° longitude boundary to the northern “mixing zone” haulouts and rookeries within southeast Alaska (Jemison *et al.*, 2013). While haulouts and rookeries in the northern portion of southeast Alaska may be important areas for wDPS animals, there continues to be little evidence that their regular range extends to the southern haulouts and rookeries in southeast Alaska (Jemison *et al.*, 2018). However, genetic data analyzed in Hastings *et al.* (2020) indicated that up to 1.4 percent of Steller sea lions near Lutak Inlet may be members of the western DPS.

Gran Point is the closest major haulout and designated critical habitat area, approximately 10 miles (16 kilometers) from the Project site and outside of Taiya Inlet. The Lutak Inlet eulachon (*Thaleichthys pacificus*) run between April and May correlates with higher sea lion numbers near the Project site, with the Taiya Point haulout (approximately 10 miles (16.1 kilometers) away) being a popular land site (NOAA, 2022b).

During the White Pass & Yukon Route Railroad dock dolphin project, Steller

sea lions were sighted on 27 separate days with 165 individuals observed. A majority of the sightings occurred during April and May, with only six individuals sighted in March. Although a few sightings were 500 m from pile driving activities, most sightings were recorded over 1,000 m away from the pile driving site. Sightings were of single individuals and rafts up to 25 individuals (Owl Ridge Natural Resource Consultants, 2019). Monitoring at the Alaska Marine Lines, Inc. dock improvement project in Lutak observed lone Steller sea lions on 2 separate days (November 12 and 15, 2020). The sightings were between 800 m and 1,400 m from the pile driving (Tom Mortensen Associates, LLC, 2020). It is expected that groups of 40 may occur from mid-March through May during the eulachon run and groups of 2 the rest of the year.

Harbor Seal

Harbor seals inhabit coastal and estuarine waters off Alaska. They haul out on rocks, reefs, beaches, and drifting glacial ice. They are opportunistic feeders and often adjust their distribution to take advantage of locally and seasonally abundant prey (Womble *et al.*, 2009; Allen and Angliss, 2015). Harbor seals occurring in the project area belong to the Lynn Canal/Stephens Passage (LC/SP) stock. Harbor seals are common in Lutak Inlet and in Chilkat Inlet where there is a small haulout at Pyramid Island. They are abundant in the Chilkat and Chilkoot rivers in late fall and winter during spawning runs of salmon (*Onchorhynchus spp.*) and in the spring (mid-March through mid-May) when eulachon are present. As many as about 100 individuals have been observed actively feeding in Lutak Inlet near the mouth of the Chilkoot River, and at up-river locations during these fish runs (ADF&G, 2016).

Seven hundred thirty-five harbor seals were observed on 46 days of in-water activity, with sightings occurring in all months of the project. The majority of the harbor seal observations were near Yakutania Point, a harbor seal haulout

site. Most of the sightings occurred at least 1,000 m from the project site, however harbor seals came as close as 150 m and as far as 5,000 m. Harbor seals were observed travelling, swimming, playing, milling, looking, hauled out, sinking, and feeding (Owl Ridge Natural Resource Consultants, 2019). During the Alaska Marine Lines, Inc. dock improvement project in Lutak one lone harbor seal was observed 800 m away from the source. It is expected that groups of 100 may occur from mid-March through May and groups of 5 throughout the rest of the year.

Marine Mammal Hearing

Hearing is the most important sensory modality for marine mammals underwater, and exposure to anthropogenic sound can have deleterious effects. To appropriately assess the potential effects of exposure to sound, it is necessary to understand the frequency ranges marine mammals are able to hear. Not all marine mammal species have equal hearing capabilities (*e.g.*, Richardson *et al.*, 1995; Wartzok and Ketten, 1999; Au and Hastings, 2008). To reflect this, Southall *et al.* (2007, 2019) recommended that marine mammals be divided into hearing groups based on directly measured (behavioral or auditory evoked potential techniques) or estimated hearing ranges (behavioral response data, anatomical modeling, etc.). Note that no direct measurements of hearing ability have been successfully completed for mysticetes (*i.e.*, low-frequency cetaceans). Subsequently, NMFS (2018) described generalized hearing ranges for these marine mammal hearing groups. Generalized hearing ranges were chosen based on the approximately 65-decibel (dB) threshold from the normalized composite audiograms, with the exception for lower limits for low-frequency cetaceans where the lower bound was deemed to be biologically implausible and the lower bound from Southall *et al.* (2007) retained. Marine mammal hearing groups and their associated hearing ranges are provided in table 3.

TABLE 3—MARINE MAMMAL HEARING GROUPS
[NMFS, 2018]

Hearing group	Generalized hearing range*
Low-frequency (LF) cetaceans (baleen whales)	7 Hz to 35 kHz.
Mid-frequency (MF) cetaceans (dolphins, toothed whales, beaked whales, bottlenose whales)	150 Hz to 160 kHz.
High-frequency (HF) cetaceans (true porpoises, <i>Kogia</i> , river dolphins, Cephalorhynchid, <i>Lagenorhynchus cruciger</i> & <i>L. australis</i>).	275 Hz to 160 kHz.
Phocid pinnipeds (PW) (underwater) (true seals)	50 Hz to 86 kHz.

TABLE 3—MARINE MAMMAL HEARING GROUPS—Continued
[NMFS, 2018]

Hearing group	Generalized hearing range *
Otariid pinnipeds (OW) (underwater) (sea lions and fur seals)	60 Hz to 39 kHz.

* Represents the generalized hearing range for the entire group as a composite (*i.e.*, all species within the group), where individual species' hearing ranges are typically not as broad. Generalized hearing range chosen based on ~65 dB threshold from normalized composite audiogram, with the exception for lower limits for LF cetaceans (Southall *et al.*, 2007) and PW pinniped (approximation).

The pinniped functional hearing group was modified from Southall *et al.* (2007) on the basis of data indicating that phocid species have consistently demonstrated an extended frequency range of hearing compared to otariids, especially in the higher frequency range (Hemilä *et al.*, 2006; Kastelein *et al.*, 2009; Reichmuth and Holt, 2013).

For more detail concerning these groups and associated frequency ranges, please see NMFS (2018) for a review of available information.

Potential Effects of Specified Activities on Marine Mammals and Their Habitat

This section provides a discussion of the ways in which components of the specified activity may impact marine mammals and their habitat. The Estimated Take of Marine Mammals section later in this document includes a quantitative analysis of the number of individuals that are expected to be taken by this activity. The Negligible Impact Analysis and Determination section considers the content of this section, the Estimated Take of Marine Mammals section, and the Proposed Mitigation section, to draw conclusions regarding the likely impacts of these activities on the reproductive success or survivorship of individuals and whether those impacts are reasonably expected to, or reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.

Description of Sound Sources

The marine soundscape is comprised of both ambient and anthropogenic sounds. Ambient sound is defined as the all-encompassing sound in a given place and is usually a composite of sound from many sources both near and far. The sound level of an area is defined by the total acoustical energy being generated by known and unknown sources. These sources may include physical (*e.g.*, waves, wind, precipitation, earthquakes, ice, atmospheric sound), biological (*e.g.*, sounds produced by marine mammals, fish, and invertebrates), and anthropogenic sound (*e.g.*, vessels, dredging, aircraft, construction).

The sum of the various natural and anthropogenic sound sources at any given location and time—which comprise “ambient” or “background” sound—depends not only on the source levels (as determined by current weather conditions and levels of biological and shipping activity) but also on the ability of sound to propagate through the environment. In turn, sound propagation is dependent on the spatially and temporally varying properties of the water column and sea floor, and is frequency-dependent. As a result of the dependence on a large number of varying factors, ambient sound levels can be expected to vary widely over both coarse and fine spatial and temporal scales. Sound levels at a given frequency and location can vary by 10 to 20 dB from day to day (Richardson *et al.*, 1995). The result is that, depending on the source type and its intensity, sound from the specified activity may be a negligible addition to the local environment or could form a distinctive signal that may affect marine mammals.

In-water construction activities associated with the project would include impact pile driving, vibratory pile driving, vibratory pile removal, DTH installation. The sounds produced by these activities fall into one of two general sound types: impulsive and non-impulsive. Impulsive sounds (*e.g.*, explosions, gunshots, sonic booms, impact pile driving) are typically transient, brief (less than 1 second), broadband, and consist of high peak sound pressure with rapid rise time and rapid decay (ANSI, 1986; NIOSH, 1998; ANSI, 2005; NMFS, 2018). Non-impulsive sounds (*e.g.*, aircraft, machinery operations such as drilling or dredging, vibratory pile driving, and active sonar systems) can be broadband, narrowband or tonal, brief or prolonged (continuous or intermittent), and typically do not have the high peak sound pressure with rapid rise/decay time that impulsive sounds do (ANSI, 1995; NIOSH, 1998; NMFS, 2018). The distinction between these two sound types is important because they have differing potential to cause physical effects, particularly with regard to

hearing (*e.g.*, Ward, 1997; Southall, *et al.* 2007).

Impact hammers operate by repeatedly dropping a heavy piston onto a pile to drive the pile into the substrate. Sound generated by impact hammers is characterized by rapid rise times and high peak levels, a potentially injurious combination (Hastings and Popper, 2005). Vibratory hammers install piles by vibrating them and allowing the weight of the hammer to push them into the sediment. Vibratory hammers produce significantly less sound than impact hammers. Peak sound pressure levels (SPLs) may be 180 dB or greater, but are generally 10 to 20 dB lower than SPLs generated during impact pile driving of the same-sized pile (Oestman, *et al.*, 2009). Rise time is slower, reducing the probability and severity of injury, and sound energy is distributed over a greater amount of time (Nedwell and Edwards, 2002; Carlson, *et al.*, 2005).

DTH systems would also be used during the proposed construction. A DTH hammer is essentially a drill bit that drills through the bedrock using a rotating function like a normal drill, in concert with a hammering mechanism operated by a pneumatic (or sometimes hydraulic) component integrated into the DTH hammer to increase speed of progress through the substrate (*i.e.*, it is similar to a “hammer drill” hand tool). The sounds produced by the DTH methods contain both a continuous non-impulsive component from the drilling action and an impulsive component from the hammering effect. Therefore, NMFS treats DTH systems as both impulsive and continuous, non-impulsive sound source types simultaneously.

The likely or possible impacts of the Haines Borough's proposed activities on marine mammals could involve both non-acoustic and acoustic stressors. Potential non-acoustic stressors could result from the physical presence of the equipment and personnel; however, given there are no known pinniped haul-out sites in the vicinity of the proposed project site, visual and other non-acoustic stressors would be limited, and any impacts to marine mammals are

expected to primarily be acoustic in nature.

Auditory Effects

The introduction of anthropogenic noise into the aquatic environment from pile driving or drilling is the primary means by which marine mammals may be harassed from the Haines Borough specified activity. In general, animals exposed to natural or anthropogenic sound may experience physical and psychological effects, ranging in magnitude from none to severe (Southall *et al.*, 2007; Southall *et al.*, 2019). In general, exposure to pile driving or drilling noise has the potential to result in auditory threshold shifts and behavioral reactions (*e.g.*, avoidance, temporary cessation of foraging and vocalizing, changes in dive behavior). Exposure to anthropogenic noise can also lead to non-observable physiological responses, such as an increase in stress hormones. Additional noise in a marine mammal's habitat can mask acoustic cues used by marine mammals to carry out daily functions, such as communication and predator and prey detection. The effects of pile driving or drilling noise on marine mammals are dependent on several factors, including, but not limited to, sound type (*e.g.*, impulsive vs. non-impulsive), the species, age and sex class (*e.g.*, adult male vs. mom with calf), duration of exposure, the distance between the pile and the animal, received levels, behavior at time of exposure, and previous history with exposure (Wartzok *et al.*, 2004; Southall *et al.*, 2007). Here we discuss physical auditory effects (threshold shifts) followed by behavioral effects and potential impacts on habitat.

NMFS defines a noise-induced threshold shift (TS) as a change, usually an increase, in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). The amount of threshold shift is customarily expressed in dB. A TS can be permanent or temporary. As described in NMFS (2018a), there are numerous factors to consider when examining the consequence of TS, including, but not limited to, the signal temporal pattern (*e.g.*, impulsive or non-impulsive), likelihood an individual would be exposed for a long enough duration or to a high enough level to induce a TS, the magnitude of the TS, time to recovery (seconds to minutes or hours to days), the frequency range of the exposure (*i.e.*, spectral content), the hearing and vocalization frequency range of the exposed species relative to

the signal's frequency spectrum (*i.e.*, how animal uses sound within the frequency band of the signal; *e.g.*, Kastelein *et al.*, 2014), and the overlap between the animal and the source (*e.g.*, spatial, temporal, and spectral). When considering auditory effects for the DOT&PF's proposed activities, vibratory pile driving is considered a non-impulsive source, while impact pile driving is treated as an impulsive source. DTH systems are considered to have both non-impulsive and impulsive components.

Permanent Threshold Shift (PTS)—NMFS defines PTS as a permanent, irreversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). PTS does not generally affect more than a limited frequency range, and an animal that has incurred PTS has incurred some level of hearing loss at the relevant frequencies; typically animals with PTS are not functionally deaf (Richardson *et al.*, 1995; Au and Hastings, 2008). Available data from humans and other terrestrial mammals indicate that a 40 dB threshold shift approximates PTS onset (Ward *et al.*, 1958; Ward *et al.*, 1959; Ward, 1960; Kryter *et al.*, 1966; Miller, 1974; Ahroon *et al.*, 1996; Henderson *et al.*, 2008). PTS criteria for marine mammals are estimates, as with the exception of a single study unintentionally inducing PTS in a harbor seal (Kastak *et al.*, 2008), there are no empirical data measuring PTS in marine mammals largely due to the fact that, for various ethical reasons, experiments involving anthropogenic noise exposure at levels inducing PTS are not typically pursued or authorized (NMFS, 2018).

Temporary Threshold Shift (TTS)—A temporary, reversible increase in the threshold of audibility at a specified frequency or portion of an individual's hearing range above a previously established reference level (NMFS, 2018). Based on data from cetacean TTS measurements (Southall *et al.*, 2007; Southall *et al.*, 2019), a TTS of 6 dB is considered the minimum threshold shift clearly larger than any day-to-day or session-to-session variation in a subject's normal hearing ability (Schlundt *et al.*, 2000; Finneran *et al.*, 2000; Finneran *et al.*, 2002). As described in Finneran (2015), marine mammal studies have shown the amount of TTS increases with SELcum in an accelerating fashion: at low exposures with lower SELcum, the amount of TTS is typically small and the growth curves have shallow slopes. At exposures with higher SELcum, the

growth curves become steeper and approach linear relationships with the noise SEL.

Depending on the degree (elevation of threshold in dB), duration (*i.e.*, recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that takes place during a time when the animal is traveling through the open ocean, where ambient noise is lower and there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. We note that reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.*, 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Many studies have examined noise-induced hearing loss in marine mammals (see Finneran (2015) and Southall *et al.* (2019) for summaries). TTS is the mildest form of hearing impairment that can occur during exposure to sound (Kryter, 2013). While experiencing TTS, the hearing threshold rises, and a sound must be at a higher level in order to be heard. In terrestrial and marine mammals, TTS can last from minutes or hours to days (in cases of strong TTS). In many cases, hearing sensitivity recovers rapidly after exposure to the sound ends. For cetaceans, published data on the onset of TTS are limited to captive bottlenose dolphin (*Tursiops truncatus*), beluga whale (*Delphinapterus leucas*), harbor porpoise, and Yangtze finless porpoise (*Neophocoena asiaticaorientalis*) (Southall *et al.*, 2019). For pinnipeds in water, measurements of TTS are limited to harbor seals, elephant seals (*Mirounga angustirostris*), bearded seals (*Erignathus barbatus*), and California sea lions (*Zalophus californianus*) (Kastak *et al.*, 1999; Kastak *et al.*, 2007; Kastelein *et al.*, 2019b; Kastelein *et al.*, 2019c; Reichmuth *et al.*, 2019; Sills *et al.*, 2020; Kastelein *et al.*, 2021; Kastelein *et al.*, 2022a; Kastelein *et al.*, 2022b). These studies examine hearing thresholds measured in marine mammals before and after exposure to intense or long-duration sound exposures. The difference between the

pre-exposure and post-exposure thresholds can be used to determine the amount of threshold shift at various post-exposure times.

The amount and onset of TTS depends on the exposure frequency. Sounds at low frequencies, well below the region of best sensitivity for a species or hearing group, are less hazardous than those at higher frequencies, near the region of best sensitivity (Finneran and Schlundt, 2013). At low frequencies, onset-TTS exposure levels are higher compared to those in the region of best sensitivity (*i.e.*, a low frequency noise would need to be louder to cause TTS onset when TTS exposure level is higher), as shown for harbor porpoises and harbor seals (Kastelein *et al.*, 2019a; Kastelein *et al.*, 2019c). Note that in general, harbor seals and harbor porpoises have a lower TTS onset than other measured pinniped or cetacean species (Finneran, 2015). In addition, TTS can accumulate across multiple exposures, but the resulting TTS will be less than the TTS from a single, continuous exposure with the same SEL (Mooney *et al.*, 2009; Finneran *et al.*, 2010; Kastelein *et al.*, 2014; 2015). This means that TTS predictions based on the total, cumulative SEL will overestimate the amount of TTS from intermittent exposures, such as sonars and impulsive sources. Nachtigall *et al.* (2018) describe measurements of hearing sensitivity of multiple odontocete species (bottlenose dolphin, harbor porpoise, beluga, and false killer whale (*Pseudorca crassidens*) when a relatively loud sound was preceded by a warning sound. These captive animals were shown to reduce hearing sensitivity when warned of an impending intense sound. Based on these experimental observations of captive animals, the authors suggest that wild animals may dampen their hearing during prolonged exposures or if conditioned to anticipate intense sounds. Another study showed that echo-locating animals (including odontocetes) might have anatomical specializations that might allow for conditioned hearing reduction and filtering of low-frequency ambient noise, including increased stiffness and control of middle ear structures and placement of inner ear structures (Ketten *et al.*, 2021). Data available on noise-induced hearing loss for mysticetes are currently lacking (NMFS, 2018). Additionally, the existing marine mammal TTS data come from a limited number of individuals within these species.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, and there is no PTS

data for cetaceans, but such relationships are assumed to be similar to those in humans and other terrestrial mammals. PTS typically occurs at exposure levels at least several decibels above (a 40-dB threshold shift approximates PTS onset; *e.g.*, Kryter *et al.*, 1966; Miller, 1974) that inducing mild TTS (a 6-dB threshold shift approximates TTS onset; *e.g.*, Southall *et al.*, 2007). Based on data from terrestrial mammals, a precautionary assumption is that the PTS thresholds for impulsive sounds (such as impact pile driving pulses as received close to the source) are at least 6 dB higher than the TTS threshold on a peak-pressure basis and PTS cumulative sound exposure level thresholds are 15 to 20 dB higher than TTS cumulative sound exposure level thresholds (Southall *et al.*, 2007). Given the higher level of sound or longer exposure duration necessary to cause PTS as compared with TTS, it is considerably less likely that PTS could occur.

Furthermore, installing piles for this project requires a combination of impact pile driving, vibratory pile driving, and DTH drilling. For the project, these activities would not occur at the same time and there would likely be pauses in activities producing the sound during each day. Given these pauses and that many marine mammals are likely moving through the action area and not remaining for extended periods of time, the potential for any TS declines.

Behavior Effects

Exposure to noise from pile driving and removal also has the potential to behaviorally disturb marine mammals. Available studies show wide variation in response to underwater sound; therefore, it is difficult to predict specifically how any given sound in a particular instance might affect marine mammals perceiving the signal. If a marine mammal does react briefly to an underwater sound by changing its behavior or moving a small distance, the impacts of the change are unlikely to be significant to the individual, let alone the stock or population. However, if a sound source displaces marine mammals from an important feeding or breeding area for a prolonged period, impacts on individuals and populations could be significant (*e.g.*, Lusseau and Bejder, 2007; Weilgart, 2007; NRC, 2005; Southall *et al.*, 2021).

Disturbance may result in changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or

feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where sound sources are located. Pinnipeds may increase their haul out time, possibly to avoid in-water disturbance (Thorson and Reyff, 2006). Behavioral responses to sound are highly variable and context-specific and any reactions depend on numerous intrinsic and extrinsic factors (*e.g.*, species, state of maturity, experience, current activity, reproductive state, auditory sensitivity, time of day), as well as the interplay between factors (*e.g.*, Richardson *et al.*, 1995; Wartzok *et al.*, 2003; Southall *et al.*, 2007, Southall *et al.* 2021; Weilgart, 2007; Archer *et al.*, 2010). Behavioral reactions can vary not only among individuals but also within exposures of an individual, depending on previous experience with a sound source, context, and numerous other factors (Ellison *et al.*, 2012; Southall *et al.*, 2021), and can vary depending on characteristics associated with the sound source (*e.g.*, whether it is moving or stationary, number of sources, distance from the source). In general, pinnipeds seem more tolerant of, or at least habituate more quickly to, potentially disturbing underwater sound than do cetaceans, and generally seem to be less responsive to exposure to industrial sound than most cetaceans. For a review of studies involving marine mammal behavioral responses to sound, see: Southall *et al.*, 2007; Gomez *et al.*, 2016; and Southall *et al.*, 2021.

Disruption of feeding behavior can be difficult to correlate with anthropogenic sound exposure, so it is usually inferred by observed displacement from known foraging areas, the appearance of secondary indicators (*e.g.*, bubble nets or sediment plumes), or changes in dive behavior. As for other types of behavioral response, the frequency, duration, and temporal pattern of signal presentation, as well as differences in species sensitivity, are likely contributing factors to differences in response in any given circumstance (*e.g.*, Croll *et al.*, 2001; Nowacek *et al.*, 2004; Madsen *et al.*, 2006; Yazvenko *et al.*, 2007). A determination of whether foraging disruptions incur fitness consequences would require information on or estimates of the energetic requirements of the affected individuals and the relationship between prey availability, foraging effort and success, and the life history stage of the animal.

The area likely impacted by the project is relatively small compared to the available habitat in the surrounding waters of the Lynn Canal.

In 2019, the White Pass & Yukon Route Railroad dolphin replacement project (84 FR 4777, February 19, 2019) documented observations of marine mammals during construction activities (*i.e.*, pile driving) in Skagway, AK. This project was roughly 15 mi (24 km) from the proposed project site and features that are very similar (*i.e.* narrow inlet off the Lynn Canal). During the 57-day (March–May) protected species monitoring 26 killer whales and 2 humpback whales were observed traveling, diving, and swimming. There were 735 harbor seals and 165 Steller sea lions observed during the monitoring period of the project. Harbor seals and Steller sea lions were observed travelling, swimming, playing, milling, traveling, resting, porpoising, looking, hauled out, sinking, and feeding (Owl Ridge Natural Resource Consultants, 2019). During the monitoring of the 2020 Alaska Marine Lines, Inc. dock in Lutak, AK (85 FR 22139, April 21, 2020) protected species observers (PSOs) recorded two Steller sea lions and one harbor seal in the Level B harassment zone. Both species spent less than 5 minutes in the zone (Tom Mortensen Associates, LLC, 2021). No visible signs of disturbance were noted for any of these species that were present in at either project. Given the similarities in activities and habitat and the fact the same species are involved, we expect similar behavioral responses of marine mammals to the specified activity. That is, disturbance, if any, is likely to be temporary and localized (*e.g.*, small area movements).

Airborne Acoustic Effects—Pinnipeds that occur near the project site could be exposed to airborne sounds associated with pile driving and removal that have the potential to cause behavioral harassment, depending on their distance from pile driving activities. Cetaceans are not expected to be exposed to airborne sounds that would result in harassment as defined under the MMPA.

Airborne noise would primarily be an issue for pinnipeds that are swimming near the project site within the range of noise levels exceeding the acoustic thresholds. We recognize that pinnipeds in the water could be exposed to airborne sound that may result in behavioral harassment when looking with their heads above water. Most likely, airborne sound would cause behavioral responses similar to those discussed above in relation to underwater sound. For instance, anthropogenic sound could cause pinnipeds to exhibit changes in their normal behavior, such as reduction in vocalizations, or cause them to

temporarily abandon the area and move further from the source. However, these animals would previously have been “taken” because of exposure to underwater sound above the behavioral harassment thresholds, which are in all cases larger than those associated with airborne sound. Thus, the behavioral harassment of these animals is already accounted for in these estimates of potential take. Therefore, we do not believe that authorization of incidental take resulting from airborne sound for pinnipeds is warranted, and airborne sound is not discussed further here.

Marine Mammal Habitat Effects

The proposed project would occur within the same footprint as existing marine infrastructure. The nearshore habitat where the proposed project would occur is an area of relatively high marine vessel traffic. Most marine mammals do not generally use the area within the immediate vicinity of the project area. Temporary, intermittent, and short-term habitat alteration may result from increased noise levels within the Level A and Level B harassment zones. Effects on marine mammals will be limited to temporary displacement from pile installation and removal noise, and effects on prey species will be similarly limited in time and space.

Water Quality—Temporary and localized reduction in water quality will occur as a result of in-water construction activities. Most of this effect will occur during the installation and removal of piles and bedrock removal when bottom sediments are disturbed. The installation and removal of piles and bedrock removal will disturb bottom sediments and may cause a temporary increase in suspended sediment in the project area. During pile extraction, sediment attached to the pile moves vertically through the water column until gravitational forces cause it to slough off under its own weight. The small resulting sediment plume is expected to settle out of the water column within a few hours. Studies of the effects of turbid water on fish (marine mammal prey) suggest that concentrations of suspended sediment can reach thousands of milligrams per liter before an acute toxic reaction is expected (Burton, 1993).

Impacts to water quality from DTH hammers are expected to be similar to those described for pile driving. Impacts to water quality would be localized and temporary and would have negligible impacts on marine mammal habitat. Effects to turbidity and sedimentation are expected to be short-term, minor,

and localized. Since the currents are strong in the area, following the completion of sediment-disturbing activities, suspended sediments in the water column should dissipate and quickly return to background levels in all construction scenarios. Turbidity within the water column has the potential to reduce the level of oxygen in the water and irritate the gills of prey fish species in the proposed project area. However, turbidity plumes associated with the project would be temporary and localized, and fish in the proposed project area would be able to move away from and avoid the areas where plumes may occur. Therefore, it is expected that the impacts on prey fish species from turbidity, and therefore on marine mammals, would be minimal and temporary. In general, the area likely impacted by the proposed construction activities is relatively small compared to the available marine mammal habitat in southeast Alaska.

Effects on Prey

Construction activities would produce continuous (*i.e.*, vibratory pile driving) and impulsive (*i.e.*, impact driving) sounds and a both continuous and impulsive sounds from DTH installation. Fish react to sounds that are especially strong and/or intermittent low-frequency sounds. Short duration, sharp sounds can cause overt or subtle changes in fish behavior and local distribution. Hastings and Popper (2005) identified several studies that suggest fish may relocate to avoid certain areas of sound energy. Additional studies have documented effects of pile driving on fish, although several are based on studies in support of large, multiyear bridge construction projects (*e.g.*, Scholik and Yan, 2001; Scholik and Yan, 2002; Popper and Hastings, 2009). Sound pulses at received levels may cause noticeable changes in behavior (Pearson *et al.*, 1992; Skalski *et al.*, 1992). SPLs of sufficient strength have been known to cause injury to fish and fish mortality.

Impacts on marine mammal prey (*i.e.*, fish or invertebrates) of the immediate area due to the acoustic disturbance are possible. The duration of fish or invertebrate avoidance or other disruption of behavioral patterns in this area after pile driving stops is unknown, but a rapid return to normal recruitment, distribution and behavior is anticipated. Further, significantly large areas of fish and marine mammal foraging habitat are available in the nearby vicinity in the Lynn Canal.

The duration of the construction activities is relatively short, with pile driving and removal activities expected

last less than one-year. Each day, construction would occur for no more than 12 hours during the day and pile driving activities would be restricted to daylight hours. The most likely impact to fish from pile driving activities at the project area would be temporary behavioral avoidance of the area. In general, impacts to marine mammal prey species are expected to be minor and temporary due to the short timeframe for the project.

Construction activities, in the form of increased turbidity, have the potential to adversely affect fish in the project area. Increased turbidity is expected to occur in the immediate vicinity (on the order of 10 ft (3 m) or less) of construction activities. However, suspended sediments and particulates are expected to dissipate quickly within a single tidal cycle. Given the limited area affected and high tidal dilution rates any effects on fish are expected to be minor or negligible. In addition, best management practices would be in effect, which would limit the extent of turbidity to the immediate project area.

In summary, given the relatively short daily duration of sound associated with individual pile driving and events and the relatively small areas being affected, pile driving activities associated with the proposed action are not likely to have a permanent, adverse effect on any fish habitat, or populations of fish species. Thus, we conclude that impacts of the specified activity are not likely to have more than short-term adverse effects on any prey habitat or populations of prey species. Further, any impacts to marine mammal habitat are not expected to result in significant or long-term consequences for individual marine mammals, or to contribute to adverse impacts on their populations.

Estimated Take of Marine Mammals

This section provides an estimate of the number of incidental takes proposed for authorization through the proposed IHA, which will inform both NMFS' consideration of "small numbers," and the negligible impact determinations.

Harassment is the only type of take expected to result from these activities. Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as any act of pursuit, torment, or annoyance, which (i) has the potential to injure a marine mammal or marine mammal stock in the wild (Level A harassment); or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing,

nursing, breeding, feeding, or sheltering (Level B harassment).

Authorized takes would primarily be by Level B harassment, as use of the construction equipment (*i.e.*, pile driving) has the potential to result in disruption of behavioral patterns for individual marine mammals. There is also some potential for auditory injury (Level A harassment) to result, primarily for high frequency species and phocids, because predicted auditory injury zones are larger and beyond Haines Borough's capability to reasonably monitor. Auditory injury is unlikely to occur for other species groups, based on the combination of expected occurrence and monitoring capabilities relative to estimated Level A harassment zone sizes. The proposed mitigation and monitoring measures are expected to minimize the severity of the taking to the extent practicable.

As described previously, no serious injury or mortality is anticipated or proposed to be authorized for this activity. Below we describe how the proposed take numbers are estimated.

For acoustic impacts, generally speaking, we estimate take by considering: (1) acoustic thresholds above which NMFS believes the best available science indicates marine mammals will be behaviorally harassed or incur some degree of permanent hearing impairment; (2) the area or volume of water that will be ensonified above these levels in a day; (3) the density or occurrence of marine mammals within these ensonified areas; and, (4) the number of days of activities. We note that while these factors can contribute to a basic calculation to provide an initial prediction of potential takes, additional information that can qualitatively inform take estimates is also sometimes available (*e.g.*, previous monitoring results or average group size). Below, we describe the factors considered here in more detail and present the proposed take estimates.

Acoustic Thresholds

NMFS recommends the use of acoustic thresholds that identify the received level of underwater sound above which exposed marine mammals would be reasonably expected to be behaviorally harassed (equated to Level B harassment) or to incur PTS of some degree (equated to Level A harassment).

Level B Harassment—Though significantly driven by received level, the onset of behavioral disturbance from anthropogenic noise exposure is also informed to varying degrees by other factors related to the source or exposure context (*e.g.*, frequency, predictability, duty cycle, duration of the exposure,

signal-to-noise ratio, distance to the source), the environment (*e.g.*, bathymetry, other noises in the area, predators in the area), and the receiving animals (hearing, motivation, experience, demography, life stage, depth) and can be difficult to predict (*e.g.*, Southall *et al.*, 2007, Southall *et al.*, 2021, Ellison *et al.*, 2012). Based on what the available science indicates and the practical need to use a threshold based on a metric that is both predictable and measurable for most activities, NMFS typically uses a generalized acoustic threshold based on received level to estimate the onset of behavioral harassment. NMFS generally predicts that marine mammals are likely to be behaviorally harassed in a manner considered to be Level B harassment when exposed to underwater anthropogenic noise above root-mean-squared pressure received levels (RMS SPL) of 120 dB (referenced to 1 micropascal (re 1 μ Pa)) for continuous (*e.g.*, vibratory pile driving, drilling) and above RMS SPL 160 dB re 1 μ Pa for non-explosive impulsive (*e.g.*, seismic airguns) or intermittent (*e.g.*, scientific sonar) sources. Generally speaking, Level B harassment take estimates based on these behavioral harassment thresholds are expected to include any likely takes by TTS as, in most cases, the likelihood of TTS occurs at distances from the source less than those at which behavioral harassment is likely. TTS of a sufficient degree can manifest as behavioral harassment, as reduced hearing sensitivity and the potential reduced opportunities to detect important signals (conspecific communication, predators, prey) may result in changes in behavior patterns that would not otherwise occur.

Haines Borough's proposed activity includes the use of continuous (vibratory pile driving) and impulsive (impact pile driving) sources, and therefore the RMS SPL thresholds of 120 and 160 dB re 1 μ Pa are applicable. DTH systems have both continuous and intermittent (impulsive) components as discussed in the Description of Sound Sources section above. When evaluating Level B harassment, NMFS recommends treating DTH as a continuous source and applying the RMS SPL thresholds of 120 dB re 1 μ Pa.

Level A harassment—NMFS' Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing (Version 2.0 of Technical Guidance, 2018) identifies dual criteria to assess auditory injury (Level A harassment) to five different marine mammal groups (based on hearing sensitivity) as a result of exposure to noise from two different

types of sources (impulsive or non-impulsive). The Haines Borough's proposed construction includes the use of impulsive (impact pile driving) and non-impulsive (vibratory pile driving) sources. As described above, DTH includes both impulsive and non-

impulsive characteristics. When evaluating Level A harassment, NMFS recommends treating DTH as an impulsive source.

These thresholds are provided in the table below. The references, analysis, and methodology used in the

development of the thresholds are described in NMFS' 2018 Technical Guidance, which may be accessed at: <http://www.fisheries.noaa.gov/national/marine-mammal-protection/marine-mammal-acoustic-technical-guidance>.

TABLE 4—THRESHOLDS IDENTIFYING THE ONSET OF PERMANENT THRESHOLD SHIFT

Hearing group	PTS onset acoustic thresholds* (received level)	
	Impulsive	Non-impulsive
Low-Frequency (LF) Cetaceans	Cell 1: $L_{pk,flat}$: 219 dB; $L_{E,LF,24h}$: 183 dB	Cell 2: $L_{E,LF,24h}$: 199 dB.
Mid-Frequency (MF) Cetaceans	Cell 3: $L_{pk,flat}$: 230 dB; $L_{E,MF,24h}$: 185 dB	Cell 4: $L_{E,MF,24h}$: 198 dB.
High-Frequency (HF) Cetaceans	Cell 5: $L_{pk,flat}$: 202 dB; $L_{E,HF,24h}$: 155 dB	Cell 6: $L_{E,HF,24h}$: 173 dB.
Phocid Pinnipeds (PW) (Underwater)	Cell 7: $L_{pk,flat}$: 218 dB; $L_{E,PW,24h}$: 185 dB	Cell 8: $L_{E,PW,24h}$: 201 dB.
Otariid Pinnipeds (OW) (Underwater)	Cell 9: $L_{pk,flat}$: 232 dB; $L_{E,OW,24h}$: 203 dB	Cell 10: $L_{E,OW,24h}$: 219 dB.

* Dual metric acoustic thresholds for impulsive sounds: Use whichever results in the largest isopleth for calculating PTS onset. If a non-impulsive sound has the potential of exceeding the peak sound pressure level thresholds associated with impulsive sounds, these thresholds should also be considered.

Note: Peak sound pressure (L_{pk}) has a reference value of 1 μ Pa, and cumulative sound exposure level (L_E) has a reference value of 1 μ Pa²s. In this table, thresholds are abbreviated to reflect American National Standards Institute standards (ANSI 2013). However, peak sound pressure is defined by ANSI as incorporating frequency weighting, which is not the intent for this Technical Guidance. Hence, the subscript "flat" is being included to indicate peak sound pressure should be flat weighted or unweighted within the generalized hearing range. The subscript associated with cumulative sound exposure level thresholds indicates the designated marine mammal auditory weighting function (LF, MF, and HF cetaceans, and PW and OW pinnipeds) and that the recommended accumulation period is 24 hours. The cumulative sound exposure level thresholds could be exceeded in a multitude of ways (*i.e.*, varying exposure levels and durations, duty cycle). When possible, it is valuable for action proponents to indicate the conditions under which these acoustic thresholds will be exceeded.

Ensonified Area

Here, we describe operational and environmental parameters of the activity that are used in estimating the area ensonified above the acoustic thresholds, including source levels and transmission loss coefficient.

The sound field in the project area is the existing background noise plus additional construction noise from the proposed project. Marine mammals are expected to be affected via sound generated by the primary components of the project (*i.e.*, impact pile driving, vibratory pile driving and removal, DTH). The maximum (underwater) area ensonified above the thresholds for behavioral harassment referenced above is 20.86 km² (12.96 mi²), and would consist of the entire area of Lutak Inlet (see Figure 20 in the Haines Borough's application). Additionally, vessel traffic and other commercial and industrial activities in the project area may contribute to elevated background noise levels which may mask sounds produced by the project.

Transmission loss (TL) is the decrease in acoustic intensity as an acoustic pressure wave propagates out from a source. TL parameters vary with frequency, temperature, sea conditions, current, source and receiver depth, water depth, water chemistry, and bottom composition and topography. The general formula for underwater TL is:

$$TL = B * \log_{10} (R_1/R_2),$$

where:

TL = transmission loss in dB

B = transmission loss coefficient

R_1 = the distance of the modeled SPL from the driven pile, and

R_2 = the distance from the driven pile of the initial measurement

This formula neglects loss due to scattering and absorption, which is assumed to be zero here. The degree to which underwater sound propagates away from a sound source is dependent on a variety of factors, most notably the water bathymetry and presence or absence of reflective or absorptive conditions including in-water structures and sediments. Spherical spreading occurs in a perfectly unobstructed (free-field) environment not limited by depth or water surface, resulting in a 6-dB reduction in sound level for each doubling of distance from the source ($20 * \log[\text{range}]$). Cylindrical spreading occurs in an environment in which sound propagation is bounded by the water surface and sea bottom, resulting in a reduction of 3 dB in sound level for each doubling of distance from the source ($10 * \log[\text{range}]$). A practical spreading value of 15 is often used under conditions, such as the project site, where water increases with depth as the receiver moves away from the shoreline, resulting in an expected propagation environment that would lie between spherical and cylindrical

spreading loss conditions. Practical spreading loss is assumed here.

The intensity of pile driving sounds is greatly influenced by factors such as the type of piles, hammers, and the physical environment in which the activity takes place. In order to calculate the distances to the Level A harassment and the Level B harassment sound thresholds for the methods and piles being used in this project, the applicant and NMFS used acoustic monitoring data from other locations to develop proxy source levels for the various pile types, sizes and methods. The project includes vibratory, impact, and DTH pile installation of steel pipe and sheet piles and vibratory removal of steel pipe piles. Source levels for 36 in steel piles are used as a proxy for 42 in steel piles, as 36 in source levels are higher than those available for 42 in piles. Using these higher values is the more conservative approach for mitigation measures and take estimate calculations. NMFS consulted multiple sources to determine valid proxy source levels for the impact installation of sheet piles, as indicated in table 5. This is the best available data for sheet pile source levels and is based on 24-in sheet piles used for a project in California. Source levels for each pile size and driving method are presented in table 5.

TABLE 5—PROXY SOUND SOURCE LEVELS FOR PILE SIZES AND DRIVING METHODS

Pile size	Method	Proxy source level			Literature source
		dB RMS re 1μPa	dB SEL re 1μPa ² sec	dB peak re 1μPa	
16 in	Vibratory	161	N/A	N/A	Navy 2015.
24 in	Vibratory	161	N/A	N/A	Navy 2015.
36 in	Vibratory	166	N/A	N/A	Navy 2015.
42 in	Vibratory	170	N/A	N/A	Illingworth and Rodkin, 2019.
55.5 in sheet pile	Vibratory	162	N/A	N/A	Molnar <i>et al.</i> 2020.
36 in	Impact	192	184	211	Navy 2015.
42 in	Impact	192	184	211	Navy 2015.
55.5 in sheet pile	Impact	190	180	205	Caltrans 2015.
42 in	DTH	174	164	194	NMFS 2022.

The ensonified area associated with Level A harassment is more technically challenging to predict due to the need to account for a duration component. Therefore, NMFS developed an optional User Spreadsheet tool to accompany the Technical Guidance that can be used to relatively simply predict an isopleth distance for use in conjunction with marine mammal density or occurrence to help predict potential takes. We note that because of some of the assumptions included in the methods underlying this

optional tool, we anticipate that the resulting isopleth estimates are typically going to be overestimates of some degree, which may result in an overestimate of potential take by Level A harassment. However, this optional tool offers the best way to estimate isopleth distances when more sophisticated modeling methods are not available or practical. For stationary sources such as impact or vibratory pile driving and removal and DTH, the optional User Spreadsheet tool predicts

the distance at which, if a marine mammal remained at that distance for the duration of the activity, it would be expected to incur PTS. Inputs used in the optional User Spreadsheet tool, and the resulting estimated isopleths, are reported below. Inputs used in the optional User Spreadsheet tool (table 6), and the resulting estimated isopleths and the calculated Level B harassment isopleth (table 7), are reported below. For source levels of each pile please refer to Table 5.

TABLE 6—USER SPREADSHEET INPUT PARAMETERS USED FOR CALCULATING LEVEL A HARASSMENT ISOPLETHS

Pile size and installation method	Spreadsheet tab used	Weighting factor adjustment (kHz)	Number of strikes per pile	Number of piles per day	Activity duration (minutes)
16-in vibratory removal	A.1 Vibratory pile driving	2.5	N/A	4	45
24-in vibratory removal	A.1 Vibratory pile driving	2.5	N/A	1	45
36-in vibratory installation (temporary).	A.1 Vibratory pile driving	2.5	N/A	4	15
36-in vibratory removal (temporary).	A.1 Vibratory pile driving	2.5	N/A	4	15
42-in vibratory installation	A.1 Vibratory pile driving	2.5	N/A	4	45
55-in sheet pile vibratory installation.	A.1 Vibratory pile driving	2.5	N/A	6	30
36-in impact installation (temporary).	E.1 Impact pile driving	2	900	4	N/A
42-in impact installation	E.1 Impact pile driving	2	1,500	4	N/A
55-in sheet pile impact installation.	E.1 Impact pile driving	2	900	6	N/A
42-in DTH installation	E.2 DTH systems	2	324,000	2	N/A

TABLE 7—CALCULATED LEVEL A AND LEVEL B HARASSMENT ISOPLETHS

Activity	Level A harassment zone (m)					Level B harassment zone (m)
	LF-cetaceans	MF-cetaceans	HF-cetaceans	Phocids	Otariids	
16-in vibratory removal	14.2	1.3	21.8	8.6	0.6	5,412
24-in vibratory removal	5.6	0.5	8.3	3.4	0.2	
36-in vibratory installation (temporary)	14.7	1.3	21.8	8.9	0.6	11,659
36-in vibratory removal (temporary)	14.7	1.3	21.8	8.9	0.6	
42-in vibratory installation	42.9	3.8	63.4	26.1	1.8	16,343
55-in sheet pile vibratory installation	16.6	1.5	24.5	10.1	0.7	6,310
36-in impact installation (temporary)	2,734.9	97.3	3,257.7	1,463.6	106.6	1,359
42-in impact installation	3,844.5	136.7	4,579.4	2,057.4	149.8	1,359
55-in sheet pile impact installation	1,939.4	69.0	2,310.1	1,037.9	75.6	1,000
42-in DTH installation	4,046.9	143.9	4,820.5	2,165.7	157.7	39,811

Marine Mammal Occurrence

In this section we provide information about the occurrence of marine mammals, including density or other relevant information which will inform the take calculations.

When available, peer-reviewed scientific publications were used to estimate marine mammal abundance in the project area. Data from monitoring reports from previous projects in Lutak and Skagway were used. However, scientific surveys and resulting data, such as population estimates, densities, and other quantitative information, are lacking for some marine mammal populations and most areas of southeast Alaska, including Lutak Inlet. Therefore, Haines Borough additionally gathered qualitative information from discussions with knowledgeable local people in the Lutak area. Assumptions regarding the size of expected groups of different species, and the frequency of occurrence of those groups, were proposed by Haines Borough on the basis of the aforementioned information. NMFS has reviewed the available information and concurs that these choices are reasonable.

Here we describe how the information provided is synthesized to produce a quantitative estimate of the take that is reasonably likely to occur and proposed for authorization. Since reliable densities are not available, the take numbers are based on the assumed maximum number of animals in a group at a given time and the occurrence of those groups per day multiplied by the duration of each activity. Tables for each species are presented to show the calculation of take during the project. The take calculation for this project is: Incident take estimate = number of individuals in a group * groups per day * days of pile-related activity

Humpback Whale

Humpback whale presence in Lutak is irregular year-round. From mid-May through September whales are assumed to occur in groups of two and from October to April in groups of one. It is expected that in early summer (mid-May through July) one group every two days may occur and at all other times of the year one group every 10 days would occur in the project area (Solstice AK, 2023 and Happywhale, 2023). Therefore, using the equation given above, the total number of Level B harassment takes for humpback whales would be 26. Given that 2 percent of the humpback whales in southeast Alaska are expected to be members of the Mexico stock (Wade *et al.*, 2016), one take is assumed to be from the Mexico

stock and 25 takes from the Hawaii stock.

The largest Level A harassment zone for humpback whales extends 4,050 m from the noise source (table 9). All construction work would be shut down prior to a humpback whale entering the Level A harassment zone specific to the in-water activity underway at the time. In consideration of the infrequent occurrence of humpback whales in the project area and proposed shutdown requirements, no take by Level A harassment is anticipated or proposed for humpback whales.

Killer Whale

Killer whales occur in the Lutak Inlet year round with higher occurrences in the spring. Group sizes of 15 animals are expected with 1 group every 20 days from mid-March through May and 1 group every 30 days for the remainder of the year (Hart Crowser, Inc. and KPFF Consulting Engineers 2016). There are three stocks of killer whales that may be present in the project area, with the following proportions of overall killer whale occurrence expected: Alaska Residents, 75 percent; West Coast Transients, 13 percent; and Northern Residents, 12 percent (Section 6 of the IHA application). The applicant estimated these occurrence proportions by determining the total number of animals in all three stocks and dividing that number by the number of animals in a given stock. Therefore, with 130 expected total takes by Level B harassment, 103 takes are expected to be from the Alaska Resident stock, 19 takes are expected from the West Coast Transient stock, and 16 takes are expected from the Northern Resident stock.

The largest Level A harassment zone for killer whales extends 150 meters from the noise source (table 9). Killer whales are generally conspicuous and protected species observers (PSO) are expected to detect killer whales and implement a shutdown before the animals enter the Level A harassment zone. Therefore, takes by Level A harassment are not anticipated or proposed to be authorized.

Harbor Porpoise

Harbor porpoise are present year round in the Lynn Canal and are expected to be present in groups of two every 30 days at the project site. Haines Borough requested a total of 29 takes of harbor porpoise for the duration of the project. Of the 29 takes it is expected that 13 of those takes could be by Level A harassment, over 153 days of impact installation of 36-in, 42-in, and 55-in sheet piles and DTH activities. For

construction activities that are of short duration and the take estimate was below the expected group size, the expected group size (*e.g.*, two animals) was used as a proxy for take calculations for those activities. The remaining 16 takes would be expected to be by Level B harassment.

Harbor porpoises are known to be an inconspicuous species and are challenging for protected species observers (PSOs) to sight, making any approach to a specific area potentially difficult to detect. The largest Level A harassment zone results from impact driving of 42-in piles, and extends 4,820.5 m from the source for high frequency cetaceans (table 7). We propose a distance of 200 m as an effective shutdown zone, given the difficulty of observing harbor porpoise at greater distances (see Proposed Mitigation section). Therefore, some take by Level A harassment is expected.

Dall's Porpoise

Groups of four Dall's porpoise are expected to occur once every 30 days during the proposed project (Dahlheim *et al.*, 2009), resulting in an estimate of 31 takes by Level B harassment. Although no Dall's porpoise were observed during recent monitoring of other projects in the area, tour boat operators occasionally observe Dall's porpoise in Taiya Inlet (SolsticeAK, 2023). Therefore, the applicant has requested authorization of take as described above. NMFS concurs with this request and proposes to authorize the take.

The largest Level A harassment zone for Dall's porpoise extends 4,820.5 m from the source during DTH installation of 42-in piles (table 7). Although Haines Borough would implement a significantly smaller shutdown zone (*i.e.*, 200-m), given the low likelihood of occurrence of Dall's porpoises in the area take by Level A harassment is not anticipated and is not proposed to be authorized.

Steller Sea Lion

Steller sea lions are frequently observed in the project area. Group sizes vary during seasonal fish runs in the area. Groups of 40 animals per day are expected from mid-March through May when animals frequent the project site, including the Taiya point haulout. At other times of the year groups of 2 animals per day are expected in the project area.

During the impact installation of 36-in and 42-in piles and the DTH installation of 42-in piles, groups of 2 sea lions per day are expected to occur within the respective Level A

harassment zones over 146 days associated with these activities. On this basis, we propose to authorize 292 takes of Steller sea lions by Level A harassment. Given that 1.4 percent of Steller sea lions are members of the ESA listed western DPS in the project area, 4 of the 292 takes by Level A harassment would likely be western DPS individuals. The largest Level A harassment zone for Steller sea lions is 150 m (table 7) but it may be difficult for PSOs to view Steller sea lions at the outer edges of the zone and therefore some take by Level A harassment is expected.

Larger harassment zones associated with Level B harassment would encompass the Taiya point haulout. It is expected that groups of 40 Steller sea lions per day over 75 days of vibratory installation of all pile types, impact installation of 36-in and 42-in piles, and DTH installation of 42-in piles which would equate to 3,000 takes by Level B harassment. At other times of the year when the Taiya point haulout is not used group size would be two sea lions per day. During this period the

applicant would complete work over 151 days for vibratory installation of all pile types, impact installation of 36-in and 42-in piles, and DTH installation of 42-in piles which would equate to 302 takes by Level B harassment.

Harbor Seal

Harbor seals are common in the project area year round. The applicant expects groups of 100 animals from March through May when animals are more frequent feeding at the mouth of the Chilkoot River. At other times of the year groups of five animals are expected in the project area (SolsticeAK 2023).

During impact installation of 36-in, 42-in, and 55-in sheet piles and DTH installation of 42-in piles it is expected that one group of five harbor seals every 10 days would occur. Over 153 days of activity 79 total takes by Level A harassment may occur. For construction activities that are of short duration and the take estimate was below the expected group size, the expected group size (*e.g.* five animals) was used as a proxy for take calculations for those activities. The largest Level A

harassment zone results from impact driving of 42-in piles, and extends 2,057 m from the source for phocids (table 7). We propose a distance of 200 m as an effective shutdown zone, given the difficulty of observing harbor seals at greater distances (see Proposed Mitigation section). Therefore, take by Level A harassment is expected.

Similar to Steller sea lions the larger Level B harassment zones would encompass the mouth of the Chilkoot River where larger aggregations of harbor seals are known to occur. It is expected that groups of harbor seals of 100 every 10 days over 75 days of vibratory installation of all pile types, impact installation of all pile types, and DTH installation of 42-in piles, which would equate to 750 takes by Level B harassment. During other times of the year the applicant expects groups of five animals every 10 days over a 151 day period for vibratory installation of all pile types, impact installation of 36-in and 42-in piles, and DTH installation of 42-inch piles. This would result in 827 takes by Level B harassment.

TABLE 8—ESTIMATED TAKE BY LEVEL A AND LEVEL B HARASSMENT, BY SPECIES AND STOCK

Common name	Stock	Stock abundance ^a	Level A	Level B	Total proposed take	Proposed take as a percentage
Humpback Whale	Mexico	UKN	0	1	1	N/A
	Hawaii	11,278	0	25	25	0.2
Killer Whale	Alaska Resident	1,920	0	103	103	5.4
	West Coast Transients	349	0	19	19	5.4
	Eastern North Pacific Northern Residents.	302	0	16	16	5.3
Harbor Porpoise	Northern Southeast Alaska	1,619	13	16	29	1.8
Dall's Porpoise	Alaska	UKN	0	31	31	N/A
Steller sea lion	Western DPS	52,932	4	33	37	< 0.1
	Eastern DPS	43,201	288	2,319	2,607	6.0
Harbor Seal	Lynn Canal/Stephens Passage.	13,388	79	827	906	6.8

^a Stock or DPS size is Nbest according to NMFS 2022 Final Stock Assessment Reports.

Proposed Mitigation

In order to issue an IHA under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to the activity, and other means of effecting the least practicable impact on the species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance. NMFS regulations require applicants for incidental take authorizations to include information about the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting the activity or other means of effecting the least practicable adverse impact upon the affected species or

stocks, and their habitat (50 CFR 216.104(a)(11)).

In evaluating how mitigation may or may not be appropriate to ensure the least practicable adverse impact on species or stocks and their habitat, as well as subsistence uses where applicable, NMFS considers two primary factors:

(1) The manner in which, and the degree to which, the successful implementation of the measure(s) is expected to reduce impacts to marine mammals, marine mammal species or stocks, and their habitat. This considers the nature of the potential adverse impact being mitigated (likelihood, scope, range). It further considers the likelihood that the measure will be

effective if implemented (probability of accomplishing the mitigating result if implemented as planned), the likelihood of effective implementation (probability implemented as planned); and

(2) The practicability of the measures for applicant implementation, which may consider such things as cost, and impact on operations.

The following measures would apply to Haines Borough's mitigation requirements:

Implementation of Shutdown Zones— For all pile driving/removal activities, Haines Borough would implement shutdowns within designated zones. The purpose of a shutdown zone is generally to define an area within which

shutdown of activity would occur upon sighting of a marine mammal (or in anticipation of an animal entering the defined area). Implementation of shutdowns would be used to avoid or minimize incidental Level A harassment takes from vibratory, impact, and DTH pile removal and installation (Table 8). For all pile driving/removal activities, a minimum 10-m shutdown zone must be established. NMFS has recommended

shutdown zones of 200 m for high-frequency cetaceans and phocids, despite significantly larger estimated Level A harassment zones, in order to prescribe implementation of a zone that may be reasonably observed under typical conditions for these cryptic species. It is reasonable to expect that these species would be difficult to detect from distances further than 200 m by PSOs (table 9). All other shutdown

zones for pile driving and removal activities are based on the Level A harassment zones and therefore vary by pile size and marine mammal hearing group (table 9). The placement of PSOs during all pile driving activities (described in detail in the Monitoring and Reporting section) would ensure the full extent of shutdown zones are visible to PSOs.

TABLE 9—SHUTDOWN ZONES DURING PILE INSTALLATION AND REMOVAL

Activity	Pile size	Minutes or strikes per pile	Piles per day	Shutdown zones (m)				
				LF cetaceans	MF cetaceans	HF cetaceans	Phocids	Otariids
Vibratory Removal	16-in	45 min	4	15	10	30	10	10
	24-in	45 min	1	10				
Vibratory Installation	36-in (temporary)	15 min	4	15	10	30	10	10
	36-in (temporary)	15 min	4	15	10	30	10	10
	42-in	45 min	4	60	10	85	35	10
	55-in sheet pile	30 min	6	20	10	25	10	10
Impact Installation	36-in (temporary)	900 strikes	4	2,735	110	200	200	110
	42-in	1,500 strikes	4	3,845	150			150
	55-in sheet pile	900 strikes	6	1,940	70			80
DTH drilling	42-in	300 min/324,000 strikes	2	4,050	145			160

Establishment of Monitoring Zones—Haines Borough has identified monitoring zones correlated with the larger of the Level B harassment or Level A harassment zones. Monitoring zones provide utility for observing by establishing monitoring protocols for areas adjacent to the shutdown zones. In some cases the calculated monitoring zones are smaller than the Level A shutdown zones as presented in table 10. This is due to the project area being bounded by land to 7,000 m on the western most shore of the inlet and 5,820 m on the eastern shore. Monitoring zones enable observers to be aware of and communicate the presence of marine mammals in the project area outside the shutdown zone and thus prepare for a potential cessation of activity should the animal enter the shutdown zone. PSOs would monitor the entire visible area to maintain the best sense of where animals are moving relative to the zone boundaries defined in tables 9 and 10. Placement of PSOs on the shorelines around Lutak Inlet allow PSOs to observe marine mammals within and near the inlet. The applicant may also voluntarily place a PSO on a skiff in Taiya Inlet if safe conditions allow for such activity.

TABLE 10—MARINE MAMMAL MONITORING ZONE

Activity	Monitoring zone (m)
Vibratory removal of 16-in and 24-in piles	5,425
Vibratory installation and removal of 36-in temporary piles	7,000
Vibratory installation of 42-in piles	7,000
Vibratory installation of 55-in sheet piles	6,310
Impact installation of 36-in temporary piles	*1,360
Impact installation of 42-in piles	*1,360
Impact installation of 55-in sheet piles	1,000
DTH installation of 42-in piles	7,000

* Where Level A shutdown zones are larger than the Level B harassment zones.

Soft Start—The use of soft-start procedures are believed to provide additional protection to marine mammals by providing warning and/or giving marine mammals a chance to leave the area prior to the hammer operating at full capacity. For impact pile driving, contractors would be required to provide an initial set of strikes from the hammer at reduced energy, with each strike followed by a 30-second waiting period. This procedure would be conducted a total of three times before impact pile driving begins. Soft start would be implemented

at the start of each day's impact pile driving and at any time following cessation of impact pile driving for a period of 30 minutes or longer. Soft start is not required during vibratory pile driving and removal activities.

Pre-Activity Monitoring—Prior to the start of daily in-water construction activity, or whenever a break in pile driving/removal of 30 minutes or longer occurs, PSOs would observe the shutdown and monitoring zones for a period of 30 minutes. The shutdown zone would be considered cleared when a marine mammal has not been observed within the zone for that 30-minute period. If a marine mammal is observed within the shutdown zone, a soft-start cannot proceed until the animal has left the zone or has not been observed for 15 minutes. If the monitoring zone has been observed for 30 minutes and marine mammals are not present within the zone, soft-start procedures can commence and work can continue even if visibility becomes impaired within the monitoring zone. When a marine mammal permitted for take by Level B harassment is present in the Level B harassment zone, activities may begin. No work may begin unless the entire shutdown zone is visible to the PSOs. If work ceases for more than 30 minutes, the pre-activity monitoring of both the monitoring zone and shutdown zone would commence.

Based on our evaluation of the applicant's proposed measures, NMFS has preliminarily determined that the

proposed mitigation measures provide the means of effecting the least practicable impact on the affected species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an IHA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must set forth requirements pertaining to the monitoring and reporting of such taking. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for authorizations must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present while conducting the activities. Effective reporting is critical both to compliance as well as ensuring that the most value is obtained from the required monitoring.

Monitoring and reporting requirements prescribed by NMFS should contribute to improved understanding of one or more of the following:

- Occurrence of marine mammal species or stocks in the area in which take is anticipated (*e.g.*, presence, abundance, distribution, density);
- Nature, scope, or context of likely marine mammal exposure to potential stressors/impacts (individual or cumulative, acute or chronic), through better understanding of: (1) action or environment (*e.g.*, source characterization, propagation, ambient noise); (2) affected species (*e.g.*, life history, dive patterns); (3) co-occurrence of marine mammal species with the activity; or (4) biological or behavioral context of exposure (*e.g.*, age, calving or feeding areas);
- Individual marine mammal responses (behavioral or physiological) to acoustic stressors (acute, chronic, or cumulative), other stressors, or cumulative impacts from multiple stressors;
- How anticipated responses to stressors impact either: (1) long-term fitness and survival of individual marine mammals; or (2) populations, species, or stocks;
- Effects on marine mammal habitat (*e.g.*, marine mammal prey species, acoustic habitat, or other important physical components of marine mammal habitat); and
- Mitigation and monitoring effectiveness.

Visual Monitoring

Monitoring shall be conducted by NMFS-approved observers in accordance with the monitoring plan (Appendix C of the IHA application) and Section 5 of the IHA. Trained observers shall be placed from the best vantage point(s) practicable to monitor for marine mammals and implement shutdown or delay procedures when applicable through communication with the equipment operator. Observer training must be provided prior to project start, and shall include instruction on species identification (sufficient to distinguish the species in the project area), description and categorization of observed behaviors and interpretation of behaviors that may be construed as being reactions to the specified activity, proper completion of data forms, and other basic components of biological monitoring, including tracking of observed animals or groups of animals such that repeat sound exposures may be attributed to individuals (to the extent possible).

Monitoring would be conducted 30 minutes before, during, and 30 minutes after pile driving/removal activities. In addition, observers shall record all incidents of marine mammal occurrence, regardless of distance from activity, and shall document any behavioral reactions in concert with distance from piles being driven or removed. Pile driving/removal activities include the time to install or remove a single pile or series of piles, as long as the time elapsed between uses of the pile driving equipment is no more than 30 minutes.

A minimum of one PSO would be on duty during all barge movements and other in-water construction activities and a minimum of three PSOs during all pile driving activities. Locations from which PSOs would be able to monitor for marine mammals are readily available from publicly accessible shore side areas at the project site, Lutak Road at a beach across from Takshanuk Mountain trail, and along the shoreline just south of Tanani Point along Lutak Road. PSOs would monitor for marine mammals entering the harassment zones.

PSOs would scan the waters using binoculars and would use a handheld range-finder device to verify the distance to each sighting from the project site. All PSOs would be trained in marine mammal identification and behaviors and are required to have no other project-related tasks while conducting monitoring. In addition, monitoring would be conducted by qualified observers, who would be

placed at the best vantage point(s) practicable to monitor for marine mammals and implement shutdown/delay procedures when applicable by calling for the shutdown to the hammer operator via a radio. Haines Borough would adhere to the following observer qualifications:

(i) PSOs must be independent of the activity contractor (for example, employed by a subcontractor) and have no other assigned tasks during monitoring periods;

(ii) One PSO would be designated as the lead PSO or monitoring coordinator and that observer must have prior experience working as an observer;

(iii) Other observers may substitute education (degree in biological science or related field) or training for experience; and

(iv) Haines Borough must submit observer Curriculum Vitae for approval by NMFS.

Additional recommended observer qualifications include:

- Ability to conduct field observations and collect data according to assigned protocols;
- Experience or training in the field identification of marine mammals, including the identification of behaviors;
- Sufficient training, orientation, or experience with the construction operation to provide for personal safety during observations;
- Writing skills sufficient to prepare a report of observations including but not limited to the number and species of marine mammals observed; dates and times when in-water construction activities were conducted; dates and times when in-water construction activities were suspended to avoid potential incidental injury from construction sound of marine mammals observed within a defined shutdown zone; and marine mammal behavior; and
- Ability to communicate orally, by radio or in person, with project personnel to provide real-time information on marine mammals observed in the area as necessary.

Reporting

A draft marine mammal monitoring report would be submitted to NMFS within 90 days after the completion of pile driving and removal activities. It would include an overall description of work completed, a narrative regarding marine mammal sightings, and associated PSO data sheets. Specifically, the report must include:

- Dates and times (begin and end) of all marine mammal monitoring;

- Construction activities occurring during each daily observation period, including the number and type of piles driven or removed and by what method (*i.e.*, impact driving) and for each pile or total number of strikes for each pile (impact driving);

- PSO locations during marine mammal monitoring;
- Environmental conditions during monitoring periods (at beginning and end of PSO shift and whenever conditions change significantly), including Beaufort sea state and any other relevant weather conditions including cloud cover, fog, sun glare, and overall visibility to the horizon, and estimated observable distance;

- Upon observation of a marine mammal, the following information: Name of PSO who sighted the animal(s) and PSO location and activity at time of sighting; time of sighting; identification of the animal(s) (*e.g.*, genus/species, lowest possible taxonomic level, or unidentified), PSO confidence in identification, and the composition of the group if there is a mix of species; distance and bearing of each marine mammal observed relative to the pile being driven for each sighting (if pile driving was occurring at time of sighting); estimated number of animals (min/max/best estimate); estimated number of animals by cohort (adults, juveniles, neonates, group composition, etc.); animal's closest point of approach and estimated time spent within the harassment zone; description of any marine mammal behavioral observations (*e.g.*, observed behaviors such as feeding or traveling), including an assessment of behavioral responses thought to have resulted from the activity (*e.g.*, no response or changes in behavioral state such as ceasing feeding, changing direction, flushing, or breaching);

- Number of marine mammals detected within the harassment zones, by species; and

- Detailed information about any implementation of any mitigation triggered (*e.g.*, shutdowns and delays), a description of specific actions that ensued, and resulting changes in behavior of the animal(s), if any.

If no comments are received from NMFS within 30 days, the draft final report would constitute the final report. If comments are received, a final report addressing NMFS comments must be submitted within 30 days after receipt of comments.

Reporting Injured or Dead Marine Mammals

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner

prohibited by the IHA (if issued), such as an injury, serious injury or mortality, Haines Borough would immediately cease the specified activities and report the incident to the Office of Protected Resources, NMFS, and the Alaska Regional Stranding Coordinator. The report would include the following information:

- Description of the incident;
- Environmental conditions (*e.g.*, Beaufort sea state, visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities would not resume until NMFS is able to review the circumstances of the prohibited take. NMFS would work with Haines Borough to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. Haines Borough would not be able to resume their activities until notified by NMFS.

In the event that Haines Borough discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*e.g.*, in less than a moderate state of decomposition as described in the next paragraph), Haines Borough would immediately report the incident to the Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator. The report would include the same information identified in the paragraph above. Activities would be able to continue while NMFS reviews the circumstances of the incident. NMFS would work with Haines Borough to determine whether modifications in the activities are appropriate.

In the event that Haines Borough discovers an injured or dead marine mammal and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.*, previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), Haines Borough would report the incident to the Office of Protected Resources, NMFS, and the NMFS Alaska Stranding Hotline and/or by email to the Alaska Regional Stranding Coordinator, within 24 hours of the discovery. Haines Borough would provide photographs, video footage (if available), or other documentation of the stranded animal sighting to NMFS

and the Marine Mammal Stranding Network.

Negligible Impact Analysis and Determination

NMFS has defined negligible impact as an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of takes alone is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be "taken" through harassment, NMFS considers other factors, such as the likely nature of any impacts or responses (*e.g.*, intensity, duration), the context of any impacts or responses (*e.g.*, critical reproductive time or location, foraging impacts affecting energetics), as well as effects on habitat, and the likely effectiveness of the mitigation. We also assess the number, intensity, and context of estimated takes by evaluating this information relative to population status. Consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338; September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into this analysis via their impacts on the baseline (*e.g.*, as reflected in the regulatory status of the species, population size and growth rate where known, ongoing sources of human-caused mortality, or ambient noise levels).

To avoid repetition, the majority of our analysis applies to all the species listed in table 8, given that many of the anticipated effects of this project on different marine mammal stocks are expected to be relatively similar in nature. Where there are meaningful differences between species or stocks, or groups of species, in anticipated individual responses to activities, impact of expected take on the population due to differences in population status, or impacts on habitat, they are described independently in the analysis below.

Pile driving and removal activities associated with the project as outlined previously, have the potential to disturb or displace marine mammals. Specifically, the specified activities may result in take, in the form of Level A harassment and Level B harassment from underwater sounds generated from

pile driving and removal. Potential takes could occur if individuals of these species are present in zones ensonified above the thresholds for Level A or Level B harassment identified above when these activities are underway.

Take by Level A and Level B harassment would be due to potential behavioral disturbance, TTS, and PTS. No serious injury or mortality is anticipated or proposed for authorization given the nature of the activity and measures designed to minimize the possibility of injury to marine mammals. Take by Level A harassment is only anticipated for harbor porpoise, Steller sea lions, and harbor seal. Take by Level A harassment of the ESA-listed western DPS of Steller sea lions is expected to be a very small portion of the overall DPS (<0.1 percent). Impacts to affected individuals of the western DPS are not expected to result in population-level impacts. The potential for harassment is minimized through the construction method (*i.e.*, use of direct pull removal or vibratory methods to the extent practical) and the implementation of the planned mitigation measures (see Proposed Mitigation section).

In addition to the expected effects resulting from Level B harassment, we anticipate that harbor porpoises, Steller sea lions, and harbor seals may sustain some limited Level A harassment in the form of auditory injury. However, animals in these locations that experience PTS would likely only receive slight PTS, *i.e.*, minor degradation of hearing capabilities within regions of hearing that align most completely with the energy produced by pile driving, *i.e.*, the low-frequency region below 2 kHz, not severe hearing impairment or impairment in the regions of greatest hearing sensitivity. If hearing impairment occurs, it is most likely that the affected animal would lose a few decibels in its hearing sensitivity, which in most cases is not likely to meaningfully affect its ability to forage and communicate with conspecifics. As described above, we expect that marine mammals would be likely to move away from a sound source that represents an aversive stimulus, especially at levels that would be expected to result in PTS, given sufficient notice through use of soft start.

The project also is not expected to have significant adverse effects on affected marine mammals' habitat. The project activities would not modify existing marine mammal habitat for a significant amount of time. The activities may cause some fish or invertebrates to leave the area of

disturbance, thus temporarily impacting marine mammals' foraging opportunities in a limited portion of the foraging range; but, because of the short duration of the activities, the relatively small area of the habitat that may be affected, and the availability of nearby habitat of similar or higher value, the impacts to marine mammal habitat are not expected to cause significant or long-term negative consequences. The haulout location at Taiya Point would be affected by the project for foraging Steller sea lions and occasionally harbor seals. Currently, the Taiya Point haulout location is not known to be a pupping location for Steller sea lions or harbor seals but are important areas throughout the year. Steller sea lions and to a lesser extent harbor seals at this haulout would likely result in repeated exposure of the same animals. Repeated exposures of individuals to this pile driving activity could cause Level A and Level B harassment but are unlikely to considerably disrupt foraging behavior or result in significant decrease in fitness, reproduction, or survival for the affected individuals.

In summary and as described above, the following factors primarily support our preliminary determination that the impacts resulting from this activity are not expected to adversely affect any of the species or stocks through effects on annual rates of recruitment or survival:

- No serious injury or mortality is anticipated or authorized;
- Any Level A harassment exposures (*i.e.*, to harbor seals, harbor porpoise, and Steller sea lions, only) are anticipated to result in slight PTS (*i.e.*, of a few decibels), within the lower frequencies associated with pile driving;
- The anticipated incidents of Level B harassment would consist of, at worst, temporary modifications in behavior that would not result in fitness impacts to individuals;
- The ensonified areas from the project are very small relative to the overall habitat ranges of all species and stocks;
- The lack of anticipated significant or long-term negative effects to marine mammal habitat or any other areas of known biological importance; with the exception of the haulout location at Taiya Point; and
- The proposed mitigation measures are expected to reduce the effects of the specified activity to the level of least practicable adverse impact.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the proposed monitoring and mitigation

measures, NMFS preliminarily finds that the total marine mammal take from the proposed activity will have a negligible impact on all affected marine mammal species or stocks.

Small Numbers

As noted previously, only take of small numbers of marine mammals may be authorized under sections 101(a)(5)(A) and (D) of the MMPA for specified activities other than military readiness activities. The MMPA does not define small numbers and so, in practice, where estimated numbers are available, NMFS compares the number of individuals taken to the most appropriate estimation of abundance of the relevant species or stock in our determination of whether an authorization is limited to small numbers of marine mammals. When the predicted number of individuals to be taken is fewer than one-third of the species or stock abundance, the take is considered to be of small numbers. Additionally, other qualitative factors may be considered in the analysis, such as the temporal or spatial scale of the activities.

Table 8 demonstrates the number of animals that could be exposed to the received noise levels that could cause harassment for the proposed work in Lutak Inlet. Our analysis shows that less than 6.8 percent of each affected stock could be taken by harassment. The numbers of animals proposed to be taken for these stocks would be considered small relative to the relevant stock's abundances, even if each estimated taking occurred to a new individual—an extremely unlikely scenario.

Based on the analysis contained herein of the proposed activity (including the proposed mitigation and monitoring measures) and the anticipated take of marine mammals, NMFS preliminarily finds that small numbers of marine mammals would be taken relative to the population size of the affected species or stocks.

Unmitigable Adverse Impact Analysis and Determination

In order to issue an IHA, NMFS must find that the specified activity will not have an "unmitigable adverse impact" on the subsistence uses of the affected marine mammal species or stocks by Alaskan Natives. NMFS has defined "unmitigable adverse impact" in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (i) causing the marine mammals to abandon or avoid

hunting areas, (ii) directly displacing subsistence users, or (iii) placing physical barriers between the marine mammals and the subsistence hunters, and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

In the Haines area sea lions and harbor seals are available for subsistence harvest under the MMPA. Limited subsistence harvests of marine mammals near the community of Haines has occurred in the past, with the most recent recorded/documented harvests of marine mammals in Haines in 2012 and in nearby Klukwan in 2014. The proposed activity will take place in Lutak Inlet, and no activities overlap with current subsistence hunting areas; therefore, there are no relevant subsistence uses of marine mammals adversely impacted by this action. The proposed project is not likely to adversely impact the availability of any marine mammal species or stocks that are commonly used for subsistence purposes or to impact subsistence harvest of marine mammals in the region.

Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the proposed mitigation and monitoring measures, NMFS has preliminarily determined that there will not be an unmitigable adverse impact on subsistence uses from Haines Borough's proposed activities.

Endangered Species Act

Section 7(a)(2) of the Endangered Species Act of 1973 (ESA; 16 U.S.C. 1531 *et seq.*) requires that each Federal agency insure that any action it authorizes, funds, or carries out is not likely to jeopardize the continued existence of any endangered or threatened species or result in the destruction or adverse modification of designated critical habitat. To ensure ESA compliance for the issuance of IHAs, NMFS consults internally whenever we propose to authorize take for endangered or threatened species, in this case with the Alaska Regional Office.

NMFS is proposing to authorize take of Mexico DPS of humpback whales and western DPS of Steller sea lions, which are listed under the ESA.

The Office of Protected Resources has requested initiation of section 7 consultation with the Alaska Regional Office for the issuance of this IHA. NMFS will conclude the ESA consultation prior to reaching a

determination regarding the proposed issuance of the authorization.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to Haines Borough for conducting pile driving and removal activities in, Lutak Alaska from 1-year of the date of issuance of the final IHA, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. A draft of the proposed IHA can be found at: <https://www.fisheries.noaa.gov/national/marine-mammal-protection/incidental-take-authorizations-construction-activities>.

Request for Public Comments

We request comment on our analyses, the proposed authorization, and any other aspect of this notice of proposed IHA for the proposed action. We also request comment on the potential renewal of this proposed IHA as described in the paragraph below. Please include with your comments any supporting data or literature citations to help inform decisions on the request for this IHA or a subsequent renewal IHA.

On a case-by-case basis, NMFS may issue a one-time, 1-year renewal IHA following notice to the public providing an additional 15 days for public comments when (1) up to another year of identical or nearly identical activities as described in the Description of Proposed Activity section of this notice is planned or (2) the activities as described in the Description of Proposed Activity section of this notice would not be completed by the time the IHA expires and a renewal would allow for completion of the activities beyond that described in the *Dates and Duration* section of this notice, provided all of the following conditions are met:

- A request for renewal is received no later than 60 days prior to the needed renewal IHA effective date (recognizing that the renewal IHA expiration date cannot extend beyond 1-year from expiration of the initial IHA); and
- The request for renewal must include the following:

(1) An explanation that the activities to be conducted under the requested renewal IHA are identical to the activities analyzed under the initial IHA, are a subset of the activities, or include changes so minor (*e.g.*, reduction in pile size) that the changes do not affect the previous analyses, mitigation and monitoring requirements, or take estimates (with the exception of reducing the type or amount of take); and

(2) A preliminary monitoring report showing the results of the required monitoring to date and an explanation showing that the monitoring results do not indicate impacts of a scale or nature not previously analyzed or authorized.

Upon review of the request for renewal, the status of the affected species or stocks, and any other pertinent information, NMFS determines that there are no more than minor changes in the activities, the mitigation and monitoring measures will remain the same and appropriate, and the findings in the initial IHA remain valid.

Dated: November 8, 2023.

Shannon Bettridge,

Acting Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023-25097 Filed 11-14-23; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648-XD516]

Marine Mammals and Endangered Species

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

ACTION: Notice; issuance of permits and permit amendments.

SUMMARY: Notice is hereby given that permits and permit amendments have been issued to the following entities under the Marine Mammal Protection Act (MMPA) and the Endangered Species Act (ESA), as applicable.

ADDRESSES: The permits and related documents are available for review upon written request via email to NMFS.Pr1Comments@noaa.gov.

FOR FURTHER INFORMATION CONTACT: Shasta McClenahan, Ph.D., (Permit No. 27155), Amy Hapeman (Permit No. 22156-05), and Jennifer Skidmore (Permit No. 27459); at (301) 427-8401.

SUPPLEMENTARY INFORMATION: Notices were published in the **Federal Register** on the dates listed below that requests for a permit or permit amendment had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the application and a complete description of the activities, go to <https://www.federalregister.gov> and search on the permit number provided in Table 1 below.

TABLE 1—ISSUED PERMITS AND PERMIT AMENDMENTS

Permit No.	RTID	Applicant	Previous Federal Register notice	Issuance Date
22156–05	0648–XC660	Douglas Nowacek, Ph.D., Duke University Marine Laboratory, 135 Duke Marine Lab Road, Beaufort, NC 28516.	88 FR 2070, January 12, 2023 ...	October 16, 2023.
27155	0648–XD227	Jamie Lloyd-Smith, Ph.D., University of California, Los Angeles, 610 Charles East Young Drive South, Los Angeles, CA 90095.	88 FR 55017, August 14, 2023 ...	October 11, 2023.
27459	0648–XD322	Robin Trayler, Ph.D., University of California, Merced, 5200 North Lake Road, Science and Engineering 1, 283, Merced, CA 95343.	88 FR 60650, September 5, 2023	October 23, 2023.

In compliance with the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed for Permit Nos. 27155 and 27459 are categorically excluded from the requirement to prepare an environmental assessment (EA) or environmental impact statement (EIS).

For Permit No. 22156–05, an EA was prepared analyzing the effects of the permitted activities on the human environment in compliance with NEPA. Based on the analyses in the EA, NMFS determined that issuance of the permit amendment would not significantly impact the quality of the human environment and that preparation of an EIS was not required. That determination is documented in a Finding of No Significant Impact, signed on October 16, 2023.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

Authority: The requested permits have been issued under the MMPA of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: November 9, 2023.

Julia M. Harrison,

Chief, Permits and Conservation Division,
Office of Protected Resources, National
Marine Fisheries Service.

[FR Doc. 2023–25171 Filed 11–14–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD520]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a meeting of its Scallop Advisory Panel via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Wednesday, November 29, 2023, at 8:30 a.m.

ADDRESSES:

Webinar URL information: <https://attendee.gotowebinar.com/register/8294085035285445472>.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O’Keefe, Ph.D., Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Advisory Panel will review Framework 38 (FW38): review specifications alternatives in FW38 and select final preferred alternatives. FW38 will set specifications including the overfishing limit (OFL), acceptable biological catch/annual catch limit (ABC/ACLs), days-at-sea (DAS), access area allocations for Limited Access (LA) vessels, quota and access area trip allocation to the Limited Access General Category (LAGC) Individual Fishing Quota (IFQ) component, Total

Allowable Landings (TAL) for Northern Gulf of Maine (NGOM) management area, a target-TAC for LAGC incidental catch and set-asides for the observer and research programs for fishing year 2024, and default specifications for fishing year 2025. This action also considers increasing VMS ping rates for scallop vessels to improve enforcement in the scallop fishery. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council’s intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O’Keefe, Ph.D., Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: November 9, 2023.

Key Israel Marquez,

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

[FR Doc. 2023–25241 Filed 11–14–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE**Patent and Trademark Office****Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Patent Examiner Employment Application**

AGENCY: United States Patent and Trademark Office, Department of Commerce.

ACTION: Notice of information collection; request for comment.

SUMMARY: The United States Patent and Trademark Office (USPTO), as required by the Paperwork Reduction Act of 1995, invites comments on the extension and revision of an existing information collection: 0651–0042 Patent Examiner Employment Application. The purpose of this notice is to allow 60 days for public comment preceding submission of the information collection to OMB.

DATES: To ensure consideration, comments regarding this information collection must be received on or before January 16, 2024.

ADDRESSES: Interested persons are invited to submit written comments by any of the following methods. Do not submit Confidential Business Information or otherwise sensitive or protected information.

- *Email:* InformationCollection@uspto.gov. Include “0651–0042 comment” in the subject line of the message.
- *Federal Rulemaking Portal:* <http://www.regulations.gov>.
- *Mail:* Justin Isaac, Office of the Chief Administrative Officer, United States Patent and Trademark Office,

P.O. Box 1450, Alexandria, VA 22313–1450.

FOR FURTHER INFORMATION CONTACT:

Request for additional information should be directed to Linda Majca, Chief of Workforce Employment Division—Patents, United States Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313–1450; by telephone at 571–272–0692; or by email at Linda.Majca@uspto.gov with “0651–0042 comment” in the subject line. Additional information about this information collection is also available at <http://www.reginfo.gov> under “Information Collection Review.”

SUPPLEMENTARY INFORMATION:**I. Abstract**

In the current employment environment, life science and engineering graduates are in great demand. The United States Patent and Trademark Office (USPTO) is in direct competition with the private industry for the same caliber of candidates with the requisite knowledge and skills to perform patent examination work. This information collection covers online applications to the USPTO for entry-level patent examiner positions. More specifically, the collection covers the respondent data gathered from the applications. The USPTO posts the relevant positions online and collects applicant information via the USA Staffing System.

The USA Staffing online application collects supplemental information to a candidate’s USAJOBS application. This information assists USPTO Human Resource Specialists and Hiring Managers in determining whether an applicant possesses the basic qualification requirements for a patent examiner position. From the

information collected, the USA Staffing system creates an electronic real-time candidate inventory on applicants’ expertise and technical knowledge, which allows USPTO to immediately review applications from multiple applicants. The use of such automated online systems during recruitment allows USPTO to remain competitive, meet hiring goals, and fulfill the Agency’s Congressional commitment to reduce the pendency rate for the examination of patent applications.

II. Method of Collection

Items in this information collection must be submitted electronically via the USA Staffing system.

III. Data

OMB Control Number: 0651–0042.

Forms: None.

Type of Review: Extension and revision of a currently approved information collection.

Affected Public: Individuals or households.

Respondent’s Obligation: Required to Obtain or Retain Benefits.

Estimated Number of Annual Respondents: 7,226 respondents.

Estimated Number of Annual Responses: 7,226 responses.

Estimated Time per Response: The USPTO estimates that the responses in this information collection will take the public approximately 30 minutes (0.5 hours) to complete. This includes the time to gather the necessary information, create the document, and submit the completed request to the USPTO.

Estimated Total Annual Respondent Burden Hours: 3,613 hours.

Estimated Total Annual Respondent Hourly Cost Burden: \$106,511.

TABLE 1—TOTAL BURDEN HOURS AND HOURLY COSTS TO INDIVIDUAL OR HOUSEHOLD RESPONDENTS

Item No.	Item	Estimated annual respondents	Responses per respondent	Estimated annual responses	Estimated time for response (hour)	Estimated annual burden (hour/year)	Rate ¹ (\$/hour)	Estimated annual burden
		(a)	(b)	(a) × (b) = (c)	(d)	(c) × (d) = (e)	(f)	(e) × (f) = (g)
1	Patent Examiner Employee Application.	7,226	1	7,226	0.50 (30 minutes)	3,613	\$29.48	\$106,511
	Totals	7,226		7,226		3,613		106,511

¹ USPTO uses the OPM Special Rate Table 0576—Patent Examiner 07—Step 1 (the salary divided by 2,080 (the hours per year in a standard 40-hour work-week)) as an estimate for the hourly rate: <https://www.opm.gov/special-rates/2023/Table057601012023.aspx>.

Estimated Total Annual Respondent Non-Hourly Cost Burden: \$0. There are no capital start-up, maintenance costs, recordkeeping costs, filing fees, or postage costs associated with this information collection.

IV. Request for Comments

The USPTO is soliciting public comments to:

(a) Evaluate whether the collection of information is necessary for the proper performance of the functions of the

Agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the Agency’s estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected; and

(d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

All comments submitted in response to this notice are a matter of public record. USPTO will include or summarize each comment in the request to OMB to approve this information collection. Before including an address, phone number, email address, or other personally identifiable information (PII) in a comment, be aware that the entire comment—including PII—may be made publicly available at any time. While you may ask in your comment to withhold PII from public view, USPTO cannot guarantee that it will be able to do so.

Justin Isaac,

Information Collections Officer, Office of the Chief Administrative Officer, United States Patent and Trademark Office.

[FR Doc. 2023-25157 Filed 11-14-23; 8:45 am]

BILLING CODE 3510-16-P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC-2010-0056]

Agency Information Collection Activities; Proposed Extension of Approval of Information Collection; Comment Request—Safety Standard for Bicycle Helmets

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) requests comments on a proposed extension of approval for a collection of information relating to the Safety Standard for Bicycle Helmets. The Office of Management and Budget (OMB) previously approved the collection of information under control number 3041-0127. OMB's most recent extension of approval will expire on January 31, 2024. The Commission will consider all comments received in response to this notice before requesting an extension of approval of this collection of information from OMB.

DATES: Submit comments on the collection of information by January 16, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CPSC-2010-0056, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. The Commission typically does not accept comments submitted by email, except as described below.

Mail/Hand Delivery/Courier/Written Submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504-7923.

Instructions: All submissions received must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to cpsc-os@cpsc.gov.

Docket: For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, insert docket number CPSC-2010-0056 into the "Search" box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504-7791, or by email to: pra@cpsc.gov.

SUPPLEMENTARY INFORMATION: CPSC seeks to extend the following collection of information:

Title: Safety Standard for Bicycle Helmets.

OMB Number: 3041-0127.

Type of Review: Extension of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of bicycle helmets.

Estimated Number of Respondents: The Commission estimates that 38

manufacturers and importers will issue certificates on an estimated total of 200 models annually, including both older models and new models.

Estimated Time per Response: The Commission estimates that manufacturers and importers will require 4 hours per model for recordkeeping and certification activities each year.

Total Estimated Annual Burden: Based on CPSC's estimates that manufacturers and importers will conduct recordkeeping and reporting activities for a total of 200 models, and that a total of 4 hours will be required per model, CPSC estimates that the total annual burden of this collection is 800 hours. The annualized cost to respondents for the information collection is \$26,944 (800 hours × \$33.68/hr), as estimated from total compensation data available from the U.S. Bureau of Labor Statistics.¹

General Description of Collection: In 1998, the Commission issued a safety standard for bicycle helmets (16 CFR part 1203). The standard includes requirements for labeling and instructions. The standard also requires that manufacturers and importers of bicycle helmets subject to the standard issue certificates of compliance based on a reasonable testing program. Every person issuing certificates of compliance must maintain records of their testing so the Commission can verify that the testing was conducted properly. Respondents must comply with the requirements in 16 CFR part 1203 for labeling and instructions, testing, certification, and recordkeeping.

Request for Comments:

The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

- whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;
- whether the estimated burden of the proposed collection of information is accurate;
- whether the quality, utility, and clarity of the information to be collected could be enhanced; and

¹ Total hourly compensation for office and administrative support occupations in goods-producing industries is estimated by the U.S. Bureau of Labor Statistics to be \$33.68: Employer Costs for Employee Compensation, March 2023, Table 4: (https://www.bls.gov/news.release/archives/ecec_06162023.pdf).

• whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–25192 Filed 11–14–23; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2010–0054]

Agency Information Collection Activities; Proposed Extension of Approval of Information Collection; Comment Request—Procedures for Export of Noncomplying Products

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of information collection; request for comment.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) requests comments on a proposed extension of approval of a collection of information relating to the procedures for the export of noncomplying products. The Office of Management and Budget (OMB) previously approved the collection of information under control number 3041–0003. OMB's most recent extension of approval will expire on January 31, 2024. The Commission will consider all comments received in response to this notice before requesting an extension of approval of this collection of information from OMB.

DATES: Submit comments on the collection of information by January 16, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2010–0054, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. The Commission typically does not accept comments submitted by email, except as described below.

Mail/Hand Delivery/Courier/Written Submissions: CPSC encourages you to submit electronic comments by using

the Federal eRulemaking Portal. You may, however, submit comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to cpsc-os@cpsc.gov. *Docket:* For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, insert docket number CPSC–2010–0054 into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: pra@cpsc.gov.

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Procedures for the Export of Noncomplying Products.

OMB Number: 3041–0003.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Exporters of products that do not comply with Commission requirements.

Estimated Number of Respondents: We estimate that approximately 9 notifications will be submitted by 7 firms per year. These numbers are commensurate with notification rates before the COVID–19-pandemic's disruption of trade.

Estimated Time per Response: CPSC estimates that the average time for each response is one hour.

Total Estimated Annual Burden: Based on CPSC's estimates that a total of 9 responses will be submitted each year, and that one hour will be required per response, CPSC estimates that the total annual burden of this collection is 9 hours. The annualized cost to respondents for the information collection is \$654.12 (9 hours × \$72.68/hr), as estimated from total

compensation data available from the U.S. Bureau of Labor Statistics.¹

General Description of Collection: The Commission has procedures that exporters must follow to notify the Commission of their intent to export products that are banned or fail to comply with an applicable CPSC safety standard, regulation, or statute. Respondents must comply with the requirements in 16 CFR part 1019 and file a statement with the Commission in accordance with these requirements.

Request for Comments:

The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

- whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;
- whether the estimated burden of the proposed collection of information is accurate;
- whether the quality, utility, and clarity of the information to be collected could be enhanced; and
- whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–25189 Filed 11–14–23; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. 2011–0014]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Renewal of Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer

¹ Total hourly compensation for workers in management professional and related occupations in goods-producing industries is estimated by the U.S. Bureau of Labor Statistics to be \$72.68: Employer Costs for Employee Compensation, March 2023, Table 4: (https://www.bls.gov/news.release/archives/ecec_06162023.pdf).

Product Safety Commission (CPSC or Commission) announces that the Commission has submitted to the Office of Management and Budget (OMB) a request for extension of approval of a generic clearance for the collection of qualitative feedback on agency service delivery. OMB previously approved the collection of information under control number 3041–0148. OMB's most recent extension of approval will expire on November 30, 2023. On August 28, 2023, the CPSC published a notice in the **Federal Register** to announce the agency's intention to seek extension of approval of the collection of information. The Commission received no comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information, without change.

DATES: Comments on this request for extension of approval of information collection requirements should be submitted by December 15, 2023.

ADDRESSES: Submit comments about this request by email: OIRA_submission@omb.eop.gov or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503. In addition, written comments that are sent to OMB, also should be submitted electronically at: <http://www.regulations.gov>, under Docket No.

CPSC–2023–0031, by any of the following methods:

Electronic Submissions: CPSC encourages you to submit electronic comments to the Federal eRulemaking Portal at: <https://www.regulations.gov>. Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (email), except as described below.

Mail/Hand Delivery/Courier/Confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to: cpsc-os@cpsc.gov.

Instructions: All submissions must include the agency name and docket number. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <https://www.regulations.gov>. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions

for mail/hand delivery/courier/confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>; insert the docket number, CPSC–2023–0031, into the “Search” box; and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: pra@cpsc.gov.

SUPPLEMENTARY INFORMATION: On August 28, 2023, the CPSC published a notice in the **Federal Register** to announce the agency's intention to seek extension of approval of the collection of information. 88 FR 58565. The Commission received no comments. CPSC seeks to renew the following currently approved collection of information:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 3041–0148.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Individuals and households, businesses and organizations, state local or tribal governments.

Estimated Annual Burden: CPSC will use a variety of instruments and platforms to collect information from respondents. CPSC estimates the burden of the collection of information as follows:

Type of collection	Number of respondents	Annual frequency per response	Hours per response	Total hours
Qualitative Surveys (3)	600	1	0.25	150
Focus Groups	200	1	4	800
Customer Satisfaction Surveys (3)	600	1	0.25	150
Usability Tests	200	1	0.5	100

Based on these estimates, the total estimated burden for the collection of information is estimated to be 1,200 hours annually. The annualized cost to respondents for the information collection is \$51,684 (1,200 hours × \$43.07/hr), as estimated from total compensation data available from the U.S. Bureau of Labor Statistics.¹

Description of Collection: Executive Order 12862 (Sept. 11, 1993) encourages independent Federal agencies such as

CPSC to provide service to the public that matches or exceeds the best service available in the private sector. To that end, CPSC seeks to renew OMB approval of a generic clearance to collect qualitative feedback on CPSC service delivery. Qualitative feedback means information that provides useful insights on perceptions and opinions but does not include statistical surveys that yield quantitative results that can be generalized to the population of study. This collection of information is necessary to enable CPSC to garner customer and stakeholder feedback in an efficient, timely manner, in

accordance with CPSC's commitment to improving service delivery.

This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations; provide an early warning of issues with service; and help focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will also allow for ongoing, collaborative, and actionable

¹ Total hourly compensation for all civilian workers is estimated by the U.S. Bureau of Labor Statistics to be \$43.07: “Employer Costs for Employee Compensation,” (https://www.bls.gov/news.release/archives/ecec_06162023.pdf (March 2023)).

communications between CPSC and its customers and stakeholders.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–25191 Filed 11–14–23; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2010–0112]

Agency Information Collection Activities; Extension of Collection; Comment Request; Contests, Challenges, and Awards

AGENCY: Consumer Product Safety Commission.

ACTION: Notice of information collection; request for comment.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) requests comments on a proposed extension of approval of a generic collection of information for CPSC-sponsored contests, challenges, and awards. The Office of Management and Budget (OMB) previously approved the collection of information under control number 3041–0151. OMB's most recent extension of approval will expire on January 31, 2024. The Commission will consider all comments received in response to this notice before requesting an extension of this collection of information from the Office of Management and Budget (OMB).

DATES: Submit comments on the collection of information by January 16, 2024.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2010–0112, within 60 days of publication of this notice by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. The Commission typically does not accept comments submitted by email, except as described below.

Mail/hand delivery/courier/written submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail/hand delivery/courier to: Office of

the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: <http://www.regulations.gov>. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to cpsc-os@cpsc.gov.

Docket: For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, insert docket number CPSC–2010–0112 into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: pra@cpsc.gov.

SUPPLEMENTARY INFORMATION: CPSC seeks to extend the following currently approved generic collection of information:

Title: Contests, Challenges, and Awards.

OMB Number: 3041–0151.

Type of Review: Extension of generic collection.

Frequency of Response: On occasion.

Affected Public: Contestants, award nominees, award nominators.

Estimated Number of Respondents: We estimate that there will be 500 contest or award participants each year. In addition, 20 participants may be required to provide additional information upon selection.

Estimated Time per Response: The estimated time to complete a contest or award submission is 5 hours per participant. In addition, the 20 participants expected to provide additional information upon selection will require approximately 2 additional hours.

Total Estimated Annual Burden: Based on CPSC's estimates that there will be 500 participants who each require 5 hours to complete their submissions, and that 20 participants will be asked to provide additional information that will take two hours to complete, CPSC estimates that the total annual burden of this collection is 2,540 hours. The annualized cost to respondents for the information

collection is approximately \$109,880 (2,540 hours × \$43.26/hr), as estimated from total compensation data available from the U.S. Bureau of Labor Statistics.¹

General Description of Collection: The Commission establishes contests, challenges, and awards to increase the public's knowledge and awareness of safety hazards. The Commission also recognizes through awards certain individuals, firms, and organizations that work to address issues related to consumer product safety. The information to be collected from contestants and award nominees or nominators includes contact and background information necessary to conduct a contest or award program. Limited background or biographical information similar to data found on a resume, such as a nominee's education and work experience, may be requested for some contests or awards. Additionally, substantive entries such as essays, posters, drawings, or videos may be requested for contestants and award nominees.

Request for Comments: The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

- whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;
- whether the estimated burden of the proposed collection of information is accurate;
- whether the quality, utility, and clarity of the information to be collected could be enhanced; and
- whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–25193 Filed 11–14–23; 8:45 am]

BILLING CODE 6355–01–P

¹ Total hourly compensation for all civilian workers is estimated by the U.S. Bureau of Labor Statistics to be \$43.26: Employer Costs for Employee Compensation, June 2023, Table 1, (https://www.bls.gov/news.release/archives/ecec_09122023.pdf).

CONSUMER PRODUCT SAFETY COMMISSION**[Docket No. CPSC–2010–0053]****Agency Information Collection Activities; Proposed Extension of Approval of Information Collection; Comment Request—Safety Standard for Multi-Purpose Lighters****AGENCY:** Consumer Product Safety Commission.**ACTION:** Notice of information collection; request for comment.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) requests comments on a proposed revision of approval of a collection of information regarding the Safety Standard for Multi-Purpose Lighters. The Office of Management and Budget (OMB) previously approved the collection of information under control number 3041–0130. OMB's most recent extension of approval will expire on January 31, 2024. The Commission will consider all comments received in response to this notice before requesting an extension of approval of this collection of information from OMB.

DATES: Submit comments on the collection of information by January 16, 2024.

ADDRESSES: You may submit written comments, identified by Docket No. CPSC–2010–0053, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: <http://www.regulations.gov>. Follow the instructions for submitting comments. Do not submit through this website: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. The Commission typically does not accept comments submitted by email, except as described below.

Mail/Hand Delivery/Courier/Written Submissions: CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal. You may, however, submit comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal

information provided, to: <http://www.regulations.gov>. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you may submit such comments by mail, hand delivery, or courier, or you may email them to cpsc-os@cpsc.gov. *Docket:* For access to the docket to read background documents or comments received, go to: <https://www.regulations.gov>, insert docket number CPSC–2010–0053 into the “Search” box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: pra@cpsc.gov.

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Safety Standard for Multi-Purpose Lighters.

OMB Number: 3041–0130.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of multi-purpose lighters.

Estimated Number of Respondents: Based on five years of data, there are an estimated 47 firms that import, distribute, or sell multi-purpose lighters in the United States. Based on past experience, CPSC expects that firms will conduct recordkeeping and reporting activities for an average of two multi-purpose lighter models each year.

Estimated Time per Response: The costs associated with the rule include reporting, recordkeeping, and other certification-related activities. CPSC estimates that the burden per model is 10 hours to generate test data, record it, and enter the data into a computerized dataset; five hours for annual review and removal of records; and five hours for responding to CPSC records requests—for a total of 20 hours per model.

Total Estimated Annual Burden:

Based on CPSC's estimates that 47 firms will each conduct recordkeeping and reporting activities for an average of two models per year, and that a total of 20 hours will be required per model, CPSC estimates that the total annual burden of this collection is 1,880 hours. The annualized cost to respondents for the information collection is \$63,318 (1,880 hours × \$33.68/hr), as estimated from total compensation data available from the U.S. Bureau of Labor Statistics.¹

¹ Total hourly compensation for office and administrative support occupations in goods-producing industries is estimated by the U.S.

General Description of Collection: The Commission issued a safety standard for multi-purpose lighters in 1999 (16 CFR part 1212). The standard and section 14(a)(1) of the Consumer Product Safety Act (CPSA) require that manufacturers, including importers, of multi-purpose lighters issue certificates of compliance based on a reasonable testing program. The standard also requires manufacturers and importers to establish and maintain records to demonstrate successful completion of all required tests to support the certificates of compliance that they issue. Respondents must comply with these testing, certification, and recordkeeping requirements for multi-purpose lighters.

Request for Comments:

The Commission solicits written comments from all interested persons about the proposed collection of information. The Commission specifically solicits information relevant to the following topics:

- whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;
- whether the estimated burden of the proposed collection of information is accurate;
- whether the quality, utility, and clarity of the information to be collected could be enhanced; and
- whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–25190 Filed 11–14–23; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE**Office of the Secretary**

[Docket ID: DoD–2023–HA–0111; Req No. OS–2024–00038–FR]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

Bureau of Labor Statistics to be \$33.68: Employer Costs for Employee Compensation, March 2023, Table 4: (https://www.bls.gov/news.release/archives/ecec_06162023.pdf).

ACTION: 60-day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, Defense Health Agency (DHA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Health Agency, 7700 Arlington Blvd., Falls Church, VA 22042, Amanda Grifka, 703-681-1771.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Health Care Survey of DoD Beneficiaries; OMB Control Number: 0720-HCSD.

Needs and Uses: Legal authority for this information collection is found in the 1993 National Defense Authorization Act (NDAA) (Pub. L. 102-484). The Health Care Survey of DoD

Beneficiaries (HCSDB) is the only population-based Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan Survey (v5.0) administered to a statistically representative, world-wide sample of all eligible DoD beneficiaries by the DHA. The instrument includes an additional module that is the only population-based measurement of Healthy People 2030 goals and health metrics reflecting the priorities of senior health leaders. The HCSDB is a population-based survey, not a healthcare encounter-based survey. As such, the HCSDB is the only survey able to measure access to care and other metrics for beneficiaries who may not be using the TRICARE health system due to barriers to care they encounter. This information collection, which began in 2008, continues to be of critical importance to DHA and Congress in assessing Military Health System (MHS) and Managed Care Support Contractor performance by allowing for trending by various beneficiary categories over time.

Affected Public: Individuals or households.

Annual Burden Hours: 7,125.

Number of Respondents: 28,500

Responses per Respondent: 1.

Annual Responses: 28,500.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

Dated: November 7, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023-25118 Filed 11-14-23; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2023-HA-0113; Req No. OS-2024-00039-FR]

Proposed Collection; Comment Request

AGENCY: The Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, Defense Health Agency (DHA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of

the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Defense Health Agency, 7700 Arlington Blvd., Falls Church, VA 22042, Amanda Grifka, 703-681-1771.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB

Number: TRICARE Select Survey of Beneficiaries (TSS-B); OMB Control Number: 0720-TSSB.

Needs and Uses: The TSS-B is a population-based survey, not a healthcare encounter-based survey; this makes it unique as the only survey of the entire TSS-B beneficiary population regardless of whether they have had a recent health care encounter. TSS-B is the sole source for Consumer Assessment of Healthcare Providers and Systems (CAHPS) which captures patient experience of the TSS-B population. This information collection, which began in 2009, is used in reports to Congress and by working groups within the DHA. The TSS-B data is required by DHA for Contract Data

Requirements List (CDRL) Q120. TRICARE contractors use TSS–B data under CDRL Q120 for federal contracts to evaluate and identify issues related to patient experience and access to care for TSS–B. This includes developing executive reports and action plans on CAHPS Health Plan measures, which are delivered to DHA’s Managed Care Support Program. This data is also used for regular Government Accountability Office (GAO) audits of care for TSS–B.

Affected Public: Individuals or households.

Annual Burden Hours: 1,250.

Number of Respondents: 5,000.

Responses Per Respondent: 1.

Annual Responses: 5,000.

Average Burden Per Response: 15 minutes.

Frequency: On occasion.

Dated: November 7, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–25121 Filed 11–14–23; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0108; Req No. OS–2024–00036–FR]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the OUSD(P&R) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency’s estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to ODASD(MC&FP), Mr. Trevor Dean, 1500 Defense Pentagon, Washington, DC 20301, (703) 571–2359.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: DoD Mortuary Affairs Forms; DD Form(s) 0565, 3045, 3046, 3047, 3048, 3049, 3050, 3116, 3122; OMB Control Number: 0704–0581.

Needs and Uses: The information collection requirement is necessary to obtain and document information related to deceased personnel and their family members. The information collection documents selections made by family members and others as part of the required mortuary case file. As stated in 10 United States Code (U.S.C.) 1481, “Recovery, Care, and Disposition of Remains: Decedents Covered,” the DoD may provide for the recovery, care, and disposition of the remains for active-duty Regulars, Reserve Component members, applicants, trainees, military prisoners, and others. The DoD is further authorized, per 10 U.S.C. 1482 and 10 U.S.C. 1482a to provide reimbursement, cover expenses, or otherwise provide mortuary services for decedents, including civilian employees serving with the armed forces. Mortuary affairs personnel must document information on the information collections to ensure proper care, transportation, escort, honors and disposition of remains, as applicable. Depending on the circumstances, a Person Authorized to Direct Disposition

(PADD) or Person Authorized to Effect Disposition may be asked to complete up to six forms. All PADDs will complete the DD Form 3045, but may additionally be asked to provide information on the DD Forms 3046, 3047, 3048, 3049, and/or 3050.

The DD Form 565 is a form to assist mortuary personnel with the identification of the remains of deceased personnel, family members, civilians, or other personnel that may be in the care of the DoD. Identification of deceased persons is a critical step in providing proper disposition of the remains. Information collected includes information on the respondent and a witness.

The DD Form 3116 is a report filed with Service casualty and mortuary affairs offices with information regarding the transportation of human remains of deceased active duty personnel to their place of interment. The escort also reports on the condition of remains, casket and any incident during transportation to assist the Service Casualty and Mortuary Affairs Operations Division (CMAOD) in their support of the person authorized to direct disposition of the remains. The report also informs the Service CMAOD of any issue needed to be resolved with the receiving funeral home.

The DD Form 3122 is an official request for military funeral honors at the funeral or memorial of an eligible deceased veteran. A request for military funeral honors for an eligible veteran must be supported by law. The form will be sent to military funeral honors coordinators for their review, analysis for eligibility, scheduling, and to capture costs to provide the required military funeral honors elements. The form contains contact information for the next-of-kin requesting military funeral honors.

Affected Public: Individuals or households.

DD Form 0565

Annual Burden Hours: 62.5 hours.

Number of Respondents: 250.

Responses per Respondent: 1.

Annual Responses: 250.

Average Burden per Response: 15 minutes.

DD Form 3116

Annual Burden Hours: 450 hours.

Number of Respondents: 900.

Responses per Respondent: 1.

Annual Responses: 900.

Average Burden per Response: 30 minutes.

DD Form 3122

Annual Burden Hours: 125,000.

Number of Respondents: 250,000.

Responses per Respondent: 1.

Annual Responses: 250,000.
Average Burden per Response: 30 minutes.

DD Form 3045

Annual Burden Hours: 225 hours.
Number of Respondents: 900.
Responses per Respondent: 1.
Annual Responses: 1.
Average Burden per Response: 15 minutes.

DD Form 3046

Annual Burden Hours: 15 hours.
Number of Respondents: 60.
Responses per Respondent: 1.
Annual Responses: 1.
Average Burden per Response: 15 minutes.

DD Form 3047

Annual Burden Hours: 15 hours.
Number of Respondents: 60.
Responses per Respondent: 1.
Annual Responses: 60.
Average Burden per Response: 15 minutes.

DD Form 3048

Annual Burden Hours: 15 hours.
Number of Respondents: 60.
Responses per Respondent: 1.
Annual Responses: 60.
Average Burden per Response: 15 minutes.

DD Form 3049

Annual Burden Hours: 15 hours.
Number of Respondents: 60.
Responses per Respondent: 1.
Annual Responses: 60.
Average Burden per Response: 15 minutes.

DD Form 3050

Annual Burden Hours: 15 hours.
Number of Respondents: 60.
Responses per Respondent: 1.
Annual Responses: 60.
Average Burden per Response: 15 minutes.

Total

Annual Burden Hours: 25,812.5.
Number of Respondents: 252,350.
Responses per Respondent: 1.
Annual Responses: 252,350.
Average Burden per Response: 2.75 hours.
Frequency: On occasion.

Dated: November 7, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023-25117 Filed 11-14-23; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2023-HA-0112; Req No. OS-2024-00037-FR]

Proposed Collection; Comment Request

AGENCY: The Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Defense Health Agency (DHA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and

associated collection instruments, please write to DHA, 7700 Arlington Blvd., Falls Church, VA 22042, Amanda Grifka, 703-681-1771.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Challenges of Military Couples Experiencing Breast Cancer; OMB Control Number: 0720-CEBC.

Needs and Uses: This information collection is needed to conduct a needs assessment study which will identify challenges of military couples and their experiences with breast cancer. An online survey was developed to evaluate marital satisfaction and intimacy to determine what interventions may be helpful in the future. The survey includes the Couples Satisfaction Index Scale-4, which has reported reliability and validity. The long-term aim of this study is to determine what types of support may be provided to increase marital satisfaction while maintaining healthy relationships during the breast cancer experience for military families. Further, the aim would be that making effective support available to couples experiencing breast cancer would improve prognosis and optimize overall health for the patient and the partner. The respondent population will be from Brooke Army Medical Center who are at various stages of breast cancer treatment but diagnosed within the last five years.

Affected Public: Individuals and households.

Annual Burden Hours: 20.
Number of Respondents: 60.
Responses per Respondent: 1.
Annual Responses: 60.
Average Burden per Response: 20 minutes.

Frequency: On occasion.

Dated: November 7, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023-25119 Filed 11-14-23; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2023-OS-0109; Req No. OS-2024-00035-FR]

Proposed Collection; Comment Request

AGENCY: Office of the Under Secretary of Defense for Personnel and Readiness (OUSD(P&R)), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the OUSD(P&R), DoD, announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's estimate of the burden of the proposed information collection; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 16, 2024.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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

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

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to: OEPM, Voluntary Education, Pentagon, Room 2E573 Washington, DC 20301-1500, Jonathan Woods, (571) 372-5353.

SUPPLEMENTARY INFORMATION:

Title: *Associated Form:* and *OMB Number:* Postsecondary Education Complaint Intake System; DD-2961; OMB Control Number 0704-0501.

Needs and Uses: This collection is necessary to obtain, document, and respond to complaints, questions, and other issues concerning educational programs and services provided to military students, and their adult

Family members. It allows DoD to monitor and track the types of complaint issues that are submitted, the complaint content, the educational institutions the complaints have been filed against, the type of education benefits being used, and the branch of the military Service. The information collected via the DoD Intake form is used to assist in further developing and shaping of relevant mitigating and preventative measures concerning abusive, deceptive, and fraudulent practices against Service members and Spouses who are pursuing higher education utilizing Tuition Assistance and My Career Advancement Account.

Affected Public: Individuals or households.

Annual Burden Hours: 37.5.

Number of Respondents: 150.

Responses per Respondent: 1.

Annual Responses: 150.

Average Burden Per Response: 15 minutes.

Frequency: On occasion.

Dated: November 7, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023-25116 Filed 11-14-23; 8:45 am]

BILLING CODE 6001-FR-P

DEPARTMENT OF EDUCATION

Applications for New Awards; Alaska Native Education Program

AGENCY: Office of Elementary and Secondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Department of Education (Department) is issuing a notice inviting applications for fiscal year (FY) 2024 for the Alaska Native Education (ANE) program, Assistance Listing Number 84.356A. This notice relates to the approved information collection under OMB control number 1894-0006.

DATES:

Applications Available: November 20, 2023.

Deadline for Transmittal of Applications: February 13, 2024.

Deadline for Intergovernmental Review: April 15, 2024.

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 <https://www.federalregister.gov/documents/>

2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs. Please note that these Common Instructions supersede the version published on December 27, 2021.

FOR FURTHER INFORMATION CONTACT:

Almita Reed, U.S. Department of Education, 400 Maryland Avenue SW, Washington, DC 20202. Telephone: (202) 260-1979. Email: OESE.ASKANEP@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: The purpose of the ANE program is to support innovative projects that recognize and address the unique educational needs of Alaska Natives. These projects must include the activities authorized under section 6304(a)(2) of the Elementary and Secondary Education Act of 1965, as amended (ESEA), and may include one or more of the activities authorized under section 6304(a)(3) of the ESEA, including, but not limited to, curriculum development, training and professional development, early childhood and parent outreach, and enrichment programs.

Background: The ANE program serves the unique educational needs of Alaska Natives and recognizes the roles of Alaska Native languages and cultures in the educational success and long-term well-being of Alaska Native students. The Department encourages applicants to propose a broad array of activities to achieve these purposes, including activities that are consistent with the Administration's policy focus areas, such as promoting equitable access to educational resources and opportunities. These activities may include supporting inclusive pedagogical practices in educator preparation and professional development programs and increasing the number and diversity of experienced effective educators, including those from the community they serve.

As noted below, construction projects that will support the operation of an existing or proposed ANE program will be a permissible activity only if Congress specifically authorizes the use of FY 2024 funds for this purpose. However, we note that, in each of the last 20 fiscal years, Congress has authorized, through appropriations acts, that ANE funds may be used for

construction. If an applicant is interested in both proposing a construction project and a separate project, we encourage the applicant to submit separate applications for each project, in case Congress does not authorize construction through appropriations. If Congress does not authorize the use of FY 2024 funds for construction, we will notify applicants who applied for such purpose that we are unable to fund construction.

Priority: This notice contains one absolute priority.

Consistent with 34 CFR 75.105(b)(2)(v), the absolute priority is from allowable activities specified in the statute (see section 6304(a)(2)(A) and (B) of the ESEA).

Absolute Priority: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, this priority is an absolute priority. Under 34 CFR 75.105(c)(3), we consider only applications that meet the priority. In the project abstract, applicants must clearly identify the specific allowable activities the proposed project addresses. The applicant must address both parts of the priority.

This priority is:

Alaska Native Education Activities.

Projects designed to—

(a) Develop and implement plans, methods, strategies, and activities to improve the educational outcomes of Alaska Natives; and

(b) Collect data to assist in the evaluation of the programs carried out under the ANE program.

Note: The construction of facilities that will support the operation of an existing or proposed ANE program will be a permissible activity only if Congress specifically authorizes the use of FY 2024 funds for this purpose. If an applicant is interested in both proposing a construction project and a separate project, we encourage the applicant to submit separate applications for each project. If Congress does not authorize the use of FY 2024 funds for construction, we will notify applicants who applied for such purpose that we are unable to fund construction.

Definitions: For FY 2024 and any subsequent year in which we make awards from the list of unfunded applications from this competition, the following definitions apply. The definitions of “Alaska Native” and “Alaska Native organization” are from section 6306 of the ESEA (20 U.S.C. 7546). The definitions of “demonstrates a rationale,” “logic model,” “project component,” and “relevant outcome” are from 34 CFR 77.1. The definition of “Native” is from section 3(b) of the

Alaska Native Claims Settlement Act (43 U.S.C. 1602(b)). In addition, the definitions of “experience operating programs that fulfill the purposes of the ANE program,” “official charter or sanction,” and “predominately governed by Alaska Natives” are from the notice of final definitions and requirements for the Alaska Native Education Program, published in the **Federal Register** on June 4, 2019 (84 FR 25682) (NFR).

Alaska Native has the same meaning as the term Native has in section 3(b) of the Alaska Native Claims Settlement Act (43 U.S.C. 1602(b)) and includes the descendants of individuals so defined.

Alaska Native organization (ANO) means an organization that has or commits to acquire expertise in the education of Alaska Natives and is—

(a) An Indian Tribe, as defined in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 5304), that is an Indian Tribe located in Alaska;

(b) A Tribal organization, as defined in section 4 of such Act (25 U.S.C. 5304), that is a Tribal organization located in Alaska; or

(c) An organization listed in clauses (i) through (xii) of section 619(4)(B) of the Social Security Act (42 U.S.C. 619(4)(B)(i) through (xii)), or the successor of an entity so listed.

Demonstrates a rationale means a key project component included in the project’s logic model is informed by research or evaluation findings that suggest the project component is likely to improve relevant outcomes.

Experience operating programs that fulfill the purposes of the ANE program means that, within the past four years, the entity has received and satisfactorily administered, in compliance with applicable terms and conditions, a grant under the ANE program or another Federal or non-Federal program that focused on meeting the unique education needs of Alaska Native children and families in Alaska.

Logic model (also referred to as a theory of action) means a framework that identifies key project components of the proposed project (*i.e.*, the active “ingredients” that are hypothesized to be critical to achieving the relevant outcomes) and describes the theoretical and operational relationships among the key project components and relevant outcomes.

Native means a citizen of the United States who is a person of one-fourth degree or more Alaska Indian (including Tsimshian Indians not enrolled in the Metlaktila Indian Community) Eskimo, or Aleut blood, or combination thereof. The term includes any Native as so

defined either or both of whose adoptive parents are not Natives. It also includes, in the absence of proof of a minimum blood quantum, any citizen of the United States who is regarded as an Alaska Native by the Native village or Native group of which he claims to be a member and whose father or mother is (or, if deceased, was) regarded as Native by any village or group. Any decision of the Secretary of the Interior regarding eligibility for enrollment shall be final.

Official charter or sanction means a signed letter or written agreement from an Alaska Native Tribe or ANO that is dated within 120 days prior to the date of the submission of the application and expressly (1) authorizes the applicant to conduct activities authorized under the ANE program and (2) describes the nature of those activities.

Predominately governed by Alaska Natives means that at least 80 percent of the entity’s governing board (*i.e.*, the board elected or appointed to direct the policies of the organization) are Alaska Natives.

Project component means an activity, strategy, intervention, process, product, practice, or policy included in a project. Evidence may pertain to an individual project component or to a combination of project components (*e.g.*, training teachers on instructional practices for English learners and follow-on coaching for these teachers).

Relevant outcome means the student outcome(s) or other outcome(s) the key project component is designed to improve, consistent with the specific goals of the program.

Application Requirements: The following application requirements are from section 6304(a) of the ESEA and the NFR. In order to receive funding, an applicant must meet the following requirements:

(a) The applicant must provide a detailed description of the plans, methods, strategies, and activities it will develop and implement to improve the educational outcomes of Alaska Natives and how the applicant will develop and implement such plans, methods, strategies, and activities. (ESEA section 6304(a)(2))

(b) The applicant must provide a detailed description of the data it will collect to assist in the evaluation of the programs carried out under the ANE program, including data that address the performance measures in section VI.5 (Performance Measures) of this notice; and how the applicant will collect such data. (ESEA section 6304(a)(2))

(c) Group Application Requirements:

An applicant that applies as part of a partnership must meet this requirement,

in addition to the requirements in paragraphs (a) and (b) above.

(1) An ANO that applies for a grant in partnership with a State educational agency (SEA) or local educational agency (LEA) must serve as the fiscal agent for the project.

(2) Group applications under the ANE program must include a partnership agreement that includes a Memorandum of Understanding or a Memorandum of Agreement (MOU/MOA) between the members of the partnership identified and discussed in the grant application. Each MOU/MOA must—

(i) Be signed by all partners and dated within 120 days prior to the date of the submission of the application;

(ii) Clearly outline the work to be completed by each partner that will participate in the grant in order to accomplish the goals and objectives of the project; and

(iii) Demonstrate an alignment among the activities, roles, and responsibilities described in the grant application for each of the partners in the partnership agreement. (NFR)

(d) Applicants Establishing Eligibility through a Charter or Sanction from an Alaska Native Tribe or ANO:

For an entity that does not meet the eligibility requirements for an ANO, established in section 6304(a)(1) and 6306(2) of the ESEA and the definitions in this notice, and that seeks to establish eligibility through a charter or sanction provided by an Alaska Native Tribe or ANO as required under section 6304(a)(1)(C)(ii) of the ESEA, the following documentation is required, in addition to the information in Application Requirements (a) through (c) above:

(1) Written documentation demonstrating that the entity is physically located in the State of Alaska.

(2) Written documentation demonstrating that the entity has experience operating programs that fulfill the purposes of the ANE program.

(3) Written documentation demonstrating that the entity is predominately governed by Alaska Natives (as defined in this notice), including the total number, names, and Tribal affiliations of members of the governing board.

(4) A copy of the official charter or sanction (as defined in this notice) provided to the entity by an Alaska Native Tribe or ANO. (NFR)

Note: OESE invites an applicant to indicate whether it intends to consolidate its ANE grant funds into a current or future 477 plan in accordance with the provisions of Public Law 115–93 (see <https://www.govinfo.gov/>

[content/pkg/PLAW-115publ93/pdf/PLAW-115publ93.pdf](https://www.govinfo.gov/content/pkg/PLAW-115publ93/pdf/PLAW-115publ93.pdf)), the Indian Employment, Training and Related Services Consolidation Act of 2017 (25 U.S.C. 3401 *et seq.* see <https://www.govinfo.gov/content/pkg/USCODE-2021-title25/pdf/USCODE-2021-title25-chap36-sec3401.pdf>). Any request to consolidate ANE funds into a 477 plan must be made separately to the U.S. Department of Interior. For further information on the integration of grant funds under this and related programs, contact the Division of Workforce Development, Office of Indian Services, Bureau of Indian Affairs, U.S. Department of the Interior at Office of Indian Services, Division of Workforce Development, Bureau of Indian Affairs, 1849 C Street NW, MS–3645–MIB, Washington, DC 20245, Telephone: (202) 219–3938.

ANE grantees who are in their last year of ANE funding from a previous grant and have currently integrated that previous grant under an approved 477 plan must apply for a new ANE grant under this competition by submitting an application that meets all of the requirements included in this notice. If such an applicant receives a new ANE grant under this competition and wants to consolidate the new ANE grant in a 477 plan, it must submit a request to the U.S. Department of Interior to do so.

Statutory Hiring Preference:

(a) Awards that are primarily for the benefit of Indians are subject to the provisions of section 7(b) of the Indian Self-Determination and Education Assistance Act (93 Pub. L. 638). That section requires that, to the greatest extent feasible, a grantee—

(1) Give to Indians preferences and opportunities for training and employment in connection with the administration of the grant; and

(2) Give to Indian organizations and to Indian-owned economic enterprises, as defined in section 3 of the Indian Financing Act of 1974 (25 U.S.C. 1452(e)), preference in the award of subcontracts in connection with the administration of the grant.

(b) For purposes of this requirement, an Indian is a member of any federally recognized Indian Tribe.

Program Authority: Title VI, part C of the ESEA (20 U.S.C. 7541–7546).

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 75, 77, 79, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management

and Budget 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 Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474. (d) The NFR.

Note: The regulations in 34 CFR part 86 apply to institutions of higher education only.

II. Award Information

Type of Award: Discretionary grants.
Estimated Available Funds: The Administration requested \$44,953,000 for ANE for FY 2024, of which we intend to use an estimated \$15,900,000 for this competition. The actual level of funding, if any, depends on final congressional action. However, we are inviting applications to allow enough time to complete the grant process if Congress appropriates funds for this program.

Estimated Range of Awards: \$300,000–\$1,500,000 for each 12-month budget period.

Estimated Number of Awards: 11–53.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

III. Eligibility Information

1. Eligible Applicants:

(a) Alaska Native organizations with experience operating programs that fulfill the purposes of the ANE program;

(b) Alaska Native organizations that do not have experience operating programs that fulfill the purposes of the ANE program, but are in partnership with—

(i) An SEA or LEA; or

(ii) An Alaska Native organization that operates a program that fulfills the purposes of the ANE program; or

(c) An entity located in Alaska, and predominately governed by Alaska Natives, that does not meet the definition of an Alaska Native organization but—

(i) Has experience operating programs that fulfill the purposes of the ANE program; and

(ii) Is granted an official charter or sanction from at least one Alaska Native Tribe or Alaska Native organization to carry out programs that meet the purposes of the ANE program.

2. a. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

b. *Indirect Cost Rate Information:* This program uses 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.

c. *Administrative Cost Limitation*: No more than 5 percent of funds awarded for a grant under this program may be used for administrative costs (ESEA section 6305). Note that, since fiscal year 2020, Congress has included language in appropriations acts to clarify that the statutory 5 percent limit does not include indirect costs. In the event such language is not included in the FY 2024 appropriations act, the Department will work with successful applicants to make budget adjustments to align with administrative cost restrictions, if necessary.

For additional information please see the *Funding Restrictions* section of this notice.

3. *Subgrantees*: A grantee under this competition may not award subgrants to entities to directly carry out project activities described in its application.

4. *Build America, Buy America Act*: If Congress specifically authorizes the use of FY 2024 funds for the construction of facilities that will support the operation of an existing or proposed ANE program, this program is subject to the Build America, Buy America Act (Pub. L. 117–58) domestic sourcing requirements. Accordingly, under this program, grantees and their contractors may not use their grant funds for infrastructure projects or activities (e.g., construction, remodeling, and broadband infrastructure) unless—

- (a) All iron and steel used in the infrastructure project or activity are produced in the United States;
- (b) All manufactured products used in the infrastructure project or activity are produced in the United States; and
- (c) All construction materials are manufactured in the United States.

Grantees may request waivers to these requirements by submitting a Build America, Buy America Act Waiver Request Form. For more information, including a link to the Waiver Request Form, see the Department's Build America Buy America Waivers website at <https://www2.ed.gov/policy/fund/guid/buy-america/index.html>.

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.federal>

[register.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs](https://www.federalregister.gov/documents/2022/12/07/2022-26554/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs). Please note that these Common Instructions supersede the version published on December 27, 2021.

2. *Submission of Proprietary Information*: Given the types of projects that may be proposed in applications for the ANE program, your application may include business information that you consider proprietary. In 34 CFR 5.11, we define “business information” and describe the process we use in determining whether any of that information is proprietary and, thus, protected from disclosure under Exemption 4 of the Freedom of Information Act (5 U.S.C. 552, as amended). Because we plan to make successful applications available to the public, you may wish to request confidentiality of business information.

Consistent with Executive Order 12600, please designate in your application any information that you believe is exempt from disclosure under Exemption 4. In the appropriate Appendix section of your application, under “Other Attachments Form,” please list the page number or numbers on which we can find this information. For additional information please see 34 CFR 5.11(c).

3. *Intergovernmental Review*: This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. Information about Intergovernmental Review of Federal Programs under Executive Order 12372 is in the application package for this program.

4. *Funding Restrictions*: No more than 5 percent of FY 2024 funds awarded for a grant under this program may be used for administrative costs (ESEA section 6305).

Note: In general, for purposes of this competition, the 5 percent limit on administrative costs under ESEA section 6305 includes direct and indirect administrative costs. As described in the *Administrative Cost Limitation* section of this notice, the Department anticipates that Congress will clarify, through the FY 2024 appropriations act, that this 5 percent limit does not include indirect costs, and, in the event such language is not included in the FY 2024 appropriations act, will work with successful applicants to make budget adjustments to align with administrative cost restrictions, if necessary.

We reference regulations outlining additional funding restrictions in the *Applicable Regulations* section of this notice.

5. *Recommended Page Limit*: The application narrative is where you, the applicant, address the selection criteria that reviewers use to evaluate your application. We recommend that you (1) limit the application narrative to no more than 30 pages and (2) use the following standards:

- A “page” is 8.5” x 11”, on one side only, with 1” margins at the top, bottom, and both sides.
- Double-space (no more than three lines per vertical inch) all text in the application narrative.
- Use a font that is either 12 point or larger or no smaller than 10 pitch (characters per inch).
- Use one of the following fonts: Times New Roman, Courier, Courier New, or Arial.

The recommended page limit does not apply to the cover sheet; the budget section, including the narrative budget justification; the assurances and certifications; or the one-page abstract, the resumes, the bibliography, or the letters of support. However, the recommended page limit does apply to all of the application narrative.

V. Application Review Information

1. *Selection Criteria*: The selection criteria for this competition are from 34 CFR 75.210. The maximum score for all of the selection criteria is 100 points. The maximum score for each criterion is included in parentheses following the title of the specific selection criterion. Each criterion also includes the factors that reviewers will consider in determining the extent to which an applicant meets the criterion.

The selection criteria are as follows:

(a) *Need for project (up to 10 points)*

The Secretary considers the need for the proposed project. In determining the need for the proposed project, the Secretary considers the extent to which specific gaps or weaknesses in services, infrastructure, or opportunities have been identified and will be addressed by the proposed project, including the nature and magnitude of those gaps or weaknesses.

(b) *Quality of the project design (up to 30 points)*

The Secretary considers the quality of the design of the proposed project. In determining the quality of the design of the proposed project, the Secretary considers the extent to which the proposed project demonstrates a rationale (as defined in this notice).

(c) *Quality of project personnel (up to 10 points)*

The Secretary considers the quality of the personnel who will carry out the proposed project. In determining the quality of project personnel, the

Secretary considers the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (up to 5 points).

In addition, the Secretary considers the qualifications, including relevant training and experience, of key project personnel (up to 5 points).

(d) *Quality of the management plan (up to 30 points)*

The Secretary considers the quality of the management plan for the proposed project. In determining the quality of the management plan for the proposed project, the Secretary considers the adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks.

(e) *Quality of the project evaluation (up to 20 points)*

The Secretary considers the quality of the evaluation to be conducted of the proposed project. In determining the quality of the evaluation, the Secretary considers the following factors:

(1) The extent to which the methods of evaluation will provide valid and reliable performance data on relevant outcomes (up to 10 points).

(2) The extent to which the methods of evaluation include the use of objective performance measures that are clearly related to the intended outcomes of the project and will produce quantitative and qualitative data to the extent possible (up to 10 points).

Note: The quality of the project evaluation selection criterion relates to performance measure (1) under the Performance Measures section of this notice.

2. *Review and Selection Process:* We remind potential applicants that, in reviewing applications in any discretionary grant competition, the Secretary 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, and compliance with grant conditions. The Secretary 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, the Secretary 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, and 110.23).

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, the Secretary 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.

5. *In General.* In accordance with the Office of Management and Budget's guidance located at 2 CFR part 200, all applicable Federal laws, and relevant Executive guidance, the Department will review and consider applications for funding pursuant to this notice inviting applications in accordance with—

(a) Selecting recipients most likely to be successful in delivering results based on the program objectives through an objective process of evaluating Federal award applications (2 CFR 200.205);

(b) Prohibiting the purchase of certain telecommunication and video surveillance services or equipment in alignment with section 889 of the National Defense Authorization Act of 2019 (Pub. L. 115–232) (2 CFR 200.216);

(c) Providing a preference, to the extent permitted by law, to maximize use of goods, products, and materials produced in the United States (2 CFR 200.322); and

(d) Terminating agreements in whole or in part to the greatest extent authorized by law if an award no longer effectuates the program goals or agency priorities (2 CFR 200.340).

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 may notify you informally, also.

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. *Open Licensing Requirements:* Unless an exception applies, if you are awarded a grant under this competition, you will be required to openly license to the public grant deliverables created in whole, or in part, with Department grant funds. When the deliverable consists of modifications to pre-existing works, the license extends only to those modifications that can be separately identified and only to the extent that open licensing is permitted under the terms of any licenses or other legal restrictions on the use of pre-existing works. Additionally, a grantee or subgrantee that is awarded competitive grant funds must have a plan to disseminate these public grant deliverables. This dissemination plan can be developed and submitted after your application has been reviewed and selected for funding. For additional information on the open licensing requirements please refer to 2 CFR 3474.20.

4. *Reporting:* (a) If you apply for a grant under this competition, 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). At the end of your project period, you must submit a final performance report, including financial information, as directed by the Secretary. 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 the Secretary under 34 CFR 75.118. The Secretary 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.

(c) Under 34 CFR 75.250(b), the Secretary may provide a grantee with additional funding for data collection analysis and reporting. In this case the Secretary establishes a data collection period.

5. *Performance Measures:* For the purposes of Department reporting under 34 CFR 75.110, we have established four performance measures for the ANE program under the absolute priority: (1) the number of grantees who attain or exceed the targets for the outcome indicators for their projects that have been approved by the Secretary; (2) the percentage of Alaska Native children participating in early learning and preschool programs who consistently demonstrate school readiness in language and literacy as measured by the Revised Alaska Development Profile; (3) the percentage of Alaska Native students in schools served by the program who earn a high school diploma in four years; and (4) the number of Alaska Native programs that primarily focus on Alaska Native culture and language.

For a grantee that includes construction in its project, if Congress authorizes such use and the Department funds such an application, the Department will use the following performance measures for the ANE program: (1) the number of grantees that attain or exceed the targets for the outcome indicators for their projects that have been approved by the Secretary; (2) the number and percentage of grantees that report annually that the overall condition of the building(s) on which their project focuses is adequate; and (3) the number and percentage of grantees that report their project is at each of the following

levels of completion: (a) not started; (b) 1–25 percent; (c) 26–50 percent; (d) 51–75 percent; (e) 76–99 percent; (f) 100 percent complete.

6. *Continuation Awards:* In making a continuation award under 34 CFR 75.253, the Secretary 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; and, if the Secretary 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, the Secretary 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 under **FOR FURTHER INFORMATION CONTACT**, individuals with disabilities can obtain this document and a copy of the application package 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, audiotope, or 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 documents of this Department 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 documents of the Department published in the **Federal Register** by using the article search feature at www.federalregister.gov. Specifically, through the advanced search feature at this site, you can limit

your search to documents published by the Department.

Adam Schott,

Deputy Assistant Secretary for Policy and Programs, Delegated the Authority to Perform the Functions and Duties of the Assistant Secretary, Office of Elementary and Secondary Education.

[FR Doc. 2023–25125 Filed 11–14–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0192]

Agency Information Collection Activities; Comment Request; Entry Evidence and Evaluation & Exit Evidence Forms

AGENCY: Office of the Secretary (OS), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before January 16, 2024.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use <http://www.regulations.gov> by searching the Docket ID number ED–2023–SCC–0192. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at <http://www.regulations.gov> by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the www.regulations.gov site is not available to the public for any reason, the Department will temporarily accept comments at ICDocketMgr@ed.gov. Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Cleveland Knight, 202–987–0064.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Entry Evidence and Evaluation & Exit Evidence Forms.

OMB Control Number: 1894–NEW.

Type of Review: New ICR.

Respondents/Affected Public: State, Local, and Tribal governments

Total Estimated Number of Annual Responses: 819.

Total Estimated Number of Annual Burden Hours: 2,927.

Abstract: ED will use the Entry Evidence ICR form and the Evaluation & Exit Evidence ICR form for discretionary grant programs that: (1) Use the standard ED 524–B Grant Performance Report form as approved by OMB. The use of the standard ED 524–B Grant Performance Report promotes the standardization and streamlining of ED discretionary grant performance reporting. These performance reporting components are necessary to standardize information collection about Entry evidence, and Evaluation & Exit evidence use in grant implementation and to ensure a better, more comprehensive understanding of the use of evidence from what is provided in a grant application to the actual implementation of the grant project.

Dated: November 8, 2023.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–25124 Filed 11–14–23; 8:45 am]

BILLING CODE 4000–01–P

ELECTION ASSISTANCE COMMISSION

Request for Comment: 2024 Election Administration and Voting Survey

AGENCY: Election Assistance Commission.

ACTION: Notice, request for comment.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the EAC announces an information collection and seeks public comment on the provisions thereof. The EAC intends to submit this proposed information collection (2024 Election Administration and Voting Survey, or EAVS) to the Director of the Office of Management and Budget for approval. The 2024 EAVS asks election officials questions concerning voting and election administration, including the following topics: Voter registration; overseas and military voting; voting by mail; early in-person voting; polling operations; provisional voting; voter participation; election technology; election policy; and other related issues.

DATES: Comments must be received by 5 p.m. Eastern on Monday, January 15, 2023.

ADDRESSES: Comments on the proposed information collection should be submitted electronically via <https://www.regulations.gov> (docket ID: EAC–2023–0008). Written comments on the proposed information collection can also be sent to the U.S. Election Assistance Commission, 633 3rd Street NW, Suite 200, Washington, DC 20001, *Attn:* EAVS. To obtain a free copy of the draft survey instrument: (1) Download a copy at <https://www.regulations.gov> (docket ID: EAC–2023–0008); or (2) write to the EAC (including your address and phone number) at U.S. Election Assistance Commission, 633 3rd Street NW, Suite 200, Washington, DC 20001, *Attn:* EAVS.

FOR FURTHER INFORMATION CONTACT: Raymond Williams at 202–924–0794, or email research@eac.gov; U.S. Election Assistance Commission, 633 3rd Street NW, Suite 200, Washington, DC 20001.

SUPPLEMENTARY INFORMATION:

Title and OMB Number: 2024 Election Administration and Voting Survey; OMB Number Pending.

Purpose: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, the EAC is publishing notice of the proposed collection of information set forth in this document.

Background: The EAC issues the EAVS to meet its obligations under the Help America Vote Act of 2002 (HAVA) to serve as a national clearinghouse and resource for the compilation of information with respect to the administration of Federal elections; to fulfill both the EAC and the Department of Defense Federal Voting Assistance Program's (FVAP) data collection requirements under the Uniformed and Overseas Citizens Absentee Voting Act (UOCAVA); and meet its National Voter Registration Act (NVRA) mandate to collect information from states concerning the impact of that statute on the administration of Federal elections. In addition, under the NVRA, the EAC is responsible for collecting information and reporting, biennially, to Congress on the impact of that statute. The information the states are required to submit to the EAC for purposes of the NVRA report are found under Title 11 of the Code of Federal Regulations.

States that respond to questions in this survey concerning voter registration-related matters will meet their NVRA reporting requirements under 52 U.S.C. 20508 and EAC regulations. Finally, UOCAVA mandates that FVAP work with the EAC and chief state election officials to develop standards for reporting UOCAVA voting information (52 U.S.C. 20302) and that FVAP will store the reported data and present the findings within the congressionally-mandated report to the President and Congress. Additionally, UOCAVA requires that “not later than 90 days after the date of each regularly scheduled general election for Federal office, each state and unit of local

government which administered the election shall (through the state, in the case of a unit of local government) submit a report to the EAC on the combined number of absentee ballots transmitted to absent uniformed services voters and overseas voters for the election and the combined number of such ballots which were returned by such voters and cast in the election, and shall make such a report available to the general public.” States that complete and timely submit the UOCAVA section of the survey to the EAC will fulfill their UOCAVA reporting requirement under 52 U.S.C. 20302. In order to fulfill the above requirements, the EAC is seeking information relating to the period from the Federal general election day 2022 +1 through the November 2024 Federal general election. The EAC will provide the data regarding UOCAVA voting to FVAP after data collection is completed. This data sharing reduces burden on local election offices because FVAP does not have to conduct its own data collection to meet its reporting requirements.

Public Comments: Public comments are invited on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
- The accuracy of the agency’s estimate of the burden of the proposed information collection;
- Ways to enhance the quality, utility, and clarity of the information to be collected; and
- Ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your submitted comments, including your personal information, will be available for public review.

Affected Public (Respondents): State or local governments, the District of Columbia, American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands.

Affected Public: State or local government.

Number of Respondents: 56.

Responses per Respondent: 1.

Estimated Burden per Response: 90 hours per collection, 45 hours annualized.

Estimated Total Annual Burden Hours: 5,040 hours per collection, 2,520 hours annualized.

Frequency: Biennially.

Camden Kelliher,

Deputy General Counsel, U.S. Election Assistance Commission.

[FR Doc. 2023–25130 Filed 11–14–23; 8:45 am]

BILLING CODE 4810–71–P

DEPARTMENT OF ENERGY

[GDO Docket No. EA–462–A]

Application for Renewal of Authorization To Export Electric Energy; Guzman Energy LLC

AGENCY: Grid Deployment Office, Department of Energy.

ACTION: Notice of application.

SUMMARY: Guzman Energy LLC (the Applicant or Guzman Energy) has applied for renewed authorization to transmit electric energy from the United States to Mexico pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 15, 2023.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to Electricity.Exports@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT: Christina Gomer, (240) 474–2403, Electricity.Exports@hq.doe.gov.

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300 *et seq.*). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export. (16 U.S.C. 824a(e)). On April 10, 2023, the authority to issue such orders was delegated to the DOE’s Grid Deployment Office (GDO) by Delegation Order No. S1–DEL–S3–2023 and Redelegation Order No. S3–DEL–GD1–2023.

On December 6, 2018, DOE issued Order No. EA–462, authorizing Guzman Energy to transmit electricity from the United States to Mexico as a power marketer for a five-year term. On October 3, 2023, Guzman Energy filed an application with DOE (Application

or App.) for renewal of their export authority for an additional five-year term. App. at 1.

In its Application, Guzman Energy states that it “provides, through various subsidiaries and affiliates, a wide spectrum of wholesale electric and energy-related products and services to a diverse range of customers.” App. at 2. The Applicant further clarifies that it “is not a franchised public utility with a transmission or distribution system and does not have captive customers.” *Id.* The Applicant asserts that it “does not have its own system on which its exports of energy could have an impact with respect to electric supply. As such, Applicant’s proposed exports would not impair the sufficiency of the electric supply on ‘its system,’ as Applicant does not own or operate an integrated transmission or distribution system.” *Id.* at 5.

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See id.* at Exhibit C. *Procedural Matters:* Any person desiring to be heard in this proceeding should file a comment or protest to the Application at Electricity.Exports@hq.doe.gov. Protests should be filed in accordance with Rule 211 of FERC’s Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at Electricity.Exports@hq.doe.gov in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning Guzman Energy’s Application should be clearly marked with GDO Docket No. EA–462–A. Additional copies are to be provided directly to Robin J. Lunt, Chief Commercial Officer, Guzman Energy LLC, 1125 17th Street, Suite 740, Denver, CO 80202, rlunt@guzmanenergy.com and Max Carpenter, Managing Director of Trading and Market Operations, Guzman Energy LLC, 1125 17th Street, Suite 740, Denver, CO 80202, mcarpenter@guzmanenergy.com.

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE’s National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of

the United States electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at <https://www.energy.gov/gdo/pending-applications-0> or by emailing Electricity.Exports@hq.doe.gov.

Signing Authority: This document of the Department of Energy was signed on November 8, 2023, by Maria Robinson, Director, Grid Deployment Office, 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 9, 2023.

Treena V. Garrett,
Federal Register Liaison Officer, U.S.
Department of Energy.

[FR Doc. 2023–25183 Filed 11–14–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: U.S. Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; request comments.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its collection, titled Contracting, OMB Control Number 1910–5190. The proposed collection will collect information related to BPA's management and oversight of contracting requirements in fulfillment of BPA's vendor contracts.

DATES: Comments regarding this collection must be received on or before December 15, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 881–8585.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Attn: Stephanie Noell, Privacy Program, by email at privacy@bpa.gov, or by phone at (503) 230–3881.

SUPPLEMENTARY INFORMATION: This information collection request contains:

- (1) *OMB No.*: 1910–5190;
- (2) *Information Collection Request Title*: Contracting;
- (3) *Type of Request*: Extension;
- (4) *Purpose*: this information collection is associated with BPA's management and oversight of contracting requirements in fulfillment of BPA vendor contracts;
- (5) *Annual Estimated Number of Respondents*: 835;
- (6) *Annual Estimated Number of Total Responses*: 5,115;
- (7) *Annual Estimated Number of Burden Hours*: 1,240;
- (8) *Annual Estimated Reporting and Recordkeeping Cost Burden*: \$0.

Statutory Authority: The Bonneville Project Act codified in 16 U.S.C. 832a; the Federal Columbia River Transmission System Act of 1974 in 16 U.S.C. 838 *et seq.*; and the Pacific Northwest Electric Power Planning and Conservation Act in 16 U.S.C. 839 *et seq.*; IRS Code 26 U.S.C. 6109; and Department of Energy Establishment Act 42 U.S.C. 7101 *et seq.*

Signing Authority: This document of the Department of Energy was signed on November 1, 2023, by Rachel L. Hull, Information collection Clearance Manager, Bonneville Power Administration, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on November 9, 2023.

Treena V. Garrett,
Federal Register Liaison Officer, U.S.
Department of Energy.

[FR Doc. 2023–25240 Filed 11–14–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[GDO Docket No. EA–287–D]

Application for Renewal of Authorization To Export Electric Energy; Emera Energy U.S. Subsidiary No. 1, Inc.

AGENCY: Grid Deployment Office, Department of Energy.

ACTION: Notice of application.

SUMMARY: Emera Energy U.S. Subsidiary No. 1, Inc. (the Applicant or EE US No. 1) has applied for renewed authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 15, 2023.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to Electricity.Exports@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT: Christina Gomer, (240) 474–2403, Electricity.Exports@hq.doe.gov.

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300 *et seq.*). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export. (16 U.S.C. 824a(e)). On April 10, 2023, the authority to issue such orders was delegated to the DOE's Grid Deployment Office (GDO) by Delegation Order No. S1–DEL–S3–2023 and Redefinition Order No. S3–DEL–GD1–2023.

In April 2004, DOE issued Order No. EA–287, authorizing EE US No. 1 to transmit electric energy from the United States to Canada as a power marketer. This authority was renewed in 2009 (Order No. EA–287–A), in 2014 (Order

No. EA-287-B), and in 2019 (Order No. EA-287-C). On October 12, 2023, EE US No. 1 filed an application with DOE (Application or App.) for renewal of their export authority for a five-year term. App at 1.

In its Application, EE US No. 1 states that it is a wholly-owned subsidiary of Emera Incorporated (Emera). App. at 1. The Application represents that EE US No. 1 is authorized to export energy from the United States to Canada and has market-based authority from FERC to provide wholesale and retail marketing services as a power marketer. *Id.* The Applicant notes that Emera holds ownership interests in various subsidiaries that provide energy services. *See id.* at 2–6. Although some of Emera’s subsidiaries own and control electric power generation and transmission facilities, the Applicant asserts that EE US No. 1 “does not own or control any electric power generation or transmission facilities and does not have a franchised electric power service area.” App. at 6.

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See* App. at Exhibit C.

Procedural Matters: Any person desiring to be heard in this proceeding should file a comment or protest to the Application at the email address provided previously. Protests should be filed in accordance with Rule 211 of FERC’s Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at the previously provided email address in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning EE US No. 1’s Application should be clearly marked with GDO Docket No. EA-287-D. Additional copies are to be provided directly to Keith Sutherland, Vice President, Legal & Regulatory Affairs, Emera Energy Inc., 5151 Terminal Road, Halifax, NS B3J 1A1, Canada, keith.sutherland@emeraenergy.com, Jeffrey Jakubiak, Vinson & Elkins LLP, 1114 Avenue of the Americas, 32nd Floor, New York, NY 10036, jjakubiak@velaw.com, and Jennifer Mansh, Vinson & Elkins LLP, 2200 Pennsylvania Avenue NW, Suite 500 West, Washington, DC 20037, JMansh@velaw.com.

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE’s National

Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at <https://www.energy.gov/gdo/pending-applications-0> or by emailing Electricity.Exports@hq.doe.gov.

Signing Authority: This document of the Department of Energy was signed on November 8, 2023, by Maria Robinson, Director, Grid Deployment Office, 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 9, 2023.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2023–25188 Filed 11–14–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[GDO Docket No. EA-388-B]

Application for Renewal of Authorization To Export Electric Energy; TEC Energy Inc.

AGENCY: Grid Deployment Office, Department of Energy.

ACTION: Notice of application.

SUMMARY: TEC Energy Inc. (the Applicant or TEC) has applied for renewed authorization to transmit electric energy from the United States to Canada pursuant to the Federal Power Act.

DATES: Comments, protests, or motions to intervene must be submitted on or before December 15, 2023.

ADDRESSES: Comments, protests, motions to intervene, or requests for more information should be addressed by electronic mail to Electricity.Exports@hq.doe.gov.

FOR FURTHER INFORMATION CONTACT: Christina Gomer, (240) 474–2403, Electricity.Exports@hq.doe.gov.

SUPPLEMENTARY INFORMATION: The United States Department of Energy (DOE) regulates electricity exports from the United States to foreign countries in accordance with section 202(e) of the Federal Power Act (FPA) (16 U.S.C. 824a(e)) and regulations thereunder (10 CFR 205.300 *et seq.*). Sections 301(b) and 402(f) of the DOE Organization Act (42 U.S.C. 7151(b) and 7172(f)) transferred this regulatory authority, previously exercised by the now-defunct Federal Power Commission, to DOE.

Section 202(e) of the FPA provides that an entity which seeks to export electricity must obtain an order from DOE authorizing that export. (16 U.S.C. 824a(e)). On April 10, 2023, the authority to issue such orders was delegated to the DOE’s Grid Deployment Office (GDO) by Delegation Order No. S1–DEL–S3–2023 and Redelegation Order No. S3–DEL–GD1–2023.

On December 19, 2013, DOE issued Order No. EA-388, authorizing TEC to transmit electric energy from the United States to Canada as a power marketer for a five-year term. This authority was renewed on December 19, 2018 (Order No. EA-388–A). On September 21, 2023, TEC filed an application with DOE (Application or App.) for renewal of its export authority for an additional five-year term. App. at 1.

In its Application, TEC states that it “does not own or control any electric generation or transmission facilities, nor is it affiliated with any entity that does.” App. at 2. TEC represents that the electricity it “will export, on either a firm or interruptible basis, will be purchased from a variety of sources voluntarily, such as wholesale generators, electric utilities and federal power marketing agencies.” *Id.* at 3. TEC represents that “[b]y definition, such power is surplus to the system of the selling generator and, therefore, the electric power that TEC will export on either a firm or interruptible basis will not impair or tend to impede the sufficiency of the electric power supply within the U.S. or the regional coordination of electric utility planning or operations.” *Id.*

The existing international transmission facilities to be utilized by the Applicant have been previously authorized by Presidential permits issued pursuant to Executive Order 10485, as amended, and are appropriate for open access transmission by third parties. *See id.* at Exhibit C.

Procedural Matters: Any person desiring to be heard in this proceeding

should file a comment or protest to the Application at *Electricity.Exports@hq.doe.gov*. Protests should be filed in accordance with Rule 211 of Federal Energy Regulatory Commission's (FERC's) Rules of Practice and Procedure (18 CFR 385.211). Any person desiring to become a party to this proceeding should file a motion to intervene at *Electricity.Exports@hq.doe.gov* in accordance with FERC Rule 214 (18 CFR 385.214).

Comments and other filings concerning TEC's Application should be clearly marked with GDO Docket No. EA-388-B. Additional copies are to be provided directly to Etienne Lapointe, Chief Executive Officer, TEC Energy Inc., 5455 Av Gaspé, Suite 420, Montreal Quebec, H2T 3B3 Canada, *elapointe@tecenergy.ca*.

A final decision will be made on the requested authorization after the environmental impacts have been evaluated pursuant to DOE's National Environmental Policy Act Implementing Procedures (10 CFR part 1021) and after DOE evaluates whether the proposed action will have an adverse impact on the sufficiency of supply or reliability of the United States electric power supply system.

Copies of this Application will be made available, upon request, by accessing the program website at <https://www.energy.gov/gdo/pending-applications-0> or by emailing *Electricity.Exports@hq.doe.gov*.

Signing Authority: This document of the Department of Energy was signed on November 8, 2023, by Maria Robinson, Director, Grid Deployment Office, 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 9, 2023.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2023-25187 Filed 11-14-23; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2535-129]

Dominion Energy South Carolina, Inc.; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests and Establishing Procedural Schedule for Relicensing and a Deadline for Submission of Final Amendments

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

- a. *Type of Application:* New License.
- b. *Project No.:* 2535-129.
- c. *Date Filed:* October 27, 2023.
- d. *Submitted By:* Dominion Energy South Carolina, Inc.
- e. *Name of Project:* Stevens Creek Hydroelectric Project.
- f. *Location:* At the confluence of Stevens Creek and the Savannah River, in Edgefield and McCormick Counties, South Carolina, and Columbia County, Georgia. The project occupies approximately 104 acres of federal land administered by the U.S. Forest Service.
- g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)-825(r).
- h. *Applicant Contact:* Amy Bresnahan, Dominion Energy South Carolina, Inc., 220 Operation Way, Mail Code A221, Cayce, SC 29033-3712; (803) 217-9965; email—*Amy.Bresnahan@dominionenergy.com*.
- i. *FERC Contact:* Jeanne Edwards at (202) 502-6181; or email at *jeanne.edwards@ferc.gov*.
- j. *Cooperating Agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See*, 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and

serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* December 8, 2023.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.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: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Stevens Creek Project (P-2535-129).

m. The application is not ready for environmental analysis at this time.

n. The Stevens Creek Project consists of these existing facilities: (1) a single dam with an integral powerhouse intake and lock consisting of (a) a 102.5-foot-long non-overflow section with a top elevation of 198.54 feet National Geodetic Vertical Datum 1929 (NGVD), (b) a 2,000-foot-long overflow spillway with a top elevation of 183.5 feet NGVD, (c) a 1,000-foot-long, 5-foot-high flashboard section from the lock to the center of the spillway, (d) a 1,000 foot-long, 4-foot-high steel flashboard section from the center of the spillway to the South Carolina abutment, (e) an 85-foot-wide, 165.5-foot-long concrete gravity navigation lock, with a lock chamber that is 30-foot-wide, 150-foot-long, and has a 29-foot-lift, located between the powerhouse and spillway section, (f) a 388-foot-long powerhouse intake, integral with the dam, protected by trashracks with 3.75-inch-clear bar spacing, and (g) a 97-foot-long non-overflow section; (2) a 388-foot-long, 52-foot-wide, 57-foot-high three-story brick powerhouse, integral with the dam, containing eight vertical Francis generating units, each rated at 3,125 horsepower, a total generating capacity of 17.28 megawatts, and total hydraulic capacity of 8,300 cubic feet per second; (3) a 2,400-acre reservoir with a storage capacity of 23,699-acre-feet at a full pond elevation of 187.5 feet NGVD; (4) generator leads from the powerhouse to a switchyard located approximately 100

feet from the powerhouse; and (5) ancillary equipment.

The Stevens Creek Project operates as a re-regulating project, mitigating the downstream effects of the routinely wide-ranging discharges from the upstream U.S. Army Corps of Engineers J. Strom Thurmond hydroelectric project. The Stevens Creek reservoir normally fluctuates between an elevation of 183.0 feet NGVD and 187.5 feet NGVD, using available storage capacity to re-regulate flows released from Thurmond Dam.

o. Copies of the application 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 (P-2535). For assistance, contact FERC Online Support at FERCOnlineSupport@ferc.gov, or call (866) 208-3676 (toll-free) or (202) 502-8659 (TTY).

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

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.

q. Procedural schedule and final amendments: the application will be processed according to the following preliminary schedule. Revisions to the schedule will be made as appropriate.

Milestone	Target date
Issue Deficiency Letter (if necessary)	January 2024.
Request Additional Information (if necessary)	January 2024.
Issue Acceptance Letter	May 2024.
Issue Scoping Document 1 for comments	June 2024.
Request Additional Information (if necessary)	August 2024.
Issue Scoping Document 2 (if necessary)	August 2024.
Issue Notice of Ready for Environmental Analysis	September 2024.

r. Final amendments to the application must be filed with the Commission no later than 30 days from the issuance date of the notice of ready for environmental analysis.

Dated: November 8, 2023.

Kimberly D. Bose,
Secretary.

[FR Doc. 2023-25180 Filed 11-14-23; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC24-16-000.

Applicants: EGP Stillwater Solar, LLC, EGP Stillwater Solar PV II, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act of EGP Stillwater Solar, LLC, et al.

Filed Date: 11/7/23.

Accession Number: 20231107-5157.

Comment Date: 5 p.m. ET 11/28/23.

Take notice that the Commission received the following Complaints and Compliance filings in EL Dockets:

Docket Numbers: EL24-12-000.

Applicants: Independent Market Monitor for PJM v. PJM Interconnection, L.L.C.

Description: Complaint of Independent Market Monitor for PJM v. PJM Interconnection, L.L.C.

Filed Date: 11/7/23.

Accession Number: 20231107-5098.

Comment Date: 5 p.m. ET 11/27/23.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14-41-009; ER14-42-009; ER16-498-008; ER16-499-008; ER16-500-008; ER16-2277-002; ER16-2289-003; ER18-1174-003; ER20-2448-004; ER21-133-004; ER21-736-005; ER21-1962-005; ER21-2634-003; ER22-2784-002.

Applicants: MN8 Energy Marketing LLC, Solar Star Lost Hills, LLC, Mulberry BESS LLC, RE Slate 1 LLC, HDSE, LLC, American Kings Solar, LLC, Imperial Valley Solar 2, LLC, Golden Fields Solar I, LLC, Solar Star California XLI, LLC, RE Mustang 4 LLC, RE Mustang 3 LLC, RE Mustang LLC, RE Rosamond Two LLC, RE Rosamond One LLC.

Description: Notice of Non-Material Change in Status of RE Rosamond One LLC, et al.

Filed Date: 11/1/23.

Accession Number: 20231101-5288.

Comment Date: 5 p.m. ET 11/22/23.

Docket Numbers: ER23-2887-001.
Applicants: Arizona Public Service Company.

Description: Tariff Amendment: Rate Schedule No. 265, Amendment No. 4 to be effective 11/18/2023.

Filed Date: 11/8/23.

Accession Number: 20231108-5062.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER24-264-000.

Applicants: DesertLink, LLC.

Description: Errata to October 31, 2023, tariff filing of DesertLink, LLC.

Filed Date: 11/6/23.

Accession Number: 20231106-5175.

Comment Date: 5 p.m. ET 11/20/23.

Docket Numbers: ER24-359-000.

Applicants: Crow Creek Solar, LLC.

Description: Baseline eTariff Filing: Crow Creek Solar, LLC Application for Market-Based Rates to be effective 1/7/2024.

Filed Date: 11/7/23.

Accession Number: 20231107-5134.

Comment Date: 5 p.m. ET 11/28/23.

Docket Numbers: ER24-360-000.

Applicants: Keystone Appalachian Transmission Company.

Description: Baseline eTariff Filing: 2023-11-07 KATCo Certificate of Concurrence—Baseline Rate Schedule Filing to be effective 11/7/2023.

Filed Date: 11/7/23.

Accession Number: 20231107-5138.

Comment Date: 5 p.m. ET 11/28/23.

Docket Numbers: ER24-362-000.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: ISO New England Inc. and New England Power Pool filing of Installed Capacity Requirements, Hydro-Quebec Interconnection Capability Credits and Related Values for Forward Capacity Auction 18, 2027-2028 Capacity Commitment Period.

Filed Date: 11/7/23.

Accession Number: 20231107–5164.

Comment Date: 5 p.m. ET 11/28/23.

Docket Numbers: ER24–363–000.

Applicants: Bronco Plains Wind, LLC.

Description: Baseline eTariff Filing: Bronco Plains Wind I & Bronco Plains Wind II—Co-Tenancy SFA to be effective 11/9/2023.

Filed Date: 11/8/23.

Accession Number: 20231108–5103.

Comment Date: 5 p.m. ET 11/29/23.

Docket Numbers: ER24–364–000.

Applicants: Niagara Mohawk Power Corporation.

Description: Notice of Cancellation of the Interconnection Agreement between Niagara Mohawk and Northbrook Lyons Falls LLC.

Filed Date: 11/7/23.

Accession Number: 20231107–5165.

Comment Date: 5 p.m. ET 11/28/23.

Docket Numbers: ER24–365–000.

Applicants: Bronco Plains Wind II, LLC.

Description: Baseline eTariff Filing: Letter of Concurrence to Co-Tenancy SFA with Bronco Plains Wind to be effective 11/9/2023.

Filed Date: 11/8/23.

Accession Number: 20231108–5133.

Comment Date: 5 p.m. ET 11/29/23.

Docket Numbers: ER24–366–000.

Applicants: Sentinel Energy Center, LLC.

Description: Baseline eTariff Filing: Black Start Agreement Between CAISO and Sentinel to be effective 1/8/2024.

Filed Date: 11/8/23.

Accession Number: 20231108–5138.

Comment Date: 5 p.m. ET 11/29/23.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH24–3–000.

Applicants: CMS Energy Corporation.
Description: CMS Energy Corporation submits FERC 65–B Notice of Change in Fact to Waiver Notification.

Filed Date: 11/6/23.

Accession Number: 20231106–5174.

Comment Date: 5 p.m. ET 11/27/23.

The filings are accessible in the Commission's eLibrary system (<https://elibrary.ferc.gov/idmws/search/fercgensearch.asp>) by querying the docket number.

Any person desiring to intervene, 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 8, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–25195 Filed 11–14–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11553–01–OA]

Local Government Advisory Committee (LGAC): Notice of Charter Renewal

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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), 5 U.S.C. app. 2., the Local Government Advisory Committee (LGAC) is in the public interest and is necessary in connection with the performance of EPA's duties. Accordingly, the LGAC will be renewed for an additional two-year period. The purpose of the LGAC is to provide advice and recommendations to EPA's Administrator on ways to improve its partnership with local governments and provide more efficient and effective environmental protection.

FOR FURTHER INFORMATION CONTACT:

Paige Lieberman, Designated Federal Officer, LGAC, U.S. EPA, at (202) 564–9957/LGAC@epa.gov.

Dated: November 9, 2023.

Paige Lieberman,

EPA Designated Federal Officer, Local Government Advisory Committee.

[FR Doc. 2023–25233 Filed 11–14–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[Docket ID: EPA–HQ–OEJECR–2023–0530; FRL: 11540–01–OEJECR]

Agency Information Collection Activities; Proposed Information Collection Request; Comment Request; Environmental Justice Thriving Communities Technical Assistance Centers (TCTAC) Program: Post-Award Reporting and Public Outreach Information Collections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), Environmental Justice Thriving Communities Technical Assistance Centers (TCTAC) Program: Post-Award Reporting and Public Outreach Information Collections (EPA ICR Number 2794.01, OMB Control Number 2035–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a request for approval of a new collection. This notice allows for 60 days for public comments.

DATES: Comments must be submitted on or before January 16, 2024.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OEJECR–2023–0530, to EPA online using www.regulations.gov (our preferred method), by email to Docket_OMS@epa.gov, or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT:

Aarti Iyer, Office of the Chief Financial Officer, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; email address: iyer.aarti@epa.gov; phone: 202-564-0214.

SUPPLEMENTARY INFORMATION: This is a request for approval of a new collection. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

This notice allows 60 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at www.regulations.gov or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202-566-1744. For additional information about EPA's public docket, visit <http://www.epa.gov/dockets>.

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate forms of information technology. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: To help expand historically underserved and overburdened communities' access to critical resources, the U.S. Environmental Protection Agency (EPA) has collaborated with the U.S. Department of Energy to develop the Environmental Justice Thriving Communities Technical Assistance Centers (TCTAC) Program. The 18 Centers will operate in cooperative agreements with EPA to

remove barriers and improve access for communities who wish to apply for financial assistance awards to tackle their environmental justice concerns. The Centers will provide assistance and training to build capacity in: identifying sources of funding; navigating grant application systems; compiling strong grant proposals; managing grants; and developing partnerships and coalitions. With this Information Collection Request (ICR), EPA seeks authorization to collect post-award information from each Center to track their progress. Collection of this information enables EPA to assess and manage the TCTAC Program, which ensures responsible stewardship of public funds; rigorous evidence-based learning and improvement; and transparent accountability to the American public. This ICR also requests authorization for the Centers to collect input and insights from communities who seek to obtain technical assistance services, as well as stakeholders who have valuable experience and expertise in community engagement and empowerment. These information collections will enable the Centers to document local priorities, needs, and norms to ensure that they develop useful and relevant technical assistance and training services. Furthermore, feedback about these services will enable the Centers to conduct self-assessments to identify best practices and areas for improvement. Lastly, this ICR requests authorization for the National Centers in the TCTAC Program to conduct quarterly needs assessments for the Regional Centers, in order to identify the best ways in which the National Centers can support, expand, and bolster the technical assistance that local communities may need.

Form Numbers: None.

Respondents/affected entities: To be determined.

Respondent's obligation to respond: Mandatory for grant recipients as per reporting requirements included in EPA regulations 2 CFR parts 200 and 1500, and voluntary for public outreach information collections via surveys and focus groups.

Estimated number of respondents: To be determined. This data will be available for the next public review period.

Frequency of response: To be determined. This data will be available for the next public review period.

Total estimated burden: To be determined. This data will be available for the next public review period.

Total estimated cost: To be determined. This data will be available for the next public review period.

Changes in the Estimates: This is a new collection therefore there is no change in burden.

Matthew Tejada,

Deputy Assistant Administrator for Environmental Justice, Office of Environmental Justice and External Civil Rights.

[FR Doc. 2023-25109 Filed 11-14-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OEJECR-2023-0099; FRL-11515-01-OEJECR]

White House Environmental Justice Advisory Council; Notification of Virtual Public Meeting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of a public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the U.S. Environmental Protection Agency (EPA) hereby provides notice that the White House Environmental Justice Advisory Council (WHEJAC) will meet on the date and time described below. The meeting is open to the public. For additional information about registering to attend the meeting or to provide a public comment, please see "Registration" under **SUPPLEMENTARY INFORMATION**. Pre-registration is required.

DATES: The WHEJAC will convene a virtual public meeting on Wednesday, December 6, 2023, from approximately 2 p.m. to 7:45 p.m. ET. Meeting discussions will focus on several topics including, but not limited to, workgroup activities, proposed recommendations from the WHEJAC for the Council on Environmental Quality (CEQ) and the White House Environmental Justice Interagency Council (IAC), CEQ briefings, and a new formal charge for the WHEJAC. A public comment period relevant to current WHEJAC charges will be considered by the WHEJAC at the meeting on Wednesday, December 6, 2023 (see **SUPPLEMENTARY INFORMATION**). Members of the public who wish to participate during the public comment period must register by 11:59 p.m., ET, Wednesday, November 29, 2023.

FOR FURTHER INFORMATION CONTACT:

Audrie Washington, WHEJAC Designated Federal Officer, U.S. EPA; email: wherac@epa.gov; telephone: (202) 441-7295. Additional information about the WHEJAC is available at <https://www.epa.gov/environmentaljustice/>

white-house-environmental-justice-advisory-council.

SUPPLEMENTARY INFORMATION: The Charter of the WHEJAC (available at <https://www.epa.gov/system/files/documents/2023-03/2023%20White%20House%20Environmental%20Justice%20Advisory%20Council%20Charter.pdf>) states that the advisory committee will provide independent advice and recommendations to the Chair of CEQ and to the IAC. The WHEJAC provides advice and recommendations about how to increase the Federal Government's efforts to address current and historic environmental injustice, which may include addressing broad cross-cutting issues related, but not limited, to issues of environmental justice and pollution reduction, energy, climate change mitigation and resiliency, environmental health, and racial inequity. The WHEJAC's efforts include a broad range of strategic, scientific, technological, regulatory, community engagement, and economic issues related to environmental justice.

I. Registration

Individual registration is required for the public meeting. Information on how to register is located at <https://www.epa.gov/environmentaljustice/white-house-environmental-justice-advisory-council>. Registration for the meeting is available until the scheduled end time of the meeting. Registration to speak during the public comment period will close at 11:59 p.m., ET, on Wednesday, November 29, 2023. When registering, please provide your name, organization, city and state, and email address for follow up. Please also indicate whether you would like to provide public comment during the meeting, or if you are submitting written comments.

A. Public Comment

The WHEJAC is interested in receiving public comments relevant to the following charges, topics, and questions currently under consideration: (1) the Climate and Economic Justice Screening Tool; (2) the Environmental Justice Scorecard; (3) carbon management; (4) ways that the WHEJAC could recommend advancing environmental justice through a whole-of-government approach; and (5) environmental justice issues affecting Indigenous Peoples and Tribal Nations. With respect to environmental justice issues affecting Indigenous Peoples and Tribal Nations, the WHEJAC Indigenous Peoples and Tribal Nations Workgroup is particularly interested in receiving

comments on: Examples of environmental hazards of particular concern for Indigenous Peoples and Tribal Nations (for example, environmental hazards related to Federal activities that may affect sacred sites and areas of cultural significance, cultural or other traditions or practices, subsistence, and ways of life); ways in which the Federal government can address community impacts on, and concerns of, Indigenous Peoples and Tribal Nations; and ways in which the incorporation of Indigenous knowledge into Federal decision-making could help address environmental hazards and environmental justice concerns. More information on WHEJAC Workgroup charges is located online at: <https://www.epa.gov/environmentaljustice/white-house-environmental-justice-advisory-council>, under WHEJAC Membership and Workgroups.

Priority to speak during the meeting will be given to public commenters with comments relevant to the topics and questions listed above. Every effort will be made to hear from as many registered public commenters during the time specified on the agenda. Individuals or groups making remarks during the public comment period will be limited to three (3) minutes. Please be prepared to briefly describe your issue and your recommendation relevant to the current charges, topics, and questions under consideration by the WHEJAC. Submitting written comments for the record is strongly encouraged. You can submit your written comments in three different ways: (1) by creating comments in the Docket ID No. EPA-HQ-OEJECR-2023-0099 at <http://www.regulations.gov>, (2) by using the webform at <https://www.epa.gov/environmentaljustice/forms/white-house-environmental-justice-advisory-council-whejac-public-comment>, and (3) by sending comments via email to whejac@epa.gov. Written comments can be submitted through Wednesday, December 20, 2023.

B. Information About Services for Individuals With Disabilities or Requiring English Language Translation Assistance

To request special accommodations for a disability or other assistance, please submit your request at least five (5) working days prior to the meeting to give EPA sufficient time to process your request. All requests should be sent to

the email listed in the **FOR FURTHER INFORMATION CONTACT** section.

Matthew Tejada,

Deputy Assistant Administrator for Environmental Justice, Office of Environmental Justice and External Civil Rights.

[FR Doc. 2023-25232 Filed 11-14-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2023-0456; FRL-11424-01-OCSP]

Proposed Revisions to the National Lead Laboratory Accreditation Program (NLLAP); Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting comment on proposed revisions to EPA's document titled "Laboratory Quality System Requirements (LQSR) Revision 3.0" dated November 5, 2007, under the National Lead Laboratory Accreditation Program (NLLAP). Proposed revisions reflected in the draft document titled, "Laboratory Quality Standards for Recognition" (LQSR 4.0)," are intended to update and streamline the guidance by referencing existing laboratory standards already in practice by NLLAP participating laboratories and directly related to laboratory lead analysis, and to update the test and sampling method standards to better complement EPA's lead-based paint program activities.

DATES: Comments must be received on or before December 15, 2023.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0456, 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:

For technical information contact: Scott Drewes, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200

Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-8833; email address: drewes.scott@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you perform or may perform testing under the Agency's regulations regarding lead or otherwise interact with such testing programs. Specifically, entities potentially affected by these revisions are Fixed-Site, Mobile, and Field Sampling and Measurement Organizations (FSMOs) that perform lead testing. Analytical testing laboratories currently recognized by the NLLAP, and accreditation organizations that currently administer the NLLAP or other organizations that might seek a Memorandum of Understanding (MOU) with the Agency to become an accreditation organization could be affected by today's revisions. In addition, certified inspectors, certified risk assessors, developers, manufacturers, distributors of equipment and supplies used by FSMOs testing lead might also be affected by these revisions; and EPA-authorized state and tribal lead-based paint training and certification programs may also be affected by these revisions.

Other entities potentially affected by changes to the NLLAP for lead testing are the owners and managers of target housing and child-occupied facilities, as well as realtors, lessees, and residents, who ultimately pay for the testing services and stand to benefit by obtaining lead test results quicker.

Since other entities may also be interested, the Agency has not attempted to describe all of the specific entities that may be affected by this notice. If you have any questions regarding the applicability of this notice to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. Reasonable Availability to the Public

You may access the International Organization for Standardization and International Electrochemical Commission (ISO/IEC) Standard 17025: 2017 (E) "General requirements for the competence of testing and calibration laboratories." through the ANSI IBR reading room at <https://ibr.ansi.org> as

well as the American Society for Testing and Materials (ASTM) standard E1583-17 "Standard Practice for Evaluating Laboratories Engaged in Determination of Lead in Paint, Dust, Airborne Particulates, and Soil Taken from and Around Buildings and Related Structures" at https://astm-y.sharepoint.com/:w/g/personal/mpezzella_astm_org/EVDPKofENotKmA_Cx20yyZoB8A2L-Uh8ou1nfIEGZoHfgA?rttime=sxRRGVaB20g. These standards were incorporated into the LQSR 4.0 and referenced in this document.

C. What should I consider as I prepare my comments for EPA?

1. Submitting CBI

Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be 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>.

II. Background

EPA is identified by Congress as the federal agency responsible for establishing an accreditation program for laboratories participating in the analysis of lead in paint, soil and dust samples as a part of a national residential lead-based paint abatement and control program. In response to this federal mandate, the Office of Pollution Prevention and Toxics (OPPT) established the NLLAP which recognizes laboratories which have demonstrated the ability to accurately analyze for lead in paint, dust and soil samples. EPA also publishes the LQSR which sets the minimum lab standards under Toxic Substances Control Act (TSCA) section 405(b) for laboratory analysis of lead in paint films, soil and dust.

There are two basic components to the NLLAP. The first component is a laboratory proficiency testing program (the Environmental Laboratory

Proficiency Analytical Testing (ELPAT) Program) administered by the American Industrial Hygiene Association (AIHA) in conjunction with EPA's NLLAP. AIHA sends out ELPAT proficiency testing samples on a quarterly basis (four test rounds per year). AIHA assimilates the test results for each test round and evaluates the laboratories performance on a statistical basis. The second component of the NLLAP is a systems audit to be conducted by a laboratory accrediting organization recognized by EPA. EPA currently recognizes the organizations as accrediting organizations through a memorandum of agreement (<https://www.epa.gov/lead/national-lead-laboratory-accreditation-program-nllap>). Once a laboratory successfully meets the requirements of the ELPAT Program and passes an NLLAP system audit, the laboratory is recognized by EPA under the NLLAP.

In 1993, EPA issued its first version of the LQSR, which outlined minimum requirements for NLLAP recognized laboratories. An organization requesting NLLAP recognition shall be a laboratory capable of performing sampling and/or lead testing. A laboratory shall have distinct staffing, instrumentation, sampling and test methods, as appropriate, and depending upon the type, a laboratory may have multiple physical facilities and may use field test kits. Currently, an organization must meet the requirements listed in the third version of the LQSR, also referred to as LQSR 3.0, to attain recognition under the NLLAP as a lead-testing laboratory. The last revision of the LQSR was published in 2007 and EPA is now proposing to revise and rename it to "Laboratory Quality Standards for Recognition" (LQSR 4.0).

III. Proposed Revisions

The National Technology Transfer and Advancement Act (NTTAA) requires federal agencies to use technical standards already developed or adopted by voluntary consensus standards bodies if compliance would not be inconsistent with applicable law or otherwise impracticable. The current LQSR guidance (LQSR 3.0), refers to a now outdated 2005 version of a laboratory quality standard, ISO/IEC Standard 17025: 2005 (E) "General requirements for the competence of testing and calibration laboratories". In addition, there are other laboratory standards in LQSR 3.0 that are already in practice by NLLAP participating laboratories and directly related to laboratory lead analysis, making parts of the elements in LQSR 3.0 duplicative. Therefore, EPA is proposing to

streamline the LQSR by conforming and referencing the updated ISO 17025: 2017 (E) and ASTM E1583–17. OPPT has reviewed the updated laboratory standards and identified any gaps or areas where additional clarification or criteria are needed between ISO 17025: 2017 and ASTM E1583–17 and the proposed LQSR 4.0. These additional clarifications or criteria are included throughout the proposed draft.

EPA is also proposing updates in LQSR 4.0 which are needed to support EPA's implementation of EPA's lead-based paint program, specifically the activities under 40 CFR part 745 which are being reconsidered in a separate action titled, "Reconsideration of the Dust-Lead Hazard Standards and Dust-Lead Post-Abatement Clearance Levels" (88 FR 50444, August 1, 2023) (FRL–8524–01–OCSP). For example, EPA is proposing in this action to clarify that the laboratory must demonstrate that the test and/or sampling methods used can achieve a quantitation limit equal to or less than 50% of the lowest action level for dust wipe samples for the relevant surface area (*e.g.*, windowsills, floors). EPA is requesting comment on the impact of the proposed revision as it relates to laboratory capabilities to meet the proposed lower regulatory limits. Learn more about EPA's efforts to lower the dust-lead hazard standards and post-abatement dust-lead clearance levels under TSCA sections 402 and 403: <https://www.epa.gov/lead/hazard-standards-and-clearance-levels-lead-paint-dust-and-soil-tsc-sections-402-and-403>.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: November 8, 2023.

Denise Keehner,

Director, Office of Pollution Prevention and Toxics.

[FR Doc. 2023–25141 Filed 11–14–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2023–0562; FRL–11546–01–OCSP]

Pesticides; White Paper Describing Benefits of Structured and Digital Content Labels for Pesticide Products; Notice of Availability and Request for Comment

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is announcing the availability of and soliciting public

comment on a white paper describing the benefits of the creation, submission, review, approval, and distribution of structured content and digital pesticide labels. Structured labels are information or content that is organized in a predictable way, and digital content is those categorized fields with metadata. The current process for submitting, reviewing, and approving labels is time-consuming for both registrants and regulators. The increasing complexity of pesticide labels, inconsistent label language across products, and inconsistent placement of information on the labels often creates significant challenges for pesticide users and the public seeking information about how to use the products. Structured content and digital labels could streamline and standardize the submission, review, and access to label content, providing benefits across the spectrum of stakeholders. In addition to developing a framework for structured content and digital labels, EPA intends to identify the key information needed for the structured digital label.

DATES: Submit your comments on or before March 14, 2024.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2023–0562, through <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: Christian Bongard, Information Technology and Resources Management Division (7602M), Office of Program Support, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (706) 566–2238; email address: bongard.christian@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be potentially affected by this action if you are a producer, registrant, or user of pesticide products. 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:

- Chemical Producers (NAICS 32532), *e.g.*, pesticide manufacturers or formulators of pesticide products, pesticide importers or any person or company who seeks to register a pesticide.
- Agricultural Establishments (Crop Production) (NAICS code 111).
- Nursery and Tree Production (NAICS code 111421).
- Agricultural Pest Control and Pesticide Handling on Farms (NAICS code 115112).
- Crop Advisors (NAICS codes 115112, 541690, 541712).
- Agricultural (Animal) Pest Control (Livestock Spraying) (NAICS code 115210).
- Forestry Pest Control (NAICS code 115310).
- Wood Preservation Pest Control (NAICS code 321114).
- Pesticide Registrants (NAICS code 325320).
- Pesticide Dealers (NAICS codes 424690, 424910, 444220).
- Research & Demonstration Pest Control, Crop Advisor (NAICS code 541710).
- Industrial, Institutional, Structural & Health Related Pest Control (NAICS code 561710).
- Ornamental & Turf, Rights-of-Way Pest Control (NAICS code 561730).
- Environmental Protection Program Administrators (NAICS code 924110).
- Governmental Pest Control Programs (NAICS code 926140).

Since other entities may also be interested, the Agency has not attempted to describe all the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

This action is being taken under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq.*).

C. What action is the Agency taking?

EPA is announcing the availability of and soliciting public comment on the document entitled "White Paper: Benefits of the Adoption of Structured Content and Digital Pesticide Labels" (also referred to as the White Paper), a copy of which is available in the docket. The White Paper describes a framework for the creation, submission, review, approval, and distribution of structured content and digital pesticide labels.

Structured content is information or content that is organized in a predictable way, and digital labels are typically classified with metadata. Currently, the pesticide labels are reviewed and approved during the registration process, which can involve time consuming manual reviews, approval of labeling language focused on each product, without considering consistency across products, and a non-digital label that can increase the transaction cost to both registrants and regulators. The increasing complexity of pesticide labels, inconsistent label language across products, and inconsistent placement of information on the labels, often creates significant challenges for pesticide users and the public seeking information about how to use the products. Structured content and digital labels could streamline and standardize the submission, review, and access to label content, providing benefits across the spectrum of stakeholders. In addition to developing a framework for structured content and digital labels, EPA intends to also identify the key information needed for the structured digital label during the registration process.

EPA is requesting public comment on all aspects of the Structured Label Content, including but not limited to the anticipated benefits, risks, challenges, key fields, and proposed phases of adoption. In addition, the Agency is seeking specific feedback on several topics discussed in Unit II.

D. Why is the Agency taking this action?

Historically, the pesticide registration process often leads to time consuming reviews, potential approval of inconsistent label language, and high cost to both registrants and regulators. The increasing complexity of pesticide labels and inconsistency across label language and placement of information on labeling are challenges for pesticide users and the public seeking information about how to use the products. Structured content digital labels would streamline and standardize the submission, review, and access to label content, providing benefits across the spectrum of stakeholders.

E. Does this document contain binding requirements?

This document describes EPA's proposed framework for developing structured labels and structured digital labels. The requirements in the statutes are binding on EPA and registrants, respectively, but this document does not impose any binding requirements on EPA or outside parties. The strategies outlined in this document further the

general goals of the program, and EPA may depart from the strategies where circumstances warrant and without prior notice. In general, however, EPA will continue to offer notice and comment on proposed decisions that implement these strategies.

F. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be 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 and instructions at <https://www.epa.gov/dockets/commenting-epa-dockets>.

II. Request for Comments

EPA is seeking comment on all aspects of the White Paper and is particularly interested in public comment on the following questions related to previous digitalization efforts referenced in the White Paper.

1. Are there additional benefits to the adoption of structured labeling or structured digital labeling that have not been captured? If so, please describe.

2. Are there additional challenges associated with the adoption of structured labeling or structured digital labeling that have not been captured? If so, please describe.

3. Please provide feedback on the anticipated phases the Office of Pesticide Program's work towards structured labeling and structured digital labeling.

- Can any of anticipated phases be done concurrently?
- Is there a different order to the phases?
- Are any activities necessary in the development of structured labels and structured digital labels not accounted for in the anticipated phases? If so, please describe.

4. Are there additional efforts underway around development of structured labels or structured digital labels that EPA should be aware of? If

so, please provide information for EPA's consideration.

5. Are there elements of the current "narrative" labels that could not be translated into structured labeling or structured digital labeling? If so, what are the elements and what are the barriers to their adoption?

6. Please comment on the key fields listed in Appendix 1 in this document.

III. Paperwork Reduction Act (PRA)

The strategies outlined in the White Paper describe information collection activities that do not create any new paperwork burdens that require additional approval by OMB under the PRA, 44 U.S.C. 3501 *et seq.* The information collection activities associated with pesticide registration are already approved by OMB under OMB Control No. 2070-0226, entitled "Consolidated Pesticide Registration Submission Portal" (EPA ICR No. 2624.01).

Authority: 7 U.S.C. 136 *et seq.*

Dated: November 8, 2023.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

[FR Doc. 2023-25140 Filed 11-14-23; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OA-2013-0320; FRL-11531-01-OA]

Public Comment on the Revised Technical Guidance for Assessing Environmental Justice in Regulatory Analysis

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 60-day public comment period on the draft revision of the *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (EJ Technical Guidance). The EJ Technical Guidance was first published in 2016. The EPA is updating it to reflect the state of the science; new peer-reviewed agency guidance; and new terminology, priorities, and direction, including Executive Order 14096. The purpose of this guidance is to outline analytic expectations and discuss technical approaches and methods that can be used by agency analysts to evaluate EJ concerns for regulatory actions. This technical guidance builds on the EPA's experience in evaluating environmental

justice concerns within the rulemaking analytic process and underscores the EPA's ongoing commitment to ensuring the just treatment and meaningful involvement of all people with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.

DATES: Comments must be received on or before January 15, 2024.

ADDRESSES: You may send comments, identified by Docket ID No. EPA-HQ-OA-2013-0320, by any of the following methods:

- **Federal eRulemaking Portal:** <https://www.regulations.gov/> (our preferred method). Follow the online instructions for submitting comments.
- **Mail:** U.S. Environmental Protection Agency, EPA Docket Center, Office of Policy, 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. Ann Wolverton, National Center for Environmental Economics, Office of Policy (Mail Code 1809A), Environmental Protection Agency, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone number: 202-566-2278; email address: Wolverton.ann@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Public Participation.

A. Informational Webinars

The EPA will host two informational webinars on the draft revised technical guidance.

- Wednesday, December 6, 2:30–4:00 p.m. EST: To join the live event, see the weblink at: <https://www.epa.gov/environmental-economics/epa-draft-revision-technical-guidance-assessing-environmental-justice>.

To join by phone: +1 202-991-0477, Conference ID: 197 258 337#.

- Tuesday, December 12, 3:00–4:30 p.m. EST: To join the live event, see the

weblink at: <https://www.epa.gov/environmental-economics/epa-draft-revision-technical-guidance-assessing-environmental-justice>.

To join by phone: +1 202-991-0477, Conference ID: 398 827 52#.

B. Written Comments

Submit your comments, identified by Docket ID No. EPA-HQ-OA-2013-0320, 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.

II. General Information

A. Where can I find the document?

The draft revision of the *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* is available at <https://www.epa.gov/environmental-economics/epa-draft-revision-technical-guidance-assessing-environmental-justice>.

B. What is the purpose of the document?

The *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* (Guidance) addresses the issue of how to analytically consider environmental justice in regulatory analyses. It directs EPA analysts to assess whether environmental justice concerns exist prior to the rulemaking and whether such concerns are likely to be exacerbated or mitigated for each regulatory option under consideration. The technical guidance makes recommendations designed to ensure greater consistency across EPA assessments of EJ concerns for

regulatory actions. The recommendations encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time and resource constraints, and analytic challenges will vary by media and circumstance. They are not designed to be prescriptive and do not mandate the use of a specific approach. Updates to the technical guidance reflect advancements in the state of the science; other new peer-reviewed Agency guidance documents; and new priorities and direction related to the conduct of environmental justice analysis, including Executive Order 14096. The technical guidance builds on the EPA's experience in evaluating environmental justice as part of the rulemaking analytic process and underscores the EPA's ongoing commitment to ensuring the just treatment and meaningful involvement of all people with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies. The technical guidance will enable the EPA to conduct better analysis of regulations which will ultimately enable the EPA to make better decisions.

C. How will my comments be used?

Public comment received on the draft revision of the *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis* will be reviewed and considered for incorporation into or modification of text in the final revised draft of the Guidance. The final draft Guidance will then undergo internal EPA review and revision, and then be finalized for publication following peer review by the EPA's Science Advisory Board. An EPA Science Advisory Board (SAB) review of this document will be announced in December 2023. Information on the SAB review can be found here: https://sab.epa.gov/ords/sab/r/sab_apex/sab/home.

Victoria Arroyo,

Associate Administrator, Office of Policy.

[FR Doc. 2023-25126 Filed 11-14-23; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL DEPOSIT INSURANCE CORPORATION

[OMB No. 3064-0085; -0149; -0194]

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its obligations under the Paperwork Reduction Act of 1995 (PRA), invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the existing information collections described below (OMB Control No. 3064–0085; –0149 and –0194).

DATES: Comments must be submitted on or before January 16, 2024.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- *Agency website:* <https://www.fdic.gov/resources/regulations/federal-register-publications/>.

- *Email:* comments@fdic.gov. Include the name and number of the collection in the subject line of the message.

- *Mail:* Manny Cabeza (202–898–3767), Regulatory Counsel, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street NW building (located on F Street NW), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted to the OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Manny Cabeza, Regulatory Counsel, 202–898–3767, mcabeza@fdic.gov, MB–3128, Federal Deposit Insurance Corporation, 550 17th Street NW, Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

Proposal to renew the following currently approved collection of information:

1. *Title:* Recordkeeping and Disclosure Requirements in Connection with Regulation B (Equal Credit Opportunity).

OMB Number: 3064–0085.

Affected Public: Insured state nonmember banks and state savings associations.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN
[OMB No. 3064–0085]

Information collection description	Type of burden	Obligation to respond	Estimated number of respondents	Estimated average annual frequency of responses	Estimated total annual responses	Estimated time per response	Estimated annual burden (hours)
Credit Reporting History (1002.10)	Reporting	Mandatory	3,309	850	2,812,650	2 minutes	93,755
<i>Total Reporting Burden</i>							93,755
Disclosure for Optional Self-Test (1002.5).	Third-Party Disclosure.	Voluntary	972	2,500	2,430,000	1 minute	40,500
Notifications (1002.9)	Third-Party Disclosure.	Mandatory	3,309	1,715	5,674,935	2 minutes	189,165
Appraisal Report Upon Request (1002.12(a)(1)).	Third-Party Disclosure.	Mandatory	3,309	190	628,710	1 minute	10,479
Notice of Right to Appraisal (1002.14(a)(2)).	Third-Party Disclosure.	Mandatory	3,309	1,650	5,459,850	1 minute	90,998
<i>Total Third-Party Disclosure Burden</i>							331,142
Record Retention (Applications, Actions, Pre-Screened Solicitations)(1002.12).	Recordkeeping	Mandatory	3,309	360	1,191,240	1 minute	19,854
Record Retention (Self-Testing)(1002.12).	Recordkeeping	Mandatory	972	1	972	2 hours	1,944
Record Retention (Self-Testing Self-Correction) (1002.15).	Recordkeeping	Mandatory	243	1	243	8 hours	1,944
<i>Total Recordkeeping Burden</i>							23,742

Total Estimated Annual Burden: 448,639 hours.

General Description of Collection: Regulation B (12 CFR part 1002) issued by the Consumer Financial Protection Bureau, prohibits creditors from discriminating against applicants on any bases specified by the Equal Credit Opportunity Act; imposes, reporting,

record keeping and disclosure requirements; establishes guidelines for gathering and evaluating credit information; and requires creditors to give applicants certain written notices. There is no change in the method or substance of the collection.

2. *Title:* Affiliate Marketing/Consumer Opt-out Notices.

OMB Number: 3064–0149.

Forms: None.

Affected Public: Insured state nonmember banks and state savings associations that have affiliates and consumers that have a relationship with the foregoing.

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN
[OMB No. 3064–0149]

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
Affiliate Marketing Disclosure—Implementation. (Mandatory).	Third-Party Disclosure (Annual)	8	1	06:00	144
Consumer Opt Out Notices (Voluntary).	Third-Party Disclosure (Annual)	857,027	1	00:05	71,419
Affiliate Marketing Disclosure—Ongoing (Mandatory).	Third-Party Disclosure (Annual)	990	1	02:00	1,980

SUMMARY OF ESTIMATED ANNUAL BURDEN—Continued
[OMB No. 3064–0149]

Information collection (obligation to respond)	Type of burden (frequency of response)	Number of respondents	Number of responses per respondent	Time per response (HH:MM)	Annual burden (hours)
<i>Total Annual Burden (Hours):</i>					73,543

Source: FDIC.

General Description of Collection: Section 214 of the FACT Act requires financial institutions that wish to share information about consumers with their affiliates, to inform such consumers that they have the opportunity to opt out of such marketing solicitations. The disclosure notices and consumer responses thereto comprise the elements

of this collection of information. There is no change in the method or substance of the collection.

3. **Title:** Covered Financial Company Asset Purchaser Eligibility Certification.

OMB Number: 3064–0194.

Forms: 7300/10.

Affected Public: Any individual or entity that is a potential purchaser of

assets from (1) the FDIC as receiver for a Covered Financial Company (CFC); or (2) a bridge financial company (BFC) which requires the approval of the FDIC, as receiver for the predecessor CFC and as the sole shareholder of the BFC (e.g., the BFC's sale of a significant business line).

Burden Estimate:

SUMMARY OF ESTIMATED ANNUAL BURDEN
[OMB No. 3064–0194]

Information collection (obligation to respond)	Type of burden (frequency of responses)	Number of respondents	Number of responses per respondents	Time per response (HH:MM)	Annual burden (hours)
Covered Financial Company Asset Sales Purchaser Eligibility Certification.	Reporting	66	1	02:30	165
<i>Total Annual Burden (Hours):</i>					165

Source: FDIC.

General Description of Collection: The Covered Financial Company (CFC) Asset Purchaser Eligibility implements the statutory requirement that assets held by the FDIC in the course of liquidating any covered financial company not be sold to persons who contributed in specified ways to the demise of a covered financial company. The FDIC implemented this requirement in its regulations at 12 CFR 380.13. Prospective purchasers are required to complete and submit a Purchaser Eligibility Certification (PEC) to the FDIC. The PEC is a self-certification by a prospective purchaser that it does not fall into any of the categories of individuals or entities that are prohibited by statute or regulation from purchasing assets of a CFC. The PEC will be required of any individual or entity that is a potential purchaser of assets from the FDIC, whether in its corporate capacity or as a conservator or receiver, for (1) a CFC; or (2) a Bridge Financial Company (BFC).

The FDIC is increasing the total burden associated with this collection from 5 hours to 165 hours. The estimate for the number of respondents has increased from 10 to 66. The responses per respondent is unchanged from the 2021 submission. The estimate for hours per response represents a 1.5-hour increase from the 2021 submission. This

increase is due to a change in calculation methodology.

Request for Comment

Comments are invited on: (a) Whether the collections of information are necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collections, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collections of information on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Federal Deposit Insurance Corporation.

Dated at Washington, DC, November 8, 2023.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2023–25110 Filed 11–14–23; 8:45 am]

BILLING CODE P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m. on November 16, 2023.

PLACE: This Board meeting will be open to public observation only by webcast. Visit <https://www.fdic.gov/news/board-matters/video.html> for a link to the webcast. FDIC Board Members and staff will participate from FDIC Headquarters, 550 17th Street NW, Washington, DC.

Observers requiring auxiliary aids (e.g., sign language interpretation) for this meeting should email DisabilityProgram@fdic.gov to make necessary arrangements.

STATUS: Open to public observation via webcast.

MATTERS TO BE CONSIDERED: The Federal Deposit Insurance Corporation's Board of Directors will meet to consider the following matters:

Discussion Agenda

Memorandum and resolution re: Final Rule on Special Assessment Pursuant to Systemic Risk Determination.

Briefing on the Restoration Plan Semiannual Update.

Summary Agenda

No substantive discussion of the following items is anticipated. The Board will resolve these matters with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of Minutes of a Board of Directors' Meeting Previously Distributed.

Memorandum and resolution re: Designated Reserve Ratio for 2024.

Summary reports, status reports, and reports of actions taken pursuant to authority delegated by the Board of Directors.

CONTACT PERSON FOR MORE INFORMATION:

Direct requests for further information concerning the meeting to Debra A. Decker, Executive Secretary of the Corporation, at 202-898-8748.

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

Dated at Washington, DC, on November 9, 2023.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2023-25274 Filed 11-13-23; 11:15 am]

BILLING CODE 6714-01-P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at <https://www.federalreserve.gov/foia/request.htm>. Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments 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 November 29, 2023.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690-1414.

Comments can also be sent electronically to Comments.applications@chi.frb.org:

1. *Kristine L. MacDonald Ixonia Trust, Joan P. Lubar Ixonia Trust, Susan A. Lubar Ixonia Trust, and Sheldon B. and Marianne Lubar Ixonia Trust, all of Milwaukee, Wisconsin, and David J. Lubar, as trustee to all the aforementioned trusts, Fox Point, Wisconsin;*

Ixonia Bancshares Investors, LP, a Delaware limited partnership and qualified family partnership, Ixonia, Wisconsin;

David J. Lubar Ixonia Trust, Milwaukee, Wisconsin, and Patrick Lubar, as trustee, Fox Point, Wisconsin; and the Ixonia Control Trust, Milwaukee, Wisconsin, David J. Lubar, as trustee, and Patrick Lubar, as secondary trustee; to join the Lubar Family Control Group, a group acting in concert, to acquire voting shares of Ixonia Bancshares, Inc., and thereby indirectly acquire voting shares of Ixonia Bank, both of Ixonia, Wisconsin.

B. Federal Reserve Bank of Kansas City (Jeffrey Imgarten, Assistant Vice President) One Memorial Drive, Kansas City, Missouri 64198-0001. Comments can also be sent electronically to KCApplicationComments@kc.frb.org:

1. *Randall J. Blue, Sedalia, Colorado, Kipton J. Blue, Leawood, Kansas, and Karl R. Swartz, Wichita, Kansas, as co-trustees of the V. Jerry Blue Master Trust, the Republic Financial Trust 1, and the Republic Financial Trust 2, all of Wichita, Kansas; to become members of the Guenther/Swartz/Blue Control Group, a group acting in concert, to acquire voting shares of Republic Financial Corporation, and thereby indirectly acquire voting shares of Southwest National Bank, both of Wichita, Kansas.*

In addition, Karl R. Swartz, to become co-trustee of the V. Jerry Blue Irrevocable Grandchildren's GST Trust, the Justin R. Blue Share of Grandchildren's Irrevocable GST Trust, the V. Jerry Blue Grandchildren's Exempt GST Trust, the Randall J. Blue Share of V. Jerry Blue Insurance Trust No. 1, the Kipton R. Blue Share of V. Jerry Blue Insurance Trust No. 1, the Justin R. Blue Share of V. Jerry Blue Insurance Trust No. 2, the Zachary W. Blue Share of V. Jerry Blue Insurance Trust No. 2, the Taylor B. Blue Share of V. Jerry Blue Insurance Trust No. 2, the

Adam S. Blue Share of V. Jerry Blue Insurance Trust No. 2, the Benjamin J. Blue Share of V. Jerry Blue Insurance Trust No. 2, and the Amanda L. Blue Share of V. Jerry Blue Insurance Trust No. 2, all of Wichita, Kansas; to acquire voting shares of Republic Financial Corporation, and thereby indirectly acquire voting shares of Southwest National Bank.

2. *The Bruce L. Trimble Irrevocable Trust fbo Morgan Trimble, Morgan Trimble, as trustee, both of LeRoy, Kansas; to join the Trimble Family Group, a group acting in concert, to acquire voting shares of Flint Hills Bancshares, Inc. (the Company), and thereby indirectly acquire voting shares of The Citizens State Bank (the Bank), both of Gridley, Kansas.*

In addition, Bruce L. Trimble, Subshare of the Ival L. Trimble 12/9/97 Irrevocable Trust, Cynthia Renee Trimble, Subshare of the Ival L. Trimble 12/9/97 Irrevocable Trust, Tanner Trimble, Subshare of the Ival L. Trimble 12/9/97 Irrevocable Trust, Morgan Trimble, Subshare of the Ival L. Trimble 12/9/97 Irrevocable Trust, Bruce L. Trimble, as sole trustee of these subshare trusts and all of Leroy, Kansas;

Randall L. Trimble, Subshare of the Ival L. Trimble 12/9/97 Irrevocable Trust, Walker Trimble, Subshare of the Ival L. Trimble 12/9/97 Irrevocable Trust, both of Burlington, Kansas; Kennedy Trimble, Subshare of the Ival L. Trimble 12/9/97 Irrevocable Trust, Lenexa, Kansas; Randall L. Trimble, as sole trustee of these subshare trusts, Burlington, Kansas; and

Cynthia Renee Trimble Revocable Living Trust for Closely Held Stock Dated January 30, 2019, Cynthia Trimble, as trustee, both of Leroy, Kansas;

To join the Trimble Family Group, a group acting in concert, to retain voting shares of the Company, and and thereby indirectly retain voting shares of the Bank. Bruce L. Trimble and Randall L. Trimble, both individually, were previously permitted by the Reserve Bank to control the company and become members of the Trimble Family Group.

B. Federal Reserve Bank of Dallas (Karen Smith, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201-2272. Comments can also be sent electronically to Comments.applications@dal.frb.org:

1. *Margaret Long, Montague, Texas; to retain voting shares of Sanger Bancshares, Inc., and indirectly retain voting shares of Sanger Bank, both of Sanger, Texas.*

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023-25227 Filed 11-14-23; 8:45 am]

BILLING CODE 6210-01-P

FEDERAL RESERVE SYSTEM

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice, request for comment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) invites comment on a proposal to extend for three years, without revision, the Applications for Employment with the Board of Governors of the Federal Reserve System (FR 28; OMB No. 7100-0181).

DATES: Comments must be submitted on or before January 16, 2024.

ADDRESSES: You may submit comments, identified by FR 28, by any of the following methods:

- Agency website: <https://www.federalreserve.gov/foia/proposedregs.aspx>. Follow the instructions for submitting comments at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx>.
- Email: regs.comments@federalreserve.gov. Include the OMB number or FR number in the subject line of the message.
- FAX: (202) 452-3819 or (202) 452-3102.
- Mail: Federal Reserve Board of Governors, Attn: Ann E. Misback, Secretary of the Board, Mailstop M-4775, 2001 C St NW, Washington, DC 20551.

All public comments are available from the Board's website at <https://www.federalreserve.gov/apps/foia/proposedregs.aspx> as submitted, unless modified for technical reasons or to remove personally identifiable information at the commenter's request. Accordingly, comments will not be edited to remove any confidential business information, identifying information, or contact information. Public comments may also be viewed electronically or in paper in Room M-4365A, 2001 C St NW, Washington, DC 20551, between 9:00 a.m. and 5:00 p.m. on weekdays, except for Federal holidays. For security reasons, the Board requires that visitors make an appointment to inspect comments. You may do so by calling (202) 452-3684. Upon arrival, visitors will be required to present valid government-issued photo

identification and to submit to security screening in order to inspect and photocopy comments.

Additionally, commenters may send a copy of their comments to the Office of Management and Budget (OMB) Desk Officer for the Federal Reserve Board, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW, Washington, DC 20503, or by fax to (202) 395-6974.

FOR FURTHER INFORMATION CONTACT:

Federal Reserve Board Clearance Officer—Nuha Elmaghribi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, nuha.elmaghribi@frb.gov, (202) 452-3884.

SUPPLEMENTARY INFORMATION: On June 15, 1984, OMB delegated to the Board authority under the Paperwork Reduction Act (PRA) to approve and assign OMB control numbers to collections of information conducted or sponsored by the Board. In exercising this delegated authority, the Board is directed to take every reasonable step to solicit comment. In determining whether to approve a collection of information, the Board will consider all comments received from the public and other agencies.

During the comment period for this proposal, a copy of the proposed PRA OMB submission, including the draft reporting form and instructions, supporting statement (which contains more detail about the information collection and burden estimates than this notice), and other documentation, will be made available on the Board's public website at <https://www.federalreserve.gov/apps/reportingforms/home/review> or may be requested from the agency clearance officer, whose name appears above. Final versions of these documents will be made available at <https://www.reginfo.gov/public/do/PRAMain>, if approved.

Request for Comment on Information Collection Proposal

The Board invites public comment on the following information collection, which is being reviewed under authority delegated by the OMB under the PRA. Comments are invited on the following:

- a. Whether the proposed collection of information is necessary for the proper performance of the Board's functions, including whether the information has practical utility;
- b. The accuracy of the Board's estimate of the burden of the proposed information collection, including the

validity of the methodology and assumptions used;

c. Ways to enhance the quality, utility, and clarity of the information to be collected;

d. Ways to minimize the burden of information collection on respondents, including through the use of automated collection techniques or other forms of information technology; and

e. Estimates of capital or startup costs and costs of operation, maintenance, and purchase of services to provide information.

At the end of the comment period, the comments and recommendations received will be analyzed to determine the extent to which the Board should modify the proposal.

Proposal Under OMB Delegated Authority To Extend for Three Years, Without Revision, the Following Information Collection

Collection Title: Applications for Employment with the Board of Governors of the Federal Reserve System.

Collection Identifier: FR 28.

OMB Control Number: 7100-0181.

General Description of Collection: The FR 28 is comprised of the Application for Employment (FR 28a), Applicant's Voluntary Self-Identification (FR 28s), Research Assistant Candidate Survey of Interests and Computer Experience (FR 28i), and Pre-Hire Conflict of Interest Screening Form (FR 28c).

The Application for Employment (FR 28a) collects information to determine the qualifications of applicants for employment with the Board (such as education and training, employment record, and other information since the time the applicant left high school). Among other things, the FR 28a is used to examine, rate, or assess the applicant's qualifications, and to contact the applicant to arrange an interview. The Applicant's Voluntary Self-Identification (FR 28s) is an optional form that collects information on the applicant's gender, race, and ethnicity. The Research Assistant Candidate Survey of Interests and Computer Experience (FR 28i) collects information on a Research Assistant (RA) applicant's level of interest in various economic topics and experience in different data analytics/programs. The Pre-Hire Conflict of Interest Screening Form (FR 28c) collects information from external applicants after they have been selected for an interview at the Board regarding certain financial interests that could pose a conflict of interest based on the duties of the position for which they are applying. Although certain conflicts of interest information is requested on the

FR 28a, the FR 28c requests additional information to make sure that conflicts of interest are fully vetted before an applicant is employed at the Board.

The information collected through the FR 28 is used to assist the Board in recruiting and hiring individuals for Board employment, retaining qualified employees, and periodically reviewing its hiring practices.

Frequency: Event-generated.

Respondents: Individuals seeking employment with the Board.

Total estimated number of respondents: 17,150.

Total estimated annual burden hours: 7,208.¹

Board of Governors of the Federal Reserve System, November 8, 2023.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–25115 Filed 11–14–23; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–24–0666]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled “National Healthcare Safety Network (NHSN)” to the Office of Management and Budget (OMB) for review and approval. CDC previously published a “Proposed Data Collection Submitted for Public Comment and Recommendations” notice on August 21, 2023 to obtain comments from the public and affected agencies. CDC received one comment related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

National Healthcare Safety Network (NHSN) (OMB Control No. 0920–0666, Exp. 6/30/2026)—Revision—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Division of Healthcare Quality Promotion (DHQP), National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC) collects data from healthcare facilities in the National Healthcare Safety Network (NHSN) under OMB Control Number 0920–0666. During the early stages of its development, NHSN began as a voluntary surveillance system in 2005 managed by DHQP. NHSN provides facilities, states, regions, and the nation with data necessary to identify problem areas, measure the progress of

prevention efforts, and ultimately eliminate healthcare-associated infections (HAIs) nationwide. NHSN allows healthcare facilities to track blood safety errors and various HAI prevention practice methods such as healthcare personnel influenza vaccine status and corresponding infection control adherence rates.

Enrollment in NHSN has continuously increased, with over 37,000 actively reporting healthcare facilities across the U.S. Of the total enrolled healthcare facilities, there are over 6,000 acute care facilities; 8,400 dialysis facilities; 600 long-term acute care facilities; 400 inpatient rehabilitation facilities; 800 inpatient psychiatric facilities; nearly 20,000 long-term care facilities; and 6,000 ambulatory surgery facilities. NHSN currently has eight components: Patient Safety (PS), Healthcare Personnel Safety (HPS), Biovigilance (BV), Long-Term Care Facility (LTCF), Outpatient Procedure (OPC), Dialysis Component, Neonatal Component, and Medication Safety Component.

Data reported under the Patient Safety Component are used to determine the magnitude of the healthcare-associated adverse events and trends in the rates of the events, in the distribution of pathogens, and in the adherence to prevention practices. Data will help detect changes in the epidemiology of adverse events resulting from new medical therapies and changing patient risks. Additionally, reported data is being used to describe the epidemiology of antimicrobial use and resistance and to better understand the relationship of antimicrobial therapy to this rising problem.

Under the Healthcare Personnel Safety Component, protocols and data on events—both positive and adverse—are used to determine: (1) the magnitude of adverse events in healthcare personnel; and (2) compliance with immunization and sharps injuries safety guidelines.

Under the Biovigilance Component, data on adverse reactions and incidents associated with blood transfusions are reported and analyzed to provide national estimates of adverse reactions and incidents.

Under the Long-Term Care Facility Component (LTCF), data is captured from skilled nursing facilities. Reporting methods under the LTCF component have been created by using forms from the PS Component as a model with modifications to specifically address the specific characteristics of LTCF residents and the unique data needs of these facilities reporting into NHSN.

¹ More detailed information regarding this collection, including more detailed burden estimates, can be found in the OMB Supporting Statement posted at <https://www.federalreserve.gov/apps/reportingforms/home/review>. On the page displayed at the link, you can find the OMB Supporting Statement by referencing the collection identifier, FR 28.

The Outpatient Procedure Component (OPC) gathers data on the impact of infections and outcomes related to operative procedures performed in Ambulatory Surgery Centers (ASCs). The OPC is used to monitor two event types: Same Day Outcome Measures and Surgical Site Infections (SSIs).

The Dialysis Component offers a simplified user interface for dialysis users to streamline their data entry and analyses processes as well as provide options for expanding in the future to include dialysis surveillance in settings other than outpatient facilities.

The Neonatal Component includes one module, Late-Onset Sepsis/Meningitis (LOS/MEN). This module will track late-onset sepsis and meningitis events in very low birthweight neonates housed in Level II/III, Level III, and Level IV nursery locations.

The Medication Safety Component tracks medication safety and adverse drug events (ADEs) that are among the most common causes of iatrogenic harm in U.S. hospitals.

NHSN has increasingly served as the operating system for HAI reporting compliance through legislation established by the states. As of March 2019, 36 states, the District of Columbia and the City of Philadelphia, Pennsylvania have opted to use NHSN as their primary system for mandated reporting. Reporting compliance is completed by healthcare facilities in their respective jurisdictions, with

emphasis on those states and municipalities acquiring varying consequences for failure to use NHSN. Additionally, healthcare facilities in five U.S. territories (Puerto Rico, American Samoa, the U.S. Virgin Islands, Guam, and the Northern Mariana Islands) are voluntarily reporting to NHSN. Additional territories are projected to follow with similar use of NHSN for reporting purposes.

NHSN's data is used to aid in the tracking of HAIs and guide infection prevention activities/practices that protect patients. The Centers for Medicare and Medicaid Services (CMS) and other payers use these data to determine incentives for performance at healthcare facilities across the US and surrounding territories, and members of the public may use some protected data to inform their selection among available providers. Each of these parties is dependent on the completeness and accuracy of the data. CDC and CMS work closely and are fully committed to ensuring complete and accurate reporting, which are critical for protecting patients and guiding national, state, and local prevention priorities. CMS collects some HAI data and healthcare personnel influenza vaccination summary data, which is done on a voluntary basis as part of its Fee-for-Service Medicare quality reporting programs, while others may report data required by a federal mandate. Facilities that fail to report

quality measure data are subject to partial payment reduction in the applicable Medicare Fee-for-Service payment system. CMS links their quality reporting to payment for Medicare-eligible acute care hospitals, inpatient rehabilitation facilities, long-term acute care facilities, oncology hospitals, inpatient psychiatric facilities, dialysis facilities, and ambulatory surgery centers. Facilities report HAI data and healthcare personnel influenza vaccination summary data to CMS via NHSN as part of CMS's quality reporting programs to receive full payment. Still, many healthcare facilities, even in states without HAI reporting legislation, submit limited HAI data to NHSN voluntarily.

NHSN's data collection updates continue to support the incentive programs managed by CMS. For example, survey questions support requirements for CMS's quality reporting programs. Additionally, CDC has collaborated with CMS on a voluntary National Nursing Home Quality Collaborative, which focuses on recruiting nursing homes to report HAI data to NHSN and to retain their continued participation. The proposed changes in this new ICR include revisions to 23 existing data collection forms and nine new forms. In this Revision, CDC requests OMB approval for an estimated annual burden 1,784,296 hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Form number and name	Number of respondents	Number of responses per respondent	Avg. burden per response (min./hour 60)
57.100 NHSN Registration Form	2,000	1	5/60
57.101 Facility Contact Information	2,000	1	10/60
57.103 Patient Safety Component—Annual Hospital Survey	5,311	1	135/60
57.104 NHSN Facility Administrator Change Request Form	800	1	5/60
57.105 Group Contact Information	1,000	1	5/60
57.106 Patient Safety Monthly Reporting Plan	7,821	12	15/60
57.108 Primary Bloodstream Infection (BSI)	5,775	5	39/60
57.111 Pneumonia (PNEU)	1,800	2	31/60
57.112 Ventilator-Associated Event	5463	8	29/60
57.113 Pediatric Ventilator-Associated Event (PedVAE)	334	1	31/60
57.114 Urinary Tract Infection (UTI)	6000	5	21/60
57.115 Custom Event	600	91	36/60
57.116 Denominators for Neonatal Intensive Care Unit (NICU)	1,100	12	4/60
57.117 Denominators for Specialty Care Area (SCA)/Oncology (ONC)	500	12	5/60
57.118 Denominators for Intensive Care Unit (ICU)/Other locations (not NICU or SCA)	5500	60	5/60
57.120 Surgical Site Infection (SSI)	3,800	12	36/60
57.121 Denominator for Procedure	3,800	12	10/60
57.122 HAI Progress Report State Health Department Survey	55	1	28/60
57.123 Antimicrobial Use and Resistance (AUR)-Microbiology Data Electronic Upload Specification Tables	5,500	12	5/60
57.124 Antimicrobial Use and Resistance (AUR)-Pharmacy Data Electronic Upload Specification Tables	5,500	12	5/60
57.125 Central Line Insertion Practices Adherence Monitoring	500	213	26/60
57.126 MDRO or CDI Infection Form	720	11	31/60
57.127 MDRO and CDI Prevention Process and Outcome Measures Monthly Monitoring	5,500	29	15/60
57.128 Laboratory-identified MDRO or CDI Event	4800	79	21/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form number and name	Number of respondents	Number of responses per respondent	Avg. burden per response (min./hour 60)
57.129 Adult Sepsis	50	250	25/60
57.135 Late Onset Sepsis/Meningitis Denominator Form: Late Onset Sepsis/Meningitis Denominator Form: Data Table for monthly electronic upload	300	6	5/60
57.136 Late Onset Sepsis/Meningitis Event Form: Data Table for Monthly Electronic Upload	300	6	5/60
57.137 Long-Term Care Facility Component—Annual Facility Survey	17,700	1	120/60
57.138 Laboratory-identified MDRO or CDI Event for LTCF	1,086	24	20/60
57.139 MDRO and CDI Prevention Process Measures Monthly Monitoring for LTCF	1,019	12	20/60
57.140 Urinary Tract Infection (UTI) for LTCF	339	36	35/60
57.141 Monthly Reporting Plan for LTCF	1,099	12	15/60
57.142 Denominators for LTCF Locations	714	12	35/60
57.143 Prevention Process Measures Monthly Monitoring for LTCF	357	12	5/60
57.149 Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	125	52	60/60
57.150 LTAC Annual Survey	392	1	89/60
57.151 Rehab Annual Survey	1,160	1	89/60
57.200 Healthcare Personnel Safety Component Annual Facility Survey	50	1	480/60
57.204 Healthcare Worker Demographic Data	50	200	20/60
57.205 Exposure to Blood/Body Fluids	50	50	60/60
57.206 Healthcare Worker Prophylaxis/Treatment	50	30	15/60
57.207 Follow-Up Laboratory Testing	50	50	15/60
57.210 Healthcare Worker Prophylaxis/Treatment-Influenza	50	50	10/60
57.211 Weekly Healthcare Personnel Influenza Vaccination Cumulative Summary for Non-Long-Term Care Facilities	125	52	60/60
57.214 Annual Healthcare Personnel Influenza Vaccination Summary	5,000	1	120/60
57.218 Weekly Resident Influenza Vaccination Cumulative Summary for Long-Term Care Facilities	2,500	52	60/60
57.300 Hemovigilance Module Annual Survey	500	1	86/60
57.301 Hemovigilance Module Monthly Reporting Plan	500	12	60/60
57.303 Hemovigilance Module Monthly Reporting Denominators	500	12	77/60
57.305 Hemovigilance Incident	500	10	10/60
57.306 Hemovigilance Module Annual Survey—Non-acute care facility	500	1	36/60
57.307 Hemovigilance Adverse Reaction—Acute Hemolytic Transfusion Reaction	500	4	21/60
57.308 Hemovigilance Adverse Reaction—Allergic Transfusion Reaction	500	4	21/60
57.309 Hemovigilance Adverse Reaction—Delayed Hemolytic Transfusion Reaction	500	1	21/60
57.310 Hemovigilance Adverse Reaction—Delayed Serologic Transfusion Reaction	500	2	21/60
57.311 Hemovigilance Adverse Reaction—Febrile Non-hemolytic Transfusion Reaction	500	4	21/60
57.312 Hemovigilance Adverse Reaction—Hypotensive Transfusion Reaction	500	1	21/60
57.313 Hemovigilance Adverse Reaction—Infection	500	1	21/60
57.314 Hemovigilance Adverse Reaction—Post Transfusion Purpura	500	1	21/60
57.315 Hemovigilance Adverse Reaction—Transfusion Associated Dyspnea	500	1	20/60
57.316 Hemovigilance Adverse Reaction—Transfusion Associated Graft vs. Host Disease	500	1	21/60
57.317 Hemovigilance Adverse Reaction—Transfusion Related Acute Lung Injury	500	1	21/60
57.318 Hemovigilance Adverse Reaction—Transfusion Associated Circulatory Overload	500	2	21/60
57.319 Hemovigilance Adverse Reaction—Unknown Transfusion Reaction	500	1	21/60
57.320 Hemovigilance Adverse Reaction—Other Transfusion Reaction	500	1	21/60
57.400 Outpatient Procedure Component—Annual Facility Survey	350	1	10/60
57.401 Outpatient Procedure Component—Monthly Reporting Plan	350	12	15/60
57.402 Outpatient Procedure Component Same Day Outcome Measures	50	1	40/60
57.403 Outpatient Procedure Component—Monthly Denominators for Same Day Outcome Measures	50	400	40/60
57.404 Outpatient Procedure Component—SSI Denominator	300	100	10/60
57.405 Outpatient Procedure Component—Surgical Site (SSI) Event	300	36	35/60
57.408 Monthly Survey Patient Days & Nurse Staffing	2500	12	60/60
57.500 Outpatient Dialysis Center Practices Survey	7400	1	12/60
57.501 Dialysis Monthly Reporting Plan	7400	12	5/60
57.502 Dialysis Event	7400	12	15/60
57.503 Denominator for Outpatient Dialysis	7400	24	10/60
57.504 Prevention Process Measures Monthly Monitoring for Dialysis	1730	12	75/60
57.505 Dialysis Patient Influenza Vaccination	615	50	10/60
57.506 Dialysis Patient Influenza Vaccination Denominator	615	5	10/60
57.507 Home Dialysis Center Practices Survey	450	1	36/60
57.130 New Form—Patient Safety Component FHIR Measure Respiratory Pathogens Surveillance (RPS)-IT Initial Set up	5,500	1	1620/60
57.130 New Form—Patient Safety Component FHIR Measure Respiratory Pathogens Surveillance (RPS)-IT Yearly Maintenance	5,500	1	1200/60
57.130 New Form—Patient Safety Component FHIR Measure Respiratory Pathogens Surveillance (RPS)-Infection Preventionist	5,500	1	6/60
57.130 New Form—Patient Safety Component CSV Data Collection-Infection Preventionist CSV Data Collection-Infection Preventionist	5500	365	2/60
57.132 New Form—Patient Safety Component FHIR Measures-HOB, HT-CDI Modules-IT Initial Set up	5500	1	1620/60

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form number and name	Number of respondents	Number of responses per respondent	Avg. burden per response (min./hour 60)
57.132 New Form—Patient Safety Component FHIR Measures-HOB, HT—CDI Modules-IT Yearly Maintenance	5500	1	1200/60
57.132 New Form—Patient Safety Component FHIR Measures-HOB, HT—CDI Modules-Infection Preventionist	5500	6	6/60
57.133 New Form—Patient Safety Component FHIR Measures-VTE Module-IT Initial Set up	5500	1	1620/60
57.133 New Form—Patient Safety Component FHIR Measures-VTE Module-IT Yearly Maintenance	5500	1	1200/60
57.133 New Form—Patient Safety Component FHIR Measures-VTE Module- Infection Preventionist	5500	6	6/60
57.600 New Form—Neonatal Component FHIR Measure-Late Onset Sepsis Meningitis (LOSMEN) Module-IT Initial Set up	5500	1	1620/60
57.600 New Form—Neonatal Component FHIR Measure-Late Onset Sepsis Meningitis (LOSMEN) Module-IT Yearly Maintenance	5500	1	1200/60
57.600 New Form—Neonatal Component FHIR Measure-Late Onset Sepsis Meningitis (LOSMEN) Module-Infection Preventionist	5500	6	6/60
57.600 New Form—Neonatal Component Late Onset Sepsis Meningitis (LOSMEN) Module CDA Data Collection-Infection Preventionist	5500	12	2/60
57.700 New Form—Medication Safety Component FHIR Measure-Glycemic Control Module Hypoglycemia-IT Initial Set up	5500	1	1620/60
57.700 New Form—Medication Safety Component FHIR Measure-Glycemic Control Module Hypoglycemia-IT Yearly Maintenance	5500	1	1200/60
57.700 New Form—Medication Safety Component FHIR Measure-Glycemic Control Module Hypoglycemia-Infection Preventionist	5500	6	6/60
57.701 New Form—Glycemic Control Module-HYPO Annual Survey	10	1	120/60
57.144 New Form—Long Term Care Respiratory Tract Infections (RTI) Module	16,500	24	25/60
57.145 New Form—Long Term Care Antimicrobial Use (LTC—AU) Module CDA	16,500	12	5/60
New Form—Billing Code Data: 8371 Upload	5500	4	5/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office,
Office of Public Health Ethics and
Regulations, Office of Science, Centers for
Disease Control and Prevention.

[FR Doc. 2023–25156 Filed 11–14–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

In accordance with 5 U.S.C. 1009(d), the Centers for Disease Control and Prevention (CDC) announces 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, and the Determination of the Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463.

Name of Committee: Safety and Occupational Health Study Section (SOHSS), National Institute for Occupational Safety and Health (NIOSH).

Dates: February 6–7, 2024.

Times: 11 a.m.–5 p.m., EST.

Place: Teleconference.

Agenda: The meeting will convene to address matters related to the conduct of Study Section business and for the Study Section to consider safety and occupational health-related grant applications.

For Further Information Contact:
Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1095 Willowdale Road, Morgantown, West Virginia 26506. Telephone: (304) 285–5951; Email: MGoldcamp@cdc.gov.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–25120 Filed 11–14–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10662]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden,

ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 16, 2024.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to <http://www.regulations.gov>. Follow the instructions for “Comment or Submission” or “More Search Options” to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number: ____, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: <https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing>.

FOR FURTHER INFORMATION CONTACT: William N. Parham at (410) 786-4669.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection’s supporting statement and associated materials (see **ADDRESSES**).

CMS-10662 Administrative Simplification HIPAA Compliance Review

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term “collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Administrative Simplification HIPAA Compliance Review; *Use:* Section 1173 of the Social Security Act (the Act), 42 U.S.C. 1320d–2, and section 264 of HIPAA require the Secretary to adopt a number of national standards to facilitate the exchange of certain health information and to protect the privacy and security of such information.

The Secretary promulgated rules that relate to compliance with, and enforcement of, the HIPAA rules, which are codified at 45 CFR part 160, subparts C, D, and E and collectively referred to as the Enforcement Rule. The Secretary first issued an interim final rule promulgating the procedural requirements for imposition of civil money penalties on violations of the privacy standards on April 17, 2003, Civil Money Penalties: Procedures for Investigations, Imposition of Penalties (68 FR 18896). The Secretary subsequently proposed a rule on April 18, 2005, HIPAA Administrative Simplification: Enforcement; Proposed Rule (70 FR 20224), proposing the amendment of 45 CFR part 160, subparts A (General Provisions), C (Compliance and Enforcement), and E (Procedures for Hearing), and proposing a new subpart D (Imposition of Civil Money Penalties) that addressed the substantive issues related to the imposition of civil money penalties and proposing the above provisions be applied to all HIPAA rules.

The purpose of this collection is to retrieve information necessary to conduct a compliance review and carry out the authority delegated to CMS as described in CMS-0014-N (68 FR 60694). These forms will be submitted to the Centers for Medicare & Medicaid Services (CMS), National Standards Group, from entities covered by HIPAA Administrative Simplification regulations. This collection is not applicable to HIPAA Privacy and Security Rules. *Form Number:* CMS-10662 (OMB control number: 0938-1390); *Frequency:* Weekly; *Affected*

Public: Private, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-profits institutions; *Number of Respondents:* 50; *Total Annual Responses:* 50; *Total Annual Hours:* 500. (For policy questions regarding this collection contact Kevin Stewart at (410) 786-6149.)

Dated: November 9, 2023.

William N. Parham, III,
Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023-25224 Filed 11-14-23; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Community-Based Child Abuse Prevention Program (Office of Management and Budget #: 0970-0155)

AGENCY: Children’s Bureau, Administration on Children, Youth and Families, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Children’s Bureau, Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), is requesting a three-year extension of the Program Instruction (PI) for the Community-Based Child Abuse Prevention (CBCAP) program (Office of Management and Budget #:0970-0155, expiration June 30, 2024), which outlines information collection requirements pursuant to receiving a grant award. There are no changes requested to the information collection process.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing infocollection@acf.hhs.gov. Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The PI, prepared in response to the enactment of the CBCAP program, as set forth in title II of the Child Abuse Prevention and Treatment

Reauthorization Act of 2010 (Pub. L. 111–320) or CAPTA, provides direction to the states and territories to accomplish the purposes of (1) supporting community-based efforts to develop, operate, expand, and where appropriate to network, initiatives aimed at the prevention of child abuse and neglect, and to support networks of coordinated resources and activities to

better strengthen and support families to reduce the likelihood of child abuse and neglect and (2) fostering an understanding, appreciation, and knowledge of diverse populations in order to be effective in preventing and treating child abuse and neglect. This PI contains information collection requirements that are found in CAPTA and pursuant to receiving a grant award.

The information submitted will be used by the agency to ensure compliance with the statute, complete the calculation of the grant award entitlement, and provide training and technical assistance to the grantee.

Respondents: State governments, quasi-public entities, and non-profit private agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Application	52	1	40	2,080
Annual Report	52	1	24	1,248
Totals				3,328

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: The CAPTA Reauthorization Act of 2010; title II of the CAPTA, Public Law 115–271 (42 U.S.C. 5116 *et seq.*).

Mary B. Jones,
ACF/OPRE Certifying Officer.

[FR Doc. 2023–25164 Filed 11–14–23; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection

Activities: Proposed Collection; Public Comment Request; of the Independent Living Services (ILS) Program Performance Report (PPR) 0985–0043

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This Proposed Extension of a Currently Approved Information Collection (IC Ext) solicits comments on the information collection requirements relating to the Administration on Disabilities' Independent Living Services Program Performance Report.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by January 16, 2024.

ADDRESSES: Submit electronic comments on the collection of information to: Peter Nye at OILPPRAComments@acl.hhs.gov. Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC 20201, Attention: Peter Nye.

FOR FURTHER INFORMATION CONTACT: Peter Nye, Administration for Community Living, Washington, DC 20201, (202) 795–7606 or OILPPRAComments@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined as and includes agency requests or

requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including using automated collection techniques when appropriate, and other forms of information technology.

The Independent Living Services (ILS) program provides financial assistance, through formula grants, to all fifty states, the District of Columbia, Puerto Rico, American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and US Virgin Islands for expanding, and improving the

provision of, IL services. The Designated State Entity (DSE) is the agency that, on behalf of the state, receives, accounts for, and disburses funds received under Part B of the Rehabilitation Act of 1973, as amended (the Act). Funds are also made available for the provision of training and technical assistance to Statewide Independent Living Councils (SILCs). The Rehabilitation Act of 1973, as amended, requires three IL program reports: (1) State Plan for Independent Living (SPIL); (2) ILS Program Performance Report; and (3) Center for Independent Living (CIL) Program Performance Report.

This request is for the ILS PPR, which is submitted annually by the SILC and DSE in every state, territory, and outlying area that receives Part B funds and in the District of Columbia.

The ILS PPRs are used by ACL to assess grantees' compliance with title VII of the Act, with 45 CFR part 1329 of the Code of Federal Regulations, and with applicable provisions of the HHS

Regulations at 45 CFR part 75. The ILS PPR serves as the primary basis for ACL's monitoring activities in fulfillment of its responsibilities under sections 706 and 722 of the Act. The PPR is also used by ACL to design CIL and SILC training and technical assistance programs authorized by section 721 of the Act.

ACL will adhere to best practices for collection of all demographic information in accordance with OMB guidance—including, but not limited to guidance specific to the collection of sexual orientation and gender identity (SOGI) items that support alignment with Executive Order 13985 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, Executive Order 14075 on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals, and Executive Order 13988 on Preventing and Combating Discrimination on the

Basis of Gender Identity and Sexual Orientation. Understanding these disparities can and should lead to improved service delivery for ACL's programs and populations.

The proposed data collection tools may be found on the ACL website for review at: <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

The PPR Instrument and Instructions will be sent to representatives of fifty states, the District of Columbia, Puerto Rico, American Samoa, the Commonwealth of the Northern Mariana Islands, Guam, and US Virgin Islands. The approximate burden for completion will be thirty-six hours per respondent, which includes time to review the instructions, read the questions, and complete responses. This results in a total survey burden estimate of 2,016 hours.

Respondent/data collection activity	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Survey	56	1	36	2016

Dated: November 8, 2023.
Alison Barkoff,
Principal Deputy Administrator for the Administration for Community Living, performing the duties of the Administrator and the Assistant Secretary for Aging.
[FR Doc. 2023–25133 Filed 11–14–23; 8:45 am]
BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection
Activities: Proposed Collection; Public Comment Request; of the ACL Generic Clearance for the Collection of Routine Customer Feedback OMB 0985–NEW

AGENCY: Administration for Community Living, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: The Administration for Community Living (ACL) is announcing an opportunity for the public to comment on the proposed collection of information listed above. Under the Paperwork Reduction Act of 1995 (PRA), Federal agencies are required to publish a notice in the **Federal Register** concerning each proposed collection of information, including each proposed

extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This Information Collection (IC) solicits comments on the IC requirements relating to the ACL Generic Clearance for the Collection of Routine Customer Feedback, a generic mechanism for Collecting Service Delivery Feedback under the Paperwork Reduction Act.

DATES: Comments on the collection of information must be submitted electronically by 11:59 p.m. (EST) or postmarked by January 16, 2024.

ADDRESSES: Submit electronic comments on the collection of information to: ACL's Center for Management and Budget Tomakie.Washington@acl.hhs.gov. Submit written comments on the collection of information to Administration for Community Living, 330 C Street SW, Washington, DC, 20201, Attention: Center for Management and Budget PRA Comments.

FOR FURTHER INFORMATION CONTACT: Tomakie Washington at 202–795–7336 or Tomakie.Washington@acl.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. “Collection of information” is defined as and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. The PRA requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, ACL is publishing a notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, ACL invites comments on our burden estimates or any other aspect of this collection of information, including:

(1) whether the proposed collection of information is necessary for the proper performance of ACL's functions, including whether the information will have practical utility;

(2) the accuracy of ACL's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine burden estimates;

(3) ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) ways to minimize the burden of the collection of information on respondents, including using automated collection techniques when appropriate, and other forms of information technology.

The Administration for Community Living (ACL) at the Department of Health and Human Services (HHS) is requesting a generic clearance for purposes collecting data with a focus on the awareness, understanding, attitudes, preferences, or experiences of customers or other stakeholders relating to existing or future services, products, or communication materials. ACL defines routine customer feedback as information that provides useful insights to improve existing or future service deliveries, products, or communication materials. ACL is requesting approval for customer surveys with the purpose of the collecting data to assist the agency in improving existing or future service deliveries, products, or communication materials; responses are voluntary; the collection does not impose a significant

burden on respondents; the collection does not employ statistical methods to have practical utility; and the data results are not publicly shared.

The types of information collection activities will include:

1. Customer Comment Card/Complaint Form
2. Customer Satisfaction Qualitative Surveys
3. Technical Assistance
4. Usability Testing (e.g., website or Software)
5. Small Discussion Group
6. Focus Group
7. One-time or panel discussion groups
8. Moderated, un-moderated, in-person, and/or remote-usability studies
9. Testing of a survey or other collection to refine questions
10. Post-transaction customer surveys
11. On-line surveys

ACL was created around the fundamental principle that older adults and people of all ages with disabilities should be able to live where they choose, with the people they choose, and with the ability to participate fully

in their communities. By funding services and supports provided primarily by networks of community-based organizations, and with investments in research, education, and innovation, ACL helps make this principle a reality for millions of Americans. Integral to this role, ACL will use this mechanism to conduct routine customer feedback for ACL programs. The proposed data collection template may be found on the ACL website for review at: <https://www.acl.gov/about-acl/public-input>.

Estimated Program Burden: ACL estimates the burden of this collection of information as follows:

The annual burden hours (2,521) requested, and the anticipated number of respondents (10,086) are based on the number of potential customer feedback respondents. Over the course of a three-year clearance for this generic information collection, ACL estimates a three-year burden drawdown amount of 7,564.5 burden hours and 30,258 respondents.

ESTIMATED ANNUALIZED BURDEN TABLE

Type of respondent	Form	Annual number of respondents	Number of responses per respondent	Burden hours per response	Total annual burden hours
ACL Potential Customer or Stakeholder.	ACL Generic Clearance for the Collection of Routine Customer Feedback.	10,086	1	.25	2, 521

Dated: November 8, 2023.

Alison Barkoff,

Principal Deputy Administrator for the Administration for Community Living, performing the duties of the Administrator and the Assistant Secretary for Aging.

[FR Doc. 2023-25129 Filed 11-14-23; 8:45 am]

BILLING CODE 4154-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-0806]

Advisory Committee; Nonprescription Drugs Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of Federal advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the Nonprescription Drugs Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has

determined that it is in the public interest to renew the Nonprescription Drugs Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until the August 27, 2025, expiration date.

DATES: Authority for the Nonprescription Drugs Advisory Committee will expire on August 27, 2025, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Moon Hee Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, NDAC@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to 41 CFR 102-3.65 and approval by the Department of Health and Human Services and by the General Services Administration, FDA is announcing the renewal of the Nonprescription Drugs Advisory Committee (the Committee). The Committee is a discretionary Federal advisory committee established

to provide advice to the Commissioner. The Committee advises the Commissioner or designee in discharging responsibilities as they relate to helping to ensure safe and effective drugs for human use and, as required, any other product for which FDA has regulatory responsibility.

The Committee reviews and evaluates available data concerning the safety and effectiveness of over-the-counter (nonprescription) human drug products, or any other FDA-regulated product, for use in the treatment of a broad spectrum of human symptoms and diseases and advises the Commissioner either on the promulgation of monographs establishing conditions under which these drugs are generally recognized as safe and effective and not misbranded or on the approval of new drug applications for such drugs. The Committee serves as a forum for the exchange of views regarding the prescription and nonprescription status, including switches from one status to another, of these various drug products and combinations thereof. The Committee may also conduct peer

review of agency sponsored intramural and extramural scientific biomedical programs in support of FDA's mission and regulatory responsibilities.

The Committee shall consist of 10 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in the fields of internal medicine, family practice, clinical toxicology, clinical pharmacology, pharmacy, dentistry, and related specialties. Members will be invited to serve for overlapping terms of up to 4 years. Non-Federal members of this committee will serve as Special Government Employees, representatives, or Ex-Officio members. Federal members will serve as Regular Government Employees, or Ex-Officios. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons. In addition to the voting members, the Committee may include one non-voting representative member who is identified with industry interests. There may also be an alternate industry representative.

Further information regarding the most recent charter and other information can be found at <https://www.fda.gov/advisory-committees/nonprescription-drugs-advisory-committee/nonprescription-drugs-advisory-committee-charter> or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the Committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at <https://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: November 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-25100 Filed 11-14-23; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2021-0830]

National Boating Safety Advisory Committee; Vacancies

AGENCY: United States Coast Guard, Department of Homeland Security.

ACTION: Request for applications.

SUMMARY: The U.S. Coast Guard is accepting applications to fill four vacancies on the National Boating Safety Advisory Committee (Committee). This Committee advises the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national recreational boating safety.

DATES: Completed applications must reach the U.S. Coast Guard on or before December 15, 2023.

ADDRESSES: Applications must include (a) a cover letter expressing interest in an appointment to the National Boating Safety Advisory Committee, (b) a resume detailing the applicant's relevant experience for the position applied for, and (c) a brief biography. Applications should be submitted via email with the subject line "Application for NBSAC" to Mr. Jeff Decker at NBSAC@uscg.mil.

FOR FURTHER INFORMATION CONTACT: Mr. Jeff Decker, Alternate Designated Federal Officer of the National Boating Safety Advisory Committee; telephone 574-607-8235 or email at NBSAC@uscg.mil.

SUPPLEMENTARY INFORMATION: The National Boating Safety Advisory Committee is a Federal advisory committee. The Committee was established on December 4, 2018, by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018*, Public Law 115-282, 132 Stat. 4192, and is codified in 46 U.S.C. 15105. The Committee must operate under the provisions of the *Federal Advisory Committee Act*, (Pub. L. 117-286, 5 U.S.C., ch. 10), and 46 U.S.C. 15109. The National Boating Safety Advisory Committee provides advice, consults with, and make recommendations to the Secretary of Homeland Security, via the Commandant of the U.S. Coast Guard, on matters relating to national recreational boating safety.

The Committee is required to meet at least once a year in accordance with 46 U.S.C. 15109(a). We expect the Committee will hold meetings at least twice a year, but it may meet more frequently. The meetings may be held

virtually or held at the location across the country selected by the U.S. Coast Guard.

All members serve at their own expense and receive no salary or other compensation from the Federal Government. The only compensation the members may receive is for travel expenses, including per diem in lieu of subsistence, and/or actual reasonable expenses incurred in the performance of their direct duties for the Committee in accordance with Federal Travel Regulations. If you are appointed as a member of the Committee, you will be required to sign a Non-Disclosure Agreement and a Gratuitous Services Agreement.

Under provisions in 46 U.S.C. 15109(f)(6), if you are appointed as a member of the Committee, your membership term will expire on December 31st of the third full year after the effective date of your appointment. Members serve at the pleasure of the Secretary of Homeland Security and may be removed prior to the end of their term for just cause. The Secretary of Homeland Security may require an individual to have passed an appropriate security background examination before appointment to the Committee, 46 U.S.C. 15109(f)(4).

In this solicitation for Committee members, we will consider applications for four (4) positions:

State official responsible for State boating safety programs (4 positions).

Each member of the Committee serves as a representative and must have particular expertise, knowledge, and experience in matters relating to the function of the Committee, which is to advise the Secretary of Homeland Security on the matters described above.

The members who will fill the four positions will be appointed to represent the positions described above and are not Special Government Employees as defined in 18 U.S.C. 202(a).

In order for the Department, to fully leverage broad-ranging experience and education, the National Boating Safety Advisory Committee must be diverse with regard to professional and technical expertise. The Department is committed to pursuing opportunities, consistent with applicable law, to compose a committee that reflects the diversity of the Nation's people.

If you are interested in applying to become a member of the Committee, email your application to NBSAC@uscg.mil as provided in the **ADDRESSES** section of this notice. Applications must include: (1) a cover letter expressing interest in an appointment to the National Boating Safety Advisory Committee; (2) a resume detailing the

applicant's relevant experience and (3) a brief biography of the applicant by the deadline in the **DATES** section of this notice.

The U.S. Coast Guard will not consider incomplete or late applications.

Dated: November 8, 2023.

Amy M. Beach,

Captain, U.S. Coast Guard, Director of Inspections and Compliance.

[FR Doc. 2023-25150 Filed 11-14-23; 8:45 am]

BILLING CODE 9110-04-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. CISA-2023-0024]

National Security Telecommunications Advisory Committee

AGENCY: Cybersecurity and Infrastructure Security Agency (CISA), Department of Homeland Security (DHS).

ACTION: Notice of partially closed Federal advisory committee meeting.

SUMMARY: CISA is publishing this notice to announce the President's National Security Telecommunications Advisory Committee (NSTAC) meeting on December 7, 2023, in Washington, DC. This meeting will be partially closed to the public. The public can access the open portion of the meeting via teleconference.

DATES:

Meeting Registration: Registration to attend the meeting is required and must be received no later than 5:00 p.m. Eastern Standard Time (EST) on November 30, 2023. For more information on how to participate, please contact NSTAC@cisa.dhs.gov.

Speaker Registration: Registration to speak during the meeting's public comment period must be received no later than 5:00 p.m. EST on November 30, 2023.

Written Comments: Written comments must be received no later than 5:00 p.m. EST on November 30, 2023.

Meeting Date: The NSTAC will meet on December 7, 2023, from 9:00 a.m. to 12:30 p.m. EST. The meeting may close early if the committee has completed its business.

ADDRESSES: The December 2023 NSTAC Meeting's open session is set to be held from 11:30 a.m. to 12:30 p.m. EST in person at 1650 Pennsylvania Avenue NW Washington, DC 20504. Members of the public may participate via teleconference. For access to the conference call bridge, or to request special assistance, please email

NSTAC@cisa.dhs.gov by 5:00 p.m. EST on November 30, 2023. The NSTAC is committed to ensuring all participants have equal access regardless of disability status. If you require a reasonable accommodation due to a disability to fully participate, please contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

Comments: Members of the public are invited to provide comments on issues that will be considered by the committee as listed in the **SUPPLEMENTARY INFORMATION** section below. Associated materials that may be discussed during the meeting will be made available for review at <https://www.cisa.gov/nstac> prior to the day of the meeting. Comments should be submitted by 5:00 p.m. EST on November 30, 2023, and must be identified by Docket Number CISA-2023-0024. Comments may be submitted by one of the following methods:

- **Federal eRulemaking Portal:** www.regulations.gov. Please follow the instructions for submitting written comments.

- **Email:** NSTAC@cisa.dhs.gov. Include the Docket Number CISA-2023-0024 in the subject line of the email.

Instructions: All submissions received must include the words "Cybersecurity and Infrastructure Security Agency" and the Docket Number for this action. Comments received will be posted without alteration to www.regulations.gov, including any personal information provided. You may wish to review the Privacy & Security Notice available via a link on the homepage of www.regulations.gov.

Docket: For access to the docket and comments received by the NSTAC, please go to www.regulations.gov and enter docket number CISA-2023-0024.

A public comment period is scheduled to be held during the meeting from 12:00 to 12:10 p.m. EST. Speakers who wish to participate in the public comment period must email NSTAC@cisa.dhs.gov to register. Speakers should limit their comments to three minutes and will speak in order of registration. Please note that the public comment period may end before the time indicated, following the last request for comments.

FOR FURTHER INFORMATION CONTACT:

Christina Berger, 202-701-6354, NSTAC@cisa.dhs.gov.

SUPPLEMENTARY INFORMATION: The NSTAC is established under the authority of Executive Order (E.O.) 12382, dated September 13, 1982, as amended by E.O. 13286 and 14048,

continued under the authority of E.O. 14109, dated September 30, 2023.

Notice of this meeting is given under FACA, 5 U.S.C. ch. 10 (Pub. L. 117-286). The NSTAC advises the President on matters related to national security and emergency preparedness (NS/EP) telecommunications and cybersecurity policy.

Agenda: The NSTAC will meet in an open session on Thursday, December 7, 2023, from 11:30 a.m. to 12:30 p.m. EST to discuss current NSTAC activities and the government's ongoing cybersecurity and NS/EP communications initiatives. This open session will include: (1) a keynote address; and (2) a status update on the Measuring and Incentivizing the Adoption of Cybersecurity Best Practices Study.

The committee will also meet in a closed session from 9:00 to 11:00 a.m. EST during which time: (1) senior government intelligence officials will provide a threat briefing concerning threats to NS/EP communications and (2) engage NSTAC members in follow-on discussion on how future studies can help inform policy to mitigate threats.

Basis for Closure: In accordance with section 10(d) of FACA and 5 U.S.C. 552b(c)(1), *The Government in the Sunshine Act*, it has been determined that a portion of the agenda requires closure.

These agenda items are the: (1) classified threat briefing and discussion, which will provide NSTAC members the opportunity to discuss information concerning threats to NS/EP communications with senior government intelligence officials; and (2) potential NSTAC study topics discussion. The briefing is anticipated to be classified at the top secret/sensitive compartmented information level. Disclosure of these threats during the briefing, as well as vulnerabilities and mitigation techniques, is a risk to the Nation's cybersecurity posture because adversaries could use this information to compromise commercial and government networks. Subjects discussed during the potential study topics discussion are tentative and are under further consideration by the committee.

Therefore, this portion of the meeting is required to be closed pursuant to section 10(d) of FACA and 5 U.S.C. 552b(c)(1) because it will disclose matters that are classified.

Dated: November 9, 2023.

Christina Berger,

Designated Federal Officer, National Security Telecommunications Advisory Committee, Cybersecurity and Infrastructure Security Agency, Department of Homeland Security.

[FR Doc. 2023–25197 Filed 11–14–23; 8:45 am]

BILLING CODE 9110–9P–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7070–N–85]

30-Day Notice of Proposed Information Collection: Single Family Application for Insurance Benefits; OMB Control No.: 2502–0429

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* December 15, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function. Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Clearance Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; email: PaperworkReductionActOffice@hud.gov.

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email: Colette.Pollard@hud.gov or telephone (202)-402–3400. This is not a toll-free number. HUD welcomes and is prepared to receive calls from individuals who

are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit <https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs>. Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on August 30, 2023 at 88 FR 59938.

A. Overview of Information Collection

Title of Information Collection: Single Family Application for Insurance Benefits.

OMB Approval Number: 2502–0429.

Type of Request: Revision of currently approved collection.

Form Numbers: HUD–9539, HUD–27011, HUD–50002, HUD–50012.

Description of the need for the information and proposed use: FHA insurance is an important source of mortgage credit for low and moderate-income borrowers. It is essential that the Federal Housing Administration (FHA) maintain a healthy mortgage insurance fund through premiums charged to the borrower by FHA. Providing policy and guidance to the single family housing mortgage industry regarding changes in FHA’s program is essential to protecting the fund. This information collection is based on the claim activity involving FHA-insured mortgage loan servicing of foreclosed mortgage loans after the foreclosure sale. This is a revision to the currently approved collection due to program activity. With each form, the Public Burden Statement is updated.

Respondents: Business or other for-profit and Individuals or households.

Estimated Number of Respondents: 1,222.

Estimated Number of Responses: 10,062,965.

Frequency of Response: On occasion.

Average Hours per Response: 0.19.

Total Estimated Burdens: 1,885,241.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of

the agency, including whether the information will have practical utility;

(2) The accuracy of the agency’s estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

(5) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 2 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Colette Pollard,

Department Reports Management Officer, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2023–25139 Filed 11–14–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6406–N–01]

Family Self-Sufficiency Achievement Metrics (“FAM”) Score

AGENCY: Office of Public and Indian Housing, Department of Housing and Urban Development (HUD).

ACTION: Notice of updated Family Self-Sufficiency Achievement Metrics (FAM) Score for the Family Self-Sufficiency (FSS) program.

SUMMARY: This notice describes updates to the FAM Score that HUD has implemented to track the program performance of Public Housing Agencies (PHAs) that receive HUD Family Self-Sufficiency (FSS) program coordinator grants and that were brought onto the Moving to Work (MTW) Demonstration after December 15, 2015. This notice does not apply to the initial MTW PHAs, which are PHAs that received MTW Demonstration designation prior to December 15, 2015.

FOR FURTHER INFORMATION CONTACT:

Questions on this notice may be addressed to Jason Amirhadi, 202–402–5467, at FSS@hud.gov.

Electronic Data Availability. This **Federal Register** notice, overview of the

revised FAM Score methodology, and a spreadsheet containing scores applying this revised methodology to FSS programs funded in any of the last three years will be available electronically from the HUD FSS web page: https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/fss.

Federal Register notices also are available electronically at <https://www.federalregister.gov/>, the U.S. Government Printing Office website.

SUPPLEMENTARY INFORMATION:

I. Background

On December 12, 2017, HUD published a notice in the **Federal Register** (82 FR 58434) describing and requesting comment on a performance measurement system that HUD planned to implement for Public Housing Agencies (PHAs) that receive HUD Family Self Sufficiency (FSS) program coordinator grants, with the exception of those in the initial MTW cohort. Through a subsequent **Federal Register** (83 FR 57493) dated November 15, 2018, HUD announced its intent to implement the revised system. Through this **Federal Register** notice, HUD is announcing adjustments to this system to strengthen its ability to effectively track the performance of PHA FSS programs. HUD has also re-calibrated the baseline for determining FAM Scores using the PIH Information Center (PIC) data through 2019.

Under section 23(i)(5) of the Housing Act of 1937 (42 U.S.C. 1437u(i)), “Program performance shall be reviewed periodically as determined by the Secretary.” Additionally, 24 CFR 984.102 states, “The Department will evaluate the performance of a PHA’s or owner’s FSS program using a scoring system that measures criteria, such as graduation from the program, increased earned income, and program participation, as provided by HUD through a **Federal Register** notice.” Accordingly, HUD has developed the FAM Score to provide HUD, Congress, PHAs, and other entities with information on the performance of individual FSS programs. The information will help grantees determine how their programs compare to others across the country in their ability to help participants to successfully graduate from the program and make progress toward economic security. The information will also help HUD understand the extent to which FSS program performance—individually and collectively—improves or declines over time.

As described more fully in the **Federal Register** notices cited above, the FAM Score consists of three

components: Earnings Performance, Graduation Rate, and Participation Rate. HUD uses data that PHAs submit through PIC, or any successor data system such as the Housing Information Portal (HIP), to calculate FAM Scores for all FSS programs that receive FSS coordinator funding from HUD other than for the initial 39 MTW PHAs. Since the methodology relies on an analysis of historical performance data, new FSS programs will not initially have a FAM Score. As new FSS programs begin operation, their FAM Scores will be based solely on their Participation Rate for their first three years, until there is enough data to produce an Earnings Performance Score or a Graduation Rate score, which require a minimum of four years of data to compute. For a complete description of the methodology for computing FAM Scores, see the description posted on HUD’s website at: https://www.hud.gov/program_offices/public_indian_housing/programs/hcv/fss.

At this time, FAM Scores do not apply to the initial 39 MTW PHAs, PHA-based FSS programs that do not receive coordinator funding, or to FSS programs administered by Multifamily Owners of Project-Based Rental Assistance (PBRA) housing. HUD is investigating options for evaluating the performance of FSS programs administered by the initial 39 MTW agencies, PHAs that do not receive FSS coordinator funding, and FSS programs administered by Multifamily PBRA Owners.

II. Summary of Adjustments to the FAM Score

Through this notice, HUD is implementing a series of adjustments to improve the FAM Score. These adjustments will help provide a more comprehensive and accurate assessment of a PHA’s performance and reduce the possibility for volatility in scores from one year to the next for reasons unrelated to a PHA’s performance. The changes are as follows:

A. For both the Earnings Performance Measure and the Graduation Rate, HUD will use a new rolling three-year average rather than a one-year measure as the basis for computing a PHA’s component score. The three-year average provides a more comprehensive measure of performance and helps correct for any significant impact in one year (e.g., the closing of a nearby factory or the impact of a natural disaster). For example, if the PIC data being used in the calculation is through December 31, 2020, HUD would determine the Earnings Performance Measure for each PHA through the end of three annual periods:

2018, 2019, and 2020. HUD would then compute the average of these three measures to determine the three-year average Earnings Performance Measure. HUD will use the three-year average Earnings Performance Measure to determine the PHA’s Earnings Performance Score by applying the applicable thresholds, which are noted below. HUD will apply the same approach in determining the Graduation Rate score.

B. HUD has modified the number of comparison households used to determine the Earnings Performance Measure in the event that more than three households are equally similar to the FSS program participant in terms of considered metrics. In selecting comparison households for purposes of determining the Earnings Performance Measure, HUD selects the three households (and more if there is a tie; see discussion below) that are most similar to each FSS participant along these metrics: earnings as of the time of the FSS household’s entry into FSS, age of head of household, length of time in the voucher or public housing program, number of adults in the household, number of children in the household, presence of a child with a disability, and presence of a non-head of household adult with a disability. HUD has added a metric (number of children in the household) to the criteria for determining the similarity of comparison households to the FSS household. In addition, HUD has found that in some cases, more than three comparison households are equally similar to the FSS household on these metrics. Previously, HUD used three households randomly selected from among these similar households as the comparison households for calculating the Earnings Performance Measure in a given year. Going forward, HUD will use all households that are equally similar to the FSS household in the calculation. This will help reduce the possibility of volatility in scores from one year to the next.

C. HUD has made changes to the adjustment it makes for local economic conditions to improve year-to-year stability of Earnings Performance Scores. To adjust for local economic conditions, HUD first uses a linear regression model to examine the relationship between the Earnings Performance Measures across PHAs and the median incomes of the counties in which each PHA serves residents. On average, unadjusted Earnings Performance Measures tend to be higher in counties with high median incomes, and lower in counties with low median incomes. HUD then adjusts for this

variation by using the relationship estimated in the linear regression and applies this adjustment factor to the earnings performance measure for each PHA, resulting in an adjusted Earnings Performance Measure that is used to determine the PHA's score for the earnings component of the FAM Score. Going forward, to improve year-to-year stability of scores, HUD will implement this adjustment to ensure the average of the adjusted earnings measure is the same as the average of the unadjusted measure.

D. HUD adjusted and clarified how joint FSS grantees are counted across years. For each of the three years included in the measures, calculations are made at the joint applicant level so that each PHA in a joint funding group has the same measure for the year. Because the component calculations are made during each of the three years, joint funding recipients are only included in a group for the time period associated with the measure in the year(s) when they are part of the joint funding group. As a result, PHAs in joint FSS programs without stable agency membership will have members with different measures and scores when averaging across all three years of calculation to produce composite measures, scores, and components.

E. Using the revised year-year average score methodology for the baseline year ending December 31, 2019 (reflecting the average of scores for 2019, 2018, and 2017), HUD has recalibrated the thresholds for converting the Earnings and Graduation measures into scores and specified the updated thresholds below. Going forward, these thresholds will be fixed to allow HUD and PHAs to gauge the extent to which individual PHAs and the entire FSS program as a whole are making progress toward higher performance levels. The only exceptions are the thresholds for determining Earnings Performance Scores, which shall be adjusted annually. This annual adjustment will account for changes in the average earnings using a custom inflation index based on the weighted hourly series for the first (lowest) quartile of wage earners within the wage growth data from the Federal Reserve Bank of Atlanta. This will help ensure that the thresholds for determining Earnings Performance Scores keep pace with wage inflation over time.

III. Revised Thresholds

The following are the updated thresholds HUD will use to compute a FAM Score for each PHA.

1. Step One: Assigning Scores to Each of the Three Measures

In Step One, HUD will assign a score of 0 to 10 to each PHA's FSS program for each of the three measures. Scores will be assigned using the thresholds and procedures described below. The ranges for awarding points between two values include those values as well as all intermediary values.

a. Earnings Performance Measure (50% of final score):

- **10 points:** three-year average Earnings Performance Measure of \$6,315 or higher.
- **7.5 points:** three-year average Earnings Performance Measure between \$4,795 and \$6,314.99.
- **0 points:** three-year average Earnings Performance Measure below \$2,283 and a p-value of <.10 on a statistical test measuring the likelihood that a PHA's three-year average Earnings Performance Measure is significantly lower than the median measure of \$4,247 (see December 12, 2017 **Federal Register** Notice at page 82 FR 58437 for an explanation of this statistical test).
- **5 points:** All PHAs that do not qualify for a 10, 7.5, or a 0.

• These thresholds will apply to Earnings Performance Measures for the 2019 audit year, which reflect an average of Earnings Performance Measures for the 2017, 2018 and 2019 calendar years. As described above, to keep pace with inflation, HUD will adjust the thresholds used to compute Earnings Performance Scores annually to reflect changes in the weighted hourly series for the first (lowest) quartile of wage earners in the wage growth data from the Federal Reserve Bank of Atlanta.

b. FSS Graduation Rate (30% of final score):

- **10 points:** three-year average FSS Graduation Rate of 42% or higher.
- **7.5 points:** three-year average FSS Graduation Rate between 32% and 41.99%.
- **0 points:** FSS Graduation Rate below 15%.
- **5 points:** All PHAs that do not qualify for a 10, 7.5, or a 0.

c. Participation Rate (20% of final score):

- **10 points:** participation rate of 2.20 or higher.
- **9 points:** participation rate between 1.95 and 2.19.
- **8 points:** participation rate between 1.70 and 1.94.
- **7 points:** participation rate between 1.45 and 1.69.
- **6 points:** participation rate between 1.2 and 1.44.
- **5 points:** participation rate between .95 and 1.19.

- **0 points:** participation rate of lower than .95.

2. Step Two: Developing the Final FAM Score and Ranking

In Step Two, after computing individual scores for each of the three measures, HUD will aggregate each PHA's scores using the weights noted above to develop a final FAM Score from 0 to 10. Based on this score, HUD will assign the following ranking to the PHA's FAM Score:

- **Category 1:** FAM Score of 7.9 or higher.
- **Category 2:** FAM Score between 4.0 and 7.89.
- **Category 3:** FAM Score between 3.5 and 3.99.
- **Category 4:** FAM Score of less than 3.5.

IV. Environmental Impact

This notice does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, leasing, rehabilitation, alteration, demolition, or new construction, or establish, revise or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this notice is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Principal Deputy Assistant Secretary for Public and Indian Housing, Richard J. Monocchio, having reviewed and approved this document, is delegating the authority to electronically sign this document to submitter, Aaron Santa Anna, who is the Federal Register Liaison for HUD, for purposes of publication in the **Federal Register**.

Aaron Santa Anna,

Federal Register Liaison for the Department of Housing and Urban Development.

[FR Doc. 2023-25231 Filed 11-14-23; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS-HQ-IA-2023-0223; FXIA16710900000-234-FF09A30000]

Foreign Endangered Species; Receipt of Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications to conduct certain activities with foreign species that are listed as endangered under the Endangered Species Act (ESA). With some exceptions, the ESA prohibits activities with listed species unless Federal authorization is issued that allows such activities. The ESA also requires that we invite public comment before issuing permits for any activity otherwise prohibited by the ESA with respect to any endangered species.

DATES: We must receive comments by December 15, 2023.

ADDRESSES:

Obtaining Documents: The applications, application supporting materials, and any comments and other materials that we receive will be available for public inspection at <https://www.regulations.gov> in Docket No. FWS-HQ-IA-2023-0223.

Submitting Comments: When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. You may submit comments by one of the following methods:

- *Internet:* <https://www.regulations.gov>. Search for and submit comments on Docket No. FWS-HQ-IA-2023-0223.
- *U.S. Mail:* Public Comments Processing, Attn: Docket No. FWS-HQ-IA-2023-0223; U.S. Fish and Wildlife Service Headquarters, MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041-3803.

For more information, see Public Comment Procedures under **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, by phone at 703-358-2185 or via email at DMAFR@fws.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I comment on submitted applications?

We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of the requested permits, we will

take into consideration any information that we receive during the public comment period.

You may submit your comments and materials by one of the methods in **ADDRESSES**. We will not consider comments sent by email or to an address not in **ADDRESSES**. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**).

When submitting comments, please specify the name of the applicant and the permit number at the beginning of your comment. Provide sufficient information to allow us to authenticate any scientific or commercial data you include. The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) those that include citations to, and analyses of, the applicable laws and regulations.

B. May I review comments submitted by others?

You may view and comment on others' public comments at <https://www.regulations.gov> unless our allowing so would violate the Privacy Act (5 U.S.C. 552a) or Freedom of Information Act (5 U.S.C. 552).

C. Who will see my comments?

If you submit a comment at <https://www.regulations.gov>, your entire comment, including any personal identifying information, will be posted on the website. If you submit a hardcopy comment that includes personal identifying information, such as your address, phone number, or email address, you may request at the top of your document that we withhold this information from public review. However, we cannot guarantee that we will be able to do so. Moreover, all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(c) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), we invite public comments on permit applications before final action is taken. With some exceptions, the ESA prohibits certain activities with listed

species unless Federal authorization is issued that allows such activities. Permits issued under section 10(a)(1)(A) of the ESA allow otherwise prohibited activities for scientific purposes or to enhance the propagation or survival of the affected species. Service regulations regarding prohibited activities with endangered species, captive-bred wildlife registrations, and permits for any activity otherwise prohibited by the ESA with respect to any endangered species are available in title 50 of the Code of Federal Regulations in part 17.

III. Permit Applications

We invite comments on the following applications.

Applicant: Miami-Dade Zoological Park and Gardens, Miami, FL; Permit No. PER5156259

The applicant requests a permit to import from Canada one greater one-horned rhinoceros (*Rhinoceros unicornis*), for the purpose of enhancing the propagation or survival of the species. This notification is for a single import.

Applicant: Midwestern University, Glendale, AZ; Permit No. PER5156944

The applicant requests authorization to import scientific samples collected from wild salvaged mantled howler monkey (*Alouatta palliata*), black-handed spider monkey (*Ateles geoffroyi*), red-backed squirrel monkey (*Saimiri oerstedii*), and ocelot (*Leopardus pardalis*), all of which are found in Costa Rica, for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Tulane University, New Orleans, LA; Permit No. PER5230668

The applicant requests a permit to import biological samples collected from wild live or salvaged South American tapir (*Tapirus terrestris*) from Brazil for the purpose of enhancing the survival of the species through scientific research. This notification is for a single import.

Applicant: Ryder Scientific, R.L.L.P., dba Ryder Scientific, Putnam Valley, NY; Permit No. PER5322138

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species, to enhance the propagation or survival of the species. This notification covers activities to be conducted by the applicant over a 5-year period.

Common name	Scientific name
Nile crocodile	<i>Crocodylus niloticus</i> .
Cuban crocodile	<i>Crocodylus rhombifer</i> .
Siamese crocodile	<i>Crocodylus siamensis</i> .
West African dwarf crocodile	<i>Osteolaemus tetraspis</i> .
Saltwater crocodile	<i>Crocodylus porosus</i> .
Galapagos tortoise	<i>Chelonoidis niger</i> .
Military macaw	<i>Ara militaris</i> .

Multiple Trophy Applicants

The following applicants request permits to import sport-hunted trophies of male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancing the propagation or survival of the species.

- Jeffrey Becker, Forsyth, IL; Permit No. PER5225366
- John Bethany, Arlington Heights, IL; Permit No. PER5225407

IV. Next Steps

After the comment period closes, we will make decisions regarding permit issuance. If we issue permits to any of the applicants listed in this notice, we will publish a notice in the **Federal Register**. You may locate the notice announcing the permit issuance by searching <https://www.regulations.gov> for the permit number listed above in this document. For example, to find information about the potential issuance of Permit No. 12345A, you would go to [regulations.gov](https://www.regulations.gov) and search for "12345A".

V. Authority

We issue this notice under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and its implementing regulations.

Brenda Tapia,

Supervisory Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2023-25165 Filed 11-14-23; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R1-ES-2023-N081;
FXES11130100000-234-FF01E00000]

Endangered Species; Receipt of Recovery Permit Applications

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of permit applications; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service, have received applications for permits to conduct activities intended to enhance the propagation and survival of endangered species under the Endangered Species Act. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive your written comments on or before December 15, 2023.

ADDRESSES:

Document availability and comment submission: Submit a request for a copy of the application and related documents and submit any comments by one of the following methods. All requests and comments should specify the applicant name and application number (e.g., Dana Ross, ES001705):

- **Email:** permitsR1ES@fws.gov.
- **U.S. Mail:** Marilet Zablan, Regional

Program Manager, Restoration and Endangered Species Classification, Ecological Services, U.S. Fish and Wildlife Service, Pacific Regional Office, 911 NE 11th Avenue, Portland, OR 97232-4181.

FOR FURTHER INFORMATION CONTACT:

Karen Colson, Regional Recovery Permit Coordinator, Ecological Services, (503) 231-6283 (telephone); permitsR1ES@fws.gov (email). Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite the public to comment on applications for permits under section 10(a)(1)(A) of

the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The requested permits would allow the applicants to conduct activities intended to promote recovery of species that are listed as endangered under the ESA.

Background

With some exceptions, the ESA prohibits activities that constitute take of listed species unless a Federal permit is issued that allows such activity. The ESA's definition of "take" includes such activities as pursuing, harassing, trapping, capturing, or collecting, in addition to hunting, shooting, harming, wounding, or killing.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered or threatened species for scientific purposes that promote recovery or for enhancement of propagation or survival of the species. These activities often include such prohibited actions as capture and collection. Our regulations implementing section 10(a)(1)(A) for these permits are found in the Code of Federal Regulations (CFR) at 50 CFR 17.22 for endangered wildlife species, 50 CFR 17.32 for threatened wildlife species, 50 CFR 17.62 for endangered plant species, and 50 CFR 17.72 for threatened plant species.

Permit Applications Available for Review and Comment

Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild. The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies.

Application number	Applicant, city, state	Species	Location	Take activity	Permit action
ES003483	U.S. Geological Survey, Pacific Island Eco-systems Research Center, Honolulu, HI.	Yayaguak or Mariana swiftlet (<i>Aerodramus bartschi</i>).	Hawaii	Harass by capture, handle, hold, and release; band and attach radio transmitters; biosample; survey, play recorded vocalizations; conduct social attraction; use cameras to monitor nesting sites, map caves, and utilize weather loggers; and collect biological material (feathers, eggshells, guano).	Amend.
ES014497	Haleakala National Park, Kula, HI.	<i>Bidens campylothea</i> ssp. <i>pentamera</i> (ko"oko"olau), <i>B. campylothea</i> ssp. <i>waihoiensis</i> (ko"oko"olau), <i>B. micrantha</i> ssp. <i>kalealaha</i> (ko"oko"olau), <i>Calamagrostis expansa</i> (Maui reedgrass), <i>Clermontia lindseyana</i> ("öhä wai), <i>C. oblongifolia</i> ssp. <i>mauiensis</i> ("öhä wai), <i>C. peleana</i> ssp. <i>singuliflora</i> ("öhä wai), <i>C. samuelli</i> ssp. <i>samuelli</i> ("öhä wai), <i>Ctenitis squamigera</i> (pauoa), <i>Cyanea asplenifolia</i> (hähä), <i>C. copelandii</i> ssp. <i>haleakalaensis</i> (hähä), <i>C. duvalliorum</i> (hähä), <i>C. glabra</i> (hähä), <i>C. grimesiana</i> ssp. <i>grimesiana</i> (hähä), <i>C. hamatiflora</i> ssp. <i>hamatiflora</i> (hähä), <i>C. horrida</i> (nui hähä), <i>C. kunthiana</i> (hähä), <i>C. maritae</i> (hähä), <i>Cyclosorus boydiae</i> (kupukupu makalii or Boyds maiden fern), <i>Cyrtandra ferripilosa</i> (haiwale), <i>Diplazium molokaiense</i> (no common name (NCN)), <i>Gardenia remyi</i> (nanu), <i>Geranium arboreum</i> (nohoanu or Hawaiian red flowered geranium), <i>G. hanaense</i> (nohoanu), <i>G. multiflorum</i> (nohoanu), <i>Huperzia mannii</i> , (wāwae"iote), <i>H. stemmermanniae</i> (NCN), <i>Ischaemum byrone</i> (Hilo ischaemum), <i>Joinvillea ascendens</i> ssp. <i>ascendens</i> ("ohe), <i>Melicope balloui</i> (alani), <i>M. ovalis</i> (alani), <i>Microlepis strigosa</i> var. <i>mauiensis</i> (Maui fern), <i>Nothoestrum latifolium</i> ("aiea), <i>Ochrosia haleakalae</i> (holei), <i>Phyllostegia bracteata</i> (NCN), <i>P. brevidens</i> ssp. <i>ambigua</i> (NCN), <i>P. haliakalae</i> (NCN), <i>Plantago princeps</i> var. <i>laxiflora</i> (ale), <i>Platanthera holochila</i> (NCN), <i>Ranunculus hawaiiensis</i> (makou), <i>R. mauiensis</i> (makou), <i>Sanicula sandwicensis</i> (NCN), <i>Schiedea diffusa</i> ssp. <i>diffusa</i> (NCN), <i>S. haleakalensis</i> (NCN), <i>S. hookeri</i> (NCN), <i>Solanum incompletum</i> (pōpolo kū mai), <i>Wikstroemia villosa</i> ("ākia).	Hawaii	Remove/reduce to possession by survey, monitor; collect seeds, fruits, cuttings, inflorescences, leaves, and herbarium specimens; propagate and outplant; and salvage.	Renew.
Hawaiian goose or nene (<i>Branta sandvicensis</i>), Hawaiian petrel or 'ua ua'. (<i>Pterodroma sandwichensis</i>), crested honeycreeper or 'akohekohe. (<i>Palmeria dolei</i>), Maui parrotbill or kiwikiu. (<i>Pseudonestor xanthophrys</i>). PER4532489	Hawaii	Harass by survey and monitor; capture, hold, measure, weigh, band, release, and recapture; predator control; conduct playback calls and "pishing" (verbal calling); and salvage.	Renew.		
	Wildlife Services—Oregon, Portland, OR.	Gray wolf (<i>Canis lupus</i>)	Oregon	Harm and harass by implementing depredation and conflict abatement activities; monitoring by capture, immobilization, and collaring; and salvage.	New.

Public Availability of Comments

Written comments we receive become part of the administrative record associated with this action. Before including your address, phone number,

email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may

be made publicly available at any time. While you can request in your comment that we withhold your personal identifying information from public review, we cannot guarantee that we

will be able to do so. All submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, will be made available for public disclosure in their entirety.

Next Steps

If we decide to issue a permit to the applicant listed in this notice, we will publish a notice in the **Federal Register**.

Authority: We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Marilet A. Zablan,

Regional Program Manager for Restoration and Endangered Species Classification, Pacific Region.

[FR Doc. 2023-25177 Filed 11-14-23; 8:45 am]

BILLING CODE 4333-15-P

DEPARTMENT OF THE INTERIOR

Office of the Secretary

[245D0102DM_DS62470000;
DMSN00000.000000_DX.62407.CEN00000;
OMB Control Number 1085-0001]

Agency Information Collection Activities; Source Directory of American Indian and Alaska Native Owned and Operated Arts and Crafts Businesses

AGENCY: Indian Arts and Crafts Board, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Indian Arts and Crafts Board (IACB) are proposing to renew an information collection with revisions.

DATES: Interested persons are invited to submit comments on or before January 16, 2024.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Jeffrey Parrillo, Departmental Information Collection Clearance Officer, 1849 C Street NW, Washington, DC 20240; or by email to DOI-PRA@ios.doi.gov. Please reference OMB Control Number 1085-0001 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Meridith Stanton, Director, Indian Arts and Crafts Board, 1849 C Street NW, Washington, DC 20240; or by email at IACB@ios.doi.gov, or by telephone at (202) 208-3773. Individuals in the United States who are deaf, deafblind, hard of hearing, or have

a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

- (1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;
- (2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;
- (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and
- (4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying

information from public review, we cannot guarantee that we will be able to do so.

Abstract: The *Source Directory of American Indian and Alaska Native Owned and Operated Arts and Crafts Businesses* is a program of the Indian Arts and Crafts Board that promotes American Indian and Alaska Native arts and crafts. The *Source Directory* is a listing of American Indian and Alaska Native owned and operated arts and crafts businesses that may be accessed by the public on the Indian Arts and Crafts Board's website, www.doi.gov/iacb.

The service of being listed in this directory is provided free-of-charge to members of federally recognized tribes. Businesses listed in the *Source Directory* include American Indian and Alaska Native artists and craftspeople, cooperatives, tribal arts and crafts enterprises, businesses privately owned-and-operated by American Indian and Alaska Native artists, designers, and craftspeople, and businesses privately owned-and-operated by American Indian and Alaska Native merchants who retail and/or wholesale authentic Indian and Alaska Native arts and crafts.

The Director of the IACB uses this information to determine whether an individual or business applying to be listed in the *Source Directory* meets the requirements for listing. The approved application will be printed in the *Source Directory*. The *Source Directory* is updated as needed to include new businesses and to update existing information. Applicants or current enrollees submit Form DI-5001, "Source Directory Business Listing Application" which collects the following information:

- Type of listing they are applying for:
 - New listing;
 - Renewal/changes;
 - Individual; or
 - Group.
- Business name;
- Manager and owner name, along with Tribal affiliation; and
- Tribal or group affiliation of signer.

Revisions to This Form With This Renewal

Changes to this form include adding individual fields for Business Name, Artist Name, Business Address, State/Country, Business Email, Business website, Business Hours, Business Telephone, Tribal Affiliation, Description of Products and Preferred Contact Information. This was done in order to help applicants fill out completed information for their businesses as the field labeled Business

Information was being filled out incompletely.

Title of Collection: Source Directory of American Indian and Alaska Native Owned and Operated Arts and Crafts Businesses.

OMB Control Number: 1085–0001.

Form Number: DI–5001.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Individuals/households, businesses.

Total Estimated Number of Annual Respondents: 100.

Total Estimated Number of Annual Responses: 100.

Estimated Completion Time per Response: 15 minutes.

Total Estimated Number of Annual Burden Hours: 25 hours.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Nonhour Burden Cost: None.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Meridith Stanton,

Director.

[FR Doc. 2023–25103 Filed 11–14–23; 8:45 am]

BILLING CODE 4334–63–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_OR_FRN_MO4500175978]

Notice of Public Meetings of the Western Oregon Resource Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of public meetings.

SUMMARY: In accordance with the Federal Land Policy and Management Act and the Federal Advisory Committee Act of 1972, the U.S. Department of the Interior, Bureau of Land Management (BLM) Western Oregon Resource Advisory Council (RAC) has scheduled public meetings for December 5–6, 2023.

DATES: The Western Oregon RAC will meet virtually on December 5 and December 6, 2023. On December 5, the meeting will begin at 9 a.m. and adjourn at 4 p.m. Pacific time (PT). On December 6, the meeting will begin at 9 a.m. and adjourn at 3 p.m. PT.

ADDRESSES: The meetings will be held virtually over the Zoom platform. Please contact Megan Harper, Public Affairs Specialist for the Coos Bay District, at (541) 751–4353 or m1harper@blm.gov to receive a link to attend the Zoom meeting.

FOR FURTHER INFORMATION CONTACT:

Megan Harper, Public Affairs Specialist, Coos Bay District, 1300 Airport Lane, North Bend, OR 97504; phone: (541) 751–4353; email: m1harper@blm.gov. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The 15-member Western Oregon RAC advises the Secretary of the Interior, through the BLM, on a variety of public land issues across public lands in Western Oregon, including the Coos Bay, Medford, Northwest Oregon, and Roseburg Districts and part of the Lakeview District. The December 5 and 6, 2023, meetings will focus on reviewing projects that have been proposed to receive funding under Title II of the Secure Rural Schools and Community Self-Determination Act. Final agendas will be available on the RAC's web page 2 weeks in advance of the meeting at <https://www.blm.gov/get-involved/resource-advisory-council/near-you/oregon-washington/western-oregon-rac>.

The meetings are open to the public, and a public comment period will be held at 3 p.m. PT on December 5, and at 1:30 p.m. PT on December 6. Depending on the number of persons wishing to comment, time allotted for individual oral comments may be limited. The public may present written comments to the RAC. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT**

section of this notice at least 7 business days prior to the meeting to give the BLM sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Detailed minutes for the RAC meetings will be maintained in the Coos Bay District Office and will be available for public inspection and reproduction during regular business hours within 90 days following the meeting. Previous minutes, membership information, and upcoming agendas are available at: <https://www.blm.gov/get-involved/resource-advisory-council/near-you/oregon-washington>.

(Authority: 43 CFR 1784.4–2)

Heather L. Whitman,

Designated Federal Officer.

[FR Doc. 2023–25143 Filed 11–14–23; 8:45 am]

BILLING CODE 4331–24–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036930; PPWOCRADNO–PCU00RP14.R50000]

Notice of Inventory Completion: University of Oregon, Museum of Natural and Cultural History, Eugene, OR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Oregon Museum of Natural and Cultural History (UOMNCH) 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. The human remains were removed from Honolulu County, HI.

DATES: Repatriation of the human remains in this notice may occur on or after December 15, 2023.

ADDRESSES: Dr. Pamela Endzweig, Director of Anthropological Collections, 1224 University of Oregon, Eugene, OR 97403–1224, telephone (541) 346–5120, email endzweig@uoregon.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 UOMNCH. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including

the results of consultation, can be found in the inventory or related records held by the UOMNCH.

Description

Human remains representing, at minimum, three individuals, were removed from Honolulu County, HI. Records for Accession 100FA indicate that these human remains were removed from an unknown location on the Island of Oahu and were donated by a private party to the UOMNCH (formerly Museum of Natural History) in 1940. The human remains, which are very fragmentary, belong to one young adult and one middle aged adult, both of unknown sex, and one individual, possibly female, 12–18 years old. No associated funerary objects are present.

In 1993, other human remains from Accession 100FA that belonged to two individuals (catalogued as 11–107 and 11–108) were repatriated by UOMNCH to Hui Mālama I Nā Kūpuna O Hawai'i Nei. In 2023, a skeletal remain belonging to one of those individuals was repatriated to Hui Iwi Kuamo'o (the successor of Hui Mālama I Nā Kūpuna O Hawai'i Nei).

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the UOMNCH has determined that:

- The human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Aha Maā lama Corporation (aka The Caring Council Corporation); Ahahui Siwila Hawai'i O Kapoōlei (aka Kapolei Hawaiian Civic Club); Association of Hawaiian Civic Clubs (AHCC); Department of Hawaiian Homelands; Friends of Tolani Palace; Hawaiian Civic Club of Wahiawa (HCCW); Hawaiian Genealogy Society; Ho'okano Family Land Trust; Hui Iwi

Kuamo'o; Hui Kaleleiki Ohana; Kaha I Ka Panoa Kaleponi Hawaiian Civic Club; Kaiwi Olelo O'Hawaii; Kalaeloa Heritage and Legacy Foundation; Kamealoha; Kamehameha Schools; Kawaihapai Ohana; Kawaileo Law A Limited Liability Law Company; Kekumano 'Ohana'; Ko'olau Foundation; Ko'olaupoko Hawaiian Civic Club; Kululoi'a Lineage—I ke Kai'o Kululoi'a; Ma'a 'Ohana c/o Lani Ma'a Lapilio; Mahu Ohana; Native Hawaiian Advisory Council; Native Hawaiian Church; O'ahu Island Burial Council; Office of Hawaiian Affairs; Ohana Keaweamahi; Ohana Keohokalole; Pa Ku'i-a-lua; and P'uuhonua O Waimanalo.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **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 15, 2023. If competing requests for repatriation are received, the UOMNCH 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 UOMNCH is responsible for sending a copy of this notice to the 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 10.9, 10.10, and 10.14.

Dated: November 8, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–25216 Filed 11–14–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036925; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: Sutter County Museum, Yuba City, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Sutter County Museum intends to repatriate certain cultural items that meet the definition of either 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. The cultural items were removed from Sutter County and Yuba County, CA.

DATES: Repatriation of the cultural items in this notice may occur on or after December 15, 2023.

ADDRESSES: Molly Bloom, Sutter County Museum, 1333 Butte House Road, Yuba City, CA 95993, telephone (530) 822–7141, email mbloom@co.sutter.ca.us.

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 Sutter County Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the Sutter County Museum.

Description

The 115 lots of cultural items were removed from Sutter County and Yuba County, CA. The 72 lots of unassociated funerary objects are 10 lots of bead objects, 13 lots of bone objects, 27 lots of modified stone objects, 20 lots of projectile points, one lot of shell objects, and one lot of wood objects. The 43 lots of objects of cultural patrimony are 39 lots of modified stone objects and four lots of projectile points.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes,

peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological information, archeological information, oral tradition, and expert opinion in the form of Native American traditional knowledge.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Sutter County Museum has determined that:

- The 72 cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a
- The 43 cultural items described above have ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the United Auburn Indian Community of the Auburn Rancheria of California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **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 15, 2023. If competing requests for repatriation are received, the Sutter County 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 Sutter County 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 10.8, 10.10, and 10.14.

Dated: November 8, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–25209 Filed 11–14–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

**[NPS–WASO–NAGPRA–NPS0036928;
PPWOCRADNO–PCU00RP14.R50000]**

Notice of Intent To Repatriate Cultural Items: The Children's Museum of Indianapolis, Indianapolis, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), The Children's Museum of Indianapolis intends to repatriate certain cultural items that meet the definition of sacred objects and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from Nebraska.

DATES: Repatriation of the cultural items in this notice may occur on or after December 15, 2023.

ADDRESSES: Jennifer Noffze, The Children's Museum of Indianapolis, 3000 N Meridian Street, Indianapolis, IN 46208, telephone (317) 334–3722, email jenn@childrensmuseum.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 Children's Museum of Indianapolis. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by The Children's Museum of Indianapolis.

Description

In 1967, The Children's Museum of Indianapolis acquired a sacred object through a trade with the Museum of the American Indian in New York City. The item came from the Winnebago Tribe in Nebraska, and it dates to circa 1880. The sacred object is a medicine pouch made of animal hide and decorated with multicolored beads in a diamond zigzag pattern on a white background.

In 1967, The Children's Museum of Indianapolis purchased a sacred object pipestem from the Museum of the American Indian in New York City. The item came from the Winnebago Tribe in Nebraska, and it dates to the period 1860–1880. The sacred object is a carved wooden pipestem displaying a twisted design.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical, historical, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, The Children's Museum of Indianapolis has determined that:

- The two cultural items described above are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the Winnebago Tribe of Nebraska.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **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 15, 2023. If competing requests for repatriation are received, The Children's Museum of Indianapolis 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 Children's Museum of Indianapolis is responsible for sending a copy of this

notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: November 8, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–25212 Filed 11–14–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036929;
PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: The Children's Museum of Indianapolis, Indianapolis, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), The Children's Museum of Indianapolis intends to repatriate a certain 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. The cultural item was removed from Wyoming.

DATES: Repatriation of the cultural item in this notice may occur on or after December 15, 2023.

ADDRESSES: Jennifer Noffze, The Children's Museum of Indianapolis, 3000 N Meridian Street, Indianapolis, IN 46208, telephone (317) 334–3722, email jenn@childrensmuseum.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 Children's Museum of Indianapolis. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by The Children's Museum of Indianapolis.

Description

In 1946, William Carter donated an object of cultural patrimony to The Children's Museum of Indianapolis. According to the accession file, the item came from the Shoshone Reservation,

near Yellowstone Park, it belonged to Chief Washakie, and it dates to 1883. The object of cultural patrimony is a feathered headdress comprised of dyed horsehair, ermine tails, human hair, 10 brass bells, and a red wool tail lined with white cotton.

Cultural Affiliation

The cultural item in this notice is connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical, historical, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, The Children's Museum of Indianapolis has determined that:

- The one cultural item described above has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural item and the Eastern Shoshone Tribe of the Wind River Reservation, Wyoming.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the Responsible Official identified in **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 15, 2023. If competing requests for repatriation are received, The Children's Museum of Indianapolis 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 Children's Museum of Indianapolis is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: November 8, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–25214 Filed 11–14–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036924;
PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: The University of Kansas, Lawrence, KS

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the University of Kansas 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. The human remains were removed from Dixie County, FL.

DATES: Repatriation of the human remains in this notice may occur on or after December 15, 2023.

ADDRESSES: Dr. Thomas Torma, NAGPRA Program Manager, The University of Kansas, Office of Audit, Risk & Compliance, 1450 Jayhawk Boulevard, 351 Strong Hall, Lawrence, KS 66045, telephone (406) 850–2220, email t-torma@ku.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 University of Kansas. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the University of Kansas.

Description

Human remains representing, at minimum, one individual were removed from Dixie County, FL. At an unspecified date in the 1970s or 1980s, a private collector of paleontological resources donated his collection of Hemingfordian period faunal remains to

the University of Kansas. In 1991, in response to the passage of NAGPRA, the University conducted a review of this collection, during which the remains of this individual were identified and transferred to the University's Museum of Anthropology. In 1996, the Museum of Anthropology was closed, and the archeology collection was transferred to the Biodiversity Institute. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archeological and geographical.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the University of Kansas has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Seminole Tribe of Florida.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **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 15, 2023. If competing requests for repatriation are received, the University of Kansas 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

University of Kansas is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: November 8, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–25208 Filed 11–14–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

**[NPS–WASO–NAGPRA–NPS0036926;
PPWOCRADNO–PCU00RP14.R50000]**

Notice of Intent To Repatriate Cultural Items: James B. and Rosalyn L. Pick Museum of Anthropology at Northern Illinois University, DeKalb, IL (Formerly Anthropology Museum at Northern Illinois University)

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the James B. and Rosalyn L. Pick Museum of Anthropology at Northern Illinois University (Pick Museum) intends to repatriate a cultural item that meets the definition of a sacred 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 15, 2023.

ADDRESSES: Dr. Christy DeLair, Museum Director, James B. and Rosalyn L. Pick Museum of Anthropology at Northern Illinois University, 1425 W Lincoln Hwy., DeKalb, IL 60015, telephone (815) 753–0230, email cdelair@niu.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 James B. and Rosalyn L. Pick Museum of Anthropology at Northern Illinois University. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by the James B. and Rosalyn L. Pick Museum of

Anthropology at Northern Illinois University.

Description

In 1966, the Pick Museum purchased a medicine face mask (catalog no. 66–8–8) from the Original Curio and Prospectors Shop in Santa Fe, NM. Pick Museum records identify the medicine face as Seneca and suggest that its provenience is the Cattaraugus Reservation. The medicine face is a sacred object.

Cultural Affiliation

The cultural item in this notice is connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, geographical, historical, oral traditional, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the James B. and Rosalyn L. Pick Museum of Anthropology at Northern Illinois University has determined that:

- The one cultural item described above is a specific ceremonial object needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents.
- There is a relationship of shared group identity that can be reasonably traced between the cultural item and the Seneca Nation of Indians.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the Responsible Official identified in **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 15, 2023. If competing requests for repatriation are received, the James B. and Rosalyn L. Pick Museum of Anthropology at Northern

Illinois University 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 James B. and Rosalyn L. Pick Museum of Anthropology at Northern Illinois University is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: November 8, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–25210 Filed 11–14–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036932;
PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: The Children's Museum of Indianapolis, Indianapolis, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), The Children's Museum of Indianapolis intends to repatriate a certain cultural item that meets the definition of a sacred object and that has a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural item was removed from Drew County, Arkansas.

DATES: Repatriation of the cultural item in this notice may occur on or after December 15, 2023.

ADDRESSES: Jennifer Noffze, The Children's Museum of Indianapolis, 3000 N Meridian Street, Indianapolis, IN 46208, telephone (317) 334–3722, email jenn@childrensmuseum.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 Children's Museum of Indianapolis. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held

by The Children's Museum of Indianapolis.

Description

In 1968, Earl Townsend, Jr., donated a sacred object to The Children's Museum of Indianapolis. It was formerly in the collection of Robert E. Bell of Marion, Ohio. The sacred object is a stone celt that was found in a grave in Drew County, Arkansas. This location is within the treaty land of the Quapaw Nation.

Cultural Affiliation

The cultural item in this notice is connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical, historical, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, The Children's Museum of Indianapolis has determined that:

- The one cultural item described above is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural item and the Quapaw Nation.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the Responsible Official identified in **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 15, 2023. If competing requests for repatriation are received, The Children's Museum of Indianapolis 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 Children's Museum of Indianapolis is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: November 8, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–25215 Filed 11–14–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036927;
PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: The Children's Museum of Indianapolis, Indianapolis, IN

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), The Children's Museum of Indianapolis intends to repatriate a certain 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 15, 2023.

ADDRESSES: Jennifer Noffze, The Children's Museum of Indianapolis, 3000 N Meridian Street, Indianapolis, IN 46208, telephone (317) 334–3722, email jenn@childrensmuseum.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 Children's Museum of Indianapolis. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by The Children's Museum of Indianapolis.

Description

In 1942, Mrs. Clinton LaRue Hare donated an object of cultural patrimony to The Children's Museum of Indianapolis. The item came from the Plateau Region of the United States. No information is available concerning the date of its creation. The object of cultural patrimony is a necklace comprised of wolf teeth and beads.

Cultural Affiliation

The cultural item in this notice is connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical, historical, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, The Children's Museum of Indianapolis has determined that:

- The one cultural item described above has ongoing historical, traditional, or cultural importance central to the Native American group or culture itself, rather than property owned by an individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural item and the Modoc Nation.

Requests for Repatriation

Additional, written requests for repatriation of the cultural item in this notice must be sent to the Responsible Official identified in **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 15, 2023. If competing requests for repatriation are received, The Children's Museum of Indianapolis 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 Children's Museum of Indianapolis is responsible

for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, 10.10, and 10.14.

Dated: November 8, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–25211 Filed 11–14–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036923; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: U.S. Department of the Interior, National Park Service, Canaveral National Seashore, Titusville, FL

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), U.S. Department of the Interior, National Park Service, Canaveral National Seashore (CANA) has completed an inventory of human remains and has determined that there is no cultural affiliation between the human remains and any Indian Tribe. The human remains were removed from Volusia County, FL.

DATES: Disposition of the human remains in this notice may occur on or after December 15, 2023.

ADDRESSES: Carmen Thomson, Superintendent, Canaveral National Seashore, 212 S Washington Avenue, Titusville, FL 32796, telephone (321) 267–1110, email *carmen_thomson@nps.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 superintendent, CANA. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by CANA.

Description

Human remains representing, at minimum, 17 individuals were removed from Volusia County, FL, in 1984 during excavations at Turtle Mound under a National Park Service contract with

Florida State University. The site dates to the St. Johns II period (CE 800–1450). No associated funerary objects are present.

Aboriginal Land

The human remains in this notice were removed from known geographic locations. These locations are the aboriginal lands of one or more Indian Tribes. The following information was used to identify the aboriginal land: a final judgment of the Indian Claims Commission and a treaty.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes, CANA has determined that:

- The human remains described in this notice represent the physical remains of 17 individuals of Native American ancestry.
- No relationship of shared group identity can be reasonably traced between the human remains and any Indian Tribe.
- The human remains described in this notice were removed from the aboriginal land of the Miccosukee Tribe of Indians; Seminole Tribe of Florida; and The Seminole Nation of Oklahoma.

Requests for Disposition

Written requests for disposition of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for disposition may be submitted by:

1. Any one or more of the Indian Tribes 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, or who shows that the requestor is an aboriginal land Indian Tribe.

Disposition of the human remains described in this notice to a requestor may occur on or after December 15, 2023. If competing requests for disposition are received, CANA must determine the most appropriate requestor prior to disposition. Requests for joint disposition of the human remains are considered a single request and not competing requests. CANA is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9 and 10.11.

Dated: November 8, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–25217 Filed 11–14–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000
245S180110; S2D2S SS08011000
SX064A000 24XS501520; OMB Control
Number 1029–0107]

Agency Information Collection Activities; Subsidence Insurance Program Grants

AGENCY: Office of Surface Mining
Reclamation and Enforcement, Interior.

ACTION: Notice of information collection;
request for comment.

SUMMARY: In accordance with the
Paperwork Reduction Act of 1995, we,
the Office of Surface Mining
Reclamation and Enforcement (OSMRE),
are proposing to renew an information
collection.

DATES: Interested persons are invited to
submit comments on or before
December 15, 2023.

ADDRESSES: Written comments and
recommendations for the proposed
information collection should be sent
within 30 days of publication of this
notice to [www.reginfo.gov/public/do/](http://www.reginfo.gov/public/do/PRAMain)
PRAMain. Find this particular
information collection by selecting
“Currently under 30-day Review—Open
for Public Comments” or by using the
search function. Please provide a copy
of your comments to Mark Gehlhar,
Office of Surface Mining Reclamation
and Enforcement, 1849 C Street NW,
Room 4556–MIB, Washington, DC
20240, or by email to [mgehlhar@](mailto:mgehlhar@osmre.gov)
osmre.gov. Please reference OMB
Control Number 1029–0107 in the
subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To
request additional information about
this ICR, contact Mark Gehlhar by email
at mgehlhar@osmre.gov, or by telephone
at (202) 208–2716. Individuals in the
United States who are deaf, deafblind,
hard of hearing, or have a speech
disability may dial 711 (TTY, TDD, or
TeleBraille) to access
telecommunications relay services.
Individuals outside the United States
should use the relay services offered
within their country to make
international calls to the point-of-
contact in the United States. You may
also view the ICR at [http://](http://www.reginfo.gov/public/do/PRAMain)
www.reginfo.gov/public/do/PRAMain.

SUPPLEMENTARY INFORMATION: In
accordance with the Paperwork
Reduction Act of 1995 (PRA; 44 U.S.C.
3501 *et seq.*) and 5 CFR 1320.8(d)(1), we
provide the general public and other
Federal agencies with an opportunity to
comment on new, proposed, revised,
and continuing collections of
information. This helps us assess the
impact of our information collection
requirements and minimize the public’s
reporting burden. It also helps the
public understand our information
collection requirements and provide the
requested data in the desired format.

A **Federal Register** notice with a 60-
day public comment period soliciting
comments on this collection of
information was published on August 8,
2023 (88 FR 53519). No comments were
received.

As part of our continuing effort to
reduce paperwork and respondent
burdens, we are again soliciting
comments from the public and other
Federal agencies on the proposed ICR
that is described below. We are
especially interested in public comment
addressing the following:

- (1) Whether or not the collection of
information is necessary for the proper
performance of the functions of the
agency, including whether or not the
information will have practical utility;
- (2) The accuracy of our estimate of the
burden for this collection of
information, including the validity of
the methodology and assumptions used;
- (3) Ways to enhance the quality,
utility, and clarity of the information to
be collected; and
- (4) How might the agency minimize
the burden of the collection of
information on those who are to
respond, including through the use of
appropriate automated, electronic,
mechanical, or other technological
collection techniques or other forms of
information technology, *e.g.*, permitting
electronic submission of response.

Comments that you submit in
response to this notice are a matter of
public record. Before including your
address, phone number, email address,
or other personal identifying
information in your comment, you
should be aware that your entire
comment—including your personal
identifying information—may be made
publicly available at any time. While
you can ask us in your comment to
withhold your personal identifying
information from public review, we
cannot guarantee that we will be able to
do so.

Abstract: States and Indian tribes
having an approved reclamation plan
may establish, administer and operate
self-sustaining State and Indian Tribe-

administered programs to insure private
property against damages caused by
land subsidence resulting from
underground mining. States and Indian
tribes interested in requesting monies
for their insurance programs would
apply to the Director of OSMRE.

Title of Collection: Subsidence
insurance program grants.

OMB Control Number: 1029–0107.

Form Number: None.

Type of Review: Extension of a
currently approved collection.

Respondents/Affected Public: State
and Tribal governments.

**Total Estimated Number of Annual
Respondents:** 1.

**Total Estimated Number of Annual
Responses:** 1.

**Estimated Completion Time per
Response:** 8 hours.

**Total Estimated Number of Annual
Burden Hours:** 8.

Respondent’s Obligation: Required to
obtain or retain a benefit.

Frequency of Collection: Once.

**Total Estimated Annual Nonhour
Burden Cost:** None.

An agency may not conduct or
sponsor and a person is not required to
respond to a collection of information
unless it displays a currently valid OMB
control number.

The authority for this action is the
Paperwork Reduction Act of 1995 (44
U.S.C. 3501 *et seq.*).

Mark J. Gehlhar,

*Information Collection Clearance Officer,
Division of Regulatory Support.*

[FR Doc. 2023–25228 Filed 11–14–23; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF JUSTICE

[OMB Number 1140–0026]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; Report of Theft or Loss—Explosive Materials

AGENCY: Bureau of Alcohol, Tobacco,
Firearms and Explosives, Department of
Justice.

ACTION: 60-Day notice.

SUMMARY: The Bureau of Alcohol,
Tobacco, Firearms and Explosives
(ATF), 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 16, 2024.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, contact: John J. Basile, EIPB, either by mail at 3750 Corporal Rd. Huntsville, AL 35898, by email at john.basile@atf.gov; or telephone at 307-287-9200.

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: Any licensee or permittee who has knowledge of the theft or loss of any explosive materials from his stock shall, within 24 hours of discovery, report the theft or loss by telephoning 1-800-800-3855 (nationwide toll free number) and on the Report of Theft or Loss—Explosives—ATF Form 5400.5, in accordance with the instructions on the form. The information collection (IC) OMB Number 1140-0026 is being revised to include material changes to the form, such as added categories that include checkboxes (with a description and example scenarios), instruction clarification, and header revision (to include reference to voluntary reporting of explosives recovered or located).

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.
2. *The Title of the Form/Collection:* Report of Theft or Loss—Explosive Materials.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* Form number: ATF Form 5400.5.

Component: Bureau of Alcohol, Tobacco, Firearms and Explosives, U.S. Department of Justice.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public: Private Sector—business or other for-profit institutions.

The obligation to respond is: Mandatory per 27 CFR 555.30 (a).

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 130 respondents will utilize this form once annually, and it will take each respondent approximately 1 hour and 48 minutes to complete their responses.

6. *An estimate of the total annual burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 234 hours, which is equal to 130 (total respondents) * 1 (# of response per respondent) * 1.8 (1 hour and 48 minutes).

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* \$0.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response (minutes)	Total annual burden (hours)
ATF Form 5400.5	130	1	130	108	234

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 8, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023-25136 Filed 11-14-23; 8:45 am]

BILLING CODE 4410-FY-P

DEPARTMENT OF JUSTICE

[OMB Number 1110-0008]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Monthly Return of Arson Offenses Known to Law Enforcement

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Federal Bureau of Investigation (FBI), Criminal Justice Information Services 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. The proposed information collection

was previously published in the **Federal Register** on September 15, 2023, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 15, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Edward L. Abraham, Crime and Law Enforcement Statistics Unit Chief, FBI, CJIS Division, Module D-1, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; email: elabraham@fbi.gov or telephone number: 304-625-4830.

SUPPLEMENTARY INFORMATION:

Written comments and suggestions from the public and affected agencies

concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and/or
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following Website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review—Open for Public Comments" or by using the search function and entering either the title of the information collection or the OMB Control Number 1110–0008. This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *Title of the Form/Collection:* Monthly Return of Arson Offenses Known to Law Enforcement.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form number is 1–725. The applicable component within DOJ is the CJIS Division, FBI.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* *Affected Public:* Affected Public State, local and tribal governments, Federal Government. Abstract: Under 34 United States Code 41303, Uniform Federal Crime Reporting Act of 1988; the Anti-Arson Act of 1982; and FBI, General Functions, 28 Code of Federal Regulations section 0.85 (f); this collection requests the number of reported arson offenses from federal, state, local, tribal, and territorial LEAs in order for the FBI's Uniform Crime Reporting (UCR) Program to serve as the national clearinghouse for the collection and dissemination of arson data and to publish these statistics.

5. *Obligation To Respond:* Voluntary.

6. *Total Estimated Number of Respondents:* 5,200.

7. *Estimated Time Per Respondent:* 9 minutes.

8. *Frequency:* 12 times a year/ monthly.

9. *Total Estimated Annual Time Burden:* 9,360 hours.

10. *Total Estimated Annual Other Costs Burden:* \$107,000.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 9, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25151 Filed 11–14–23; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1123–0NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; New Collection; Application for Pardon After Completion of Sentence

AGENCY: Office of the Pardon Attorney, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office of the Pardon Attorney, 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 16, 2024.

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 Kira Gillespie, Deputy Pardon Attorney, Office of the Pardon Attorney, 950 Pennsylvania Avenue NW, Main Justice—RFK Building, Washington, DC 20530; kira.gillespie@usdoj.gov; (202) 616–6073.

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: Applicants seeking commutation of sentence by the President will be asked to respond to this collection. The principal purpose for collecting this information is to enable the Office of the Pardon Attorney to process applicants' requests for pardon after completion of sentence. The information is necessary to verify applicants' identities, conduct investigation of the applicants' backgrounds, criminal records, and conduct since their conviction, and to provide notice to the Federal Bureau of Investigation, U.S. Attorneys' Offices, U.S. Probation Offices, and federal courts in the event of grants of executive clemency.

Overview of This Information Collection

1. *Type of Information Collection:* New collection.

2. *The Title of the Form/Collection:* Application for Pardon After Completion of Sentence.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* There is no agency form number for this collection. The applicable component within the Department of Justice is the Office of the Pardon Attorney.

4. *Affected public who will be asked or required to respond, as well as the*

obligation to respond: Affected Public: Individuals or households. The obligation to respond is voluntary.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* Available information suggests that potentially 500 to 1,000 applicants will complete petitions annually. We estimate an average of 180 minutes for

each applicant to respond to the collection.

6. *An estimate of the total annual burden (in hours) associated with the collection:* Considering the above projected figures, we estimate 1,500 to 3,000 hours of annual burden to the public.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* \$0.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
Application	1,000	1/annually	1,000	180 min	3,000
Unduplicated Totals	1,000		1,000		3,000

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 9, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023-25178 Filed 11-14-23; 8:45 am]

BILLING CODE 4410-29-P

DEPARTMENT OF JUSTICE

[OMB Number 1110-0005]

Agency Information Collection Activities; Proposed eCollection eComments Requested; ASRE of Persons Arrested Under 18 Years of Age; ASRE of Persons Arrested 18 Years of Age and Over

AGENCY: Federal Bureau of Investigation, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Federal Bureau of Investigation (FBI), Criminal Justice Information Services 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. The proposed information collection was previously published in the **Federal Register** on September 15, 2023, allowing a 60-day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until December 15, 2023.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Edward L. Abraham, Crime and Law Enforcement Statistics Unit Chief, FBI, CJIS Division, Module D-1, 1000 Custer Hollow Road, Clarksburg, West Virginia 26306; telephone number: 304-625-4830, email: elabraham@fbi.gov.

SUPPLEMENTARY INFORMATION:

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and/or
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*,

permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function and entering either the title of the information collection or the OMB Control Number 1110-0005. This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of this information collection:

1. *Type of Information Collection:* Extension of a previously approved collection.

2. *Title of the Form/Collection:* ASRE of Persons Arrested Under 18 Years of Age; ASRE of Persons Arrested 18 Years of Age and Over.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* The form numbers are 1-708a and 1-708. The applicable component within DOJ is the CJIS Division, FBI.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* Affected Public: State, local and tribal governments, Federal Government.

Abstract: Under the Uniform Federal Crime Reporting Act of 1988, 34 U.S.C. 41303; the William Wilberforce Trafficking Victims Protection Reauthorization Act of 1988, 34 U.S.C. 41309; and 28 CFR 0.85(f), FBI, General Functions, this collection requests the number of arrests from federal, state, county, city, tribal, and territorial LEAs in order for the FBI's Uniform Crime Reporting (UCR) Program to obtain ASRE data in furtherance of serving as the national clearinghouse for the collection and dissemination of criminal statistics and to publish these statistics.

5. *Obligation to Respond:* Mandatory per 28 CFR 0.85(f).

6. *Total Estimated Number of Respondents:* 4,800.

7. *Estimated Time per Respondent:* 12 minutes for form 1–708a and 15 minutes for 1–708.

8. *Frequency:* 12 per year/monthly.

9. *Total Estimated Annual Time Burden:* 12,960 hours.

10. *Total Estimated Annual Other Costs Burden:* \$107,000.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Policy and Planning Staff, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: November 9, 2023.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–25146 Filed 11–14–23; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (OJJDP) Docket No. 1820]

Meeting of the Coordinating Council on Juvenile Justice and Delinquency Prevention

AGENCY: Coordinating Council on Juvenile Justice and Delinquency Prevention.

ACTION: Notice of meeting.

SUMMARY: The Coordinating Council on Juvenile Justice and Delinquency Prevention announces its next meeting.

DATES: Wednesday, December 6, 2023, at 1:00 p.m.–4:00 p.m. ET.

ADDRESSES: The meeting will take place at the Department of Justice, 950

Pennsylvania Ave. NW, Washington, DC, Room 7411.

FOR FURTHER INFORMATION CONTACT: Visit the website for the Coordinating Council at www.juvenilecouncil.gov or contact Maegen Barnes, Project Manager/Federal Contractor, by telephone (732) 948–8862, email at Maegen.Currie@usdoj.gov; or Julie Herr, Designated Federal Official (DFO), OJJDP, by telephone at (202) 598–6885, email at Julie.Herr@usdoj.gov. Please note that the above phone numbers are not toll free.

SUPPLEMENTARY INFORMATION: The Coordinating Council on Juvenile Justice and Delinquency Prevention (“Council”), established by statute in the Juvenile and Delinquency Prevention Act of 1974 section 206(a) (34 U.S.C. 11116(a)), will meet to carry out its advisory functions. Information regarding this meeting will be available on the Council’s web page at www.juvenilecouncil.gov. In light of space constraints, in-person attendance for this meeting will be limited, however the meeting will be available to the public via video conference. Prior registration is required (see below). In addition, meeting documents will be viewable via this website including meeting announcements, agendas, minutes and reports.

Although designated agency representatives may attend in lieu of members, the Council’s formal membership consists of the following secretaries and/or agency officials; Attorney General (Chair), Administrator of the Office of Juvenile Justice and Delinquency Prevention (Vice Chair), Secretary of Health and Human Services, Assistant Secretary for Mental Health and Substance Use, Secretary of the Interior, Secretary of Labor, Secretary of Education, Secretary of Housing and Urban Development, Director of the Office of National Drug Control Policy, Chief Executive Officer of AmeriCorps and the Assistant Secretary of Homeland Security for the U.S. Immigration and Customs Enforcement. Ten additional members are appointed by the President of the United States, the Speaker of the U.S. House of Representatives, the U.S. Senate Majority Leader and the Chairman of the Committee on Indian Affairs of the Senate. Further agencies that take part in Council activities include the Departments of Agriculture and Defense and the Consumer Financial Protection Bureau.

Council meeting agendas are available on www.juvenilecouncil.gov. Agendas will generally include: (a) Opening remarks and introductions; (b)

Presentations and discussion of agency work; and (c) Subcommittee reports and recommendations.

Members of the public who wish to attend, must register in advance of the meeting at the meeting registration site, by no later than Wednesday, November 29, 2023. Should issues arise with online registration, or to register by email, the public should contact Maegen Barnes, Senior Program Manager/Federal Contractor (see above for contact information). If submitting registrations by email, attendees should include all of the following: Name, Title, Organization/Affiliation, Full Address, Phone Number, and Email. Registration for this is also found online at www.juvenilecouncil.gov.

Interested parties may submit written comments and questions in advance to Maegen Barnes, Senior Program Manager/Federal Contractor (contact information above). All comments and questions should be submitted no later than 5:00 p.m. EST on Wednesday, November 29, 2023.

The Council will limit public statements if they are found to be duplicative. Written questions submitted by public attendees may also be considered by the Council, time permitting.

Julie Herr,

Designated Federal Official, Office of Juvenile Justice and Delinquency Prevention.

[FR Doc. 2023–25230 Filed 11–14–23; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used As An Intake Air Course To Ventilate Working Sections and Areas Where Mechanized Mining Equipment Is Being Installed or Removed

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency

receives on or before December 14, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency’s estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Michael Howell by telephone at 202–693–6782, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: The Safety Standards for Underground Coal Mine Ventilation—Belt Entry rule provides safety requirements for the use of the conveyor belt entry as a ventilation intake to course fresh air to working sections and areas where mechanized mining equipment is being installed or removed in mines with three or more entries. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on June 7, 2023 (88 FRN 37282).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

Agency: DOL–MSHA.

Title of Collection: Safety Standards for Underground Coal Mine Ventilation—Belt Entry Used as an Intake Air Course to Ventilate Working Sections and Areas Where Mechanized

Mining Equipment is Being Installed or Removed.

OMB Control Number: 1219–0138.

Affected Public: Businesses or other for-profits.

Number of Respondents: 14.

Frequency: On occasion.

Number of Responses: 157.

Annual Burden Hours: 658 hours.

Total Estimated Annual Other Costs Burden: \$280.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2023–25132 Filed 11–14–23; 8:45 am]

BILLING CODE 4510–43–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Records of Tests and of Examinations of Personnel Hoisting Equipment

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Mine Safety and Health Administration (MSHA)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before December 15, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting “Currently under 30-day Review—Open for Public Comments” or by using the search function.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency’s estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of

automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT:

Michael Howell by telephone at 202–693–6782, or by email at DOL_PRA_PUBLIC@dol.gov.

SUPPLEMENTARY INFORMATION: This information collection requires records of specific tests and inspections of mine personnel hoisting systems, including wire ropes, to ensure that the system remains safe to operate while in use. Review of the record indicates whether deficiencies are developing in the equipment, and in particular the wire rope, so that corrective action may be taken before an accident occurs. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on August 1, 2023 (88 FRN 50178).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

Agency: DOL–MSHA.

Title of Collection: Records of Tests and of Examinations of Personnel Hoisting Equipment.

OMB Control Number: 1219–0034.

Affected Public: Businesses or other for-profits.

Number of Respondents: 225.

Frequency: On occasion.

Number of Responses: 61,265.

Annual Burden Hours: 5,117 hours.

Total Estimated Annual Other Costs Burden: \$270,000.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Michael Howell,

Senior Paperwork Reduction Act Analyst.

[FR Doc. 2023–25131 Filed 11–14–23; 8:45 am]

BILLING CODE 4510–43–P

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 2023–6]

Artificial Intelligence and Copyright

AGENCY: Copyright Office, Library of Congress.

ACTION: Notice of inquiry; extension of comment period.

SUMMARY: The United States Copyright Office is extending the deadline to submit reply comments in connection with a study of the copyright law and policy issues raised by artificial intelligence systems.

DATES: Written reply comments are due no later than 11:59 p.m. Eastern Time on Wednesday, December 6, 2023.

ADDRESSES: For reasons of governmental efficiency, the Copyright Office is using the *regulations.gov* system for the submission and posting of public comments in this proceeding. All comments should be submitted electronically through *regulations.gov*. Specific instructions for submitting comments are available on the Copyright Office website at <https://copyright.gov/policy/artificial-intelligence>. If electronic submission is not feasible, please contact the Office using the contact information below for special instructions.

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

SUPPLEMENTARY INFORMATION: On August 30, 2023, the U.S. Copyright Office issued a notice of inquiry seeking comments from the public on several questions about the copyright law and policy issues raised by artificial intelligence systems. The notice set a deadline for initial comments on October 18, 2023 and for reply comments on November 15, 2023.¹ On September 21, 2023, these deadlines were extended to October 30, 2023 and November 29, 2023, respectively.²

To ensure that members of the public have sufficient time to prepare responses to the Office's questions and submitted comments, and to ensure that the Office can proceed on a timely basis with its inquiry of the issues identified in its notice with the benefit of a complete record, the Office is extending the deadline for reply comments. Reply comments will be due by 11:59 p.m. Eastern Time on December 6, 2023.

Dated: November 8, 2023.

Suzanne V. Wilson,
General Counsel and Associate Register of Copyrights.

[FR Doc. 2023-25128 Filed 11-14-23; 8:45 am]

BILLING CODE 1410-30-P

NATIONAL CREDIT UNION ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., Thursday, November 16, 2023.

PLACE: Board Room, 7th Floor, Room 7B 1775 Duke Street (All visitors must use Diagonal Road Entrance), Alexandria, VA 22314-3428.

STATUS: Open.

MATTERS TO BE CONSIDERED:

1. Board Briefing, Share Insurance Fund Quarterly Report.
2. NCUA Rules and Regulations, Charitable Donation Accounts.

RECESS: 12:00 p.m.

TIME AND DATE: 2:00 p.m., Thursday, November 16, 2023.

PLACE: NCUA Event Center, Lobby, 1775 Duke Street (All visitors must use Diagonal Road Entrance), Alexandria, VA 22314-3428.

STATUS: Open.

MATTER TO BE CONSIDERED:

1. Board Briefing, NCUA's 2024-2025 Budget.

CONTACT PERSON FOR MORE INFORMATION: Melane Conyers-Ausbrooks, Secretary of the Board, Telephone: 703-518-6304.

Melane Conyers-Ausbrooks,
Secretary of the Board.

[FR Doc. 2023-25286 Filed 11-13-23; 11:15 am]

BILLING CODE 7535-01-P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

The National Science Board hereby gives notice of the scheduling of a teleconference of the National Science Board/National Science Foundation Commission on Merit Review (MRX) for the transaction of National Science Board business pursuant to the NSF Act and the Government in the Sunshine Act.

TIME AND DATE: Wednesday, November 15, 2023, from 10:30-11:30 a.m. EST.

PLACE: This meeting will be via videoconference through the National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The agenda is: Committee Chair's opening remarks regarding the agenda; Discussion of data collection workplan to obtain information that informs MRX recommendations and suggestions for the National Science Foundation; and Closing remarks.

CONTACT PERSON FOR MORE INFORMATION: Point of contact for this meeting is:

Chris Blair, cblair@nsf.gov, 703/292-7000. Meeting information and updates may be found at www.nsf.gov/nsb.

Ann E. Bushmiller,

Senior Counsel to the National Science Board Office.

[FR Doc. 2023-25287 Filed 11-13-23; 11:15 am]

BILLING CODE 7555-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40-1162; NRC-2023-0076]

Western Nuclear, Inc.; Split Rock Site

AGENCY: Nuclear Regulatory Commission.

ACTION: License termination and transfer; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is noticing the establishment of the U.S. Department of Energy (DOE) as the long-term custodian of the Split Rock site and the transfer of the Split Rock site to DOE, under the general license provisions of NRC's regulations. The NRC also notices the termination of Western Nuclear, Inc.'s (WNI) Wyoming Source Material License No. WYSUA-0056 for the Split Rock uranium mill tailings site in Jeffrey City, Wyoming.

DATES: The license termination of Wyoming Source Material License No. WYSUA-0056 occurred on October 31, 2023. The transfer of the Split Rock site to DOE is effective November 7, 2023.

ADDRESSES: Please refer to Docket ID NRC-2023-0076 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-2023-0076. 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

¹ 88 FR 59942 (Aug. 30, 2023).

² 88 FR 65205 (Sept. 21, 2023).

301–415–4737, or by email to PDR.Resource@nrc.gov. For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the “Availability of Documents” section.

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

FOR FURTHER INFORMATION CONTACT: Tom Lancaster, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6563; email: Thomas.Lancaster@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The Split Rock site is approximately 2 miles northeast of Jeffrey City, Wyoming, in southeastern Fremont County. The Split Rock site is regulated under title II of the Uranium Mill Tailings Radiation Control Act of 1978

(title 42 *United States Code* section 7901 [42 U.S.C. 7901]).

II. Discussion

On October 30, 2023, the NRC concurred with the State of Wyoming’s determination that applicable standards and requirements for the protection of public health, safety and the environment had been met for the WNI Split Rock uranium mill tailings disposal site. WNI and the U.S. Bureau of Land Management transferred ownership of land at the Split Rock site to the DOE, as required by part 40 of title 10 of the *Code of Federal Regulations* (10 CFR), appendix A, criterion 11, prior to termination of WNI’s Source Material License by the State of Wyoming. By letter dated August 11, 2023, the DOE submitted the final Long-Term Surveillance Plan (LTSP) for the Split Rock disposal site for review and acceptance by the NRC. The NRC staff completed its technical review of the LTSP and determined that the LTSP satisfies the long-term surveillance requirements in 10 CFR part 40, appendix A, criterion 12, and 10 CFR 40.28, for the Split Rock tailings disposal site. Additionally, the NRC prepared an environmental assessment (EA) for this LTSP in accordance with

its regulations. Based on the EA, the NRC has concluded that a finding of no significant impact (FONSI) is appropriate. The FONSI was noticed in the **Federal Register** on October 30, 2023 (88 FR 74211).

III. Notice of Approval

Accordingly, notice is hereby given that the NRC has accepted the LTSP for the Split Rock site. As documented in NRC’s letter dated November 7, 2023, acceptance of this LTSP established the DOE as the long-term custodian and caretaker of the Split Rock site under the general license specified in 10 CFR 40.28. The State of Wyoming terminated WNI’s Source Material License No. WYSUA–0056 for the Split Rock site on October 31, 2023, and notified WNI by letter dated October 31, 2023. The NRC finds these actions complete all requirements for closure of the Split Rock site under the Uranium Mill Tailings Radiation Control Act of 1978, as amended.

IV. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

Document description	ADAMS accession No.
Letter dated October 30, 2023, from B. VonTill, NRC, to B. Obrien, Wyoming Department of Environmental Quality, regarding NRC concurrence of meeting all applicable standards for the WNI Minerals Corporation Split Rock Uranium Mill Tailings Disposal Site.	ML23271A217.
Letter dated August 11, 2023, from N. Keller, DOE, to T. Lancaster, NRC, submitting the final Long-Term Surveillance Plan for the Split Rock Disposal Site, Jeffrey City, Wyoming.	ML23223A152 (Package).
Letter dated November 7, 2023, from B. VonTill, NRC, to J. Glascock, DOE, regarding acceptance of the Long-Term Surveillance Plan for the WNI Minerals Corporation Split Rock Uranium Mill Tailings Disposal Site.	ML23271A189 (Package).
Letter dated October 31, 2023, from K. Wendtland and T. Parfitt, Wyoming Department of Environmental Quality, to L. Corte, WNI, regarding termination of WNI’s Source Material License No. WYSUA–0056.	ML23311A036.

Dated: November 9, 2023.

For the Nuclear Regulatory Commission.

Marc S. Ferdas,

Acting Deputy Director, Division of Decommissioning, Uranium Recovery and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2023–25213 Filed 11–14–23; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50–275 and 50–323; NRC–2022–0094]

Pacific Gas and Electric Company; Diablo Canyon Nuclear Power Plant, Units 1 and 2

AGENCY: Nuclear Regulatory Commission.

ACTION: License amendment application; withdrawal by applicant.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has granted the request of Pacific Gas and Electric Company (the licensee) to withdraw its application dated February 16, 2022, as supplemented by letters dated June 20, 2022, September 8, 2022, and April 4, 2023, for proposed amendments to Facility Operating License Nos. DPR–80 and DPR–82, issued to the licensee for operation of the Diablo Canyon Nuclear Power Plant, Units 1 and 2, located in San Luis Obispo County, California. The proposed amendments would have permitted alternative security measures for the implementation of an early warning system.

DATES: This document was published in the **Federal Register** on November 15, 2023.

ADDRESSES: Please refer to Docket ID NRC–2022–0094 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–2022–0094. 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: Samson Lee, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, telephone: 301-415-3168; email: Samson.Lee@nrc.gov.

SUPPLEMENTARY INFORMATION: The NRC has granted the request of the licensee to withdraw its application dated February 16, 2022 (ADAMS Accession No. ML22048A526), as supplemented by letters dated June 20, 2022 (ADAMS Accession No. ML22173A135), September 8, 2022 (ADAMS Accession No. ML22251A295), and April 4, 2023 (ADAMS Accession No. ML23102A037) for proposed amendments to Facility Operating License Nos. DPR-80 and DPR-82 for the Diablo Canyon Nuclear Power Plant, Units 1 and 2, located in San Luis Obispo, County, California.

The proposed amendments would have permitted alternative security measures for the implementation of an early warning system.

The Commission had previously issued a Notice of Consideration of Issuance of Amendment published in the **Federal Register** on May 3, 2022 (87 FR 26232). However, by letter dated October 13, 2023 (ADAMS Accession No. ML23286A302), the licensee withdrew the proposed change.

Dated: November 8, 2023.

For the Nuclear Regulatory Commission.

Samson S. Lee,

Senior Project Manager, Plant Licensing Branch IV, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2023-25101 Filed 11-14-23; 8:45 am]

BILLING CODE 7590-01-P

OFFICE OF PERSONNEL MANAGEMENT

President's Commission on White House Fellowships Advisory Committee: Closed Meeting

AGENCY: President's Commission on White House Fellowships, Office of Personnel Management.

ACTION: Notice of meeting.

SUMMARY: The President's Commission on White House Fellowships (PCWHF) was established by an executive order in 1964. The PCWHF is an advisory committee composed of Special Government Employees appointed by the President.

FOR FURTHER INFORMATION CONTACT: Rosemarie Vela, 712 Jackson Place NW, Washington, DC 20503, Phone: 202-395-4522.

SUPPLEMENTARY INFORMATION:

Name of Committee: President's Commission on White House Fellowships Mid-Year Meeting.

Date: January 19, 2024.

Time: 8 a.m.-5:30 p.m.

Place: Eisenhower Executive Office Building, 1650 Pennsylvania Ave. NW, Washington, DC 20500.

Agenda: The Commission holds a mid-year meeting to talk with current Fellows on how their placements are going and discuss preparation for future events.

Authority: Executive Orders 11183 and 14109.

Office of Personnel Management.

Kayyonne Marston,

Federal Register Liaison.

[FR Doc. 2023-25060 Filed 11-14-23; 8:45 am]

BILLING CODE 6325-69-P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2024-47 and CP2024-47; MC2024-48 and CP2024-48; MC2024-49 and CP2024-49]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 17, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>.

www.prc.gov. Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202-789-6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Introduction
- II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (<http://www.prc.gov>). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.¹

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and

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).

39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s)*.: MC2024–47 and CP2024–47; *Filing Title*: USPS Request to Add Priority Mail & USPS Ground Advantage Contract 101 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: November 8, 2023; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative*: Jennaca D. Upperman; *Comments Due*: November 17, 2023.

2. *Docket No(s)*.: MC2024–48 and CP2024–48; *Filing Title*: USPS Request to Add Priority Mail & USPS Ground Advantage Contract 102 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: November 8, 2023; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative*: Jennaca D. Upperman; *Comments Due*: November 17, 2023.

3. *Docket No(s)*.: MC2024–49 and CP2024–49; *Filing Title*: USPS Request to Add Priority Mail & USPS Ground Advantage Contract 103 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date*: November 8, 2023; *Filing Authority*: 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative*: Jennaca D. Upperman; *Comments Due*: November 17, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,
Secretary.

[FR Doc. 2023–25175 Filed 11–14–23; 8:45 am]

BILLING CODE 7710–FW–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 15, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 7, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 788 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–46, CP2024–46.

Sean C. Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2023–25253 Filed 11–14–23; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 15, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 7, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 100 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–45, CP2024–45.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2023–25257 Filed 11–14–23; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 15, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 7, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 99 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–44, CP2024–44.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2023–25256 Filed 11–14–23; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 15, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 9, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 105 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024–51, CP2024–51.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2023–25259 Filed 11–14–23; 8:45 am]
BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 15, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 6, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 97 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024-41, CP2024-41.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2023-25254 Filed 11-14-23; 8:45 am]
BILLING CODE 7710-12-P

POSTAL SERVICE

International Product Change—Priority Mail Express International, Priority Mail International & First-Class Package International Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a Priority Mail Express International, Priority Mail International & First-Class Package International Service contract to the list of Negotiated Service Agreements in the Competitive Product List in the Mail Classification Schedule.

DATES: Date of notice: November 15, 2023.

FOR FURTHER INFORMATION CONTACT: Christopher C. Meyerson, (202) 268-7820.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 7, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 30 to Competitive Product List*. Documents are available at

www.prc.gov, Docket Nos. MC2024-43 and CP2024-43.

Colleen Hibbert-Kapler,
Attorney, Ethics and Legal Compliance.
[FR Doc. 2023-25237 Filed 11-14-23; 8:45 am]
BILLING CODE 7710-12-P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* November 15, 2023.

FOR FURTHER INFORMATION CONTACT: Sean Robinson, 202-268-8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on November 6, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 98 to Competitive Product List*. Documents are available at www.prc.gov, Docket Nos. MC2024-42, CP2024-42.

Sean Robinson,
Attorney, Corporate and Postal Business Law.
[FR Doc. 2023-25255 Filed 11-14-23; 8:45 am]
BILLING CODE 7710-12-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98892; File No. SR-NYSEAMER-2023-56]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Amend Rule 7.31E

November 8, 2023.

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 31, 2023, NYSE American LLC (“NYSE American” or the “Exchange”) filed with the Securities and Exchange

Commission (the “Commission”) the proposed rule change as described in Items I, II, and III 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 amend Rule 7.31E to provide for the use of ALO Reserve Orders. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31E to provide for the use of ALO Reserve Orders.

ALO Orders

Rule 7.31E(e)(2) defines an ALO Order as a Non-Routable Limit Order that, unless it receives price improvement, will not remove liquidity from the Exchange Book. An ALO Order can be designated to be cancelled if it would be displayed at a price other than its limit price for any reason. An ALO Order can be designated as non-displayed.

As described in Rule 7.31E(e)(2)(A), an Aggressing ALO Order to buy (sell) will trade if its limit price crosses the working price of any displayed or non-displayed orders to sell (buy) on the Exchange Book priced equal to or below (above) the PBO (PBB) of an Away Market, in which case it will trade as the liquidity taker with such orders.

As noted above, Rule 7.31E(e)(2) provides that an ALO Order may be

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

designated to cancel if it would be displayed at a price other than its limit price. If an ALO Order is not so designated, any untraded quantity of such order to buy (sell) is processed as follows (Rules 7.31E(e)(2)(B)(i) and (ii)):

- If the limit price of the ALO Order locks the display price of any order to sell (buy) ranked Priority 2—Display Orders on the Exchange Book, it will have a working price and display price (if designated to display) one MPV below (above) the price of the displayed order on the Exchange Book.

- If the limit price of the ALO Order locks or crosses the PBO (PBB) of an Away Market, it will have a working price equal to the PBO (PBB) of the Away Market and a display price (if designated to display) one MPV below (above) the PBO (PBB) of the Away Market.

Rule 7.31E(e)(2)(C) provides that any untraded quantity of an ALO Order to buy (sell) will have a working price and display price (if designated to display) equal to its limit price if it locks non-displayed orders to sell (buy) on the Exchange Book. Rule 7.31E(e)(2)(D) provides that an ALO Order to buy (sell) will not be assigned a working price or display price above (below) the limit price of such order.

Once resting on the Exchange Book, ALO Orders may be re-priced or trade, or both, as described in Rule 7.31E(e)(2)(E):

- If order(s) to sell (buy) ranked Priority 2—Display Orders or the PBO (PBB) of an Away Market re-prices higher (lower), an ALO Order to buy (sell) will trade or be priced, or both, consistent with Rules 7.31E(e)(2)(A), (e)(2)(B)(i) and (ii), and (e)(2)(C).

- If the PBO (PBB) of an Away Market re-prices lower (higher) to be equal to or lower (higher) than its last display price or if its limit price no longer locks or crosses the PBO (PBB) of the Away Market, an ALO Order to buy (sell) will be priced pursuant to Rules 7.31E(e)(1)(A)(ii)(c) and (d). If the PBO (PBB) of an Away Market re-prices lower (higher) than the working price of a non-displayed ALO Order to buy (sell), such order will have a working price equal to the PBO (PBB) of the Away Market.

Reserve Orders

Rule 7.31E(d)(1) provides for Reserve Orders, which are Limit or Inside Limit Orders with a quantity of the size displayed and with a reserve quantity (“reserve interest”) of the size that is not displayed. The displayed quantity of a Reserve Order is ranked Priority 2—Display Orders, and the reserve interest is ranked Priority 3—Non-Display

Orders. Both the display quantity and the reserve interest of an arriving marketable Reserve Order are eligible to trade with resting interest in the Exchange Book or to route to Away Markets. The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in Rule 7.31E(d)(2)(A).

As described in Rule 7.31E(d)(1)(A), the display quantity of a Reserve Order must be entered in round lots, and the displayed portion of a Reserve Order will be replenished when the display quantity is decremented to below a round lot. The replenish quantity will be the minimum display size of the order or the remaining quantity of the reserve interest if it is less than the minimum display quantity.

Rule 7.31E(d)(1)(B) provides that each time the display quantity of a Reserve Order is replenished from reserve interest, a new working time is assigned to the replenished quantity (each display quantity with a different time is referred to as a “child” order), while the reserve interest retains the working time of the original order entry. In addition, when a Reserve Order is replenished from reserve interest and already has two child orders that equal less than a round lot, the child order with the later working time will rejoin the reserve interest and be assigned the new working time assigned to the next replenished quantity. If a Reserve Order is not routable, the replenish quantity will be assigned a display and working price consistent with the instructions for the order.

Rule 7.31E(d)(1)(C) provides that a Reserve Order must be designated Day and may only be combined with a Non-Routable Limit Order. Rule 7.31E(d)(1)(C) also currently provides that a Reserve Order may not be designated as an ALO Order.

Rule 7.31E(d)(1)(D) provides that routable Reserve Orders will be evaluated for routing both on arrival and each time their display quantity is replenished.

Rule 7.31E(d)(1)(E) provides that a request to reduce the size of a Reserve Order will cancel the reserve interest before cancelling the display quantity, and, if the Reserve Order has more than one child order, the child order with the latest working time will be cancelled first.

Rule 7.31E(d)(1)(F) provides that, if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of such Reserve Order will not change and

the reserve interest that replenishes the display quantity will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Rule 7.31E(d)(1)(F) further provides that, when the PBBO uncrosses, the display price and working price will be adjusted as provided for under Rule 7.31E(e)(1) relating to Non-Routable Limit Orders.

ALO Reserve Orders

The Exchange proposes to amend Rule 7.31E to provide for the use of ALO Reserve Orders. The proposed change is not intended to introduce any new functionality or modify any current functionality, but rather to facilitate the combination of two order types currently offered by the Exchange. As proposed, ALO Reserve Orders would, except as otherwise noted, operate consistent with current Rule 7.31E(d)(1) regarding Reserve Orders and current Rule 7.31E(e)(2) regarding ALO Orders. To allow for the use of ALO Reserve Orders, the Exchange first proposes to amend Rule 7.31E(d)(1)(C) to delete the last sentence of such rule, which currently provides that a Reserve Order may not be designated as an ALO Order.

The proposed change is intended to allow ALO Orders, as described in Rule 7.31E(e)(2) and the paragraphs thereunder,⁴ to have a displayed quantity, along with non-displayed reserve interest, as described in Rule 7.31E(d)(1). The display quantity of an ALO Reserve Order would be replenished as provided in Rules 7.31E(d)(1)(A) and (B). As ALO Reserve Orders are non-routable, under Rule 7.31E(d)(1)(B)(ii), the replenish quantity of an ALO Reserve Order would be assigned a display price and working price consistent with the behavior of ALO Orders as described in current Exchange rules.

Aggressing ALO Reserve Orders would trade in accordance with current Rule 7.31E(e)(2)(A). If an ALO Reserve Order is designated to cancel, it will cancel if it would be displayed at a price other than its limit price for any reason, as described in Rule 7.31E(e)(2). Otherwise, any untraded quantity of an ALO Reserve Order would continue to be processed as ALO Orders are currently, as described in Rules 7.31E(e)(2)(B) and (C). Similarly, the working price of the reserve interest of a resting ALO Reserve Order would be adjusted as provided for in Rule

⁴ The Exchange does not propose to allow non-displayed ALO Orders to be designated as Reserve Orders, given that a Reserve Order must have both displayed and non-displayed portions, and thus proposes to amend Rule 7.31E(e)(2) to specify accordingly.

7.31E(d)(1) (*i.e.*, in accordance with Rule 7.31E(d)(2)(A)). Rule 7.31E(d)(1)(E) would also apply to requests to reduce the size of ALO Reserve Orders.

As described in Rule 7.31E(d)(1)(F), when the PBBO is crossed and the display quantity of an ALO Reserve Order to buy (sell) is decremented to less than a round lot, the display price and working price of the order would not change, but the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). The Exchange proposes to amend Rule 7.31E(d)(1)(F) to add new rule text describing how the display price and working price of an ALO Reserve Order would be adjusted when a previously crossed PBBO uncrosses. Specifically, the Exchange proposes to add text to the last sentence of Rule 7.31E(d)(1)(F) providing that the display price and working price of an ALO Reserve Order would be adjusted in accordance with Rule 7.31E(e)(2)(E), which describes how ALO Orders resting on the Exchange Book are repriced and/or traded. Because ALO Orders behave differently from other Non-Routable Limit Orders and may only trade when they receive price improvement, the Exchange proposes to add text to Rule 7.31E(e)(2)(F) clarifying that ALO Reserve Orders would have their display price and working price adjusted consistent with the rules applicable to ALO Orders when the PBBO uncrosses.

The proposed change is intended to facilitate the combined use of two existing order types available on the Exchange, thereby providing ETP Holders with enhanced flexibility and optionality when trading on the Exchange. The proposed change could also promote increased liquidity and trading opportunities on the Exchange, to the benefit of all market participants. The Exchange also believes the proposed change would permit the Exchange to offer functionality already available on at least one other equities exchange, thereby promoting competition among equities exchanges.⁵

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 in the fourth quarter of 2023.

2. Statutory Basis

The proposed rule change is consistent with section 6(b) of the Act,⁶ in general, and furthers the objectives of section 6(b)(5),⁷ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market because it would allow for the combined use of two existing order types available on the Exchange and permit the Exchange to offer functionality similar to that already available on at least one other equities exchange.⁸ ETP Holders would be free to choose to use the proposed ALO Reserve Order type or not, and the proposed change would not otherwise impact the operation of the Reserve Order or ALO Order as described in current Exchange rules. The Exchange also believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market, as well as protect investors and the public interest, by expanding the options available to ETP Holders when trading on the Exchange and promoting increased liquidity and additional trading opportunities for all market participants.

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. In addition, as noted above, Exchange believes the proposed rule change would allow the Exchange to offer functionality already available on at least one other equities exchange⁹ and thus would promote competition among equities exchanges. The Exchange also believes that, to the extent the proposed change increases opportunities for order execution, the

proposed change would promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B)¹³ of the Act 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:

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii). 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 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.

¹³ 15 U.S.C. 78s(b)(2)(B).

⁵ See, e.g., MEMX Rules 11.8(b)(4) and (7) (providing that a Limit Order may include a reserve quantity and may be designated with a Post Only instruction); see also MEMX User Manual, available at <https://info.memxtrading.com/wp-content/uploads/2023/03/MEMX-User-Manual-03.10.23.pdf>, at 9 (providing that a Limit Order designated Day may have both reserve quantity and Post Only instructions).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

⁸ See note 5, *supra*.

⁹ See *id.*

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-NYSEAMER-2023-56 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-NYSEAMER-2023-56. 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-NYSEAMER-2023-56 and should be submitted on or before December 6, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023-25105 Filed 11-14-23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98893; File No. SR-NYSEAMER-2023-25]

Self-Regulatory Organizations; NYSE National, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.31

November 9, 2023.

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 31, 2023, NYSE National, Inc. ("NYSE National" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III 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 amend Rule 7.31 to provide for the use of ALO Reserve Orders. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31 to provide for the use of ALO Reserve Orders.

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

ALO Orders

Rule 7.31(e)(2) defines an ALO Order as a Non-Routable Limit Order that, unless it receives price improvement, will not remove liquidity from the Exchange Book. An ALO Order can be designated to be cancelled if it would be displayed at a price other than its limit price for any reason. An ALO Order can be designated as non-displayed.

As described in Rule 7.31(e)(2)(A), an Aggressing ALO Order to buy (sell) will trade if its limit price crosses the working price of any displayed or non-displayed orders to sell (buy) on the Exchange Book priced equal to or below (above) the PBO (PBB) of an Away Market, in which case it will trade as the liquidity taker with such orders.

As noted above, Rule 7.31(e)(2) provides that an ALO Order may be designated to cancel if it would be displayed at a price other than its limit price. If an ALO Order is not so designated, any untraded quantity of such order to buy (sell) is processed as follows (Rules 7.31(e)(2)(B)(i) and (ii)):

- If the limit price of the ALO Order locks the display price of any order to sell (buy) ranked Priority 2—Display Orders on the Exchange Book, it will have a working price and display price (if designated to display) one MPV below (above) the price of the displayed order on the Exchange Book.
- If the limit price of the ALO Order locks or crosses the PBO (PBB) of an Away Market, it will have a working price equal to the PBO (PBB) of the Away Market and a display price (if designated to display) one MPV below (above) the PBO (PBB) of the Away Market.

Rule 7.31(e)(2)(C) provides that any untraded quantity of an ALO Order to buy (sell) will have a working price and display price (if designated to display) equal to its limit price if it locks non-displayed orders to sell (buy) on the Exchange Book. Rule 7.31(e)(2)(D) provides that an ALO Order to buy (sell) will not be assigned a working price or display price above (below) the limit price of such order.

Once resting on the Exchange Book, ALO Orders may be re-priced or trade, or both, as described in Rule 7.31(e)(2)(E):

- If order(s) to sell (buy) ranked Priority 2—Display Orders or the PBO (PBB) of an Away Market re-prices higher (lower), an ALO Order to buy (sell) will trade or be priced, or both, consistent with Rules 7.31(e)(2)(A), (e)(2)(B)(i) and (ii), and (e)(2)(C).
- If the PBO (PBB) of an Away Market re-prices lower (higher) to be equal to or lower (higher) than its last display price

¹⁴ 17 CFR 200.30-3(a)(12).

or if its limit price no longer locks or crosses the PBO (PBB) of the Away Market, an ALO Order to buy (sell) will be priced pursuant to Rules 7.31(e)(1)(A)(ii)(c) and (d). If the PBO (PBB) of an Away Market re-prices lower (higher) than the working price of a non-displayed ALO Order to buy (sell), such order will have a working price equal to the PBO (PBB) of the Away Market.

Reserve Orders

Rule 7.31(d)(1) provides for Reserve Orders, which are Limit or Inside Limit Orders with a quantity of the size displayed and with a reserve quantity ("reserve interest") of the size that is not displayed. The displayed quantity of a Reserve Order is ranked Priority 2—Display Orders, and the reserve interest is ranked Priority 3—Non-Display Orders. Both the display quantity and the reserve interest of an arriving marketable Reserve Order are eligible to trade with resting interest in the Exchange Book or to route to Away Markets. The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in Rule 7.31(d)(2)(A).

As described in Rule 7.31(d)(1)(A), the display quantity of a Reserve Order must be entered in round lots, and the displayed portion of a Reserve Order will be replenished when the display quantity is decremented to below a round lot. The replenish quantity will be the minimum display size of the order or the remaining quantity of the reserve interest if it is less than the minimum display quantity.

Rule 7.31(d)(1)(B) provides that each time the display quantity of a Reserve Order is replenished from reserve interest, a new working time is assigned to the replenished quantity (each display quantity with a different time is referred to as a "child" order), while the reserve interest retains the working time of the original order entry. In addition, when a Reserve Order is replenished from reserve interest and already has two child orders that equal less than a round lot, the child order with the later working time will rejoin the reserve interest and be assigned the new working time assigned to the next replenished quantity. If a Reserve Order is not routable, the replenish quantity will be assigned a display and working price consistent with the instructions for the order.

Rule 7.31(d)(1)(C) provides that a Reserve Order must be designated Day and may only be combined with a Non-Routable Limit Order or Primary Pegged Order. Rule 7.31(d)(1)(C) also currently

provides that a Reserve Order may not be designated as an ALO Order.

Rule 7.31(d)(1)(D) provides that routable Reserve Orders will be evaluated for routing both on arrival and each time their display quantity is replenished.

Rule 7.31(d)(1)(E) provides that a request to reduce the size of a Reserve Order will cancel the reserve interest before cancelling the display quantity, and, if the Reserve Order has more than one child order, the child order with the latest working time will be cancelled first.

Rule 7.31(d)(1)(F) provides that, if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of such Reserve Order will not change and the reserve interest that replenishes the display quantity will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Rule 7.31(d)(1)(F) further provides that, when the PBBO uncrosses, the display price and working price will be adjusted as provided for under Rule 7.31(e)(1) relating to Non-Routable Limit Orders.

ALO Reserve Orders

The Exchange proposes to amend Rule 7.31 to provide for the use of ALO Reserve Orders. The proposed change is not intended to introduce any new functionality or modify any current functionality, but rather to facilitate the combination of two order types currently offered by the Exchange. As proposed, ALO Reserve Orders would, except as otherwise noted, operate consistent with current Rule 7.31(d)(1) regarding Reserve Orders and current Rule 7.31(e)(2) regarding ALO Orders. To allow for the use of ALO Reserve Orders, the Exchange first proposes to amend Rule 7.31(d)(1)(C) to delete the last sentence of such rule, which currently provides that a Reserve Order may not be designated as an ALO Order.

The proposed change is intended to allow ALO Orders, as described in Rule 7.31(e)(2) and the paragraphs thereunder,⁴ to have a displayed quantity, along with non-displayed reserve interest, as described in Rule 7.31(d)(1). The display quantity of an ALO Reserve Order would be replenished as provided in Rules 7.31(d)(1)(A) and (B). As ALO Reserve

Orders are non-routable, under Rule 7.31(d)(1)(B)(ii), the replenish quantity of an ALO Reserve Order would be assigned a display price and working price consistent with the behavior of ALO Orders as described in current Exchange rules.

Aggregating ALO Reserve Orders would trade in accordance with current Rule 7.31(e)(2)(A). If an ALO Reserve Order is designated to cancel, it will cancel if it would be displayed at a price other than its limit price for any reason, as described in Rule 7.31(e)(2). Otherwise, any untraded quantity of an ALO Reserve Order would continue to be processed as ALO Orders are currently, as described in Rules 7.31(e)(2)(B) and (C). Similarly, the working price of the reserve interest of a resting ALO Reserve Order would be adjusted as provided for in Rule 7.31(d)(1) (*i.e.*, in accordance with Rule 7.31(d)(2)(A)). Rule 7.31(d)(1)(E) would also apply to requests to reduce the size of ALO Reserve Orders.

As described in Rule 7.31(d)(1)(F), when the PBBO is crossed and the display quantity of an ALO Reserve Order to buy (sell) is decremented to less than a round lot, the display price and working price of the order would not change, but the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). The Exchange proposes to amend Rule 7.31(d)(1)(F) to add new rule text describing how the display price and working price of an ALO Reserve Order would be adjusted when a previously crossed PBBO uncrosses. Specifically, the Exchange proposes to add text to the last sentence of Rule 7.31(d)(1)(F) providing that the display price and working price of an ALO Reserve Order would be adjusted in accordance with Rule 7.31(e)(2)(E), which describes how ALO Orders resting on the Exchange Book are repriced and/or traded. Because ALO Orders behave differently from other Non-Routable Limit Orders and may only trade when they receive price improvement, the Exchange proposes to add text to Rule 7.31(e)(2)(F) clarifying that ALO Reserve Orders would have their display price and working price adjusted consistent with the rules applicable to ALO Orders when the PBBO uncrosses.

The proposed change is intended to facilitate the combined use of two existing order types available on the Exchange, thereby providing ETP Holders with enhanced flexibility and optionality when trading on the Exchange. The proposed change could also promote increased liquidity and

⁴ The Exchange does not propose to allow non-displayed ALO Orders to be designated as Reserve Orders, given that a Reserve Order must have both displayed and non-displayed portions, and thus proposes to amend Rule 7.31(e)(2) to specify accordingly.

trading opportunities on the Exchange, to the benefit of all market participants. The Exchange also believes the proposed change would permit the Exchange to offer functionality already available on at least one other equities exchange, thereby promoting competition among equities exchanges.⁵

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 in the fourth quarter of 2023.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Section 6(b)(5),⁷ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market because it would allow for the combined use of two existing order types available on the Exchange and permit the Exchange to offer functionality similar to that already available on at least one other equities exchange.⁸ ETP Holders would be free to choose to use the proposed ALO Reserve Order type or not, and the proposed change would not otherwise impact the operation of the Reserve Order or ALO Order as described in current Exchange rules. The Exchange also believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market, as well as protect investors and the public interest, by expanding the options available to ETP Holders when trading on the Exchange and promoting increased liquidity and

additional trading opportunities for all market participants.

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. In addition, as noted above, Exchange believes the proposed rule change would allow the Exchange to offer functionality already available on at least one other equities exchange⁹ and thus would promote competition among equities exchanges. The Exchange also believes that, to the extent the proposed change increases opportunities for order execution, the proposed change would promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such

action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹³ of the Act 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-NYSENAT-2023-25 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSENAT-2023-25. 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

⁵ See, e.g., MEMX Rules 11.8(b)(4) and (7) (providing that a Limit Order may include a reserve quantity and may be designated with a Post Only instruction); see also MEMX User Manual, available at <https://info.memxtrading.com/wp-content/uploads/2023/03/MEMX-User-Manual-03.10.23.pdf>, at 9 (providing that a Limit Order designated Day may have both reserve quantity and Post Only instructions).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

⁸ See note 5, *supra*.

⁹ See *id.*

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii). 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 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.

¹³ 15 U.S.C. 78s(b)(2)(B).

withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSENAT–2023–25 and should be submitted on or before December 6, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–25203 Filed 11–14–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98882; File No. SR–FICC–2023–014]

Self-Regulatory Organizations; Fixed Income Clearing Corporation; Order Approving Proposed Rule Change Relating to the GSD and MBSD Schedules of Haircuts for Eligible Clearing Fund Securities

November 8, 2023.

I. Introduction

On September 22, 2023, Fixed Income Clearing Corporation (“FICC”) filed with the Securities and Exchange Commission (“Commission”) proposed rule change SR–FICC–2023–014 to modify the GSD and MBSD Schedules of Haircuts for Eligible Clearing Fund Securities, and to remove them and the related concentration limits from the respective Rules, and make other clarifying changes (“Proposed Rule Change”), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) ¹ and Rule 19b–4 thereunder. ² The Proposed Rule Change was published for comment in the **Federal Register** on October 4, 2023. ³ The Commission has received no comments on the Proposed Rule Change. For the reasons discussed below, the Commission is approving the Proposed Rule Change. ⁴

II. Background

FICC is a central counterparty (“CCP”), which means it interposes

itself as the buyer to every seller and seller to every buyer for the financial transactions it clears. FICC’s Government Securities Division (“GSD”) provides CCP services for the U.S. Government securities market, and FICC’s Mortgage Backed-Securities Division (“MBSD”) provides CCP services for the U.S. mortgage-backed securities markets. ⁵ As such, FICC is exposed to the risk that one or more of its members may fail to make a payment or to deliver securities.

A key tool that FICC uses to manage its credit exposures to its members is the daily collection of margin (referred to as “Required Fund Deposit” in the GSD and MBSD Rules) from each member. ⁶ The aggregated amount of all GSD and MBSD members’ margin constitutes the GSD Clearing Fund and MBSD Clearing Fund. The objective of the GSD and MBSD Clearing Funds is to mitigate potential losses to FICC associated with liquidating a member’s portfolio in the event FICC ceases to act for that member (hereinafter referred to as a “default”). ⁷ FICC would be able to access the Clearing Fund should a defaulting member’s own margin be insufficient to satisfy losses to FICC caused by the liquidation of that member’s portfolio.

A member may provide its required margin in the form of cash or an open account indebtedness secured by Eligible Clearing Fund Securities. ⁸ Eligible Clearing Fund Securities are defined to include certain agency, mortgage-backed, and Treasury securities. ⁹ These securities are valued based on the prior Business Day’s closing market price, less a haircut, and may be subject to a concentration

limit. ¹⁰ FICC states that haircuts are used to protect FICC and its members from price fluctuations, *i.e.*, if FICC is required to liquidate collateral of an insolvent member and such collateral is worth less at the time of liquidation than when it is pledged to FICC. ¹¹ FICC also states that concentration limits are intended to reduce FICC’s risk by limiting the percentage of certain types of Eligible Clearing Fund Securities pledged by members to secure the Clearing Fund deposits, because when a member’s portfolio contains large net unsettled positions in a particular group of securities with a similar risk profile or in a particular asset type, such securities could present additional risk to FICC. ¹²

Currently, collateral haircuts applicable to relevant security types and remaining maturity terms are specified as fixed percentages in the Schedule of Haircuts for Eligible Clearing Fund Securities in the GSD Rules and MBSD Rules. ¹³ According to FICC and set forth in its internal risk management procedures, the sufficiency of collateral haircuts is evaluated through use of back-tests, stress-tests and market observations. ¹⁴ Specifically, FICC conducts daily backtesting analysis by comparing the collateral haircut for each member in simulated liquidations with the member’s actual collateral held on deposit at FICC. ¹⁵ FICC escalates any exceptions that it observes to assess the root cause and determine whether further analysis and/or review would be appropriate, taking into account whether a particular security may present inherent volatility and/or liquidity risks that could likely result in an erosion in the value of the security exceeding the applicable collateral haircut. ¹⁶ On a quarterly basis, FICC reviews the composition of the Eligible Clearing Fund Securities that members have pledged to secure their Required

⁵ GSD and MBSD maintain separate sets of rules, margin models, and clearing funds.

⁶ See GSD Rule 4 and MBSD Rule 4, *supra* note 4 (requiring members to make Required Fund Deposits to the GSD and MBSD Clearing Funds, as applicable, with the amount of each member’s deposit being determined by FICC in accordance with these rules).

⁷ The GSD Rules and MBSD Rules each identify when FICC may cease to act for a member and the types of actions FICC may take. For example, FICC may suspend a firm’s membership with FICC or prohibit or limit a member’s access to FICC’s services in the event that member defaults on a financial or other obligation to FICC. See GSD Rule 21 (Restrictions on Access to Services) and MBSD Rule 14 (Restrictions on Access to Services), *supra* note 4.

⁸ See GSD Rule 4, Section 3 (Form of Deposit) and MBSD Rule 4, Section 3 (Form of Deposit), *supra* note 4.

⁹ See GSD Rule 1 and MBSD Rule 1 (defining what constitutes Eligible Clearing Fund Securities and the components thereof, which are Eligible Clearing Fund Agency Securities, Eligible Clearing Fund Mortgage-Backed Securities, and Eligible Clearing Fund Treasury Securities), *supra* note 4.

¹⁰ See GSD Rule 4, Section 3b and MBSD Rule 4, Section 3b, *supra* note 4 (referencing the applicability of haircuts and concentration limits to certain types of Eligible Clearing Fund Securities).

¹¹ Notice of Filing, *supra* note 3, 88 FR at 68804.

¹² *Id.*

¹³ See Schedule of Haircuts for Eligible Clearing Fund Securities in the GSD Rules and MBSD Rules, *supra* note 4. The Schedule of Haircuts for Eligible Clearing Fund Securities in the GSD Rules and MBSD Rules was last modified in 2011 in order to harmonize with the increased haircuts on clearing fund collateral at the National Securities Clearing Corporation, an affiliate of FICC. See Securities Exchange Act Release No. 64488 (May 13, 2011), 76 FR 29018 (May 19, 2011) (SR–FICC–2011–03).

¹⁴ Notice of Filing, *supra* note 3, 88 FR at 68804. FICC also filed excerpts from its internal market risk management procedures as Confidential Exhibit 3b to its filing.

¹⁵ *Id.*

¹⁶ *Id.*

¹⁴ 17 CFR 200.30–3(a)(12).

¹⁵ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ See Securities Exchange Act Release No. 985925 (Sept. 28, 2023), 88 FR 68803 (Oct. 4, 2023) (File No. SR–FICC–2023–014) (“Notice of Filing”).

⁴ Capitalized terms not defined herein are defined in the GSD Rulebook (“GSD Rules”), available at https://www.dtcc.com/~media/Files/Downloads/legal/rules/ficc_gov_rules.pdf, or the MBSD Rulebook (“MBSD Rules”), available at https://www.dtcc.com/~media/Files/Downloads/legal/rules/ficc_mbsd_rules.pdf.

Fund Deposits in order to assess the sufficiency of the collateral haircuts applied and whether any haircut changes would be needed, taking into account backtesting results, any instances where the simulated losses from available historical stress testing scenario dates have exceeded the collateral haircut values, and market conditions.¹⁷

In addition to collateral haircuts, FICC applies concentration limits to certain Eligible Clearing Fund Securities set forth in the GSD and MBSD Rules. Under these limits, no more than 20 percent of a member's Required Fund Deposit may be in the form of Eligible Clearing Fund Agency Securities that are of a single issuer and no member may post as eligible collateral Eligible Clearing Fund Agency Securities of which it is the issuer.¹⁸ In addition, any deposits of Eligible Clearing Fund Agency Securities or Eligible Clearing Fund Mortgage-Backed Securities in excess of 25 percent of a member's Required Fund Deposit will be subject to a haircut that is twice the amount of the percentage noted in the haircut schedule, and a member may deposit Eligible Clearing Fund Mortgage-Backed Securities of which it is the issuer, however such securities will be subject to a premium haircut, with the initial haircut being 14 percent, and if a member also exceeds the 25 percent concentration limit, the haircut shall be 21 percent.¹⁹

Changes to the collateral haircuts and concentration limits are subject to FICC's internal governance process.²⁰ According to FICC and based on its internal risk management procedures, if FICC determines that, based on the analyses that it performs, there is insufficient/excessive collateral haircut/concentration due to an identifiable cause that affected multiple members and such cause would likely persist based on FICC's assessment of market conditions, such outcome or result could cause FICC to amend the haircuts/concentration limits in the haircut schedule.²¹ If FICC determines that a change to the haircut schedule is warranted, it would document the recommendation and rationale for the change at the time of such determination and obtain approval from an executive director or above with a notice to the risk management

committee.²² Before making adjustments to the haircut schedule, FICC measures the potential impact of such adjustments to ensure any impact is both necessary and appropriate.

III. Description of the Proposed Rule Change

In the Notice of Filing, FICC states that it has observed that under volatile market conditions with elevated frequency and magnitude of securities price movements, the collateral value of Eligible Clearing Fund Securities may shift in a relatively short period of time and the current haircuts may not sufficiently account for the change in value.²³ When the erosion in the value of the Eligible Clearing Fund Securities exceeds the relevant haircuts, FICC is exposed to increased risk of potential losses associated with liquidating a member's portfolio in the event of a member default when the defaulting member's own margin is insufficient to satisfy losses to FICC caused by the liquidation of that member's portfolio.²⁴ Similarly, when a member's portfolio contains large net unsettled positions in a particular group of securities with a similar risk profile or in a particular asset type, such securities could present additional risk to FICC.²⁵ The additional risk exposures associated with liquidating a member's portfolio in the event of a member default could lead to an increase in the likelihood that FICC would need to mutualize losses among non-defaulting members during the liquidation process.²⁶ However, any changes to the haircuts and/or concentration limits currently requires a proposed rule change to be filed with the Commission.

Therefore, to provide FICC with more flexibility in adjusting the haircuts and concentration limits so FICC can respond to changing market conditions more promptly in order to mitigate the additional risk exposure, FICC is proposing to remove the GSD and MBSD Schedules of Haircuts for Eligible Clearing Fund Securities and concentration limits from the respective Rules, and to publish the haircuts and concentration limits in a haircut schedule on FICC's website.²⁷

In addition, FICC is proposing to add language in Section 3b in GSD Rule 4 and Section 3c in MBSD Rule 4, respectively, that makes it clear that all Eligible Clearing Fund Securities pledged to secure Clearing Fund deposits shall, for collateral valuation purposes, be subject to a haircut and may be subject to a concentration limit. The proposed language would provide that FICC shall determine the applicable haircuts and any concentration limits from time to time in accordance with its internal policy and governance process, based on factors determined to be relevant by FICC, which may include, for example, backtesting results and FICC's assessment of market conditions, in order to set appropriately conservative haircuts and/or concentration limits for the Eligible Clearing Fund Securities and minimize backtesting deficiency occurrences. The proposed language would also provide that the haircuts and any concentration limits prescribed by FICC shall be set forth in a haircut schedule that is published on FICC's website. The proposed language would also state that it shall be the member's responsibility to retrieve the haircut schedule, and that FICC would provide members with at a minimum one Business Day's advance notice of any change in the haircut schedule.

FICC states that the proposed change to move the haircuts and concentration limits from the Rules to the website would enable FICC to adjust the haircuts and concentration limits without undergoing a rule filing process (although it could still necessitate an advance notice under Title VIII of the Dodd-Frank Act, if a change materially affects the nature or level of risks presented by FICC).²⁸ FICC states that by being able to make appropriate and timely adjustments to the haircuts and concentration limits, it would have the flexibility to respond to changing market conditions more promptly.²⁹ Having the flexibility to respond to changing market conditions more promptly would in turn help better ensure that FICC collects sufficient margin from members as well as risk manages its credit exposures to its members.³⁰

proposing to delete a sentence from Section 3b in GSD Rule 4 and Section 3c in MBSD Rule 4, respectively, that references haircuts set forth in the Rules, and add a general reference to applicable haircuts.

²⁸ Notice of Filing, *supra* note 3, 88 FR at 68806 and n. 8 (citing 12 U.S.C. 5465(e)(1) and 17 CFR 240.19b-4(n)(1)(i)).

²⁹ *Id.*

³⁰ *Id.*

¹⁷ *Id.* at 68804–05.

¹⁸ GSD Rule 4, Section 3b(b) and MBSD Rule 4, Section 3c(b), *supra* note 4.

¹⁹ Schedule of Haircuts for Eligible Clearing Fund Securities in GSD and MBSD Rules, *supra* note 4.

²⁰ Notice of Filing, *supra* note 3, 88 FR at 68805; see also note 14 *supra*.

²¹ *Id.*

²² *Id.*

²³ Notice of Filing, *supra* note 3, 88 FR at 68805.

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ Specifically, FICC is proposing to delete subsections (a), (b) and (c) of Section 3b (Special Provisions Relating to Deposits of Eligible Clearing Fund Securities) in GSD Rule 4 and Section 3c (Special Provisions Relating to Deposits of Eligible Clearing Fund Securities) in MBSD Rule 4, respectively, to remove all haircuts and concentration limits from the Rules. FICC is also

In its Notice of Filing, FICC also provides an overview regarding its changes to the categories relating to Treasury Inflation-Protected Securities (“TIPS”).³¹ FICC states that, as part of its daily backtesting regarding the adequacy of collateral haircuts, FICC has determined that in periods where the inflation rate fluctuates, the current haircut levels for TIPS have been

inadequate to address the fluctuations from time to time.³² This is because TIPS are indexed to the inflation rate, and prices on TIPS move inversely to their yields, *e.g.*, when the inflation rate increases, prices on TIPS decrease. When the decline in market value of TIPS exceeds the haircut for TIPS, FICC would be exposed to potential liquidation losses.³³

Accordingly, FICC is planning to address haircuts for TIPS in a separate category, as opposed to as part of a category also including Treasury Bills, Notes, and Bonds, and to increase the haircut levels for TIPS to ensure that the haircut levels would be commensurate with the particular risk attributes of TIPS.³⁴ FICC describes the new TIPS haircut categories as follows:³⁵

	Maturity	Current (%)	Proposed (%)
TIPS	Zero to 1 year	2.0	2.0
	1 year to 2 years	2.0	3.0
	2 years to 5 years	3.0	5.0
	5 years to 10 years	4.0	7.0
	10 years to 15 years	6.0	7.0
	15 years or greater	6.0	10.0

FICC conducted an impact study for the period from September 1, 2021 through August 31, 2022 (“Impact Study”).³⁶ The results of the Impact Study indicate that, if the haircut changes for TIPS had been in place, all 29 backtesting deficiencies would have been eliminated.³⁷

IV. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act³⁸ directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and rules and regulations thereunder applicable to such organization. After carefully considering the Proposed Rule Change, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to FICC. In particular, the Commission finds that the Proposed Rule Change is consistent with section 17A(b)(3)(F)³⁹ of the Act and Rules

17Ad–22(e)(5) and (e)(23), each promulgated under the Act.⁴⁰

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act⁴¹ requires that the rules of a clearing agency, such as FICC, be designed to, among other things, promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.⁴² The Commission believes that the Proposed Rule Change is consistent with section 17A(b)(3)(F) of the Act for the reasons stated below.

As stated in Part II *supra*, a key tool that FICC uses to manage its credit exposures to its members is the daily collection of margin from each member described above, and FICC applies haircuts to securities collected as margin to protect FICC and its members from price fluctuations, *i.e.*, if FICC is required to liquidate collateral of an insolvent member and such collateral is worth less at the time of liquidation than when it is pledged to FICC.

By moving the location where collateral haircuts and concentration limits are published from FICC’s Rules to its website, the Proposed Rule change would add flexibility for FICC to make timely adjustments to collateral haircuts and concentration limits during a time of potentially deteriorating market or other conditions, while preserving notice requirements to ensure that members are aware of risk management changes. This added flexibility should allow FICC to continue to ensure that it can address changing market conditions rapidly and ensure that it is collecting sufficient margin to cover its credit exposures to members and minimizing exposures from members with large collateral positions in a particular group of securities with a similar risk profile or in a particular asset type.⁴³

By helping FICC to collect sufficient margin, the Proposed Rule Change would better ensure that, in the event of a member default, FICC’s operation of its critical clearance and settlement services would not be disrupted because of insufficient financial resources. Accordingly, the Proposed Rule Change should help FICC to continue providing

³¹ TIPS are a type of Treasury security issued by the U.S. government that are indexed to inflation such that the principal value of the security rises as inflation rises.

³² Notice of Filing, *supra* note 3, 88 FR at 68806.

³³ *Id.* Specifically, during the period from September 1, 2021 to August 31, 2022, with TIPS comprising less than 10 percent of the total collateral value across the GSD and MBS divisions at FICC, FICC has observed 29 backtesting deficiencies at FICC, 26 at GSD and 3 at MBS, where the collateral value that FICC attributed to the TIPS that were posted by members as margin (inclusive of the applicable current haircuts) was insufficient to cover the liquidation of such securities by FICC without incurring a loss. *Id.* The 29 backtesting deficiencies represent a sum total of approximately \$9.4 million across four days during

the impact study period, less than 0.1% of the total collateral value at FICC on each of those days. *Id.*

³⁴ *Id.* FICC also stated that its review of TIPS haircuts at other registered clearing agencies demonstrate that FICC’s current haircut levels for TIPS are generally lower than the TIPS haircuts required by other clearing agencies and foreign CCPs, particularly with respect to maturity ranges of 10 years or longer. *Id.* (summarizing and citing various other clearing agency rules).

³⁵ *Id.* FICC also reflected the changes with respect to haircuts for TIPS on the haircut schedule filed as Exhibit 3c to the Notice of Filing, which would be posted to its website if the Proposed Rule Change were approved.

³⁶ FICC filed this Impact Study as confidential Exhibit 3a to the Notice of Filing.

³⁷ Notice of Filing, *supra* note 3, 88 FR at 68807 (also providing a more detailed summary of the Impact Study).

³⁸ 15 U.S.C. 78s(b)(2)(C).

³⁹ 15 U.S.C. 78q–1(b)(3)(F).

⁴⁰ 17 CFR 240.17Ad–22(e)(5) and (e)(23).

⁴¹ 15 U.S.C. 78q–1(b)(3)(F).

⁴² *Id.*

⁴³ In addition, the Commission believes that the changes relating to the haircuts for TIPS would allow FICC to ensure that the haircut levels would be commensurate with the particular risk attributes of TIPS, and thereby assure the safeguarding of securities and funds that are in its custody or control.

prompt and accurate clearance and settlement of securities transactions, consistent with section 17A(b)(3)(F) of the Act.⁴⁴

Moreover, because the Proposed Rule Change would continue to ensure that FICC collects sufficient margin from members, it should also help minimize the likelihood that FICC would have to access the Clearing Fund, thereby limiting non-defaulting members' exposure to mutualized losses. By helping to limit the exposure of FICC's non-defaulting members to mutualized losses, the Proposed Rule Change should help FICC assure the safeguarding of securities and funds which are in its custody or control, consistent with section 17A(b)(3)(F) of the Act.⁴⁵

Finally, the proposed clarifying changes should help to ensure that FICC's Rules are clear to members. When members better understand their rights and obligations regarding the Rules, members are more likely to act in accordance with the Rules, which should promote the prompt and accurate clearance and settlement of securities transactions. As such, the proposed clarifying changes are consistent with section 17A(b)(3)(F) of the Act.⁴⁶

B. Consistency With Rule 17Ad-22(e)(5)

Rule 17Ad-22(e)(5) under the Act⁴⁷ requires, in part, a covered clearing agency to establish, implement, maintain and enforce written policies and procedures reasonably designed to set and enforce appropriately conservative haircuts and concentration limits if the covered clearing agency requires collateral to manage its or its participants' credit exposure. As described in Part II *supra*, the proposed changes to move the collateral haircuts and concentration limits from FICC's Rules should provide FICC with more flexibility to respond to changing market conditions because adjustments to the haircuts and concentration limits would no longer require a rule change. By being able to make appropriate and timely adjustments to the haircuts and concentration limits, FICC would have the flexibility to respond to changing market conditions more promptly. Specifically, FICC would have the ability to promptly set and enforce conservative collateral haircuts and concentration limits that are reflective of the current market conditions. In this way, the proposed changes to move the

collateral haircuts and concentration limits from the Rules to the website should help FICC set and enforce appropriately conservative collateral haircuts and concentration limits, consistent with the requirements of Rule 17Ad-22(e)(5) under the Act.⁴⁸

C. Consistency With Rule 17Ad-22(e)(23)

Rule 17Ad-22(e)(23)(i) and (ii)⁴⁹ under the Act requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to, among other things, publicly disclose all relevant rules and material procedures; and provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency. Based on its review of the record, and for the reasons described below, the Commission finds that the proposed changes, taken together, are consistent with the requirements of Rule 17Ad-22(e)(23)(i) and (ii).⁵⁰

By adopting rules that require FICC to provide prior notice through public disclosures on its website relating to information on collateral haircuts and concentration limits, FICC's Rules would support the communication of information that its members may use to identify and evaluate the haircuts and concentration limits resulting from FICC's processes. As such, the Proposed Rule Change is consistent with publicly disclosing all relevant rules and material procedures; and providing sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs incurred with participation in the covered clearing agency. The Commission finds, therefore, that the Proposed Rule Change is consistent with the requirements of Rule 17Ad-22(e)(23)(i) and (ii) under the Act.⁵¹

IV. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and in particular with the requirements of section 17A of the Act⁵² and the rules and regulations promulgated thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act⁵³ that

⁴⁸ *Id.*

⁴⁹ 17 CFR 240.17Ad-22(e)(23)(i) and (ii).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² 15 U.S.C. 78q-1.

⁵³ 15 U.S.C. 78s(b)(2).

proposed rule change SR-FICC-2023-014, be, and hereby is, *approved*.⁵⁴

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵⁵

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98891; File No. SR-NYSE-2023-40]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.31

November 8, 2023.

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 31, 2023, 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, II, and III 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 amend Rule 7.31 to provide for the use of ALO Reserve Orders. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text

⁵⁴ In approving the Proposed Rule Change, the Commission considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

⁵⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴⁴ 15 U.S.C. 78q-1(b)(3)(F).

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ 17 CFR 240.17Ad-22(e)(5).

of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31 to provide for the use of ALO Reserve Orders.

ALO Orders

Rule 7.31(e)(2) defines an ALO Order as a Non-Routable Limit Order that, unless it receives price improvement, will not remove liquidity from the Exchange Book. An ALO Order can be designated to be cancelled if it would be displayed at a price other than its limit price for any reason. An ALO Order can be designated as non-displayed.

As described in Rule 7.31(e)(2)(A), an Aggressing ALO Order to buy (sell) will trade if its limit price crosses the working price of any displayed or non-displayed orders to sell (buy) on the Exchange Book priced equal to or below (above) the PBO (PBB) of an Away Market, in which case it will trade as the liquidity taker with such orders.

As noted above, Rule 7.31(e)(2) provides that an ALO Order may be designated to cancel if it would be displayed at a price other than its limit price. If an ALO Order is not so designated, any untraded quantity of such order to buy (sell) is processed as follows (Rules 7.31(e)(2)(B)(i) and (ii)):

- If the limit price of the ALO Order locks the display price of any order to sell (buy) ranked Priority 2—Display Orders on the Exchange Book, it will have a working price and display price (if designated to display) one MPV below (above) the price of the displayed order on the Exchange Book.

- If the limit price of the ALO Order locks or crosses the PBO (PBB) of an Away Market, it will have a working price equal to the PBO (PBB) of the Away Market and a display price (if designated to display) one MPV below (above) the PBO (PBB) of the Away Market.

Rule 7.31(e)(2)(C) provides that any untraded quantity of an ALO Order to buy (sell) will have a working price and display price (if designated to display) equal to its limit price if it locks non-displayed orders to sell (buy) on the Exchange Book. Rule 7.31(e)(2)(D) provides that an ALO Order to buy (sell) will not be assigned a working price or

display price above (below) the limit price of such order.

Once resting on the Exchange Book, ALO Orders may be re-priced or trade, or both, as described in Rule 7.31(e)(2)(E):

- If order(s) to sell (buy) ranked Priority 2—Display Orders or the PBO (PBB) of an Away Market re-prices higher (lower), an ALO Order to buy (sell) will trade or be priced, or both, consistent with Rules 7.31(e)(2)(A), (e)(2)(B)(i) and (ii), and (e)(2)(C).
- If the PBO (PBB) of an Away Market re-prices lower (higher) to be equal to or lower (higher) than its last display price or if its limit price no longer locks or crosses the PBO (PBB) of the Away Market, an ALO Order to buy (sell) will be priced pursuant to Rules 7.31(e)(1)(A)(ii)(c) and (d). If the PBO (PBB) of an Away Market re-prices lower (higher) than the working price of a non-displayed ALO Order to buy (sell), such order will have a working price equal to the PBO (PBB) of the Away Market.

Reserve Orders

Rule 7.31(d)(1) provides for Reserve Orders, which are Limit or Inside Limit Orders with a quantity of the size displayed and with a reserve quantity ("reserve interest") of the size that is not displayed. The displayed quantity of a Reserve Order is ranked Priority 2—Display Orders, and the reserve interest is ranked Priority 3—Non-Display Orders. Both the display quantity and the reserve interest of an arriving marketable Reserve Order are eligible to trade with resting interest in the Exchange Book or to route to Away Markets. The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in Rule 7.31(d)(2)(A).

As described in Rule 7.31(d)(1)(A), the display quantity of a Reserve Order must be entered in round lots, and the displayed portion of a Reserve Order will be replenished when the display quantity is decremented to below a round lot. The replenish quantity will be the minimum display size of the order or the remaining quantity of the reserve interest if it is less than the minimum display quantity.

Rule 7.31(d)(1)(B) provides that each time the display quantity of a Reserve Order is replenished from reserve interest, a new working time is assigned to the replenished quantity (each display quantity with a different time is referred to as a "child" order), while the reserve interest retains the working time of the original order entry. In addition, when a Reserve Order is replenished

from reserve interest and already has two child orders that equal less than a round lot, the child order with the later working time will rejoin the reserve interest and be assigned the new working time assigned to the next replenished quantity. If a Reserve Order is not routable, the replenish quantity will be assigned a display and working price consistent with the instructions for the order.

Rule 7.31(d)(1)(C) provides that a Reserve Order must be designated Day and may only be combined with a D Order, Non-Routable Limit Order, or Primary Pegged Order. Rule 7.31(d)(1)(C) also currently provides that a Reserve Order may not be designated as an ALO Order.

Rule 7.31(d)(1)(D) provides that routable Reserve Orders will be evaluated for routing both on arrival and each time their display quantity is replenished.

Rule 7.31(d)(1)(E) provides that a request to reduce the size of a Reserve Order will cancel the reserve interest before cancelling the display quantity, and, if the Reserve Order has more than one child order, the child order with the latest working time will be cancelled first.

Rule 7.31(d)(1)(F) provides that, if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of such Reserve Order will not change and the reserve interest that replenishes the display quantity will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Rule 7.31(d)(1)(F) further provides that, when the PBBO uncrosses, the display price and working price will be adjusted as provided for under Rule 7.31(e)(1) relating to Non-Routable Limit Orders.

ALO Reserve Orders

The Exchange proposes to amend Rule 7.31 to provide for the use of ALO Reserve Orders. The proposed change is not intended to introduce any new functionality or modify any current functionality, but rather to facilitate the combination of two order types currently offered by the Exchange. As proposed, ALO Reserve Orders would, except as otherwise noted, operate consistent with current Rule 7.31(d)(1) regarding Reserve Orders and current Rule 7.31(e)(2) regarding ALO Orders. To allow for the use of ALO Reserve Orders, the Exchange first proposes to amend Rule 7.31(d)(1)(C) to delete the last sentence of such rule, which

currently provides that a Reserve Order may not be designated as an ALO Order.

The proposed change is intended to allow ALO Orders, as described in Rule 7.31(e)(2) and the paragraphs thereunder,⁴ to have a displayed quantity, along with non-displayed reserve interest, as described in Rule 7.31(d)(1). The display quantity of an ALO Reserve Order would be replenished as provided in Rules 7.31(d)(1)(A) and (B). As ALO Reserve Orders are non-routable, under Rule 7.31(d)(1)(B)(ii), the replenish quantity of an ALO Reserve Order would be assigned a display price and working price consistent with the behavior of ALO Orders as described in current Exchange rules.

Aggressing ALO Reserve Orders would trade in accordance with current Rule 7.31(e)(2)(A). If an ALO Reserve Order is designated to cancel, it will cancel if it would be displayed at a price other than its limit price for any reason, as described in Rule 7.31(e)(2). Otherwise, any untraded quantity of an ALO Reserve Order would continue to be processed as ALO Orders are currently, as described in Rules 7.31(e)(2)(B) and (C). Similarly, the working price of the reserve interest of a resting ALO Reserve Order would be adjusted as provided for in Rule 7.31(d)(1) (*i.e.*, in accordance with Rule 7.31(d)(2)(A)). Rule 7.31(d)(1)(E) would also apply to requests to reduce the size of ALO Reserve Orders.

As described in Rule 7.31(d)(1)(F), when the PBBO is crossed and the display quantity of an ALO Reserve Order to buy (sell) is decremented to less than a round lot, the display price and working price of the order would not change, but the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). The Exchange proposes to amend Rule 7.31(d)(1)(F) to add new rule text describing how the display price and working price of an ALO Reserve Order would be adjusted when a previously crossed PBBO uncrosses. Specifically, the Exchange proposes to add text to the last sentence of Rule 7.31(d)(1)(F) providing that the display price and working price of an ALO Reserve Order would be adjusted in accordance with Rule 7.31(e)(2)(E), which describes how ALO Orders resting on the Exchange Book are repriced and/or traded.

Because ALO Orders behave differently from other Non-Routable Limit Orders and may only trade when they receive price improvement, the Exchange proposes to add text to Rule 7.31(e)(2)(F) clarifying that ALO Reserve Orders would have their display price and working price adjusted consistent with the rules applicable to ALO Orders when the PBBO uncrosses.

The proposed change is intended to facilitate the combined use of two existing order types available on the Exchange, thereby providing member organizations with enhanced flexibility and optionality when trading on the Exchange. The proposed change could also promote increased liquidity and trading opportunities on the Exchange, to the benefit of all market participants. The Exchange also believes the proposed change would permit the Exchange to offer functionality already available on at least one other equities exchange, thereby promoting competition among equities exchanges.⁵

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 in the fourth quarter of 2023.

2. Statutory Basis

The proposed rule change is consistent with section 6(b) of the Act,⁶ in general, and furthers the objectives of section 6(b)(5),⁷ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market because it would allow for the combined use of two existing order types available on the Exchange and permit the Exchange to offer functionality similar to that already

available on at least one other equities exchange.⁸ Member organizations would be free to choose to use the proposed ALO Reserve Order type or not, and the proposed change would not otherwise impact the operation of the Reserve Order or ALO Order as described in current Exchange rules. The Exchange also believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market, as well as protect investors and the public interest, by expanding the options available to member organizations when trading on the Exchange and promoting increased liquidity and additional trading opportunities for all market participants.

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. In addition, as noted above, Exchange believes the proposed rule change would allow the Exchange to offer functionality already available on at least one other equities exchange⁹ and thus would promote competition among equities exchanges. The Exchange also believes that, to the extent the proposed change increases opportunities for order execution, the proposed change would promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ 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

⁵ See, e.g., MEMX Rules 11.8(b)(4) and (7) (providing that a Limit Order may include a reserve quantity and may be designated with a Post Only instruction); see also MEMX User Manual, available at <https://info.memxtrading.com/wp-content/uploads/2023/03/MEMX-User-Manual-03.10.23.pdf>, at 9 (providing that a Limit Order designated Day may have both reserve quantity and Post Only instructions).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

⁸ See note 5, *supra*.

⁹ See *id.*

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

⁴ The Exchange does not propose to allow non-displayed ALO Orders to be designated as Reserve Orders, given that a Reserve Order must have both displayed and non-displayed portions, and thus proposes to amend Rule 7.31(e)(2) to specify accordingly.

it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B) ¹³ of the Act 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-NYSE-2023-40 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-2023-40. 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-2023-40 and should be submitted on or before December 6, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023-25107 Filed 11-14-23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98894; File No. SR-NYSEARCA-2023-76]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule

November 9, 2023.

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 31, 2023, NYSE Arca, Inc. ("NYSE Arca" 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.

¹⁴ 17 CFR 200.30-3(a)(12).

¹⁵ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule ("Fee Schedule") regarding certain Customer incentives. The Exchange proposes to implement the fee change effective November 1, 2023. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend the Fee Schedule to modify a qualification basis applicable to the Customer Penny Posting Credit Tiers, Customer Posting Credits [sic] in Non-Penny Issues, and Customer Incentive Program. The Exchange proposes to implement the rule change on November 1, 2023.

The Fee Schedule provides for certain incentive programs through which an OTP Holder or OTP Firm (collectively, "OTP Holder") may earn credits on posted interest. The Customer Penny Posting Credit Tiers offers qualifying OTP Holders tiered credits on electronic executions of Customer posted interest in Penny issues, and the Customer Penny [sic] Posting Credit Tiers in Non-Penny Issues offers qualifying OTP Holders tiered credits on electronic executions of Customer posted interest in non-Penny issues.⁴ OTP Holders may also qualify for the Customer Incentive Program, which offers an additional

⁴ See Fee Schedule, CUSTOMER PENNY POSTING CREDIT TIERS; CUSTOMER POSTING CREDIT TIERS IN NON-PENNY ISSUES.

¹² 17 CFR 240.19b-4(f)(6)(iii). 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 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.

¹³ 15 U.S.C. 78s(b)(2)(B).

credit on Customer posting credits in Penny or non-Penny issues.⁵

Currently, an OTP Holder that achieves 0.30% of TCADV from Customer posted interest in all issues, not including Professional Customer interest, plus executed ADV of 0.60% of U.S. equity market share posted and executed on the NYSE Arca Equities market will qualify for the credits offered in Tier 4 of the Customer Penny Posting Credit Tiers, Tier C of the Customer Posting Credit Tiers in Non-Penny Issues, and the Customer Incentive Program.

The Exchange now proposes to adjust this qualifying basis for each of the Customer Penny Posting Credit Tiers, Customer Posting Credits [sic] in Non-Penny Issues, and Customer Incentive Program to reduce the Customer posted interest TCADV requirement from 0.30% to 0.20% and the equity market ADV requirement from 0.60% to 0.50%. In other words, as proposed, an OTP Holder could qualify for Tier 4 of the Customer Penny Posting Credit Tiers, Tier C of the Customer Posting Credit Tiers in Non-Penny Issues, and the Customer Incentive Program by achieving at least 0.20% of TCADV from Customer posted interest in all issues, not including Professional Customer interest, plus executed ADV of 0.50% of U.S. equity market share posted and executed on the NYSE Arca Equities market.

The Exchange does not propose any changes to the amounts of the credits offered in the Customer Penny Posting Credit Tiers, Customer Posting Credits [sic] in Non-Penny Issues, or Customer Incentive Program. Accordingly, OTP Holders who achieve the proposed qualification described above would continue to be eligible for the (\$0.47) on electronic executions of Customer posted interest in Penny issues through Tier 4 of the Customer Penny Posting Credit Tiers; the (\$0.97) credit applied to electronic executions of Customer posted interest in non-Penny issues through the Customer Posting Credits [sic] in Non-Penny Issues; and/or the additional (\$0.03) credit on Customer posting credits offered in the Customer Incentive Program.

The Exchange cannot predict with certainty whether any OTP Holders would seek to qualify for the Customer Penny Posting Credit Tiers, Customer Posting Credit Tiers in Non-Penny Issues, or Customer Incentive Program. However, the Exchange believes that the proposed change would continue to encourage OTP Holders to direct

Customer posted interest to the Exchange by reducing the volume requirements for certain credits on Customer posted interest, thereby potentially making such credits more attainable for OTP Holders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,⁷ in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system “has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.”⁸

There are currently 17 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.⁹ Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in September 2023, the Exchange had less than 12% market share of executed volume of multiply-listed equity and ETF options trades.¹⁰

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(4) and (5).

⁸ See Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7-10-04) (“Reg NMS Adopting Release”).

⁹ The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: <https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics>.

¹⁰ Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.*, the Exchange’s market share in equity-based options increased from 10.84% for the month of

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, modifications to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The Exchange believes that the proposed changes to the Customer Penny Posting Credit Tiers, Customer Posting Credit Tiers in Non-Penny Issues, and Customer Incentive Program are reasonable because they are intended to continue to incentivize OTP Holders to send Customer posting interest to the Exchange in order to earn credits on such interest. The Exchange also believes the proposed change is reasonable because it decreases certain volume requirements for the Customer Penny Posting Credit Tiers, Customer Posting Credit Tiers in Non-Penny Issues, and Customer Incentive Program, which could make credits offered in those programs more attainable for OTP Holders.

To the extent the proposed rule change attracts greater volume and liquidity by encouraging OTP Holders to increase their options volume on the Exchange, the Exchange believes the proposed change would improve the Exchange’s overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors.

The Proposed Rule Change Is an Equitable Allocation of Credits and Fees

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits. The proposal is based on the amount and type of business transacted on the Exchange, and OTP Holders can opt to attempt to qualify for the various Customer posting credits or not. Moreover, the proposal is designed to continue to incentivize OTP Holders to aggregate all Customer posting interest at the Exchange as a primary execution venue. To the extent that the proposed change attracts more opportunities for execution of Customer posted interest on the Exchange, this increased order flow would continue to

⁵ See Fee Schedule, CUSTOMER INCENTIVE PROGRAM.

September 2022 to 11.48% for the month of September 2023.

make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes the proposed changes are not unfairly discriminatory because they would apply to all similarly-situated market participants, and the credits offered in the Customer Penny Posting [sic] Tiers, Customer Posting Credit Tiers in Non-Penny Issues, and Customer Incentive Program would continue to be available to all similarly-situated market participants on an equal and non-discriminatory basis.

The proposed change is based on the amount and type of business transacted on the Exchange, and OTP Holders are not obligated to try to qualify for the various credits, nor are they obligated to execute posted interest. To the extent that the proposed change attracts more interest to the Exchange, particularly Customer posting interest, this increased order flow would continue to make the Exchange a more competitive venue for order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange thereby improving market-wide quality and price discovery. The resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed

change would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes "more efficient pricing of individual stocks for all types of orders, large and small."¹¹

Intramarket Competition. The proposed change is designed to attract additional order flow to the Exchange, particularly Customer posted interest. The Exchange believes that the proposed change would continue to incent OTP Holders to direct Customer posting interest to the Exchange in order to earn the credits available through the Customer Penny Posting Credit Tiers, Customer Posting Credit Tiers in Non-Penny Issues, and Customer Incentive Program. Greater liquidity benefits all market participants on the Exchange and increased liquidity-posting order flow would increase opportunities for execution of other trading interest. The proposed change would apply to all similarly-situated market participants and, accordingly, would not impose a disparate burden on competition among market participants on the Exchange.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 17 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.¹² Therefore, currently no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in September 2023, the Exchange had less than 12% market

share of executed volume of multiply-listed equity and ETF options trades.¹³

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees in a manner designed to continue to incent OTP Holders to direct trading to the Exchange, to provide liquidity and to attract order flow. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement.

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

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)¹⁴ of the Act and subparagraph (f)(2) of Rule 19b-4¹⁵ thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹⁶ of the Act 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:

¹³ Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of equity-based ETF options, *see id.*, the Exchange's market share in equity-based options increased from 10.84% for the month of September 2022 to 11.48% for the month of September 2023.

¹⁴ 15 U.S.C. 78s(b)(3)(A).

¹⁵ 17 CFR 240.19b-4(f)(2).

¹⁶ 15 U.S.C. 78s(b)(2)(B).

¹¹ See Reg NMS Adopting Release, *supra* note 8, at 37499.

¹² The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, available here: <https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics>.

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-NYSEARCA-2023-76 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEARCA-2023-76. 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-NYSEARCA-2023-76 and should be submitted on or before December 6, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023-25204 Filed 11-14-23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98899; File No. SR-NYSEARCA-2023-77]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.31-E

November 9, 2023.

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 31, 2023, NYSE Arca, Inc. ("NYSE Arca" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III 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 amend Rule 7.31-E to provide for the use of ALO Reserve Orders. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31-E to provide for the use of ALO Reserve Orders.

ALO Orders

Rule 7.31-E(e)(2) defines an ALO Order as a Non-Routable Limit Order that, unless it receives price improvement, will not remove liquidity from the NYSE Arca Book. An ALO Order can be designated to be cancelled if it would be displayed at a price other than its limit price for any reason. An ALO Order can be designated as non-displayed.

As described in Rule 7.31-E(e)(2)(A), an Aggressing ALO Order to buy (sell) will trade if its limit price crosses the working price of any displayed or non-displayed orders to sell (buy) on the NYSE Arca Book priced equal to or below (above) the PBO (PBB) of an Away Market, in which case it will trade as the liquidity taker with such orders.

As noted above, Rule 7.31-E(e)(2) provides that an ALO Order may be designated to cancel if it would be displayed at a price other than its limit price. If an ALO Order is not so designated, any untraded quantity of such order to buy (sell) is processed as follows (Rules 7.31-E(e)(2)(B)(i) and (ii)):

- If the limit price of the ALO Order locks the display price of any order to sell (buy) ranked Priority 2—Display Orders on the NYSE Arca Book, it will have a working price and display price (if designated to display) one MPV below (above) the price of the displayed order on the NYSE Arca Book.

- If the limit price of the ALO Order locks or crosses the PBO (PBB) of an Away Market, it will have a working price equal to the PBO (PBB) of the Away Market and a display price (if designated to display) one MPV below (above) the PBO (PBB) of the Away Market.

Rule 7.31-E(e)(2)(C) provides that any untraded quantity of an ALO Order to buy (sell) will have a working price and display price (if designated to display) equal to its limit price if it locks non-displayed orders to sell (buy) on the NYSE Arca Book. Rule 7.31-E(e)(2)(D) provides that an ALO Order to buy (sell) will not be assigned a working price or display price above (below) the limit price of such order.

Once resting on the NYSE Arca Book, ALO Orders may be re-priced or trade, or both, as described in Rule 7.31-E(e)(2)(E):

- If order(s) to sell (buy) ranked Priority 2—Display Orders or the PBO (PBB) of an Away Market re-prices higher (lower), an ALO Order to buy (sell) will trade or be priced, or both, consistent with Rules 7.31-E(e)(2)(A), (e)(2)(B)(i) and (ii), and (e)(2)(C).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

¹⁷ 17 CFR 200.30-3(a)(12).

- If the PBO (PBB) of an Away Market re-prices lower (higher) to be equal to or lower (higher) than its last display price or if its limit price no longer locks or crosses the PBO (PBB) of the Away Market, an ALO Order to buy (sell) will be priced pursuant to Rules 7.31–E(e)(1)(A)(ii)(c) and (d). If the PBO (PBB) of an Away Market re-prices lower (higher) than the working price of a non-displayed ALO Order to buy (sell), such order will have a working price equal to the PBO (PBB) of the Away Market.

Reserve Orders

Rule 7.31–E(d)(1) provides for Reserve Orders, which are Limit or Inside Limit Orders with a quantity of the size displayed and with a reserve quantity (“reserve interest”) of the size that is not displayed. The displayed quantity of a Reserve Order is ranked Priority 2—Display Orders, and the reserve interest is ranked Priority 3—Non-Display Orders. Both the display quantity and the reserve interest of an arriving marketable Reserve Order are eligible to trade with resting interest in the NYSE Arca Book or to route to Away Markets. The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in Rule 7.31–E(d)(2)(A).

As described in Rule 7.31–E(d)(1)(A), the display quantity of a Reserve Order must be entered in round lots, and the displayed portion of a Reserve Order will be replenished when the display quantity is decremented to below a round lot. The replenish quantity will be the minimum display size of the order or the remaining quantity of the reserve interest if it is less than the minimum display quantity.

Rule 7.31–E(d)(1)(B) provides that each time the display quantity of a Reserve Order is replenished from reserve interest, a new working time is assigned to the replenished quantity (each display quantity with a different time is referred to as a “child” order), while the reserve interest retains the working time of the original order entry. In addition, when a Reserve Order is replenished from reserve interest and already has two child orders that equal less than a round lot, the child order with the later working time will rejoin the reserve interest and be assigned the new working time assigned to the next replenished quantity. If a Reserve Order is not routable, the replenish quantity will be assigned a display and working price consistent with the instructions for the order.

Rule 7.31–E(d)(1)(C) provides that a Reserve Order must be designated Day and may only be combined with a Non-

Routable Limit Order or a Primary Pegged Order. Rule 7.31–E(d)(1)(C) also currently provides that a Reserve Order may not be designated as an ALO Order.

Rule 7.31–E(d)(1)(D) provides that routable Reserve Orders will be evaluated for routing both on arrival and each time their display quantity is replenished.

Rule 7.31–E(d)(1)(E) provides that a request to reduce the size of a Reserve Order will cancel the reserve interest before cancelling the display quantity, and, if the Reserve Order has more than one child order, the child order with the latest working time will be cancelled first.

Rule 7.31–E(d)(1)(F) provides that, if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of such Reserve Order will not change and the reserve interest that replenishes the display quantity will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Rule 7.31–E(d)(1)(F) further provides that, when the PBBO uncrosses, the display price and working price will be adjusted as provided for under Rule 7.31–E(e)(1) relating to Non-Routable Limit Orders.

ALO Reserve Orders

The Exchange proposes to amend Rule 7.31–E to provide for the use of ALO Reserve Orders. The proposed change is not intended to introduce any new functionality or modify any current functionality, but rather to facilitate the combination of two order types currently offered by the Exchange. As proposed, ALO Reserve Orders would, except as otherwise noted, operate consistent with current Rule 7.31–E(d)(1) regarding Reserve Orders and current Rule 7.31–E(e)(2) regarding ALO Orders. To allow for the use of ALO Reserve Orders, the Exchange first proposes to amend Rule 7.31–E(d)(1)(C) to delete the last sentence of such rule, which currently provides that a Reserve Order may not be designated as an ALO Order.

The proposed change is intended to allow ALO Orders, as described in Rule 7.31–E(e)(2) and the paragraphs thereunder,⁴ to have a displayed quantity, along with non-displayed reserve interest, as described in Rule 7.31–E(d)(1). The display quantity of an

ALO Reserve Order would be replenished as provided in Rules 7.31–E(d)(1)(A) and (B). As ALO Reserve Orders are non-routable, under Rule 7.31–E(d)(1)(B)(ii), the replenish quantity of an ALO Reserve Order would be assigned a display price and working price consistent with the behavior of ALO Orders as described in current Exchange rules.

Aggregating ALO Reserve Orders would trade in accordance with current Rule 7.31–E(e)(2)(A). If an ALO Reserve Order is designated to cancel, it will cancel if it would be displayed at a price other than its limit price for any reason, as described in Rule 7.31–E(e)(2). Otherwise, any untraded quantity of an ALO Reserve Order would continue to be processed as ALO Orders are currently, as described in Rules 7.31–E(e)(2)(B) and (C). Similarly, the working price of the reserve interest of a resting ALO Reserve Order would be adjusted as provided for in Rule 7.31–E(d)(1) (*i.e.*, in accordance with Rule 7.31–E(d)(2)(A)). Rule 7.31–E(d)(1)(E) would also apply to requests to reduce the size of ALO Reserve Orders.

As described in Rule 7.31–E(d)(1)(F), when the PBBO is crossed and the display quantity of an ALO Reserve Order to buy (sell) is decremented to less than a round lot, the display price and working price of the order would not change, but the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). The Exchange proposes to amend Rule 7.31–E(d)(1)(F) to add new rule text describing how the display price and working price of an ALO Reserve Order would be adjusted when a previously crossed PBBO uncrosses. Specifically, the Exchange proposes to add text to the last sentence of Rule 7.31–E(d)(1)(F) providing that the display price and working price of an ALO Reserve Order would be adjusted in accordance with Rule 7.31–E(e)(2)(E), which describes how ALO Orders resting on the NYSE Arca Book are repriced and/or traded. Because ALO Orders behave differently from other Non-Routable Limit Orders and may only trade when they receive price improvement, the Exchange proposes to add text to Rule 7.31–E(e)(2)(F) clarifying that ALO Reserve Orders would have their display price and working price adjusted consistent with the rules applicable to ALO Orders when the PBBO uncrosses.

The proposed change is intended to facilitate the combined use of two existing order types available on the Exchange, thereby providing ETP Holders with enhanced flexibility and

⁴ The Exchange does not propose to allow non-displayed ALO Orders to be designated as Reserve Orders, given that a Reserve Order must have both displayed and non-displayed portions, and thus proposes to amend Rule 7.31–E(e)(2) to specify accordingly.

optionality when trading on the Exchange. The proposed change could also promote increased liquidity and trading opportunities on the Exchange, to the benefit of all market participants. The Exchange also believes the proposed change would permit the Exchange to offer functionality already available on at least one other equities exchange, thereby promoting competition among equities exchanges.⁵

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 in the fourth quarter of 2023.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Section 6(b)(5),⁷ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market because it would allow for the combined use of two existing order types available on the Exchange and permit the Exchange to offer functionality similar to that already available on at least one other equities exchange.⁸ ETP Holders would be free to choose to use the proposed ALO Reserve Order type or not, and the proposed change would not otherwise impact the operation of the Reserve Order or ALO Order as described in current Exchange rules. The Exchange also believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market, as well as protect investors and the public interest, by expanding the options available to ETP Holders

when trading on the Exchange and promoting increased liquidity and additional trading opportunities for all market participants.

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. In addition, as noted above, Exchange believes the proposed rule change would allow the Exchange to offer functionality already available on at least one other equities exchange⁹ and thus would promote competition among equities exchanges. The Exchange also believes that, to the extent the proposed change increases opportunities for order execution, the proposed change would promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may

temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹³ of the Act 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-NYSEARCA-2023-77 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-NYSEARCA-2023-77. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the 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;

⁵ See, e.g., MEMX Rules 11.8(b)(4) and (7) (providing that a Limit Order may include a reserve quantity and may be designated with a Post Only instruction); see also MEMX User Manual, available at <https://info.memxtrading.com/wp-content/uploads/2023/03/MEMX-User-Manual-03.10.23.pdf>, at 9 (providing that a Limit Order designated Day may have both reserve quantity and Post Only instructions).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

⁸ See note 5, *supra*.

⁹ See *id.*

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii). 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 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.

¹³ 15 U.S.C. 78s(b)(2)(B).

you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR-NYSEARCA-2023-77 and should be submitted on or before December 6, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98898; File No. SR-NYSECHX-2023-19]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.37

November 9, 2023.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”)² and Rule 19b-4 thereunder,³ notice is hereby given that on November 2, 2023, the NYSE Chicago, Inc. (“NYSE Chicago” 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 amend Rule 7.37 to specify the Exchange’s source of data feeds from MIAX PEARL, LLC (“MIAX PEARL”) for purposes of order handling, order execution, order routing, and regulatory compliance. The proposed rule change is available on the Exchange’s website at www.nyse.com, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to update and amend the use of data feeds table in Rule 7.37(d), which sets forth on a market-by-market basis the specific securities information processor (“SIP”) and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks related to each of those functions. Specifically, the Exchange proposes to amend the table in Rule 7.37(d) to specify that, with respect to MIAX PEARL, the Exchange will receive a MIAX PEARL direct feed as its primary source of data for order handling, order execution, order routing, and regulatory compliance, and will use the SIP Data Feed as its secondary source for data from MIAX PEARL.

The Exchange proposes to make this change operative in the fourth quarter of 2023, and, in any event, before December 31, 2023.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,⁴ in general, and furthers the objectives of Section 6(b)(5),⁵ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Additionally, the Exchange believes that the proposed

rule change is consistent with the Section 6(b)(5) requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes its proposal to update the table in Rule 7.37(d) to include the MIAX PEARL direct feed will ensure that the Rule correctly identifies and publicly states on a market-by-market basis all of the specific SIP and proprietary data feeds that the Exchange utilizes for the handling, execution, and routing of orders, and for performing the regulatory compliance checks for each of those functions. The proposed rule change also removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest by providing additional specificity, clarity, and transparency in the Exchange’s rules.

B. Self-Regulatory Organization’s Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the Exchange believes that the proposal will enhance competition because providing the public and market participants with up-to-date information about the data feeds the Exchange will use for the handling, execution, and routing of orders, as well as for regulatory compliance would enhance transparency and enable investors to better assess the quality of the Exchange’s execution and routing services. The Exchange also believes the proposal would enhance competition because it would potentially enhance the performance of its order handling and execution of orders in equity securities by receiving market data directly from MIAX PEARL. Finally, the proposed rule change would not impact competition between market participants because it will affect all market participants equally.

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

The Exchange has filed the proposed rule change pursuant to Section

¹⁴ 17 CFR 200.30-3(a)(12).

¹⁵ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

⁴ 15 U.S.C. 78f(b).

⁵ 15 U.S.C. 78f(b)(5).

19(b)(3)(A)(iii) of the Act⁶ and Rule 19b-4(f)(6) thereunder.⁷ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b-4(f)(6)⁸ 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 shall institute proceedings under Section 19(b)(2)(B)⁹ of the Act 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-NYSECHX-2023-19 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-NYSECHX-2023-19. 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-NYSECHX-2023-19 and should be submitted on or before December 6, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁰

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023-25205 Filed 11-14-23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98886; File No. SR-ISE-2023-24]

Self-Regulatory Organizations; Nasdaq ISE, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Permit the Listing and Trading of XND Options

November 8, 2023.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on October 27, 2023, Nasdaq ISE, LLC ("ISE" or "Exchange") filed with the Securities and Exchange Commission

("Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to permit the listing and trading of options based on 1/100 of the value of the Nasdaq-100 Index[®] ("Nasdaq-100").

The text of the proposed rule change is available on the Exchange's website at <https://listingcenter.nasdaq.com/rulebook/ise/rules>, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to amend the Exchange's rules to permit the listing and trading of index options on Nasdaq 100 Micro Index Options ("XND"). The XND options contract will be the same in all respects as the current Nasdaq-100 Index options ("NDX")³ contract listed on the Exchange, except that it will be based on 1/100 of the value of the Nasdaq-100 Index, and will be P.M.-Settled with an exercise settlement value based on the closing index value of the Nasdaq-100 Index on the day of expiration.⁴ The Exchange believes that the proposed contract will be valuable for retail and other investors that wish to trade micro options on the Nasdaq-100 Index. Finally, today, Nasdaq Phlx

³ See Options 4A, Section 12(a)(5).

⁴ In addition to the current Nasdaq-100 Index value, Nasdaq will disseminate an Index value for XND that is 1/100 of the value of the Nasdaq-100 Index.

⁶ 15 U.S.C. 78s(b)(3)(A)(iii).

⁷ 17 CFR 240.19b-4(f)(6).

⁸ 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.

⁹ 15 U.S.C. 78s(b)(2)(B).

¹⁰ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

LLC (“Phlx”) has approval to list and trade XND options. The rules to list and trade NDX [sic] options on ISE are identical to those of Phlx.⁵

Nasdaq-100 Index

The Nasdaq-100 Index is a modified market capitalization-weighted index that includes 100 of the largest non-financial companies listed on The Nasdaq Stock Market LLC (“Nasdaq”),⁶ based on market capitalization.⁷ It does not contain securities of financial companies, including investment companies. Security types generally eligible for the Nasdaq-100 Index include common stocks, ordinary shares, American Depositary Receipts, and tracking stocks. Security or company types not included in the Nasdaq-100 Index are closed-end funds, convertible debentures, exchange traded funds, limited liability companies, limited partnership interests, preferred stocks, rights, shares or units of beneficial interest, warrants, units and other derivative securities.⁸

XND Options Contract

Currently, the Exchange lists and trades NDX options that are based on the full value of the Nasdaq-100 Index. In an effort to attract additional interest in index options based on the Nasdaq-100 Index, the Exchange now proposes to list and trade a new micro option contract based on this index. XND options will trade independently of and in addition to NDX options, and the XND options will be subject to the same rules that presently govern the trading of index options based on the Nasdaq-100 Index, including sales practice rules, margin requirements, trading rules, and position and exercise limits. Similar to NDX, XND options will be European-style and cash-settled, and will have a contract multiplier of 100. The contract specifications for XND options will mirror in all respects those of the NDX options contract already listed on the Exchange, except that the Exchange proposes that XND options will be based on 1/100 of the value of the Nasdaq-100 Index, and will be P.M.-settled pursuant to proposed Options 4A, Section 12(a)(6). The ISE XND

option contracts will trade identically to Phlx XND options.⁹ Also, similar features are available with other index options contracts listed and/or approved for trading on the Exchange such as options on NQX (a reduced value index based on 1/5 of the value of the Nasdaq-100 Index).¹⁰ The Exchange also proposes to amend Options 4A, Section 12(a)(5)(ii) to permit options on the Nasdaq 100 Micro Index to trade a.m.-settled.¹¹

The value of the Nasdaq-100 Index has increased significantly in recent years such that the value of the index stood at 14,717.90, as of the opening of trading on October 22, 2023. As a result of the increase in the value of the underlying Nasdaq-100 Index, the premium for NDX options has also increased. The Exchange believes that this has caused NDX options to trade at a level that may be uncomfortably high for certain retail and other investors. The Exchange believes that listing options at a micro value will attract a greater source of retail customer business. Further, listing options on a micro index will provide an opportunity for investors to trade and hedge the market risk associated with the Nasdaq-100 Index.

With an exercise settlement value based on 1/100 of the Nasdaq-100 Index, the Exchange believes that retail and other investors would be able to use this trading vehicle while extending a smaller outlay of capital. Furthermore, the proposed micro index will have a notional value at a level that is comparable to similar products that have been successful in the market, including the S&P 500 Mini SPX Options Index (XSP), which had an index value of (428.45) as of the opening of trading on October 2, 2023. Of note, Phlx XND options have traded at this level since 2021. The Exchange therefore believes that basing the proposed XND options contract on 1/100 of the value of the Nasdaq-100 Index should attract additional investors, and, in turn, create a more active and liquid trading environment.

XND options will also be P.M.-settled as the Exchange believes that market participants, and in particular, retail investors, who are the target audience for this product, prefer P.M.-settled index options. P.M.-settlement is preferred by retail investors as it allows

market participants to hedge their exposure for the full week. A.M.-settled options by contrast are based on opening prices on the day of expiration and therefore stop trading on the day prior, leaving residual risk on the day of expiration. Feedback from Members that handle retail order flow has indicated that P.M.-settlement is needed to garner retail investor support for this product. In this regard, the Exchange notes that XND options on Phlx are P.M.-settled and recently received approval for permanency.¹²

Pursuant to Supplementary Material .07 to ISE Options 4A, Section 12, Phlx’s proposal to list XND would permit XND, as a broad-based index and part of the Nonstandard Expirations Program, to open for trading Weekly Expirations on XND to expire on any Monday, Wednesday, or Friday (other than the third Friday-of-the-month or days that coincide with an EOM expiration). Additionally, the Exchange proposes to amend Supplementary Material .07 to ISE Options 4A, Section 12 to permit the listing and trading of XND options that expire on any Tuesday or Thursday similar to Nasdaq-100 Index options which today expire on each business day of the week. With this proposal, XND would be permitted to open for trading Weekly Expirations to expire on any Monday, Tuesday, Wednesday, Thursday or Friday. Today, Phlx’s rules permit XND to expire on any Monday, Tuesday, Wednesday, Thursday or Friday pursuant to Options 4A, Section 12(b)(5).

Weekly Expirations in XND would be subject to all provisions of this Rule and treated the same as options on the same underlying index that expire on the third Friday of the expiration month; provided, however, that Weekly Expirations shall be P.M.-settled and new series in Weekly Expirations may be added up to and including on the expiration date for an expiring Weekly Expiration. Further, the Exchange may open for trading EOMs on any broad-based index eligible for standard options trading to expire on last trading day of the month. EOMs shall be subject to all provisions of this Rule and treated the same as options on the same underlying index that expire on the third Friday of the expiration month; provided, however, that EOMs shall be P.M.-settled and new series in EOMs may be added up to and including on the expiration date for an expiring

⁵ See Securities Exchange Act Release No. 98451 (September 20, 2023), 88 FR 66088 (September 26, 2023) (SR-Phlx-2023-07) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Make Permanent Certain P.M.-Settled Pilots).

⁶ Nasdaq is an affiliate of the Exchange.

⁷ The Nasdaq-100 Index is a broad-based index, as defined in Options 4A, Section 3.

⁸ A description of the Nasdaq-100 Index is available on Nasdaq’s website at https://indexes.nasdaqomx.com/docs/methodology_NDX.pdf.

⁹ See *supra* note 5. See also Phlx Options 4A, Section 12(a)(6).

¹⁰ See ISE Options 4A, Section 12(a)(6). NQX is P.M.-settled and a European-style and cash-settled, with a contract multiplier of 100.

¹¹ The Exchange also proposes to re-letter the internal list in Options 4A, Section 12(a)(5)(ii) as A through E.

¹² See Securities Exchange Act Release No. 98451 (September 20, 2023), 88 FR 66088 (September 26, 2023) (SR-Phlx-2023-07) (Order Granting Approval of a Proposed Rule Change, as Modified by Amendment No. 1, To Make Permanent Certain P.M.-Settled Pilots).

EOM.¹³ Today, XND options on Phlx are part of the Nonstandard Program.¹⁴

The Exchange does not believe that the introduction of a new P.M.-settled Nasdaq-100 Index contract will cause any market disruptions, as noted herein, Phlx XND options recently received approval for permanency.¹⁵ The Exchange will monitor for any disruptions caused by P.M.-settlement of the proposed XND options contract or the development of any factors that could cause such disruptions. P.M.-settled options predominate in the over-the-counter (“OTC”) market, and the Exchange is not aware of any adverse effects in the OTC market attributable to the P.M.-settlement feature. The Exchange is merely proposing to offer a P.M.-settled product in an exchange environment, which offers the additional benefits of added transparency, price discovery, and stability.

Trading Hours, Minimum Increments, Expirations and Strike Prices

XND options will be available for trading during the Exchange’s standard trading hours for index options, *i.e.*, from 9:30 a.m. to 4:15 p.m. (Eastern time), except that that on the last trading day, transactions in expiring p.m.-settled broad-based index options may be effected on the Exchange between the hours of 9:30 a.m. (Eastern time) and 4:00 p.m. (Eastern time).¹⁶ The trading hours for XND options will be the same as the trading hours for options on Nasdaq-100 Index.

XND options will trade with a minimum trading increment of \$0.01 for all options series¹⁷ similar to Phlx XND options.¹⁸ ISE proposes to adopt a new Supplementary Material .04 to Options 3, Section 3 to state that for so long as Invesco QQQ Trust Series 1 (“QQQ”) options participate in the Penny Interval Program, the minimum increments for XND options shall be the same as QQQ for all options series (including LEAPS), which shall be \$0.01 for options for all other series.

The Exchange proposes that XND options will have monthly expiration dates on the third Friday of each month (*i.e.*, Expiration Friday), and the Exchange proposes to list XND options in expiration months consistent with those of other index option products

available on the Exchange.¹⁹ In addition, the Exchange may list long term index options series (“LEAPS”) that expire from twelve (12) to sixty (60) months from the date of issuance.²⁰ With the addition of XND, the Exchange proposes to amend the first sentence of Options 4A, Section 12(b)(1)(i) to provide that “Index long term options series may be based on either the full value, reduced value or micro index value of the underlying index.” There may be up to ten (10) expiration months, none further out than sixty (60) months. Strike price intervals and continuity Rules shall not apply to such options series until the time to expiration is less than twelve (12) months. Bid/ask differentials for long-term options contracts are specified within Options 2, Section 4(b)(4)(i)(A). Further, the Exchange proposes to add rule text at Options 4A, Section 12(b)(3)(ii) that provides, “Micro index long term options series may expire at six-month intervals. When a new expiration month is listed, series may be near or bracketing the current index value. Additional series may be added when the value of the underlying index increases or decreases by ten (10) to fifteen (15) percent.” XND options would also be eligible to be added to the Short Term Option Series Program (“Weeklies”) and/or Quarterly Options Series Program (“Quarterlies”) if designated by the Exchange Supplementary Material .01 and .02 to Options 4A, Section 12, respectively.²¹

Further, as noted herein, the Exchange proposes to permit XND options to be listed and traded in accordance with the Nonstandard Expirations Program, which permits broad-based indexes to list standard options trading to expire on any Monday, Wednesday, or Friday (other than the third Friday-of-the-month or days that coincide with an End of Month (“EOM”) expiration), and permit XND options to separately expire on Tuesdays and Thursdays, similar to options on the Nasdaq-100 Index. Weekly Expirations would be subject to all provisions of Options 4A, Section 12 and would be treated the same as options on the same underlying index

that expire on the third Friday of the expiration month. New series in Weekly Expirations could be added up to and including on the expiration date for an expiring Weekly Expiration. The maximum number of expirations that could be listed for each Weekly Expiration (*i.e.*, a Monday expiration, Wednesday expiration, or Friday expiration, as applicable) in a given class would be the same as the maximum number of expirations permitted for standard options on the same broad-based index.²² Further, the Exchange could open for trading EOMs on any broad-based index eligible for standard options trading to expire on last trading day of the month. EOMs would be subject to all provisions of Options 4A, Section 12 and treated the same as options on the same underlying index that expire on the third Friday of the expiration month. However, the EOMs would be P.M.-settled and new series in EOMs could be added up to and including on the expiration date for an expiring EOM.²³ Today, Phlx XND options trade in the Nonstandards Program.²⁴

Generally, pursuant to Options 4A, Section 12(c)(1), except as provided in

²² Weekly Expirations would not need to be for consecutive Monday, Wednesday, or Friday expirations as applicable. However, the expiration date of a non-consecutive expiration would not be permitted beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. Weekly Expirations that are first listed in a given class could expire up to four weeks from the actual listing date. If the last trading day of a month were a Monday, Wednesday, or Friday and the Exchange were to list EOMs and Weekly Expirations as applicable in a given class, the Exchange would list an EOM instead of a Weekly Expiration in the given class. Other expirations in the same class would not be counted as part of the maximum number of Weekly Expirations for a broad-based index class. If the Exchange were not open for business on a respective Monday, the normally Monday expiring Weekly Expirations would expire on the following business day. If the Exchange were not open for business on a respective Wednesday or Friday, the normally Wednesday or Friday expiring Weekly Expirations would expire on the previous business day. See Supplementary Material .07(a) to Options 4A, Section 12.

²³ The maximum number of expirations that could be listed for EOMs in a given class would be the same as the maximum number of expirations permitted for standard options on the same broad-based index. EOM expirations would not need to be for consecutive end of month expirations. However, the expiration date of a non-consecutive expiration may not be beyond what would be considered the last expiration date if the maximum number of expirations were listed consecutively. EOMs that are first listed in a given class could expire up to four weeks from the actual listing date. Other expirations would not be counted as part of the maximum numbers of EOM expirations for a broad-based index class. See Supplementary Material .07(a) to Options 4A, Section 12.

²⁴ See Phlx Options 4A, Section 12(b)(5).

¹³ XND is a broad-based index.

¹⁴ See Phlx Options 4A, Section 12(b)(5).

¹⁵ See *supra* note 12.

¹⁶ See Supplementary Material .07(c) to Options 4A, Section 12.

¹⁷ This is the case as long as QQQ options (“QQQ”) participate in the Penny Interval Program.

¹⁸ See Phlx Supplementary Material .03 to Options 3, Section 3.

¹⁹ Options 4A, Section 12(a)(3) currently provides that the Exchange may list: (i) up to six (6) standard monthly expirations at any one time in a class, but will not list index options that expire more than twelve (12) months out; (ii) up to 12 standard monthly expirations at any one time for any class that the Exchange (as the Reporting Authority) uses to calculate a volatility index; and (iii) up to 12 standard (monthly) expirations in NDX options and NQX options.

²⁰ See Options 4A, Section 12(b)(3).

²¹ The Exchange expects that it will add XND options to the Weeklies program.

Options 4A, Section 12(c)(5),²⁵ the exercise (strike) price intervals will be no less than \$5, provided that the Exchange may determine to list strike prices at no less than \$2.50 intervals for options on the following indexes (which may also be known as sector indexes). The Exchange proposes to amend Options 4A, Section 12(c)(1) to add XND options to the list of classes where strike price intervals of no less than \$2.50 are generally permitted and note, “if the strike price is less than \$200.” The Exchange proposes to adopt the same strike price intervals for XND options as are listed for XND options on Phlx²⁶ and currently approved for Reduced Value Nasdaq 100 Options within Options 4A, Section 12(c)(5). Thus, notwithstanding Options 4A, Section 12(c)(1), the interval between strike prices of series of XND options will be \$1 or greater, subject to the conditions described in Options 4A, Section 12(c)(5).²⁷ The Exchange will not list LEAPS on XND options at intervals less than \$5. If the Exchange determines to add XND options to the Weeklies or Quarterlies programs such options will be listed with expirations and strike prices described in Options 4A, Section 12(c)(5).

Position and Exercise Limits; Margin

As with NDX, in determining compliance with Options 4A, Section 6, Position Limits, there will be no position limits for broad-based index option contracts in the XND class.²⁸ Although there will be no position limits for XND options, the Exchange proposes to amend Options 4A, Section 6 to include XND. Options 4A, Section 6(c) provides,

Positions in reduced-value index options shall be aggregated with positions in full-value indices. For such purposes, reduced-value contracts will be counted consistent with their value (e.g., 5 NQX reduced-value contracts equal 1 NDX full-value contract).

Since the Exchange is proposing to list a micro index contract that is based on 1/100 of the value of the Nasdaq-100 Index, Options 4A, Section 6(c) would apply. In addition, as with NDX, there would be no exercise limits for XND.²⁹

²⁵ Proposed Options 4A, Section 12(c)(1) provides that the interval between strike prices of series of Mini-Nasdaq-100 Index (“MNX” or “Mini-NDX”), Nasdaq 100 Reduced Value Index (“NQX”) or Nasdaq 100 Micro Index Options (“XND”) options will be \$1 or greater, subject to certain conditions.

²⁶ See Phlx Options 4A, Section 12(a)(2).

²⁷ See also Phlx Supplementary Material .02 to Options 4A, Section 12 describing XND options.

²⁸ The Exchange is amending Options 4A, Section 6(a) to reflect this proposed change.

²⁹ See Options 4A, Section 10 which provides that exercise limits for index options contracts shall

The same rules for position and exercise limits to XND options on Phlx.³⁰ Finally, the Exchange proposes to apply broad-based index margin requirements for the purchase and sale of XND options that are the same as margin requirements currently in place for NDX options.

Surveillance and Capacity

The Exchange represents that it has sufficient capacity to handle additional quotations and message traffic associated with the proposed listing and trading of XND options. Further, the Exchange has analyzed its capacity and represents that it believes the Exchange and the Options Price Reporting Authority (“OPRA”) have the necessary systems capacity to handle any additional traffic associated with the listing of the maximum number nonstandard expirations permitted pursuant to Supplementary Material .07 to Options 4A, Section 12.

Index options are integrated into the Exchange’s existing surveillance system architecture and are thus subject to the relevant surveillance processes. The Exchange represents that it has adequate surveillance procedures to monitor trading in XND options thereby aiding in the maintenance of a fair and orderly market.

The Exchange notes that it is amending Options 4A, Section 12 to include the Nasdaq 100 Micro Index Options within the Rule to conform to the amendments proposes herein.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,³¹ in general, and furthers the objectives of section 6(b)(5) of the Act,³² in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. Specifically, the Exchange believes that the listing and trading of a micro index P.M.-settled index option contract based on the Nasdaq-100 Index will attract order flow to the Exchange, increase the variety of listed options, and provide a valuable hedge tool to retail and other investors.

be equivalent to the position limits described in Options 4A, Section 6.

³⁰ See Phlx Options 4A, Section 6, Phlx Options 4A, Section 10.

³¹ 15 U.S.C. 78f(b).

³² 15 U.S.C. 78f(b)(5) and compete with similar products that are offered on Cboe such as SPXW and OEX.

The Exchange believes that the proposed rule change will further the Exchange’s goal of introducing new and innovative products to the marketplace. Specifically, the Exchange believes that XND options would provide additional opportunities for market participants to trade and hedge exposure to the Nasdaq-100 Index as it does today on Phlx. The proposed XND options product is identical to XND options on Phlx.³³ Additionally, the proposed XND options product is similar to NDX options that are currently listed and traded on the Exchange with two important differences: (1) XND options will be based on 1/100 the value of the Nasdaq-100 Index, and (2) XND options will be P.M.-settled. These differences are based on the Exchanges experience listing NDX options, and are designed to attract additional participation from retail and other investors.

Based on the trading of XND options on Phlx, the Exchange believes that the proposed contract specifications will be attractive to market participants, and will remove impediments to and perfect the mechanism of a free and open market and a national market system. The nonstandard expirations would expand the ability of investors to hedge risks against market movements stemming from economic releases or market events that occur during the month and at the end of the month. Accordingly, the Exchange believes that weekly expirations and EOMs should create greater trading and hedging opportunities and flexibility, and provide customers with the ability to tailor their investment objectives more closely.

Currently, the Exchange believes that there continues to be unmet market demand for exchange-listed index options on the Nasdaq-100 Index. This unmet demand stems in part from the high value of the Nasdaq-100 Index and the consequently higher cost of purchasing NDX options. The high value of the Nasdaq-100 Index has made it more difficult for retail and other investors to comfortably purchase options on the index. The Exchange believes that a micro index option would allow additional participation from these investors. Specifically, the Exchange believes that basing the contract on a micro value of the Nasdaq-100 Index will encourage additional participation by retail and other investors due to the reduced capital outlay needed to trade these options. While the NQX product has attracted retail trading volume to a certain point given that the NQX product represents

³³ See Phlx Options 4A, Section 12.

$\frac{1}{5}$ the value of the Nasdaq-100 Index, the Exchange believes that XND options, which represent $\frac{1}{100}$ of the Nasdaq-100 Index, may strike a more appropriate balance for other retail investors with its reduced size. This value is more similar to other competitive index option products, such as Cboe's Mini-S&P 500 Index ("XSP").

Furthermore, based on experience with XND options on Phlx, the Exchange believes that providing P.M.-settlement will make this product more attractive to market participants and help garner additional support for this new index options product. Specifically, the Exchange believes that P.M.-settlement will be attractive to retail and other investors that want to use these options to hedge an entire week of risk without leaving residual risk on the day of expiration, and without having to actively manage these positions, for example, by rolling their hedge into the next expiration. Finally, the Exchange proposes to offer such a product so that it can compete effectively with similar index option products offered by options markets such as Cboe which offers SPXW and OEX. Recently, the Commission approved the permanency of XND as a P.M.-settled product.³⁴ Additionally, the Exchange notes that Nasdaq has an automated closing cross that facilitates orderly closings by aggregating a large pool of liquidity, across a variety of order types, in a single venue. The Exchange believes that Nasdaq's closing procedures are well-equipped to mitigate imbalance pressure at the close. Also, the Exchange believes that the proposal will provide additional trading and hedging opportunities for investors.

XND options will be subject to the same rules that presently govern the trading of index options based on the Nasdaq-100 Index, including sales practice rules, margin requirements, trading rules, and position and exercise limits. The Exchange therefore believes that the rules applicable to trading in XND options are consistent with the protection of investors and the public interest. Furthermore, the Exchange represents that it has sufficient systems capacity and adequate surveillance procedures to handle trading in XND options.

With respect to the Exchange's proposal to adopt new Supplementary Material .04 to Options 3, Section 3 to provide that minimum increments for bids and offers for XND options be the same as those for QQQ, regardless of the value at which the option series is quoted, may promote competition and

benefit investors. This proposal aligns the minimum increments for XND options with those for QQQ options in order to allow market participants to quote in minimum increments of \$0.01 is consistent with the Act because allowing participants to quote in smaller increments may provide the opportunity for reduced spreads, thereby lowering costs to investors. In addition, because both XND and QQQ are based on the Nasdaq-100 Index it would be reasonable for the minimum increments of bids and offers to be the same for both types of options.

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. XND options would be available for trading to all market participants. The proposed rule change will facilitate the listing and trading of a new option product that will enhance competition among market participants, to the benefit of investors and the marketplace. The listing of XND will enhance competition by providing investors with an additional investment vehicle, in a fully-electronic trading environment, through which investors can gain and hedge exposure to the Nasdaq-100 Index. Furthermore, this product could offer a competitive alternative to other existing investment products that seek to allow investors to gain broad market exposure. Finally, it is possible for other exchanges to develop or license the use of a new or different index to compete with the Nasdaq-100 Index and seek Commission approval to list and trade options on such an index.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to section 19(b)(3)(A)(iii) of the Act³⁵ and Rule 19b-4(f)(6) thereunder.³⁶ Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative

for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A)(iii) of the Act³⁷ and subparagraph (f)(6) of Rule 19b-4 thereunder.³⁸

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act³⁹ normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)⁴⁰ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has requested that the Commission waive the 30-day operative delay so that it may immediately list and trade XND options on the Exchange, which are currently listed on Phlx. Further, according to the Exchange, the rules to list and trade XND options on ISE are identical to those of Phlx.⁴¹ The Exchange has stated that waiver of the operative delay would deepen the liquidity pool for XND options and allow ISE to compete with similar products that are offered on other exchanges. The Commission believes that the proposed rule change presents no novel issues and that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the operative delay and designates the proposed rule change operative upon filing.⁴²

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

³⁷ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁸ 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

³⁹ 17 CFR 240.19b-4(f)(6).

⁴⁰ 17 CFR 240.19b-4(f)(6)(iii).

⁴¹ See Phlx Options 4A, Section 12.

⁴² For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

³⁴ See *supra* note 12.

³⁵ 15 U.S.C. 78s(b)(3)(A)(iii).

³⁶ 17 CFR 240.19b-4(f)(6).

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-ISE-2023-24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-ISE-2023-24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (<https://www.sec.gov/rules/sro.shtml>). Copies of the 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-ISE-2023-24 and should be submitted on or before December 6, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴³

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023-25108 Filed 11-14-23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98901; File No. SR-NYSECHX-2023-21]

Self-Regulatory Organizations; NYSE Chicago, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Rule 7.31

November 9, 2023.

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 31, 2023, the NYSE Chicago, Inc. ("NYSE Chicago" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III 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 amend Rule 7.31 to provide for the use of ALO Reserve Orders. The proposed rule change is available on the Exchange's website at www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 7.31 to provide for the use of ALO Reserve Orders.

ALO Orders

Rule 7.31(e)(2) defines an ALO Order as a Non-Routable Limit Order that, unless it receives price improvement, will not remove liquidity from the Exchange Book. An ALO Order can be designated to be cancelled if it would be displayed at a price other than its limit price for any reason. An ALO Order can be designated as non-displayed.

As described in Rule 7.31(e)(2)(A), an Aggressing ALO Order to buy (sell) will trade if its limit price crosses the working price of any displayed or non-displayed orders to sell (buy) on the Exchange Book priced equal to or below (above) the PBO (PBB) of an Away Market, in which case it will trade as the liquidity taker with such orders.

As noted above, Rule 7.31(e)(2) provides that an ALO Order may be designated to cancel if it would be displayed at a price other than its limit price. If an ALO Order is not so designated, any untraded quantity of such order to buy (sell) is processed as follows (Rules 7.31(e)(2)(B)(i) and (ii)):

- If the limit price of the ALO Order locks the display price of any order to sell (buy) ranked Priority 2—Display Orders on the Exchange Book, it will have a working price and display price (if designated to display) one MPV below (above) the price of the displayed order on the Exchange Book.
- If the limit price of the ALO Order locks or crosses the PBO (PBB) of an Away Market, it will have a working price equal to the PBO (PBB) of the Away Market and a display price (if designated to display) one MPV below (above) the PBO (PBB) of the Away Market.

Rule 7.31(e)(2)(C) provides that any untraded quantity of an ALO Order to buy (sell) will have a working price and display price (if designated to display) equal to its limit price if it locks non-displayed orders to sell (buy) on the Exchange Book. Rule 7.31(e)(2)(D) provides that an ALO Order to buy (sell) will not be assigned a working price or display price above (below) the limit price of such order.

Once resting on the Exchange Book, ALO Orders may be re-priced or trade, or both, as described in Rule 7.31(e)(2)(E):

⁴³ 17 CFR 200.30-3(a)(12), (59).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b-4.

- If order(s) to sell (buy) ranked Priority 2—Display Orders or the PBO (PBB) of an Away Market re-prices higher (lower), an ALO Order to buy (sell) will trade or be priced, or both, consistent with Rules 7.31(e)(2)(A), (e)(2)(B)(i) and (ii), and (e)(2)(C).
- If the PBO (PBB) of an Away Market re-prices lower (higher) to be equal to or lower (higher) than its last display price or if its limit price no longer locks or crosses the PBO (PBB) of the Away Market, an ALO Order to buy (sell) will be priced pursuant to Rules 7.31(e)(1)(A)(ii)(c) and (d). If the PBO (PBB) of an Away Market re-prices lower (higher) than the working price of a non-displayed ALO Order to buy (sell), such order will have a working price equal to the PBO (PBB) of the Away Market.

Reserve Orders

Rule 7.31(d)(1) provides for Reserve Orders, which are Limit or Inside Limit Orders with a quantity of the size displayed and with a reserve quantity (“reserve interest”) of the size that is not displayed. The displayed quantity of a Reserve Order is ranked Priority 2—Display Orders, and the reserve interest is ranked Priority 3—Non-Display Orders. Both the display quantity and the reserve interest of an arriving marketable Reserve Order are eligible to trade with resting interest in the Exchange Book or to route to Away Markets. The working price of the reserve interest of a resting Reserve Order will be adjusted in the same manner as a Non-Displayed Limit Order, as provided for in Rule 7.31(d)(2)(A).

As described in Rule 7.31(d)(1)(A), the display quantity of a Reserve Order must be entered in round lots, and the displayed portion of a Reserve Order will be replenished when the display quantity is decremented to below a round lot. The replenish quantity will be the minimum display size of the order or the remaining quantity of the reserve interest if it is less than the minimum display quantity.

Rule 7.31(d)(1)(B) provides that each time the display quantity of a Reserve Order is replenished from reserve interest, a new working time is assigned to the replenished quantity (each display quantity with a different time is referred to as a “child” order), while the reserve interest retains the working time of the original order entry. In addition, when a Reserve Order is replenished from reserve interest and already has two child orders that equal less than a round lot, the child order with the later working time will rejoin the reserve interest and be assigned the new working time assigned to the next

replenished quantity. If a Reserve Order is not routable, the replenish quantity will be assigned a display and working price consistent with the instructions for the order.

Rule 7.31(d)(1)(C) provides that a Reserve Order must be designated Day and may only be combined with a Non-Routable Limit Order or Primary Pegged Order. Rule 7.31(d)(1)(C) also currently provides that a Reserve Order may not be designated as an ALO Order.

Rule 7.31(d)(1)(D) provides that routable Reserve Orders will be evaluated for routing both on arrival and each time their display quantity is replenished.

Rule 7.31(d)(1)(E) provides that a request to reduce the size of a Reserve Order will cancel the reserve interest before cancelling the display quantity, and, if the Reserve Order has more than one child order, the child order with the latest working time will be cancelled first.

Rule 7.31(d)(1)(F) provides that, if the PBBO is crossed and the display quantity of a Reserve Order to buy (sell) that is a Non-Routable Limit Order is decremented to less than a round lot, the display price and working price of such Reserve Order will not change and the reserve interest that replenishes the display quantity will be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). Rule 7.31(d)(1)(F) further provides that, when the PBBO uncrosses, the display price and working price will be adjusted as provided for under Rule 7.31(e)(1) relating to Non-Routable Limit Orders.

ALO Reserve Orders

The Exchange proposes to amend Rule 7.31 to provide for the use of ALO Reserve Orders. The proposed change is not intended to introduce any new functionality or modify any current functionality, but rather to facilitate the combination of two order types currently offered by the Exchange. As proposed, ALO Reserve Orders would, except as otherwise noted, operate consistent with current Rule 7.31(d)(1) regarding Reserve Orders and current Rule 7.31(e)(2) regarding ALO Orders. To allow for the use of ALO Reserve Orders, the Exchange first proposes to amend Rule 7.31(d)(1)(C) to delete the last sentence of such rule, which currently provides that a Reserve Order may not be designated as an ALO Order.

The proposed change is intended to allow ALO Orders, as described in Rule 7.31(e)(2) and the paragraphs

thereunder,⁴ to have a displayed quantity, along with non-displayed reserve interest, as described in Rule 7.31(d)(1). The display quantity of an ALO Reserve Order would be replenished as provided in Rules 7.31(d)(1)(A) and (B). As ALO Reserve Orders are non-routable, under Rule 7.31(d)(1)(B)(ii), the replenish quantity of an ALO Reserve Order would be assigned a display price and working price consistent with the behavior of ALO Orders as described in current Exchange rules.

Aggressing ALO Reserve Orders would trade in accordance with current Rule 7.31(e)(2)(A). If an ALO Reserve Order is designated to cancel, it will cancel if it would be displayed at a price other than its limit price for any reason, as described in Rule 7.31(e)(2). Otherwise, any untraded quantity of an ALO Reserve Order would continue to be processed as ALO Orders are currently, as described in Rules 7.31(e)(2)(B) and (C). Similarly, the working price of the reserve interest of a resting ALO Reserve Order would be adjusted as provided for in Rule 7.31(d)(1) (*i.e.*, in accordance with Rule 7.31(d)(2)(A)). Rule 7.31(d)(1)(E) would also apply to requests to reduce the size of ALO Reserve Orders.

As described in Rule 7.31(d)(1)(F), when the PBBO is crossed and the display quantity of an ALO Reserve Order to buy (sell) is decremented to less than a round lot, the display price and working price of the order would not change, but the reserve interest that replenishes the display quantity would be assigned a display price one MPV below (above) the PBO (PBB) and a working price equal to the PBO (PBB). The Exchange proposes to amend Rule 7.31(d)(1)(F) to add new rule text describing how the display price and working price of an ALO Reserve Order would be adjusted when a previously crossed PBBO uncrosses. Specifically, the Exchange proposes to add text to the last sentence of Rule 7.31(d)(1)(F) providing that the display price and working price of an ALO Reserve Order would be adjusted in accordance with Rule 7.31(e)(2)(E), which describes how ALO Orders resting on the Exchange Book are repriced and/or traded. Because ALO Orders behave differently from other Non-Routable Limit Orders and may only trade when they receive price improvement, the Exchange proposes to add text to Rule

⁴ The Exchange does not propose to allow non-displayed ALO Orders to be designated as Reserve Orders, given that a Reserve Order must have both displayed and non-displayed portions, and thus proposes to amend Rule 7.31(e)(2) to specify accordingly.

7.31(e)(2)(F) clarifying that ALO Reserve Orders would have their display price and working price adjusted consistent with the rules applicable to ALO Orders when the PBBO uncrosses.

The proposed change is intended to facilitate the combined use of two existing order types available on the Exchange, thereby providing Participants with enhanced flexibility and optionality when trading on the Exchange. The proposed change could also promote increased liquidity and trading opportunities on the Exchange, to the benefit of all market participants. The Exchange also believes the proposed change would permit the Exchange to offer functionality already available on at least one other equities exchange, thereby promoting competition among equities exchanges.⁵

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 in the fourth quarter of 2023.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Act,⁶ in general, and furthers the objectives of Section 6(b)(5),⁷ in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to remove impediments to and perfect the mechanism of a free and open market because it would allow for the combined use of two existing order types available on the Exchange and permit the Exchange to offer functionality similar to that already available on at least one other equities exchange.⁸ Participants would be free to choose to use the proposed ALO Reserve Order type or not, and the

proposed change would not otherwise impact the operation of the Reserve Order or ALO Order as described in current Exchange rules. The Exchange also believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market, as well as protect investors and the public interest, by expanding the options available to Participants when trading on the Exchange and promoting increased liquidity and additional trading opportunities for all market participants.

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. In addition, as noted above, Exchange believes the proposed rule change would allow the Exchange to offer functionality already available on at least one other equities exchange⁹ and thus would promote competition among equities exchanges. The Exchange also believes that, to the extent the proposed change increases opportunities for order execution, the proposed change would promote competition by making the Exchange a more attractive venue for order flow and enhancing market quality for all market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹ Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A)

of the Act and Rule 19b-4(f)(6)(iii) thereunder.¹²

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)¹³ of the Act 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-NYSECHX-2023-21 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-NYSECHX-2023-21. 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

⁵ See, e.g., MEMX Rules 11.8(b)(4) and (7) (providing that a Limit Order may include a reserve quantity and may be designated with a Post Only instruction); see also MEMX User Manual, available at <https://info.memxtrading.com/wp-content/uploads/2023/03/MEMX-User-Manual-03.10.23.pdf>, at 9 (providing that a Limit Order designated Day may have both reserve quantity and Post Only instructions).

⁶ 15 U.S.C. 78f(b).

⁷ 15 U.S.C. 78f(b)(5).

⁸ See note 5, *supra*.

⁹ See *id.*

¹⁰ 15 U.S.C. 78s(b)(3)(A)(iii).

¹¹ 17 CFR 240.19b-4(f)(6).

¹² 17 CFR 240.19b-4(f)(6)(iii). 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 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.

¹³ 15 U.S.C. 78s(b)(2)(B).

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-NYSECHX-2023-21 and should be submitted on or before December 6, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁴

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023-25207 Filed 11-14-23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98881; File No. SR-NSCC-2023-009]

Self-Regulatory Organizations; National Securities Clearing Corporation; Order Approving Proposed Rule Change Relating to the Schedule of Haircuts for Eligible Clearing Fund Securities

November 8, 2023.

I. Introduction

On September 22, 2023, National Securities Clearing Corporation ("NSCC") filed with the Securities and Exchange Commission ("Commission") proposed rule change SR-NSCC-2023-009 to modify the schedule of haircuts for Eligible Clearing Fund Securities, and to remove it and the related concentration limits from Procedure XV of the NSCC Rules ("Procedure XV"), and make other clarifying changes ("Proposed Rule Change"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")¹ and Rule 19b-4 thereunder.² The Proposed Rule Change was published for comment in the **Federal Register** on October 4,

2023.³ The Commission has received no comments on the Proposed Rule Change. For the reasons discussed below, the Commission is approving the Proposed Rule Change.⁴

II. Background

NSCC is a central counterparty ("CCP"), which means it interposes itself as the buyer to every seller and seller to every buyer for the financial transactions it clears. As such, NSCC is exposed to the risk that one or more of its members may fail to make a payment or to deliver securities.

A key tool that NSCC uses to manage its credit exposures to its members is the daily collection of margin (referred to as "Required Fund Deposit" in the NSCC Rules) from each member.⁵ The aggregated amount of all NSCC members' margin constitutes the Clearing Fund. The objective of the Clearing Fund is to mitigate potential losses to NSCC associated with liquidating a member's portfolio in the event NSCC ceases to act for that member (hereinafter referred to as a "default").⁶ NSCC would be able to access the Clearing Fund should a defaulting member's own margin be insufficient to satisfy losses to NSCC caused by the liquidation of that member's portfolio.

A member may provide its required margin in the form of cash or an open account indebtedness secured by Eligible Clearing Fund Securities.⁷ Eligible Clearing Fund Securities are defined to include certain agency, mortgage-backed, and Treasury securities.⁸ These securities are valued based on the prior Business Day's closing market price, less a haircut, and

may be subject to a concentration limit.⁹ NSCC states that haircuts are used to protect NSCC and its members from price fluctuations, *i.e.*, if NSCC is required to liquidate collateral of an insolvent member and such collateral is worth less at the time of liquidation than when it is pledged to NSCC.¹⁰ NSCC also states that concentration limits are intended to reduce NSCC's risk by limiting the percentage of certain types of Eligible Clearing Fund Securities pledged by members to secure the Clearing Fund deposits, because when a member's portfolio contains large net unsettled positions in a particular group of securities with a similar risk profile or in a particular asset type, such securities could present additional risk to NSCC.¹¹

Currently, collateral haircuts applicable to relevant security types and remaining maturity terms are specified as fixed percentages in Section III.(A) of Procedure XV ("Section III.(A)").¹² According to NSCC and set forth in its internal risk management procedures, the sufficiency of collateral haircuts is evaluated through use of back-tests, stress-tests and market observations.¹³ Specifically, NSCC conducts daily backtesting analysis by comparing the collateral haircut for each member in simulated liquidations with the member's actual collateral held on deposit at NSCC.¹⁴ NSCC escalates any exceptions that it observes to assess the root cause and determine whether further analysis and/or review would be appropriate, taking into account whether a particular security may present inherent volatility and/or liquidity risks that could likely result in an erosion in the value of the security exceeding the applicable collateral haircut.¹⁵ On a quarterly basis, NSCC reviews the composition of the Eligible Clearing Fund Securities that members have pledged to secure their Required Fund Deposits in order to assess the sufficiency of the collateral haircuts applied and whether any haircut changes would be needed, taking into account backtesting results, any

³ See Securities Exchange Act Release No. 98589 (Sept. 28, 2023), 88 FR 68777 (Oct. 4, 2023) (File No. SR-NSCC-2023-009) ("Notice of Filing").

⁴ Capitalized terms not defined herein are defined in the NSCC Rulebook ("NSCC Rules"), available at https://www.dtcc.com/-/media/Files/Downloads/legal/rules/nscc_rules.pdf.

⁵ See NSCC Rule 4, *supra* note 4 (requiring members to make Required Fund Deposits to the Clearing Fund with the amount of each member's deposit being determined by NSCC in accordance with these rules).

⁶ The NSCC Rules identify when NSCC may cease to act for a member and the types of actions NSCC may take. For example, NSCC may suspend a firm's membership with NSCC or prohibit or limit a member's access to NSCC's services in the event that member defaults on a financial or other obligation to NSCC. See NSCC Rule 46 (Restrictions on Access to Services), *supra* note 4.

⁷ See NSCC Rule 4, Section 1 (Required Fund Deposits), *supra* note 4.

⁸ See NSCC Rule 1 (defining what constitutes Eligible Clearing Fund Securities and the components thereof, which are Eligible Clearing Fund Agency Securities, Eligible Clearing Fund Mortgage-Backed Securities, and Eligible Clearing Fund Treasury Securities), *supra* note 4.

⁹ See Section II.(A)1. of Procedure XV, *supra* note 4.

¹⁰ Notice of Filing, *supra* note 3, 88 FR at 68777.

¹¹ *Id.*

¹² See Section III.(A) of Procedure XV, *supra* note 4. Section III.(A) was last modified in 2011 in order to conform the haircuts to requirements of NSCC's lenders under its credit facilities. See Securities Exchange Act Release No. 64487 (May 13, 2011), 76 FR 29019 (May 19, 2011) (SR-NSCC-2011-02).

¹³ Notice of Filing, *supra* note 3, 88 FR at 68777. NSCC also filed excerpts from its internal market risk management procedures as Confidential Exhibit 3b to its filing.

¹⁴ *Id.*

¹⁵ *Id.*

¹⁴ 17 CFR 200.30-3(a)(12).

¹⁵ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

instances where the simulated losses from available historical stress testing scenario dates have exceeded the collateral haircut values, and market conditions.¹⁶

In addition to collateral haircuts, NSCC applies concentration limits to certain Eligible Clearing Fund Securities set forth in the NSCC Rules. Under these limits, no more than 20 percent of a member's Required Fund Deposit may be in the form of Eligible Clearing Fund Agency Securities that are of a single issuer and no member may post as eligible collateral Eligible Clearing Fund Agency Securities of which it is the issuer.¹⁷ In addition, any deposits of Eligible Clearing Fund Agency Securities or Eligible Clearing Fund Mortgage-Backed Securities in excess of 25 percent of a member's Required Fund Deposit will be subject to a haircut that is twice the amount of the percentage noted in Section III.(A), and a member may deposit Eligible Clearing Fund Mortgage-Backed Securities of which it is the issuer, however such securities will be subject to a premium haircut, with the initial haircut being 14 percent, and if a member also exceeds the 25 percent concentration limit, the haircut shall be 21 percent.¹⁸

Changes to the collateral haircuts and concentration limits are subject to NSCC's internal governance process.¹⁹ According to NSCC and based on its internal risk management procedures, if NSCC determines that, based on the analyses that it performs, there is insufficient/excessive collateral haircut/concentration due to an identifiable cause that affected multiple members and such cause would likely persist based on NSCC's assessment of market conditions, such outcome or result could cause NSCC to amend the haircuts/concentration limits in the haircut schedule.²⁰ If NSCC determines that a change to the haircut schedule is warranted, it would document the recommendation and rationale for the change at the time of such determination and obtain approval from an executive director or above with a notice to the risk management committee.²¹ Before making adjustments to the haircut schedule, NSCC measures the potential impact of such adjustments to ensure any impact is both necessary and appropriate.²²

III. Description of the Proposed Rule Change

In the Notice of Filing, NSCC states that it has observed that under volatile market conditions with elevated frequency and magnitude of securities price movements, the collateral value of Eligible Clearing Fund Securities may shift in a relatively short period of time and the current haircuts may not sufficiently account for the change in value.²³ When the erosion in the value of the Eligible Clearing Fund Securities exceeds the relevant haircuts, NSCC is exposed to increased risk of potential losses associated with liquidating a member's portfolio in the event of a member default when the defaulting member's own margin is insufficient to satisfy losses to NSCC caused by the liquidation of that member's portfolio.²⁴ Similarly, when a member's portfolio contains large net unsettled positions in a particular group of securities with a similar risk profile or in a particular asset type, such securities could present additional risk to NSCC.²⁵ The additional risk exposures associated with liquidating a member's portfolio in the event of a member default could lead to an increase in the likelihood that NSCC would need to mutualize losses among non-defaulting members during the liquidation process.²⁶ However, any changes to the haircuts and/or concentration limits currently requires a proposed rule change to be filed with the Commission.

Therefore, to provide NSCC with more flexibility in adjusting the haircuts and concentration limits so NSCC can respond to changing market conditions more promptly in order to mitigate the additional risk exposure, NSCC is proposing to remove Section III.(A) and concentration limits from the Rules, and to publish the haircuts and concentration limits in a haircut schedule on NSCC's website.²⁷

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ Specifically, NSCC is proposing to delete subsections (a) and (b) of Section II.(A)1. of Procedure XV (Special Provisions Related to Eligible Clearing Fund Securities), and delete Section III of Procedure XV (Collateral Value of Eligible Clearing Fund Securities) to remove all haircuts and concentration limits from the Rules. NSCC is also proposing to (i) remove references to Section III of Procedure XV in two places in Rule 4, and replace them with a reference to Section II.(A) of Procedure XV; (ii) remove references to subsections 1(a) and (b) of Section II.(A) of Procedure XV and references to Section III of Procedure XV in Rule 56; and (iii) remove a reference to Section III of Procedure XV in Section II.(A) of Procedure XV, and replace it with a reference to the proposed haircut schedule, to reflect the proposed changes described above.

In addition, NSCC is proposing to add language in Section II.(A)1. that makes it clear that all Eligible Clearing Fund Securities pledged to secure Clearing Fund deposits shall, for collateral valuation purposes, be subject to a haircut and may be subject to a concentration limit. The proposed language would provide that NSCC shall determine the applicable haircuts and any concentration limits from time to time in accordance with its internal policy and governance process, based on factors determined to be relevant by NSCC, which may include, for example, backtesting results and NSCC's assessment of market conditions, in order to set appropriately conservative haircuts and/or concentration limits for the Eligible Clearing Fund Securities and minimize backtesting deficiency occurrences. The proposed language would also provide that the haircuts and any concentration limits prescribed by NSCC shall be set forth in a haircut schedule that is published on NSCC's website. The proposed language would also state that it shall be the member's responsibility to retrieve the haircut schedule, and that NSCC would provide members with at a minimum one Business Day's advance notice of any change in the haircut schedule.

NSCC states that the proposed change to move the haircuts and concentration limits from the Rules to the website would enable NSCC to adjust the haircuts and concentration limits without undergoing a rule filing process (although it could still necessitate an advance notice under Title VIII of the Dodd-Frank Act, if a change materially affects the nature or level of risks presented by NSCC).²⁸ NSCC states that by being able to make appropriate and timely adjustments to the haircuts and concentration limits, it would have the flexibility to respond to changing market conditions more promptly.²⁹ Having the flexibility to respond to changing market conditions more promptly would in turn help better ensure that NSCC collects sufficient margin from members as well as risk manages its credit exposures to its members.³⁰

In its Notice of Filing, NSCC also provides an overview regarding its changes to the categories relating to Treasury Inflation-Protected Securities ("TIPS").³¹ NSCC states that, as part of

²⁸ Notice of Filing, *supra* note 3, 88 FR at 68779 and n. 11 (citing 12 U.S.C. 5465(e)(1) and 17 CFR 240.19b-4(n)(1)(i)).

²⁹ *Id.*

³⁰ *Id.*

³¹ TIPS are a type of Treasury security issued by the U.S. government that are indexed to inflation

¹⁶ *Id.* at 68778.

¹⁷ See Section II.(A)1. of Procedure XV, *supra* note 4.

¹⁸ *Id.*

¹⁹ Notice of Filing, *supra* note 3, 88 FR at 68778; see also note 13 *supra*.

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

its daily backtesting regarding the adequacy of collateral haircuts, NSCC has determined that in periods where the inflation rate fluctuates, the current haircut levels for TIPS have been inadequate to address the fluctuations from time to time.³² This is because TIPS are indexed to the inflation rate,

and prices on TIPS move inversely to their yields, *e.g.*, when the inflation rate increases, prices on TIPS decrease. When the decline in market value of TIPS exceeds the haircut for TIPS, NSCC would be exposed to potential liquidation losses.³³

Accordingly, NSCC is planning to address haircuts for TIPS in a separate

category, as opposed to as part of a category also including Treasury Bills, Notes, and Bonds, and to increase the haircut levels for TIPS to ensure that the haircut levels would be commensurate with the particular risk attributes of TIPS.³⁴ NSCC describes the new TIPS haircut categories as follows:³⁵

	Maturity	Current (%)	Proposed (%)
TIPS	Zero to 1 year	2.0	2.0
	1 year to 2 years	2.0	3.0
	2 years to 5 years	3.0	5.0
	5 years to 10 years	4.0	7.0
	10 years to 15 years	6.0	7.0
	15 years or greater	6.0	10.0

NSCC conducted an impact study for the period from September 1, 2021 through August 31, 2022 (“Impact Study”).³⁶ The results of the Impact Study indicate that, if the haircut changes for TIPS had been in place, it would have resulted in an average daily increase of \$197,000 in the Clearing Fund assuming TIPS were deposited.³⁷

Finally, NSCC is proposing to clarify language in Sections I.(B)(1), II.(A), II.(B), II.(C) and II.(D) of Procedure XV to reflect that Mutual Fund/Insurance Services Members and other Limited Members are no longer required to make deposits into the Clearing Fund. In 2022, NSCC removed the requirement that any Limited Members, including Mutual Fund/Insurance Services Members, make any deposits to the Clearing Fund.³⁸ Sections I.(B)(1), II.(A), II.(B), II.(C) and II.(D) of Procedure XV still contain references to Mutual Fund/Insurance Service Members and/or Limited Members making deposits into the Clearing Fund, and NSCC states that it would remove those references for clarity.³⁹

IV. Discussion and Commission Findings

Section 19(b)(2)(C) of the Act⁴⁰ directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent

with the requirements of the Act and rules and regulations thereunder applicable to such organization. After carefully considering the Proposed Rule Change, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to NSCC. In particular, the Commission finds that the Proposed Rule Change is consistent with section 17A(b)(3)(F)⁴¹ of the Act and Rules 17Ad–22(e)(5) and (e)(23), each promulgated under the Act.⁴²

A. Consistency With Section 17A(b)(3)(F) of the Act

Section 17A(b)(3)(F) of the Act⁴³ requires that the rules of a clearing agency, such as NSCC, be designed to, among other things, promote the prompt and accurate clearance and settlement of securities transactions and assure the safeguarding of securities and funds which are in the custody or control of the clearing agency or for which it is responsible.⁴⁴ The Commission believes that the Proposed Rule Change is consistent with section 17A(b)(3)(F) of the Act for the reasons stated below.

As stated in Part II *supra*, a key tool that NSCC uses to manage its credit exposures to its members is the daily collection of margin from each member described above, and NSCC applies haircuts to securities collected as

margin to protect NSCC and its members from price fluctuations, *i.e.*, if NSCC is required to liquidate collateral of an insolvent member and such collateral is worth less at the time of liquidation than when it is pledged to NSCC.

By moving the location where collateral haircuts and concentration limits are published from NSCC’s Rules to its website, the Proposed Rule change would add flexibility for NSCC to make timely adjustments to collateral haircuts and concentration limits during a time of potentially deteriorating market or other conditions, while preserving notice requirements to ensure that members are aware of risk management changes. This added flexibility should allow NSCC to continue to ensure that it can address changing market conditions rapidly and ensure that it is collecting sufficient margin to cover its credit exposures to members and minimizing exposures from members with large collateral positions in a particular group of securities with a similar risk profile or in a particular asset type.⁴⁵

By helping NSCC to collect sufficient margin, the Proposed Rule Change would better ensure that, in the event of a member default, NSCC’s operation of its critical clearance and settlement services would not be disrupted because of insufficient financial resources.

such that the principal value of the security rises as inflation rises.

³² Notice of Filing, *supra* note 3, 88 FR at 68779.

³³ *Id.*

³⁴ *Id.* NSCC also stated that its review of TIPS haircuts at other registered clearing agencies demonstrate that NSCC’s current haircut levels for TIPS are generally lower than the TIPS haircuts required by other clearing agencies and foreign CCPs, particularly with respect to maturity ranges of 10 years or longer. *Id.* (summarizing and citing various other clearing agency rules).

³⁵ *Id.* NSCC also reflected the changes with respect to haircuts for TIPS on the haircut schedule filed as Exhibit 3c to the Notice of Filing, which would be posted to its website if the Proposed Rule Change were approved.

³⁶ NSCC filed this Impact Study as confidential Exhibit 3a to the Notice of Filing.

³⁷ Notice of Filing, *supra* note 3, 88 FR at 68780 (also providing a more detailed summary of the Impact Study).

³⁸ See Securities Exchange Act Release No. 93722 (Dec. 6, 2021), 86 FR 70548 (Dec. 10, 2021) (SR–NSCC–2021–015).

³⁹ Notice of Filing, *supra* note 3, 88 FR at 68779.

⁴⁰ 15 U.S.C. 78s(b)(2)(C).

⁴¹ 15 U.S.C. 78q–1(b)(3)(F).

⁴² 17 CFR 240.17Ad–22(e)(5) and (e)(23).

⁴³ 15 U.S.C. 78q–1(b)(3)(F).

⁴⁴ *Id.*

⁴⁵ In addition, the Commission believes that the changes relating to the haircuts for TIPS would allow NSCC to ensure that the haircut levels would be commensurate with the particular risk attributes of TIPS, and thereby assure the safeguarding of securities and funds that are in its custody or control.

Accordingly, the Proposed Rule Change should help NSCC to continue providing prompt and accurate clearance and settlement of securities transactions, consistent with section 17A(b)(3)(F) of the Act.⁴⁶

Moreover, because the Proposed Rule Change would continue to ensure that NSCC collects sufficient margin from members, it should also help minimize the likelihood that NSCC would have to access the Clearing Fund, thereby limiting non-defaulting members' exposure to mutualized losses. By helping to limit the exposure of NSCC's non-defaulting members to mutualized losses, the Proposed Rule Change should help NSCC assure the safeguarding of securities and funds which are in its custody or control, consistent with section 17A(b)(3)(F) of the Act.⁴⁷

Finally, the proposed clarifying changes should help to ensure that NSCC's Rules are clear to members. When members better understand their rights and obligations regarding the Rules, members are more likely to act in accordance with the Rules, which should promote the prompt and accurate clearance and settlement of securities transactions. As such, the proposed clarifying changes are consistent with section 17A(b)(3)(F) of the Act.⁴⁸

B. Consistency With Rule 17Ad-22(e)(5)

Rule 17Ad-22(e)(5) under the Act⁴⁹ requires, in part, a covered clearing agency to establish, implement, maintain and enforce written policies and procedures reasonably designed to set and enforce appropriately conservative haircuts and concentration limits if the covered clearing agency requires collateral to manage its or its participants' credit exposure. As described in Part II *supra*, the proposed changes to move the collateral haircuts and concentration limits from NSCC's Rules should provide NSCC with more flexibility to respond to changing market conditions because adjustments to the haircuts and concentration limits would no longer require a rule change. By being able to make appropriate and timely adjustments to the haircuts and concentration limits, NSCC would have the flexibility to respond to changing market conditions more promptly. Specifically, NSCC would have the ability to promptly set and enforce conservative collateral haircuts and concentration limits that are reflective

of the current market conditions. In this way, the proposed changes to move the collateral haircuts and concentration limits from the Rules to the website should help NSCC set and enforce appropriately conservative collateral haircuts and concentration limits, consistent with the requirements of Rule 17Ad-22(e)(5) under the Act.⁵⁰

C. Consistency With Rule 17Ad-22(e)(23)

Rule 17Ad-22(e)(23)(i) and (ii)⁵¹ under the Act requires each covered clearing agency to establish, implement, maintain, and enforce written policies and procedures reasonably designed to, among other things, publicly disclose all relevant rules and material procedures; and provide sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs they incur by participating in the covered clearing agency. Based on its review of the record, and for the reasons described below, the Commission finds that the proposed changes, taken together, are consistent with the requirements of Rule 17Ad-22(e)(23)(i) and (ii).⁵²

By adopting rules that require NSCC to provide prior notice through public disclosures on its website relating to information on collateral haircuts and concentration limits, NSCC's Rules would support the communication of information that its members may use to identify and evaluate the haircuts and concentration limits resulting from NSCC's processes. As such, the Proposed Rule Change is consistent with publicly disclosing all relevant rules and material procedures; and providing sufficient information to enable participants to identify and evaluate the risks, fees, and other material costs incurred with participation in the covered clearing agency. The Commission finds, therefore, that the Proposed Rule Change is consistent with the requirements of Rule 17Ad-22(e)(23)(i) and (ii) under the Act.⁵³

IV. Conclusion

On the basis of the foregoing, the Commission finds that the Proposed Rule Change is consistent with the requirements of the Act and in particular with the requirements of section 17A of the Act⁵⁴ and the rules

and regulations promulgated thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act⁵⁵ that proposed rule change SR-NSCC-2023-009, be, and hereby is, *approved*.⁵⁶

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁵⁷

Sherry R. Haywood,
Assistant Secretary.

[FR Doc. 2023-25104 Filed 11-14-23; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-98902; File No. 4-809]

Order Granting ICE Clear Europe Limited's Request To Withdraw From Registration as a Clearing Agency

November 9, 2023.

I. Introduction

On August 10, 2023, ICE Clear Europe Limited ("ICE Clear Europe") filed with the Securities and Exchange Commission ("Commission") a written request (the "Written Request")¹ to withdraw from registration as a clearing agency under section 17A of the Securities Exchange Act of 1934 (the "Exchange Act").² ICE Clear Europe also requested the withdrawal of an exemption related to the clearance and settlement of certain futures and options contracts.³ The Commission published notice of ICE Clear Europe's request in the **Federal Register** on September 14, 2023, to solicit comments from interested persons.⁴ The Commission received no comments regarding the request. For the reasons discussed below, the Commission is granting ICE Clear Europe's requests and requiring ICE Clear Europe to retain and produce upon request certain records.

II. Discussion and Commission Findings

ICE Clear Europe is registered with the Commission as a clearing agency under section 17A of the Exchange Act solely for the purpose of clearing

⁵⁵ 15 U.S.C. 78s(b)(2).

⁵⁶ In approving the Proposed Rule Change, the Commission considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

⁵⁷ 17 CFR 200.30-3(a)(12).

¹ See Letter from Hester Serafini, President, ICE Clear Europe, to Vanessa Countryman, Secretary, Commission, dated Aug. 10, 2023.

² 15 U.S.C. 78q-1.

³ See Notice of Withdrawal Request, *infra* at note 4, 88 FR at 63176.

⁴ Securities Exchange Act Release No. 98339 (Sept. 8, 2023), 88 FR 63173 (Sept. 14, 2023) (File No. 4-809) ("Notice of Withdrawal Request").

⁵⁰ *Id.*

⁵¹ 17 CFR 240.17Ad-22(e)(23)(i) and (ii).

⁵² *Id.*

⁵³ *Id.*

⁵⁴ 15 U.S.C. 78q-1.

⁴⁶ 15 U.S.C. 78q-1(b)(3)(F).

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ 17 CFR 240.17Ad-22(e)(5).

security-based swaps (“SBS”).⁵ ICE Clear Europe also is authorized as a recognized clearing house under United Kingdom (“UK”) law;⁶ recognized as a third-country central counterparty under the European Market Infrastructure Regulation;⁷ registered as a derivatives clearing organization under the Commodity Exchange Act;⁸ recognized as a foreign central counterparty under the Swiss Financial Market Infrastructure Act;⁹ and recognized as a remote clearing house in the Abu Dhabi Global Market.¹⁰ ICE Clear Europe provides clearing and settlement services for two primary categories of derivative contracts: (1) exchange-traded futures and options contracts traded on the ICE Futures Europe, ICE Futures U.S., ICE Endex and ICE Futures Abu Dhabi markets (the “F&O Business”); and (2) over-the-counter index and single-name credit default swap (“CDS”) contracts (the “CDS Business”).

In June 2022, by circular published on its website, ICE Clear Europe publicly announced its intention to terminate its CDS Business in 2023, including its clearing of SBS.¹¹ In the Written Request subsequently filed with the Commission, ICE Clear Europe

represented that it would no longer accept CDS contracts for clearing after close of business on October 26, 2023, and would subsequently terminate and settle any open CDS positions.¹² ICE Clear Europe represented further that it would settle all final amounts owed to or by each Clearing Member by November 7, 2023, and that it will not seek to engage in securities clearing activity relating to security-based swaps in reliance on any deemed registered status pursuant to section 17A(l) of the Exchange Act.¹³ ICE Clear Europe therefore submitted its request for withdrawal of its clearing agency registration pursuant to section 19(a)(3) of the Exchange Act, which states that a self-regulatory organization may “withdraw from registration by filing a written notice of withdrawal with the Commission,” upon such terms and conditions as the Commission, by rule, deems necessary or appropriate in the public interest or for the protection of investors.¹⁴

ICE Clear Europe also requested the withdrawal of an exemption it was previously granted related to the clearance and settlement of certain futures and options contracts.¹⁵ In 2013, the Commission exempted ICE Clear Europe from clearing agency registration under section 17A(b) of the Exchange Act and Rule 17Ab2–1¹⁶ thereunder in connection with ICE Clear Europe’s clearing of certain futures and options contracts on underlying U.S. equity securities (the “Securities Product Exemption”).¹⁷ ICE Clear Europe represents that it does not currently clear any equity options or single stock futures on U.S. securities,¹⁸ and that its rules are designed to prohibit ICE Clear Europe from clearing futures or options

on underlying U.S. securities for U.S. persons.¹⁹ ICE Clear Europe believes that the Securities Product Exemption will not be necessary for ICE Clear Europe’s continued operation of the F&O Business, and therefore has requested that the Commission terminate the exemption.²⁰

On November 7, 2023, ICE Clear Europe confirmed to the Commission that it stopped accepting CDS contracts as of close-of-business on October 26, 2023, closed-out all CDS positions on October 27, 2023, returned collateral related to CDS positions, and completed final settlement of amounts owed to or from members related to ICE Clear Europe’s CDS Business on November 7, 2023.²¹ It also re-confirmed the representations in the Written Request regarding record-keeping, record-production, the settlement of existing claims, and the lack of potential for future claims against it resulting from its CDS Business.²²

Based upon the representations made by ICE Clear Europe to the Commission, the Commission has determined that granting ICE Clear Europe’s requests to (i) withdraw its clearing agency registration and (ii) terminate the Securities Product Exemption are appropriate. ICE Clear Europe represents it is no longer performing actions that require registration as a clearing agency under section 17A of the Exchange Act and will not seek to engage in securities clearing activity in reliance on any “deemed registered” status pursuant to section 17A(l) of the Exchange Act.²³ In addition, ICE Clear Europe has provided specific assurances regarding record-keeping, record-production, and both the settlement of existing, and lack of potential for future, claims against it resulting from its CDS Business. Specifically, ICE Clear Europe confirmed that all known claims against it in connection with the CDS Business were settled by November 7, 2023, and that ICE Clear Europe is not aware of any potential future claims against it in connection with the CDS Business.²⁴ ICE Clear Europe also confirmed that, for a period of five years following its withdrawal from registration as a clearing agency, it will retain and maintain all documents, books, and

⁵ See 15 U.S.C. 78q–1. Pursuant to section 17A(l) of the Exchange Act, ICE Clear Europe became “deemed registered” as a clearing agency as part of its CDS Business. See Amendment to Rule Filing Requirements for Dually-Registered Clearing Agencies, Securities Exchange Act Release No. 69284 (Apr. 3, 2013), 78 FR 21046, 21047 & n.20 (Apr. 9, 2013) (File No. S7–29–11). “Clearing agency” is defined in section 3(a)(23)(A) of the Exchange Act as, in relevant part, “any person who acts as an intermediary in making payments or deliveries or both in connection with transactions in securities or who provides facilities for comparison of data respecting the terms of settlement of securities transactions, to reduce the number of settlements of securities transactions, or for the allocation of securities settlement responsibilities.” 15 U.S.C. 78c(a)(23)(A).

⁶ See UK Financial Services and Markets Act of 2000 c. 8, available at <https://www.legislation.gov.uk/ukpga/2000/8/contents>.

⁷ See Regulation (EU) No 648/2012 of the European Parliament and of the Council of 4 July 2012 on OTC derivatives, central counterparties and trade repositories.

⁸ See 7 U.S.C. 7a–1.

⁹ See Federal Act on Financial Market Infrastructures and Market Conduct in Securities and Derivatives Trading of 19 June 2015.

¹⁰ See Abu Dhabi Global Market Financial Services and Markets Regulations 2015, available at <https://en.adgm.thomsonreuters.com/rulebook/financial-services-and-markets-regulations-2015-0>.

¹¹ See Cessation of Clearing of CDS Contracts, Circular C22/076 (June 30, 2022), available at https://www.theice.com/publicdocs/clear_europe/circulars/C22076.pdf (setting Mar. 31, 2023 as the Withdrawal Date); Cessation of Clearing of CDS Contracts: Postponement of Withdrawal Date, Circular C22/109 (Sept. 26, 2022), available at https://www.theice.com/publicdocs/clear_europe/circulars/C22109.pdf (postponing Withdrawal Date to Oct. 27, 2023 in light of suggestions from CDS market participants).

¹² See Notice of Withdrawal Request, 88 FR at 63175.

¹³ See Notice of Withdrawal Request, 88 FR at 63175–76. See also 15 U.S.C. 78q–1(l). ICE Clear Europe further represents that if an affiliate of ICE Clear Europe seeks to clear SBS or another securities product, such affiliate would do so after registering with the Commission pursuant to the process set forth in Commission Rule 17Ab2–1. See Notice of Withdrawal Request, 88 FR at 63176. See also 17 CFR 240.17Ab2–1.

¹⁴ See Notice of Withdrawal Request, 88 FR at 63176; see also 15 U.S.C. 78s(a)(3).

¹⁵ See Notice of Withdrawal Request, 88 FR at 63176.

¹⁶ 15 U.S.C. 78q–1(b) and 17 CFR 240.17Ab2–1.

¹⁷ See Order Pursuant to section 17A of the Securities Exchange Act of 1934 Granting Exemption from the Clearing Agency Registration Requirement Under section 17A(b) of the Exchange Act for ICE Clear Europe Limited in Connection with its Proposal to Clear Contracts Traded on the LIFFE Administration and Management Market, Exchange Act Release No. 69872 (June 27, 2013), 78 FR 40220 (July 3, 2013).

¹⁸ See Notice of Withdrawal Request, 88 FR at 63176 n.36.

¹⁹ See *id.*; ICE Clear Europe Rule 207(g).

²⁰ See Notice of Withdrawal Request, 88 FR at 63176.

²¹ See Letter from Hester Serafini, President, ICE Clear Europe, to Vanessa Countryman, Secretary, Securities and Exchange Commission, dated Nov. 7, 2023 (“Confirmation Letter”).

²² See Confirmation Letter at 2.

²³ See Confirmation Letter at 2; 15 U.S.C. 78q–1(l).

²⁴ See Confirmation Letter at 2.

records in accordance with Rules 17a–1(a) and (b) under the Exchange Act and will furnish such information upon request in accordance Rule 17a–1(c) under the Exchange Act.²⁵ As noted above, no comments were received in response to the published notice of ICE Clear Europe’s Written Request to withdraw from registration as a clearing agency, which included ICE Clear Europe’s representations regarding maintenance of records and record production, as well as ICE Clear Europe’s representations regarding any potential for claims associated with its clearing agency registration. As further noted above, ICE Clear Europe reconfirmed, in writing, the representations made in its Written Request.

III. Conclusion

It is therefore ordered, pursuant to section 19(a)(3) of the Exchange Act,²⁶ that:

(1) Effective as of the date of this Order, ICE Clear Europe’s registration as a clearing agency under section 17A of the Exchange Act is withdrawn;

(2) Effective as of the date of this Order, the exemption under section 17A(b) of the Exchange Act in connection with ICE Clear Europe’s proposal to clear contracts traded on the LIFFE Administration and Management Market is terminated;²⁷ and

(3) For a period of five years from the effective date of withdrawal of registration as a clearing agency, ICE Clear Europe will maintain all the records required to be maintained pursuant to Rule 17A–1(a) and (b) which are in ICE Clear Europe’s possession and will produce such records upon the request of any representative of the Commission, in accordance with Commission Rule 17a–1(c).²⁸

By the Commission.

Sherry Haywood,

Assistant Secretary.

[FR Doc. 2023–25218 Filed 11–14–23; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98888; File No. SR–MEMX–2023–29]

Self-Regulatory Organizations; MEMX LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange’s Fee Schedule To Adopt Connectivity and Application Session Fees for MEMX Options

November 8, 2023.

Pursuant to section 19(b)(1) ¹ of the Securities Exchange Act of 1934 (the “Act”) ² and Rule 19b–4 thereunder,³ notice is hereby given that, on October 24, 2023, MEMX LLC (“MEMX” or the “Exchange”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing with the Commission a proposed rule change to amend the Exchange’s fee schedule applicable to Members ⁴ and non-Members (the “Fee Schedule”) pursuant to Exchange Rules 15.1(a) and (c) to (i) apply the Exchange’s current Connectivity and Application Session fees to MEMX Options Users, (ii) implement a waiver of Connectivity and Application Session fees solely related to participation on MEMX Options until January 1, 2024, and (iii) make an organizational change to its existing fee schedule for the Exchange’s pre-existing equities market (“MEMX Equities”), in order to create a separate fee schedule for Connectivity Fees (for both MEMX Equities and MEMX Options). The Exchange proposes to implement the changes to the Fee Schedule pursuant to this proposal immediately. The text of the proposed rule change is provided in Exhibit 5.

II. Self-Regulatory Organization’s Statement of the Purpose of, and the 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

The Exchange is filing a proposal to amend the Fee Schedule to: (i) apply the Exchange’s current Connectivity and Application Session fees to MEMX Options Users, (ii) implement a waiver of Connectivity and Application Session fees solely related to participation on MEMX Options until January 1, 2024, and (iii) make an organizational change to its existing fee schedule for the Exchange’s pre-existing equities market (“MEMX Equities”), in order to create a separate fee schedule for Connectivity Fees (for both MEMX Equities and MEMX Options). The Exchange believes that these changes will provide greater transparency to Members about how the Exchange assesses fees, as well as allowing Members to more easily validate their bills on a monthly basis. The Exchange notes that none of these changes amend any existing fee applicable to MEMX Equities. The Exchange is proposing to implement the proposal immediately.

As set forth below, the Exchange believes that its proposal provides a great deal of transparency regarding the cost of providing connectivity services and anticipated revenue and that the proposal is consistent with the Act and associated guidance.

(i) Fees for Connectivity to MEMX Options

As noted above, the Exchange is proposing to apply the current fees it charges to Members and non-Members ⁵ for physical connectivity to the Exchange and for application sessions (otherwise known as “logical ports”) that a Member utilizes in connection with their participation on the Exchange (together with physical connectivity,

²⁵ See Confirmation Letter at 2.

²⁶ 15 U.S.C. 78s(a)(3).

²⁷ 15 U.S.C. 78q–1(b).

²⁸ 17 CFR 240.17a–1(a), (b), and (c).

¹ 15 U.S.C. 78s(b)(1).

² 15 U.S.C. 78a.

³ 17 CFR 240.19b–4.

⁴ See Exchange Rule 1.5(p).

⁵ Types of market participants that obtain connectivity services from the Exchange but are not Members include service bureaus and extranets. Service bureaus offer technology-based services to other companies for a fee, including order entry services to Members, and thus, may access application sessions on behalf of one or more Members. Extranets offer physical connectivity services to Members and non-Members.

collectively referred to in this proposal as “connectivity services”, as described in greater detail below) to both Users of MEMX Equities and MEMX Options.⁶ Specifically, the Exchange will continue to charge \$6,000 per month for a physical connection in the data center where the Exchange primarily operates under normal market conditions (“Primary Data Center”), and \$3,000 per month for a physical connection at the geographically diverse data center, which is operated for backup and disaster recovery purposes (“Secondary Data Center”). These physical connections can be used to access both platforms, accordingly, a firm that is a Member of both MEMX Equities and MEMX Options may use a single physical connection to access its application sessions at both MEMX Equities and MEMX Options. This differs from application sessions in that a firm that is a Member of both MEMX Equities and MEMX Options would need to purchase separate application sessions for each trading platform in order to access each such trading platform. These application session fees will continue to be \$450 per month for an application session used for order entry (“Order Entry Port”) and \$450 per month for an application session for receipt of drop copies (“Drop Copy Port”), to the extent such ports are in the Primary Data Center. As is true today for MEMX Equities, the Exchange will not charge for Order Entry Ports or Drop Copy Ports in the Secondary Data Center. The Exchange’s proposal to apply the same fees to Equities and Options stems from the same cost analysis it conducted in adopting those fees to its Equities Members,⁷ which the Exchange has reviewed and updated for 2024 as detailed below. Given that the Exchange has only recently launched MEMX Options, however, and the fact that its analysis is based on projections across all potential revenue streams, the Exchange is committing to conduct a one-year review after these fees are applied. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs, or to decrease fees in the event that revenue materially exceeds expectations.

In general, the Exchange believes that exchanges, in setting fees of all types, should meet very high standards of transparency to demonstrate why each new fee or fee increase meets the

Exchange Act requirements that fees be reasonable, equitably allocated, not unfairly discriminatory, and not create an undue burden on competition among members and markets. In particular, the Exchange believes that each exchange should take extra care to be able to demonstrate that these fees are based on its costs and reasonable business needs.

In proposing to charge fees for connectivity services to MEMX Options, the Exchange has sought to be especially diligent in assessing those fees in a transparent way against its own aggregate costs of providing the related services, and also carefully and transparently assessing the impact on Members—both generally and in relation to other Members, *i.e.*, to assure the fee will not create a financial burden on any participant and will not have an undue impact in particular on smaller Members and competition among Members in general. The Exchange believes that this level of diligence and transparency is called for by the requirements of section 19(b)(1) under the Act,⁸ and Rule 19b–4 thereunder,⁹ with respect to the types of information self-regulatory organizations (“SROs”) should provide when filing fee changes, and section 6(b) of the Act,¹⁰ which requires, among other things, that exchange fees be reasonable and equitably allocated,¹¹ not designed to permit unfair discrimination,¹² and that they not impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Act.¹³ This rule change proposal addresses those requirements, and the analysis and data in each of the sections that follow are designed to clearly and comprehensively show how they are met.¹⁴

As detailed below, MEMX calculated its aggregate annual costs for providing physical connectivity to both MEMX Equities and MEMX Options in 2024 at \$11,448,322 and its aggregate annual costs for providing application sessions

at \$5,918,788. In order to cover the aggregate costs of providing connectivity to its Options and Equities Users (both Members and non-Members) going forward and to make a modest profit, as described below, the Exchange is proposing to modify its Fee Schedule, pursuant to MEMX Rules 15.1(a) and (c), to charge a fee to Options Users, as it currently does to Equities Users, of \$6,000 per month for each physical connection in the Primary Data Center and of \$3,000 per month for each physical connection in the Secondary Data Center. The Exchange also proposes to modify its Fee Schedule, pursuant to MEMX Rules 15.1(a) and (c), to charge a fee to Options Users, as it currently does to Equities Users, of \$450 per month for each Order Entry Port and Drop Copy Port in the Exchange’s Primary Data Center, as further described below.¹⁵

Cost Analysis

Background on Cost Analysis

In September 2023, MEMX completed a study of its aggregate projected costs to produce market data and connectivity across both its Equities and Options platforms in 2024 (the “Cost Analysis”). The Cost Analysis required a detailed analysis of MEMX’s aggregate baseline costs, including a determination and allocation of costs for core services provided by the Exchange—transaction execution, market data, membership services and trading permits, regulatory services, physical connectivity, and application sessions (which provide order entry, cancellation and modification functionality, risk functionality, ability to receive drop copies, and other functionality). MEMX separately divided its costs between those costs necessary to deliver each of these core services, including infrastructure, software, human resources (*i.e.*, personnel), and certain general and administrative expenses (“cost drivers”). Next, MEMX adopted an allocation methodology with various principles to guide how much of a particular cost should be allocated to each core service. For instance, fixed costs that are not driven by client activity (*e.g.*, message rates), such as data center costs, were allocated more heavily to the provision of physical

⁸ 15 U.S.C. 78s(b)(1).

⁹ 17 CFR 240.19b–4.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(4).

¹² 15 U.S.C. 78f(b)(5).

¹³ 15 U.S.C. 78f(b)(8).

¹⁴ In 2019, Commission staff published guidance suggesting the types of information that SROs may use to demonstrate that their fee filings comply with the standards of the Exchange Act (“Fee Guidance”). While MEMX understands that the Fee Guidance does not create new legal obligations on SROs, the Fee Guidance is consistent with MEMX’s view about the type and level of transparency that exchanges should meet to demonstrate compliance with their existing obligations when they seek to charge new fees. See Staff Guidance on SRO Rule Filings Relating to Fees (May 21, 2019) available at <https://www.sec.gov/tm/staff-guidancesro-rule-filings-fees>.

¹⁵ As proposed, fees for connectivity services would be assessed based on each active connectivity service product at the close of business on the first day of each month. If a product is cancelled by a Member’s submission of a written request or via the MEMX User Portal prior to such fee being assessed then the Member will not be obligated to pay the applicable product fee. MEMX will not return pro-rated fees even if a product is not used for an entire month.

⁶ MEMX Options launched on September 27, 2023.

⁷ See Securities Exchange Act Release No. 59846 (September 27, 2022), 87 FR 59845 (October 3, 2022) (SR-MEMX–2022–026).

connectivity (70%), with smaller allocations to logical ports (2%), and the remainder to the provision of transaction execution, regulatory services, and market data services (28%). In contrast, costs that are driven largely by client activity (e.g., message rates), were not allocated to physical connectivity at all but were allocated primarily to the provision of transaction execution and market data services (80%) with a smaller allocation to application sessions (20%). The allocation methodology was decided through conversations with senior management familiar with each area of the Exchange's operations. After adopting this allocation methodology, the Exchange then applied an estimated allocation of each cost driver to each core service, resulting in the cost allocations described below.

By allocating segmented costs to each core service, MEMX was able to estimate by core service the potential margin it might earn based on different fee models. The Exchange notes that as a non-listing venue it has four primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these four primary sources of revenue. The Exchange also notes that as a general matter each of these sources of revenue is based on services that are

interdependent. For instance, the Exchange's system for executing transactions is dependent on physical hardware and connectivity; only Members and parties that they sponsor to participate directly on the Exchange may submit orders to the Exchange; many Members (but not all) consume market data from the Exchange in order to trade on the Exchange; and the Exchange consumes market data from external sources in order to comply with regulatory obligations. Accordingly, given this interdependence, the allocation of costs to each service or revenue source required judgment of the Exchange and was weighted based on estimates of the Exchange that the Exchange believes are reasonable, as set forth below.

Through the Exchange's extensive Cost Analysis, the Exchange analyzed every expense item in the Exchange's general expense ledger to determine whether each such expense relates to the provision of connectivity services, and, if such expense did so relate, what portion (or percentage) of such expense actually supports the provision of connectivity services, and thus bears a relationship that is, "in nature and closeness," directly related to network connectivity services. In turn, the Exchange allocated certain costs more to physical connectivity and others to application sessions, while certain costs were only allocated to such services at a very low percentage or not at all, using

consistent allocation methodologies as described above. Based on this analysis, MEMX estimates that the cost drivers to provide connectivity services in 2024, including both physical connections and application sessions, will result in an aggregate annual cost of \$17,367,110, as further detailed below. The Exchange notes that it utilized the same principles to generate the 2021 Cost Analysis, applicable to Equities only, and at that time, the estimated annual aggregate cost to provide connectivity services was \$13,724,580. The differences between such estimated costs and the overall analysis are primarily based on: (1) the addition of MEMX Options, (ii) increased, and in some cases decreased, costs projected by the Exchange, (iii) and changes made to reallocate certain costs into categories that more closely align the Exchange's audited financial statements, as further described below.

Costs Related to Offering Physical Connectivity

The following chart details the individual line-item costs considered by MEMX to be related to offering physical connectivity as well as the percentage of the Exchange's overall costs such costs represent for such area (e.g., as set forth below, the Exchange allocated approximately 17% of its overall Human Resources cost to offering physical connectivity).

Costs driver	Costs	Percent of all
Human Resources	\$4,685,902	17
Connectivity	413,032	75
Data Center	2,654,732	70
Technology (Hardware, Software Licenses, etc.)	842,258	21
Depreciation	2,030,846	33
External Market Data		0
Allocated Shared Expenses	821,552	12
Total	11,448,322	20.7

Below are additional details regarding each of the line-item costs considered by MEMX to be related to offering physical connectivity, as well as any relevant discussion of how the costs projected for 2024 differ, if any, from the Exchange's previous Cost Analysis conducted in 2021 in adopting Connectivity Fees for its Equities platform, which are the same fees the Exchange is proposing to apply for its Options platform in this filing.¹⁶

Human Resources

In allocating personnel (Human Resources) costs, in order to not double count any allocations, the Exchange first excluded any employee time allocated towards options regulation in order to recoup costs via the Options Regulatory Fee ("ORF").¹⁷ Of the remaining employee time left over, MEMX then calculated an allocation of employee time for employees whose functions include providing and maintaining physical connectivity and performance

thereof (primarily the MEMX network infrastructure team, which spends most of their time performing functions necessary to provide physical connectivity) and for which the Exchange allocated 75% of each employee's time. The Exchange also allocated Human Resources costs to provide physical connectivity to a limited subset of personnel with ancillary functions related to establishing and maintaining such connectivity (such as information security and finance personnel), for which the Exchange allocated cost on an employee-by-employee basis (i.e., only including those personnel who do

¹⁷ See Securities Exchange Act Release No. 98585 (September 28, 2023), 88 FR 68692 (October 4, 2023) (SR-MEMX-2023-05).

¹⁶ See *supra* note 6.

support functions related to providing physical connectivity) and then applied a smaller allocation to such employees (30%).¹⁸ The Exchange notes that it has fewer than 100 employees and each department leader has direct knowledge of the time spent by those spent by each employee with respect to the various tasks necessary to operate the Exchange. The estimates of Human Resources cost were therefore determined by consulting with such department leaders, determining which employees are involved in tasks related to providing physical connectivity, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of their time such employees devote to tasks related to providing physical connectivity. The Exchange notes that senior level executives were only allocated Human Resources costs to the extent the Exchange believed they are involved in overseeing tasks related to providing physical connectivity. The Human Resources cost was calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions.

In 2021, 13.8% of the Exchange's Human Resources costs were allocated towards the provision of physical connectivity, which is slightly lower than the 17% allocation in the current Cost Analysis. The Exchange notes that this increase is due to additional hiring necessary to support network infrastructure, and that in advance of the launch of MEMX Options, this hiring started at the beginning of 2023.

Connectivity

The Connectivity cost includes external fees paid to connect to other exchanges and third parties. The Exchange notes that its connectivity to external markets is required in order to receive market data to run the Exchange's matching engine and basic operations compliant with existing regulations, primarily Regulation NMS. Approximately 75% of the Exchange's connectivity costs are allocated towards the provision of physical connectivity, which is the same percentage identified in the 2021 Cost Analysis. Of note, the 2021 Cost Analysis allocated approximately \$162,000 per month of connectivity costs towards physical connectivity, which is notably higher

than the \$34,420¹⁹ per month allocated under the current Cost Analysis. The Exchange notes that this is due to a substantial redesign in the Exchange's connectivity plan which achieved the cost savings noted. Additionally, in the 2021 Cost Analysis, certain costs were included in the Connectivity category that have since been moved into the broader Technology category.

Data Center

Data Center costs include an allocation of the costs the Exchange incurs to provide physical connectivity in the third-party data centers where it maintains its equipment (such as dedicated space, security services, cooling and power). The Exchange notes that it does not own the Primary Data Center or the Secondary Data Center, but instead, leases space in data centers operated by third parties. The Exchange has allocated a high percentage of the Data Center cost (70%) to physical connectivity because the third-party data centers and the Exchange's physical equipment contained therein is the most direct cost in providing physical access to the Exchange. In other words, for the Exchange to operate in a dedicated space with connectivity of participants to a physical trading platform, the data centers are a very tangible cost, and in turn, if the Exchange did not maintain such a presence then physical connectivity would be of no value to market participants. This slight decrease over the allocation of Data Center costs to physical connectivity from 2021 (75%) is due to the fact that at the time of the 2021 Cost Analysis there were certain one-time costs in establishing the Exchange's data center presence that it will not have in 2024, as well as the fact that in the 2021 Cost Analysis, additional costs were included in the Data Center category that are not included in the current Analysis.

Technology

The Technology category includes the Exchange's network infrastructure, other hardware, software, and software licenses used to operate and monitor physical assets necessary to offer physical connectivity to the Exchange. Of note, certain of these costs were included in the Connectivity and a separate Hardware and Software Licenses category in the 2021 Cost Analysis; however, in order to align more closely with the Exchange's audited financial statements these costs

were combined into the broader Technology category. The Exchange allocated approximately 21% of its Technology costs to physical connectivity in 2024.

Depreciation

All physical assets and software, which also includes assets used for testing and monitoring of Exchange infrastructure, were valued at cost, depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which are owned by the Exchange and some of which are leased by the Exchange in order to allow efficient periodic technology refreshes. As noted above, the Exchange allocated 33% of all depreciation costs to providing physical connectivity. This is a higher percentage than was allocated to providing physical connectivity in 2021 (18.5%), and this increase is due to a high amount of capital expenditures required to build the Exchange's options platform, none of which began to depreciate until the launch of options in September 2023. The Exchange notes, however, that it did not allocate depreciation costs for any internally developed software to build the Exchange's trading platforms to physical connectivity, as such software does not impact the provision of physical connectivity.

External Market Data

External Market Data includes fees paid to third parties, including other exchanges, to receive and consume market data from other markets. The Exchange notes that it did not allocate any External Market Data fees to the provision of physical connectivity as market data is not related to such services.

Allocated Shared Expenses

Finally, a limited portion of general shared expenses was allocated to physical connectivity as without these general shared costs the Exchange would not be able to operate in the manner that it does and provide physical connectivity. The costs included in general shared expenses include general expenses of the Exchange, including office space and office expenses (e.g., occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications costs. The Exchange notes that the cost of paying directors to serve on its Board of

¹⁸To reiterate, these allocations are applied to the percentage of employee time left over after the ORF allocation. As such, if 10% of an employee's time was allocated towards options regulation, the percentage of time allocated to physical connectivity in this example would apply to the 90% of the employee's time left over.

¹⁹This figure is arrived at by dividing the annual allocated Connectivity costs in the table on page 11 (\$413,032) by 12.

Directors is also included in the Exchange's general shared expenses, and thus a portion of such overall cost amounting to 23% of the overall cost for directors was allocated to providing physical connectivity. The Exchange notes that the 12% allocation of general shared expenses for physical connectivity is lower than that allocated to general shared expenses for application sessions based on its allocation methodology that weighted

costs attributable to each Core Service based on an understanding of each area. While physical connectivity has several areas where certain tangible costs are heavily weighted towards providing such service (e.g., Data Centers, as described above), physical connectivity does not require as many broad or indirect resources as other Core Services.

Costs Related to Offering Application Sessions

The following chart details the individual line-item costs considered by MEMX to be related to offering application sessions as well as the percentage of the Exchange's overall costs such costs represent for such area (e.g., as set forth below, the Exchange allocated approximately 12% of its overall Human Resources cost to offering application sessions).

Costs driver	Costs	Percent of all
Human Resources	\$3,251,548	12
Connectivity	7,097	0
Data Center	86,513	2
Technology (Hardware, Software Licenses, etc.)	459,116	11
Depreciation	553,931	9
External Market Data	420,394	18
Allocated Shared Expenses	1,140,189	17
Total	5,918,788	10.7

Human Resources

With respect to application sessions, MEMX calculated Human Resources cost by taking an allocation of employee time for employees whose functions include providing application sessions and maintaining performance thereof (including a broader range of employees such as technical operations personnel, market operations personnel, and software engineering personnel) as well as a limited subset of personnel with ancillary functions related to maintaining such connectivity (such as sales, membership, and finance personnel). The estimates of Human Resources cost were again determined by consulting with department leaders, determining which employees are involved in tasks related to providing application sessions and maintaining performance thereof, and confirming that the proposed allocations were reasonable based on an understanding of the percentage of their time such employees devote to tasks related to providing application sessions and maintaining performance thereof. The Exchange notes that senior level executives were only allocated Human Resources costs to the extent the Exchange believed they are involved in overseeing tasks related to providing application sessions and maintaining performance thereof. The Human Resources cost was again calculated using a blended rate of compensation reflecting salary, equity and bonus compensation, benefits, payroll taxes, and 401(k) matching contributions. As shown in the table above, for 2024, the Exchange allocated approximately 12%

of its Human Resources costs to providing application sessions, which is higher than the 7.7% it allocated in 2021. This increase is again due to additional hiring needed to support the addition of MEMX Options.

Connectivity

The Connectivity cost includes external fees paid to connect to other exchanges, as described above. The Exchange did not allocate any Connectivity costs to application sessions in the current Cost Analysis, which differs from the 2.6% allocated towards application sessions in the 2021 Cost Analysis. This difference is due to the fact that certain formerly categorized Connectivity costs are now categorized under Technology in the current 2024 Cost Analysis.

Data Center

Data Center costs includes an allocation of the costs the Exchange incurs to provide physical connectivity in the third-party data centers where it maintains its equipment as well as related costs (the Exchange does not own the Primary Data Center or the Secondary Data Center, but instead, leases space in data centers operated by third parties). As shown in the table, the Exchange allocated 2% of its Data Center costs to application sessions in the current Cost Analysis, which is in line with the 2.6% it allocated in the 2021 Cost Analysis.

Technology

The Technology category includes the Exchange's network infrastructure, other hardware, software, and software

licenses used to monitor the health of the order entry services provided by the Exchange. The Exchange allocated 11% of its Technology costs to the provision of application sessions, which is in line with the 10.1% it allocated in the 2021 Cost Analysis.

External Market Data

External Market Data includes fees paid to third parties, including other exchanges, to receive and consume market data from other markets. The Exchange allocated 18% of External Market Data fees to the provision of application sessions as such market data is necessary to offer certain services related to such sessions, such as validating orders on entry against the National Best Bid and National Best Offer ("NBBO") and checking for other conditions (e.g., whether a symbol is halted or subject to a short sale circuit breaker). Thus, as market data from other exchanges is consumed at the application session level in order to validate orders before additional processing occurs with respect to such orders, the Exchange believes it is reasonable to allocate a small amount of such costs to application sessions. The increase in allocation of External Market Data costs to the provision of application sessions compared to the 2021 Cost Analysis, in which 7.5% of its External Market Data costs were allocated, is due to a restructuring of the category. Specifically, in 2021, External Market Data only included those costs incurred to receive data from other exchanges, while costs to receive the SIP feeds and other non-exchange data feeds were categorized under Hardware

and Software Licenses. These costs are now all categorized under External Market Data.

Depreciation

All physical assets and software, which also includes assets used for testing and monitoring of order entry infrastructure, were valued at cost, depreciated or leased over periods ranging from three to five years. Thus, the depreciation cost primarily relates to servers necessary to operate the Exchange, some of which is owned by the Exchange and some of which is leased by the Exchange in order to allow efficient periodic technology refreshes. The Exchange allocated 9% of all depreciation costs to providing application sessions. In contrast to physical connectivity, described above, the Exchange did allocate depreciation costs for depreciated internally developed software to build the Exchange's platforms to application sessions because such software is related to the provision of such connectivity.

Allocated Shared Expenses

Finally, a limited portion of general shared expenses was allocated to overall application session costs as without these general shared costs the Exchange would not be able to operate in the manner that it does and provide application sessions. The costs included in general shared expenses include general expenses of the Exchange, including office space and office expenses (e.g., occupancy and overhead expenses), utilities, recruiting and training, marketing and advertising costs, professional fees for legal, tax and accounting services (including external and internal audit expenses), and telecommunications costs. The Exchange again notes that the cost of paying directors to serve on its Board of Directors is included in the calculation of Allocated Shared Expenses, and thus a portion of such overall cost amounting to less than 20% of the overall cost for directors was allocated to providing application sessions. The Exchange notes that the 17% allocation of general shared expenses for application sessions is higher than that allocated to general shared expenses for physical connectivity based on its allocation methodology that weighted costs attributable to each Core Service based on an understanding of each area. While physical connectivity has several areas where certain tangible costs are heavily weighted towards providing such service (e.g., Data Centers, as described above), application sessions require a broader level of support from Exchange

personnel in different areas, which in turn leads to a broader general level of cost to the Exchange.

Cost Analysis—Additional Discussion

In conducting its Cost Analysis, the Exchange did not allocate any of its expenses in full to any core services (including physical connectivity or application sessions) and did not double-count any expenses. Instead, as described above, the Exchange allocated applicable cost drivers across its core services and used the same Cost Analysis to form the basis of this proposal and the filing it recently submitted proposing the establishment of an ORF.²⁰ For instance, in calculating the Human Resources expenses to be allocated to physical connections, the Exchange has a team of employees dedicated to network infrastructure and with respect to such employees the Exchange allocated network infrastructure personnel with a high percentage of the time of such personnel (75%) given their focus on functions necessary to provide physical connections. The time of those same personnel were allocated only 6% to application sessions and the remaining 19% was allocated to transactions and market data. Of note, this allocation applied only to the network infrastructure employee's time that was left over after allocating for options regulation support. The Exchange did not allocate any other Human Resources expense for providing physical connections to any other employee group outside of a smaller allocation (30%) of the employee time associated with certain specified personnel who work closely with and support network infrastructure personnel. In contrast, the Exchange allocated much smaller percentages of employee time (15% or less) across a wider range of personnel groups in order to allocate Human Resources costs to providing application sessions. This is because a much wider range of personnel are involved in functions necessary to offer, monitor and maintain application sessions but the tasks necessary to do so are not a primary or full-time function.

In total, the Exchange allocated 17% of its Human Resources costs to providing physical connections and 12% of its Human Resources costs to providing application sessions, for a total allocation of 29% of its Human Resources expense to provide connectivity services. In turn, the Exchange allocated the remaining 71% of its Human Resources expense to Regulatory Services (21%), membership

(2%) and transactions and market data (48%). Thus, again, the Exchange's allocations of cost across core services were based on real costs of operating the Exchange and were not double-counted across the core services or their associated revenue streams.

As another example, the Exchange allocated depreciation expense to all core services, including physical connections and application sessions, but in different amounts. The Exchange believes it is reasonable to allocate the identified portion of such expense because such expense includes the actual cost of the computer equipment, such as dedicated servers, computers, laptops, monitors, information security appliances and storage, and network switching infrastructure equipment, including switches and taps that were purchased to operate and support the network. Without this equipment, the Exchange would not be able to operate the network and provide connectivity services to its Members and non-Members and their customers. However, the Exchange did not allocate all of the depreciation and amortization expense toward the cost of providing connectivity services, but instead allocated approximately 42% of the Exchange's overall depreciation and amortization expense to connectivity services (33% attributed to physical connections and 9% to application sessions). The Exchange allocated the remaining depreciation and amortization expense (approximately 58%) toward regulatory services (approximately 8%), and to providing transaction services and market data (approximately 50%).

Looking at the Exchange's operations holistically, the estimated total monthly costs to the Exchange for offering core services in 2024 is \$4,604,583, compared to the \$3,954,537 noted in the 2021 Cost Analysis. Based on its projections, the Exchange expects to collect approximately \$1,768,800 on a monthly basis for connectivity services. Incorporating this amount into the Exchange's overall projected revenue, including projections related to the ORF, the Exchange anticipates monthly revenue of approximately \$5,988,620 from all sources (i.e., connectivity fees and membership fees, transaction fees, ORF, and revenue from market data, both through the fees adopted in April 2022²¹ and through the revenue received from the SIPs). As such, applying the Exchange's holistic Cost Analysis to a holistic view of

²⁰ See *supra* note 16.

²¹ See Securities Exchange Act Release No. 97130 (March 13, 2013), 88 FR 16491 (March 17, 2023) (SR-MEMX-2023-04).

anticipated revenues, the Exchange would earn approximately 23% margin on its operations as a whole. The Exchange believes that this amount is reasonable.

The Exchange notes that its revenue estimates are based on projections across all potential revenue streams and will only be realized to the extent such revenue streams actually produce the revenue estimated. As a new entrant to the hyper-competitive exchange environment, and an exchange focused on driving competition, the Exchange does not yet know whether such expectations will be realized. For instance, in order to generate the revenue expected from connectivity, the Exchange will have to be successful in retaining existing options clients that wish to maintain physical connectivity and/or application sessions or in obtaining new clients that will purchase such services. Similarly, the Exchange will have to be successful in retaining a positive net capture on transaction fees in order to realize the anticipated revenue from transaction pricing.

The Exchange notes that the Cost Analysis was based on the Exchange's operations in 2023 (which is currently underway) and projections for the next year. As such, the Exchange believes that its costs will remain relatively similar in future years (as demonstrated by the comparison of the 2021 Cost Analysis to the 2024 Cost Analysis). It is possible however that such costs will either decrease or increase. To the extent the Exchange sees growth in use of connectivity services it will receive additional revenue to offset future cost increases. However, if use of connectivity services is static or decreases, the Exchange might not realize the revenue that it anticipates or needs in order to cover applicable costs. Accordingly, the Exchange is committing to conduct a one-year review after implementation of these fees. The Exchange expects that it may propose to adjust fees at that time, to increase fees in the event that revenues fail to cover costs and a reasonable mark-up of such costs. Similarly, the Exchange would propose to decrease fees in the event that revenue materially exceeds our current projections. In addition, the Exchange will periodically conduct a review to inform its decision making on whether a fee change is appropriate (e.g., to monitor for costs increasing/decreasing or subscribers increasing/decreasing in ways that suggest the then-current fees are becoming dislocated from the prior cost-based analysis) and would propose to increase fees in the event that revenues fail to cover its costs and a reasonable

mark-up, or decrease fees in the event that revenue or the mark-up materially exceeds our current projections. In the event that the Exchange determines to propose a fee change, the results of a timely review, including an updated cost estimate, will be included in the rule filing proposing the fee change. More generally, the Exchange believes that it is appropriate for an exchange to refresh and update information about its relevant costs and revenues in seeking any future changes to fees, and the Exchange commits to do so.

Proposed Fees

Physical Connectivity Fees

MEMX offers its Members the ability to connect to the Exchange in order to transmit orders to and receive information from the Exchange. Members can also choose to connect to MEMX indirectly through physical connectivity maintained by a third-party extranet. Extranet physical connections may provide access to one or multiple Members on a single connection. Users of MEMX physical connectivity services (both Members and non-Members²²) seeking to establish one or more connections with the Exchange submit a request to the Exchange via the MEMX User Portal or directly to Exchange personnel. Upon receipt of the completed instructions, MEMX establishes the physical connections requested by the User. The number of physical connections assigned to each User (for both equities and options) as of October 1, 2023, ranges from one (1) to 30, depending on the scope and scale of the Member's trading activity on the Exchange as determined by the Member, including the Member's determination of the need for redundant connectivity. Separate physical connections are not required to access the Exchange's Options and Equities platforms, as such, a User could use a single connection to access both platforms. The Exchange notes that 52% of its Members do not maintain a physical connection directly with the Exchange in the Primary Data Center (though many such Members have connectivity through a third-party provider) and 24 members, or 32% have either one or two physical ports to connect to the Exchange in the Primary Data Center.²³ Thus, only a limited number of Members, (12 members, or 16%), maintain three or more physical

ports to connect to the Exchange in the Primary Data Center.²⁴

As described above, the Exchange has previously justified its pricing with respect to MEMX Equities and believes the most fair approach, absent a significant differentiation between application costs to Equities and Options, is to apply the same pricing to all participants of either platform. As such, in order to cover the aggregate costs of providing physical connectivity to Options and Equities Users and make a modest profit, as described below, the Exchange is proposing to charge a fee of \$6,000 per month for each physical connection in the Primary Data Center and a fee of \$3,000 per month for each physical connection in the Secondary Data Center for connections to its Options platform, as it currently charges for connections to its Equities platform. There is no requirement that any Member maintain a specific number of physical connections and a Member may choose to maintain as many or as few of such connections as each Member deems appropriate. Further, as noted above, existing Equities Members may choose to use their existing physical connection(s) to access the Exchange's Options platform.

The Exchange notes, however, that pursuant to Rule 2.4 (Mandatory Participation in Testing of Backup Systems), the Exchange does require a small number of Members to connect and participate in functional and performance testing as announced by the Exchange, which occurs at least once every 12 months. Specifically, Members that have been determined by the Exchange to contribute a meaningful percentage of the Exchange's overall volume must participate in mandatory testing of the Exchange's backup systems (i.e., such Members must connect to the Secondary Data Center). The Exchange notes that designated Members are still able to use third-party providers of connectivity to access the Exchange at its Secondary Data Center, and that for its Equities platform, one of eight such designated Members does use a third-party provider instead of connecting directly to the Secondary Data Center through connectivity provided by the Exchange. Nonetheless, because some Members are required to connect to the Secondary Data Center pursuant to Rule 2.4 and to encourage Exchange Members to connect to the Secondary Data Center generally, the Exchange has proposed to charge one-half of the fee for a physical connection

²² See *supra* note 4.

²³ Of those 24 members, six (6) have designated certain of their physical ports will be used to connect to MEMX Options.

²⁴ Of those 12 members, nine (9) have designated certain of their physical ports will be used to connect to MEMX Options.

in the Primary Data Center for its Options platform, as it currently charges for Equities. The Exchange notes that its costs related to operating the Secondary Data Center were not separately calculated for purposes of this proposal, but instead, all costs related to providing physical connections were considered in the aggregate. The Exchange believes this is appropriate because had the Exchange calculated such costs separately and then determined the fee per physical connection that would be necessary for the Exchange to cover its costs for operating the Secondary Data Center, the costs would likely be much higher than those proposed for connectivity at the Primary Data Center because Members maintain significantly fewer connections at the Secondary Data Center. The Exchange believes that charging a higher fee for physical connections at the Secondary Data Center would be inconsistent with its objective of encouraging Members to connect at such data center and is inconsistent with the fees charged by other exchanges, which also provide connectivity for disaster recovery purposes at a discounted rate.²⁵

The proposed fee will not apply differently based upon the size or type of the market participant, but rather based upon the number of physical connections a User requests, based upon factors deemed relevant by each User (either a Member, service bureau or extranet). The Exchange believes these factors include the costs to maintain connectivity, business model and choices Members make in how to participate on the Exchange, as further described below.

The proposed fee of \$6,000 per month for physical connections at the Primary Data Center is designed to permit the Exchange to cover the costs allocated to providing connectivity services with a modest markup (approximately 19%), which would also help fund future expenditures (increased costs, improvements, etc.). The Exchange believes it is appropriate to charge fees that represent a reasonable markup over cost given the other factors discussed above and the need for the Exchange to maintain a highly performant and stable platform to allow Members to transact with determinism.

As noted above, the Exchange proposes a discounted rate of \$3,000 per month for physical connections at its Secondary Data Center. The Exchange has proposed this discounted rate for

Secondary Data Center connectivity in order to encourage Members to establish and maintain such connections. Also, as noted above, a small number of Members are required pursuant to Rule 2.4 to connect and participate in testing of the Exchange's backup systems, and the Exchange believes it is appropriate to provide a discounted rate for physical connections at the Secondary Data Center given this requirement. The Exchange notes that this rate is well below the cost of providing such services and the Exchange will operate its network and systems at the Secondary Data Center without recouping the full amount of such cost through connectivity services.

The proposed fee for physical connections is effective on filing and will become operative immediately, subject to the proposed waiver described below.

Application Session Fees

Similar to other exchanges, MEMX offers its Members application sessions, also known as logical ports, for order entry and receipt of trade execution reports and order messages. Members can also choose to connect to MEMX indirectly through a session maintained by a third-party service bureau. Service bureau sessions may provide access to one or multiple Members on a single session. Users of MEMX connectivity services (both Members and non-Members²⁶) seeking to establish one or more application sessions with the Exchange submit a request to the Exchange via the MEMX User Portal or directly to Exchange personnel. Upon receipt of the completed instructions, MEMX assigns the User the number of sessions requested by the User. The number of sessions assigned to each User as of August 31, 2022, ranges from one (1) to more than 150 depending on the scope and scale of the Member's trading activity on the Exchange (either through a direct connection or through a service bureau) as determined by the Member. For example, by using multiple sessions, Members can segregate order flow from different internal desks, business lines, or customers. The Exchange does not impose any minimum or maximum requirements for how many application sessions a Member or service bureau can maintain, and it is not proposing to impose any minimum or maximum session requirements for its Members or their service bureaus. The same application session cannot be used to access both MEMX Equities and MEMX Options, as such, Users will need to

purchase separate application sessions for MEMX Options, which differs from physical connections.

As described above, in order to cover the aggregate costs of providing application sessions to Options Users and to make a modest profit, as described below, the Exchange is proposing to charge a fee of \$450 per month for each Order Entry Port and Drop Copy Port in the Primary Data Center for Options application sessions, which is the same fee it currently charges for Equities application sessions. The Exchange notes that it does not propose to charge for: (1) Order Entry Ports or Drop Copy Ports in the Secondary Data Center, or (2) any Test Facility Ports or MEMOIR Gap Fill Ports, again, which it does not charge for Equities Users. The Exchange has proposed to continue to provide Order Entry Ports and Drop Copy Ports in the Secondary Data Center for Options free of charge in order to encourage Members to connect to the Exchange's backup trading systems. Similarly, because the Exchange wishes to encourage Members to conduct appropriate testing of their use of the Exchange, the Exchange has not proposed to charge for Test Facility Ports. With respect to MEMOIR Gap Fill ports, such ports are exclusively used in order to receive information when a market data recipient has temporarily lost its view of MEMX market data. The Exchange has not proposed charging for such ports because the costs of providing and maintaining such ports is more directly related to producing market data.

The proposed fee of \$450 per month for each Order Entry Port and Drop Copy Port in the Primary Data Center is designed to permit the Exchange to cover the costs allocated to providing application sessions with a modest markup (approximately 17%), which would also help fund future expenditures (increased costs, improvements, etc.).

The proposed fee is also designed to encourage Users to be efficient with their application session usage, thereby resulting in a corresponding increase in the efficiency that the Exchange would be able to realize in managing its aggregate costs for providing connectivity services. There is no requirement that any Member maintain a specific number of application sessions and a Member may choose to maintain as many or as few of such ports as each Member deems appropriate. The Exchange has designed its platform such that Order Entry Ports can handle a significant amount of message traffic (*i.e.*, over 50,000 orders

²⁵ See, e.g., the BZX options fee schedule, available at: https://www.cboe.com/us/options/membership/fee_schedule/bzx/.

²⁶ See *supra* note 4.

per second), and has no application flow control or order throttling. In contrast, other exchanges maintain certain thresholds that limit the amount of message traffic that a single logical port can handle.²⁷ As such, while several Members maintain a relatively high number of ports because that is consistent with their usage on other exchanges and is preferable for their own reasons, the Exchange believes that it has designed a system capable of allowing such Members to significantly reduce the number of application sessions maintained.

The proposed fee will not apply differently based upon the size or type of the market participant, but rather based upon the number of application sessions a User requests, based upon factors deemed relevant by each User (either a Member or service bureau on behalf of a Member). The Exchange believes these factors include the costs to maintain connectivity and choices Members make in how to segment or allocate their order flow.²⁸

The proposed fee for application sessions is effective on filing and will become operative immediately, subject to the proposed waiver described below.

Proposed Fees—Additional Discussion

As discussed above, the proposed fees for connectivity services do not by design apply differently to different types or sizes of Members. As discussed in more detail in the Statutory Basis section, the Exchange believes that the likelihood of higher fees for certain Members subscribing to connectivity services usage than others is not unfairly discriminatory because it is based on objective differences in usage of connectivity services among different Members. The Exchange's incremental aggregate costs for all connectivity services are disproportionately related

to Members with higher message traffic and/or Members with more complicated connections established with the Exchange, as such Members: (1) consume the most bandwidth and resources of the network; (2) transact the vast majority of the volume on the Exchange; and (3) require the high-touch network support services provided by the Exchange and its staff, including network monitoring, reporting and support services, resulting in a much higher cost to the Exchange to provide such connectivity services. For these reasons, MEMX believes it is not unfairly discriminatory for the Members with higher message traffic and/or Members with more complicated connections to pay a higher share of the total connectivity services fees. While Members with a business model that results in higher relative inbound message activity or more complicated connections are projected to pay higher fees, the level of such fees is based solely on the number of physical connections and/or application sessions deemed necessary by the Member and not on the Member's business model or type of Member. The Exchange notes that the correlation between message traffic and usage of connectivity services is not completely aligned because Members individually determine how many physical connections and application sessions to request, and Members may make different decisions on the appropriate ways based on facts unique to their individual businesses. Based on the Exchange's architecture, as described above, the Exchange believes that a Member even with high message traffic would be able to conduct business on the Exchange with a relatively small connectivity services footprint.

Finally, the fees for connectivity services will help to encourage connectivity services usage in a way that aligns with the Exchange's regulatory obligations. As a national securities exchange, the Exchange is subject to Regulation Systems Compliance and Integrity ("Reg SCI").²⁹ Reg SCI Rule 1001(a) requires that the Exchange establish, maintain, and enforce written policies and procedures reasonably designed to ensure (among other things) that its Reg SCI systems have levels of capacity adequate to maintain the Exchange's operational capability and promote the maintenance of fair and orderly markets.³⁰ By encouraging Users to be efficient with their usage of connectivity services, the proposed fee will support the

Exchange's Reg SCI obligations in this regard by ensuring that unused application sessions are available to be allocated based on individual User needs and as the Exchange's overall order and trade volumes increase. Additionally, because the Exchange will charge a lower rate for a physical connection to the Secondary Data Center and will not charge any fees for application sessions at the Secondary Data Center or its Test Facility, the proposed fee structure will further support the Exchange's Reg SCI compliance by reducing the potential impact of a disruption should the Exchange be required to switch to its Disaster Recovery Facility and encouraging Members to engage in any necessary system testing with low or no cost imposed by the Exchange.³¹

(ii) Options Connectivity Fee Waiver

To encourage new participants to join the Exchange as Members in order to participate in MEMX Options, the Exchange is proposing to waive all Connectivity Fees used solely for MEMX Options until January 1, 2024. As noted above, physical connections may be used to access both Equities and Options, and as such, the Exchange will internally verify whether new connections are being used solely for Options connections in order to determine whether such connection qualifies for this waiver. Separately, Members specify the Exchange to which their requested application sessions should connect, and as such, any new application sessions for MEMX Options will qualify for this waiver.

(iii) Organizational Fee Schedule Changes

The Exchange is proposing to more clearly separate Connectivity Fees from the Exchange's current fee schedule. Currently, the Exchange has separate transaction fee schedules for Equities and Options, and the current Connectivity fees appear solely on the Equities fee schedule. The Exchange proposes to remove the Connectivity fees section from the Equities fee schedule, and add hyperlinks at the bottom of the Equities and Options fee

²⁷ See, e.g., Cboe US Options BOE Specification, available at: https://cdn.cboe.com/resources/membership/US_Options_BOE_Specification.pdf (describing a 5,000 message per second Port Order Rate Threshold on Cboe BOE ports).

²⁸ The Exchange understands that some Members (or service bureaus) may also request more Order Entry Ports to enable the ability to send a greater number of simultaneous order messages to the Exchange by spreading orders over more Order Entry Ports, thereby increasing throughput (*i.e.*, the potential for more orders to be processed in the same amount of time). The degree to which this usage of Order Entry Ports provides any throughput advantage is based on how a particular Member sends order messages to MEMX, however the Exchange notes that its architecture reduces the impact or necessity of such a strategy. All Order Entry Ports on MEMX provide the same throughput, and as noted above, the throughput is likely adequate even for a Member sending a significant amount of volume at a fast pace, and is not artificially throttled or limited in any way by the Exchange.

²⁹ 17 CFR 242.1000–1007.

³⁰ 17 CFR 242.1001(a).

³¹ While some Members might directly connect to the Secondary Data Center and incur the proposed \$3,000 per month fee, there are other ways to connect to the Exchange, such as through a service bureau or extranet, and because the Exchange is not imposing fees for application sessions in the Secondary Data Center, a Member connecting through another method would not incur any fees charged directly by the Exchange. However, the Exchange notes that a third-party service provider providing connectivity to the Exchange likely would charge a fee for providing such connectivity; such fees are not set by or shared in by the Exchange.

schedules that direct the User to a single Connectivity fee schedule. The Exchange believes this format is appropriate given that the same Connectivity Fees apply to both Equities and Options Users, and separating out the fee schedule for Connectivity Fees will reduce potential confusion (*e.g.*, as to which fees a Member that participates on both MEMX Equities and MEMX Options must pay on a monthly basis to maintain connectivity to the Exchange).

The Exchange also proposes to add three additional bullet points to the new Connectivity Fee Schedule related to MEMX Options. The first will notify Members that a physical connection can be used to access MEMX Equities and/or MEMX Options. The second will clarify that an application session can only be used to access one MEMX platform, *i.e.*, MEMX Equities or MEMX Options. The third will note that Connectivity and application session fees solely related to participation on MEMX Options are waived until January 1, 2024. The Exchange notes that the existing bullet points related to Connectivity and application sessions will be included on the proposed separate Connectivity Fee Schedule, (*i.e.*, detailing the Exchange's billing practices, and making clear that the Exchange does not charge for: (1) Order Entry Ports or Drop Copy Ports in the Secondary Data Center, or (2) any Test Facility Ports or MEMOIR Gap Fill Ports).

2. Statutory Basis

The Exchange believes that the proposed fees for connectivity services to MEMX Options are reasonable, equitable and not unfairly discriminatory because, as described above, the proposed pricing for connectivity services is directly related to the relative costs to the Exchange to provide those respective services and does not impose a barrier to entry to smaller participants.

The Exchange recognizes that there are various business models and varying sizes of market participants conducting business on the Exchange. The Exchange's incremental aggregate costs for all connectivity services are disproportionately related to Members with higher message traffic and/or Members with more complicated connections established with the Exchange, as such Members: (1) consume the most bandwidth and resources of the network; (2) transact the vast majority of the volume on the Exchange; and (3) require the high-touch network support services provided by the Exchange and its staff, including network monitoring, reporting

and support services, resulting in a much higher cost to the Exchange to provide such connectivity services. Accordingly, the Exchange believes the allocation of the proposed fees that increase based on the number of physical connections or application sessions is reasonable based on the resources consumed by the respective type of market participant (*i.e.*, lowest resource consuming Members will pay the least, and highest resource consuming Members will pay the most), particularly since higher resource consumption translates directly to higher costs to the Exchange.

With regard to reasonableness, the Exchange understands that when appropriate given the context of a proposal the Commission has taken a market-based approach to examine whether the SRO making the proposal was subject to significant competitive forces in setting the terms of the proposal. In looking at this question, the Commission considers whether the SRO has demonstrated in its filing that: (i) there are reasonable substitutes for the product or service; (ii) "platform" competition constrains the ability to set the fee; and/or (iii) revenue and cost analysis shows the fee would not result in the SRO taking supra-competitive profits. If the SRO demonstrates that the fee is subject to significant competitive forces, the Commission will next consider whether there is any substantial countervailing basis to suggest the fee's terms fail to meet one or more standards under the Exchange Act. If the filing fails to demonstrate that the fee is constrained by competitive forces, the SRO must provide a substantial basis, other than competition, to show that it is consistent with the Exchange Act, which may include production of relevant revenue and cost data pertaining to the product or service.

MEMX believes the proposed fees for connectivity services are fair and reasonable as a form of cost recovery for the Exchange's aggregate costs of offering connectivity services to Members and non-Members. The proposed fees are expected to generate monthly revenue of \$1,768,800 providing cost recovery to the Exchange for the aggregate costs of offering connectivity services, based on a methodology that narrowly limits the cost drivers that are allocated cost to those closely and directly related to the particular service. In addition, this revenue will allow the Exchange to continue to offer, to enhance, and to continually refresh its infrastructure as necessary to offer a state-of-the-art trading platform. The Exchange believes

that, consistent with the Act, it is appropriate to charge fees that represent a reasonable markup over cost given the other factors discussed above. The Exchange also believes the proposed fee is a reasonable means of encouraging Users to be efficient in the connectivity services they reserve for use, with the benefits to overall system efficiency to the extent Members and non-Members consolidate their usage of connectivity services or discontinue subscriptions to unused physical connectivity.

The Exchange further believes that the proposed fees, as they pertain to purchasers of each type of connectivity alternative, constitute an equitable allocation of reasonable fees charged to the Exchange's Members and non-Members and are allocated fairly amongst the types of market participants using the facilities of the Exchange.

As described above, the Exchange believes the proposed fees are equitably allocated because the Exchange's incremental aggregate costs for all connectivity services are disproportionately related to Members with higher message traffic and/or Members with more complicated connections established with the Exchange, as such Members: (1) consume the most bandwidth and resources of the network; (2) transact the vast majority of the volume on the Exchange; and (3) require the high-touch network support services provided by the Exchange and its staff, including network monitoring, reporting and support services, resulting in a much higher cost to the Exchange to provide such connectivity services.

Commission staff previously noted that the generation of supra-competitive profits is one of several potential factors in considering whether an exchange's proposed fees are consistent with the Act.³² As described in the Fee Guidance, the term "supra-competitive profits" refers to profits that exceed the profits that can be obtained in a competitive market. The proposed fee structure would not result in excessive pricing or supra-competitive profits for the Exchange. The proposed fee structure is merely designed to permit the Exchange to cover the costs allocated to providing connectivity services with a modest markup (on average, approximately 18%), which would also help fund future expenditures (increased costs, improvements, etc.). The Exchange believes that this is fair, reasonable, and equitable. Accordingly, the Exchange believes that its proposal is consistent

³² See Fee Guidance, *supra* note 13.

with section 6(b)(4)³³ of the Act because the proposed fees will permit recovery of the Exchange's costs and will not result in excessive pricing or supra-competitive profit.

The proposed fees for Options connectivity services will allow the Exchange to cover certain costs incurred by the Exchange associated with providing and maintaining necessary hardware and other network infrastructure as well as network monitoring and support services; without such hardware, infrastructure, monitoring and support the Exchange would be unable to provide the connectivity services. The Exchange routinely works to improve the performance of the network's hardware and software. The costs associated with maintaining and enhancing a state-of-the-art exchange network is a significant expense for the Exchange, and thus the Exchange believes that it is reasonable and appropriate to help offset those costs by adopting fees for connectivity services. As detailed above, the Exchange has four primary sources of revenue that it can potentially use to fund its operations: transaction fees, fees for connectivity services, membership and regulatory fees, and market data fees. Accordingly, the Exchange must cover its expenses from these four primary sources of revenue. The Exchange's Cost Analysis estimates the costs to provide connectivity services at \$1,447,000. Based on current connectivity services usage, the Exchange would generate monthly revenues of approximately \$1,768,800. This represents a modest profit when compared to the cost of providing connectivity services and that profit represents a modest increase over the profit estimated in the 2021 Cost Analysis (a reasonable goal for a newly formed business, *i.e.*, growing from non-profitable, to break-even to modestly profitable).³⁴ Even if the Exchange earns that amount or incrementally more, the Exchange believes the proposed fees for connectivity services are fair and reasonable because they will not result in excessive pricing or supra-competitive profit, when comparing the total expense of MEMX associated with providing connectivity services versus the total projected revenue of the Exchange associated with network connectivity services. As noted above, when incorporating the projected revenue from connectivity services into

the Exchange's overall projected revenue, including projections related to recently adopted market data fees, the Exchange anticipates monthly revenue of \$5,988,620 from all sources. As such, applying the Exchange's holistic Cost Analysis to a holistic view of anticipated revenues, the Exchange would earn approximately 23% margin on its operations as a whole. The Exchange believes that this amount is reasonable and is again evidence that the Exchange will not earn a supra-competitive profit.

The Exchange notes that other exchanges offer similar connectivity options to market participants and that the Exchange's fees are a discount as compared to the majority of such fees.³⁵ With respect to physical connections, MIAIX Options ("MIAIX"), MIAIX Pearl, LLC ("MIAIX Pearl"), MIAIX Emerald, LLC ("MIAIX Emerald"), each of the Nasdaq Stock Market LLC ("Nasdaq") options exchanges,³⁶ NYSE American Options ("NYSE American"), NYSE Arca Options ("NYSE Arca"), Cboe Exchange, Inc. ("Cboe Options"), Cboe BZX Options ("BZX Options"), and Cboe EDGX Options ("EDGX Options") charge between \$7,000–\$22,000 per month for physical connectivity at their primary data centers that is comparable to that offered by the Exchange.³⁷

³⁵ One significant differentiation between the Exchanges is that while it offers different types of physical connections, including 10Gb, 25Gb, 40Gb, and 100Gb connections, the Exchange does not propose to charge different prices for such connections. In contrast, most of the Exchange's competitors provide scaled pricing that increases depending on the size of the physical connection. The Exchange does not believe that its costs increase incrementally based on the size of a physical connection but instead, that individual connections and the number of such separate and disparate connections are the primary drivers of cost for the Exchange.

³⁶ Including Nasdaq PHLX ("PHLX"), Nasdaq Options Market ("NOM"), Nasdaq BX Options ("BX"), Nasdaq ISE ("ISE"), Nasdaq GEMX ("GEMX"), and Nasdaq MRX ("MRX").

³⁷ See the MIAIX fee schedule, available at: https://www.miaxglobal.com/sites/default/files/fee-schedule-files/MIAIX_Options_Fee_Schedule_10022023.pdf; the MIAIX Pearl fee schedule, available at: https://www.miaxglobal.com/sites/default/files/fee-schedule-files/MIAIX_Pearl_Options_Fee_Schedule_09122023.pdf; the MIAIX Emerald fee schedule, available at: https://www.miaxglobal.com/sites/default/files/fee-schedule-files/MIAIX_Emerald_Fee_Schedule_10122023_3.pdf; the Nasdaq Options markets fee schedule, at <http://www.nasdaqtrader.com/trader.aspx?id=pricelisttrading2>; the NYSE Connectivity fee schedule, at: https://www.nyse.com/publicdocs/Wireless_Connectivity_Fees_and_Charges.pdf; the Cboe fee schedule, at: <https://www.cboe.com/us/options/membership/fee-schedule/bzx/>; the EDGX Options fee schedule, available at: <https://www.cboe.com/us/options/membership/fee-schedule/edgx/>, and the BOX Options fee schedule, available at: <https://boxoptions.com/fee-schedule/>. This range is based

Nasdaq, NYSE American and NYSE Arca also charge installation fees, which are not proposed to be charged by the Exchange. With respect to application sessions, BX, PHLX, GEMX, MRX, BOX Options ("BOX"), Cboe Options, BZX Options and EDGX charge between \$500–\$800 per month for order entry and drop ports.³⁸ The Exchange further notes that several of these exchanges each charge for other logical ports that the Exchange will continue to provide for free, such as application sessions for testing and disaster recovery purposes.³⁹ While the Exchange's proposed Options connectivity fees are lower than certain of the fees charged by the Nasdaq options exchanges, MIAIX Options, MIAIX Pearl, MIAIX Emerald, NYSE American, NYSE Arca, BOX, Cboe, BZX and EDGX, MEMX believes that it offers significant value to Members over these other exchanges in terms of bandwidth available over such connectivity services, which the Exchange believes is a competitive advantage, and differentiates its connectivity versus connectivity to other exchanges.⁴⁰ Additionally, the Exchange's proposed connectivity fees to its disaster recovery facility are within the range of the fees charged by other exchanges for similar connectivity alternatives.⁴¹ The Exchange believes that its proposal to offer certain application sessions free of charge is reasonable, equitably allocated and not unfairly discriminatory because such proposal is intended to encourage Member connections and use of backup and testing facilities of the Exchange, and, with respect to MEMOIR Gap Fill ports, such ports are used exclusively in connection with the receipt and

on a review of the fees charged for 10–40Gb connections at each of these exchanges and relates solely to the physical port fee or connection charge, excluding co-location fees and other fees assessed by these exchanges. The Exchange notes that it does not offer physical connections with lower bandwidth than 10Gb and that Members and non-Members with lower bandwidth requirements typically access the Exchange through third-party extranets or service bureaus.

³⁸ See *id.*

³⁹ See *id.*

⁴⁰ As noted above, all physical connections offered by MEMX are at least 10Gb capable and physical connections provided with larger bandwidth capabilities will be provided at the same rate as such connections. In contrast to other exchanges, MEMX has not proposed different types of physical connections with higher pricing for those with greater capacity. See *supra* note 33. The Exchange also reiterates that MEMX application sessions are capable of handling significant amount of message traffic (*i.e.*, over 50,000 orders per second), and have no application flow control or order throttling, in contrast to competitors that have imposed message rate thresholds. See *supra* note 26 and accompanying text.

⁴¹ See *supra* note 24.

³³ 15 U.S.C. 78f(b)(4).

³⁴ Specifically, in the 2021 Cost Analysis, the Exchange estimated the total costs to provide connectivity services at \$1,143,715 and estimated monthly revenues of \$1,233,750.

processing of market data from the Exchange.

In conclusion, the Exchange submits that its proposed fee structure satisfies the requirements of sections 6(b)(4) and 6(b)(5) of the Act⁴² for the reasons discussed above in that it provides for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities, does not permit unfair discrimination between customers, issuers, brokers, or dealers, and is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system and in general to protect investors and the public interest, particularly as the proposal neither targets nor will it have a disparate impact on any particular category of market participant.

The Exchange believes that the waiver of Connectivity Fees for physical connections and application sessions used solely for Options until January 1, 2024 is reasonable, equitable, and not unfairly discriminatory in that it will apply uniformly to all Options Users. The Exchange is proposing the waiver to provide an incentive for options trading firms to apply for membership to MEMX Options, which has recently launched. The options markets are quote-driven markets and are dependent on liquidity providers for liquidity and price discovery. The proposal will be of particular importance in encouraging liquidity providers to become members of the Exchange, which may result in more trading opportunities, enhanced competition, and improved overall market quality on the Exchange.

The Exchange believes that the proposed reorganization of its fee schedule to establish a separate fee schedule for Connectivity Fees is reasonable and equitable because it is a non-substantive change and does not involve changing any existing fees or rebates that apply to trading activity on MEMX Equities. Further, the changes are designed to make the fee schedule easier to read and for Members to validate the bills they receive from the Exchange. The Exchange also believes this reorganization is non-discriminatory because it applies uniformly to all Members. The Exchange believes the proposed fee schedule will be clearer and less confusing for Members of the Exchange and will eliminate potential Member confusion, thereby removing impediments to and perfecting the mechanism of a free and open market

and a national market, and in general, protecting investors and the public interest.

advance notice of any changes to the ORF imposed by the Exchange.[sic]

B. Self-Regulatory Organization's Statement on Burden on Competition

The [sic] In accordance with section 6(b)(8) of the Act,⁴³ the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intramarket Competition

The Exchange does not believe that the proposed rule change to apply the same connectivity fees to Options Users as it does to Equities Users would place certain market participants at the Exchange at a relative disadvantage compared to other market participants because the proposed connectivity pricing is associated with relative usage of the Exchange by each market participant and does not impose a barrier to entry to smaller participants. As noted above, the Exchange has previously justified its pricing with respect to MEMX Equities and believes the most fair approach, absent a significant differentiation between application costs to Equities and Options, is to apply the same pricing to all participants of either platform. The Exchange believes its proposed pricing is reasonable and lower than what other options exchanges charge and, when coupled with the availability of third-party providers that also offer connectivity solutions, that participation on the Exchange is affordable for all market participants, including smaller trading firms. Therefore, the fees may stimulate intramarket competition by attracting additional firms to become Members of MEMX Options. As described above, the connectivity services purchased by market participants typically increase based on their additional message traffic and/or the complexity of their operations. The market participants that utilize more connectivity services typically utilize the most bandwidth, and those are the participants that consume the most resources from the network. Accordingly, the proposed fees for connectivity services do not favor certain categories of market participants in a manner that would impose a burden on competition; rather, the allocation of the proposed connectivity fees reflects the network resources consumed by the various size of market

participants and the costs to the Exchange of providing such connectivity services.

As it relates to the reorganization of the fee schedule and the Options Connectivity Fee Waiver, as discussed above, the Exchange does not believe that the proposed changes would impose any burden on intramarket competition because such changes would encourage new participants to participate on the Exchange, thereby enhancing liquidity and market quality on the Exchange, as well as enhancing the attractiveness of the Exchange as a trading venue. The Exchange believes this would encourage market participants to direct order flow to the Exchange.

The Exchange does not believe that the proposed changes would impose any burden on intramarket competition because such changes will incentivize new participants to join MEMX Options and the majority of the Exchange's current Equities members joined at a time when MEMX Equities did not charge connectivity fees (also to incentivize such participants to join), and thus have already received this benefit. The options markets are quote-driven markets and are dependent on liquidity providers for liquidity and price discovery. The proposal will be of particular importance in encouraging liquidity providers to become members of the Exchange, which may result in more trading opportunities, enhanced competition, and improved overall market quality on the Exchange. For the foregoing reasons, the Exchange believes the proposed changes would not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act.

Intermarket Competition

The Exchange does not believe the proposed fees for Options Connectivity place an undue burden on competition on other SROs that is not necessary or appropriate. Additionally, other exchanges have similar connectivity alternatives for their participants, but with higher rates to connect.⁴⁴ The Exchange is also unaware of any assertion that the proposed fees for connectivity services would somehow unduly impair its competition with other exchanges. As a new entrant in an already highly competitive environment for equity options trading, MEMX does not have the market power necessary to set prices for services that are unreasonable or unfairly discriminatory in violation of the Exchange Act. In sum, MEMX's proposed Connectivity

⁴² 15 U.S.C. 78f(b)(4) and (5).

⁴³ 15 U.S.C. 78f(b)(8).

⁴⁴ See *supra* notes 34–38 and accompanying text.

Fees for Options Members are comparable to and generally lower than fees charged by other options exchanges for the same or similar services.

Additionally, as described above, the proposed reorganization of the fee schedule and Connectivity Fee Waiver will incentive market participants to join the Exchange during the Fee Waiver period. Accordingly, the Exchange believes the proposal would not burden, but rather promote, intermarket competition by enabling it to better compete with other options exchanges.

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)(ii) of the Act⁴⁵ and Rule 19b-4(f)(2)⁴⁶ 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 shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (<https://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include file number SR-MEMX-2023-29 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549-1090.

All submissions should refer to file number SR-MEMX-2023-29. 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-MEMX-2023-29 and should be submitted on or before December 6, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.⁴⁷

Christina Z. Milnor,

Assistant Secretary.

[FR Doc. 2023-25102 Filed 11-14-23; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

Meeting of the Interagency Task Force on Veterans Small Business Development

AGENCY: Small Business Administration (SBA).

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The SBA is issuing this notice to announce the date, time, and agenda for the next meeting of the Interagency Task Force on Veterans Small Business Development (IATF).

DATES: Wednesday, December 6, 2023, from 1:00 p.m. to 3:00 p.m. ET.

ADDRESSES: The meeting will be held virtually via Microsoft Teams.

FOR FURTHER INFORMATION CONTACT: The meeting is open to the public via Microsoft Teams; however advance notice of attendance is strongly encouraged. To RSVP and confirm attendance, the public should email veteransbusiness@sba.gov with subject line, "RSVP for December 6, 2023, IATF Public Meeting." To submit a written comment, individuals should email veteransbusiness@sba.gov with subject line, "Response for December 6, 2023, IATF Public Meeting" no later than December 1, 2023, or contact the Office of Veterans Business Development (OVBD) at (202) 205-6773. Comments received in advanced will be addressed as time allows during the public comment period. All other submitted comments will be included in the meeting record. During the live meeting, those who wish to comment will be able to do so during the public comment period. Participants can join the meeting via computer at this link: <https://bit.ly/IATF-Dec23>, or by phone. Call in (audio only): Dial: +1 206-413-7980; Phone Conference ID 564 607 216#. All applicable documents will be posted on the IATF website prior to the meeting: <https://www.sba.gov/about-sba/sba-locations/headquarters-offices/office-veterans-business-development#sba-card-collection-heading-7381>. For more information on veteran-owned small business programs, please visit www.sba.gov/ovbd.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., appendix 2), SBA announces the meeting of the Interagency Task Force on Veterans Small Business Development (IATF). The IATF is established pursuant to Executive Order 13540 to coordinate the efforts of Federal agencies to improve capital, business development opportunities, and pre-established federal contracting goals for small business concerns owned and controlled by veterans and service-disabled veterans. The purpose of this meeting is to discuss efforts that support veteran-owned small businesses, updates on past and current events, and the IATF's objectives for fiscal year 2024.

Dated: November 9, 2023.

Andrienne Johnson,
Committee Manager Officer.

[FR Doc. 2023-25219 Filed 11-14-23; 8:45 am]

BILLING CODE 8026-09-P

⁴⁵ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴⁶ 17 CFR 240.19b-4(f)(2).

⁴⁷ 17 CFR 200.30-3(a)(12).

SOCIAL SECURITY ADMINISTRATION**[Docket No: SSA–2023–0043]****Agency Information Collection
Activities: Proposed Request and
Comment Request**

The Social Security Administration (SSA) publishes a list of information collection packages requiring clearance by the Office of Management and Budget (OMB) in compliance with Public Law 104–13, the Paperwork Reduction Act of 1995, effective October 1, 1995. This notice includes revisions of OMB-approved information collections, and one new information collection for OMB-approval.

SSA is soliciting comments on the accuracy of the agency's burden estimate; the need for the information; its practical utility; ways to enhance its quality, utility, and clarity; and ways to minimize burden on respondents, including the use of automated collection techniques or other forms of information technology. Mail, email, or fax your comments and recommendations on the information collection(s) to the OMB Desk Officer and SSA Reports Clearance Officer at the following addresses or fax numbers.

(OMB), Office of Management and Budget, Attn: Desk Officer for SSA, Fax: 202–395–6974
(SSA), Social Security Administration, OLCA, Attn: Reports Clearance Director, Mail Stop 3253 Altmeyer, 6401 Security Blvd., Baltimore, MD 21235, Fax: 833–410–1631, Email address: OR.Reports.Clearance@ssa.gov

Or you may submit your comments online through <https://www.reginfo.gov/public/do/PRAMain> by clicking on Currently under Review—Open for Public Comments and choosing to click on one of SSA's published items.

Please reference Docket ID Number [SSA–2023–0043] in your submitted response.

I. The information collections below are pending at SSA. SSA will submit them to OMB within 60 days from the date of this notice. To be sure we consider your comments, we must receive them no later than January 16, 2024. Individuals can obtain copies of the collection instruments by writing to the above email address.

1. Beyond Benefits Study (BBS)—0960–NEW. The BBS will provide SSA with information regarding the needs of individuals who, due to medical improvement or a change in eligibility, have “exited” (called Exiters), or are likely to “exit” (called Possible Exiters) the Social Security Disability Insurance (SSDI) program, the Supplemental Security Income (SSI) program, or both. The BBS will provide SSA with a clearer understanding of the challenges and needs of the target population as Exiters leave the safety net and security of disability benefits and attempt to return to work. SSA will use the findings from the BBS to identify potential interventions and policies to help Exiters and Possible Exiters achieve sustainable, substantial work leading to self-sufficiency.

In seeking to understand the needs (e.g., service, medical, and employment) of Exiters and Possible Exiters, the study aims to answer three primary research questions: (1) what are the service, medical, and employment needs required to achieve sustainable, substantive employment among individuals who exit SSDI/SSI programs; (2) what are the types of services, resources, and interventions that will help exiting individuals obtain and retain employment, and should SSA consider a larger test study; and (3) what policy recommendations will facilitate substantive and sustainable employment among individuals who exit SSDI/SSI programs?

The BBS will help SSA answer these questions by collecting data through surveys, interviews, and focus groups. Quantitative data collection via the

survey will include 4,000 participants stratified by exit status and other criteria. The sample will include 2,000 Possible Exiters, 1,000 Short-term Exiters (have exited within the last year), and 1,000 Long-term Exiters (have exited within the last 1–5 years) with 75% of respondents in each group having a high-scoring likelihood of medical improvement based on the Continuing Disability Review (CDR) profiling model. The sample will be further stratified by program type (SSDI versus SSI) and by recommended determinants of self-sufficiency (e.g., age, type of impairment, and urban or rural locality).

The Motivational Interviewing Pilot Test will recruit 50 Exiters to participate in six sessions. During these sessions, motivational interviewers assess each participant's readiness to return to work using a standardized screener and explore the interest and motivation relating to obtaining and retaining employment as well as career advancement. Participants who drop out after the first session will be replaced.

Data collection via the interviews and focus groups will include (1) qualitative in-depth interviews with Exiters and Possible Exiters (70 individuals); (2) ten focus groups with Exiters and Possible Exiters (140 individuals, total); (3) two focus groups with service providers (20 individuals, total); (4) in-depth interviews with state and agency leadership (30 individuals); and, (5) a focus group with the motivational interview (MI) practitioners (five individuals). The respondents are individuals who have volunteered to take part in the study and are exiting (Exiters) or may be exiting (Possible Exiters) SSA's disability program(s) due to medical improvement or changes in eligibility; vocational service providers; state and agency leadership; and motivational interviewers.

Type of Request: Request for a new information collection.

Study component	Number of respondents	Frequency of responses	Average burden per response (minutes)	Total burden hours	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Interviews with Exiters and Possible Exiters (incl. Informed consent and pre-collection questions)	70	1	65	76	*\$12.81	**\$974
Focus groups with Exiters and Possible Exiters (incl. Informed consent and pre-collection questions)	140	1	65	152	* 12.81	** 1,947
Focus group with service providers (incl. Informed consent and pre-collection questions)	20	1	65	22	* 24	** 528
Focus group with motivational interviewer practitioners (incl. Informed consent)	5	1	65	5	* 35	** 175
In-depth interviews with state and agency leadership (incl. Informed consent and pre-collection questions)	30	1	65	33	* 56	** 1,848
Survey (incl. Informed consent and pre-collection questions)	4,000	1	50	3,333	* 12.81	** 42,696
MI Pilot (incl. Informed consent and pre-collection questions) ...	50	6	60	300	* 12.81	** 3,843

Study component	Number of respondents	Frequency of responses	Average burden per response (minutes)	Total burden hours	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
Total	4,315	4,565		3,921		** 52,011

* We base this figure on average DI payments wages for disability recipients as reported by SSA data (<https://www.ssa.gov/legislation/2023factsheet.pdf>).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. *Help America Vote Act—0960–0706.* House Rule 3295, the Help America Vote Act of 2002, mandates that States verify the identities of newly registered voters. When newly registered voters do not have driver's licenses or State-issued ID cards, they must supply the last four digits of their Social Security number to their local

State election agencies for verification. The election agencies forward this information to their State Motor Vehicle Administration (MVA) and the State MVA inputs the data into the American Association of MVAs, a central consolidation system that routes the voter data to SSA's Help America Vote Verification (HAVV) system. Once

SSA's HAVV system confirms the identity of the voter, the information returns along the same route in reverse until it reaches the State election agency. The respondents are the State MVAs seeking to confirm voter identities.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Number of responses	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Total annual opportunity cost (dollars) **
HAVV	48	102,200	4,905,600	2	163,520	\$22.07 *	\$3,608,886 **

* We based this figure on average local government information and records clerk's salary shown on the Bureau of Labor Statistic's website (<https://www.bls.gov/oes/current/oes434199.htm>).

** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

II. SSA submitted the information collections below to OMB for clearance. Your comments regarding these information collections would be most useful if OMB and SSA receive them 30 days from the date of this publication. To be sure we consider your comments, we must receive them no later than December 15, 2023. Individuals can obtain copies of these OMB clearance packages by writing to the OR.Reports.Clearance@ssa.gov.

1. *Application for a Social Security Number (SSN) Card, the Social Security Number Application Process (SSNAP), and Internet SSN Replacement Card (iSSNRC) Application—20 CFR 422.103–422.110—0960–0066.* SSA collects information on the SS–5 (used in the United States) and SS–5–FS (used outside the United States) to issue original or replacement Social Security cards. SSA also enters the application data into the SSNAP application when issuing a card via telephone or in person. In addition, hospitals collect the same information on SSA's behalf for newborn children through the Enumeration at Birth (EAB) process. In this process, parents of newborns provide hospital birth registration clerks with information required to register

these newborns. Hospitals send this information to State Bureaus of Vital Statistics (BVS), and they send the information to SSA's National Computer Center. SSA then uploads the data to the SSA mainframe along with all other enumeration data, and we assign the newborn a SSN and issue a Social Security card. The vast majority of applications for original SSN cards utilize EAB. In addition, the iSSNRC internet application collects information similar to the paper SS–5 for no-change replacement SSN cards for adult U.S. citizens. The iSSNRC modality allows certain applicants for SSN replacement cards to complete the internet application and submit the required evidence online rather than completing a paper Form SS–5. Finally, oSSNAP collects information similar to that which we collect on the paper SS–5 for no change situations, with the exception of name change, new or replacement SSN cards for U.S. Citizens (adult and minor children), and replacement cards only for non-U.S. citizens. oSSNAP allows these applicants for new or replacement SSN cards to start the application process on-line, receive a list of evidentiary documents, and then submit the application data to SSA for

further processing by SSA employees. Applicants then visit a local SSA office to complete the application process. In some instances, SSA collects race and ethnicity information as part of the SSN card application process. Response to the race and ethnicity questions is voluntary. SSA plans to expand the EAB process to include SSA receipt of race and ethnicity information for the newborn and parent(s) when the parent(s) consent to release of this voluntary information. Obtaining parental consent for this new data will require States and Jurisdictions to add questions to collect a newborn's race and ethnicity information. This will also require BVS to electronically share the race and ethnicity of parent(s) and newborns, for instances when the record shows the state of jurisdiction obtained parental consent, consistent with the EAB process. The respondents for this information collection are applicants for original and replacement Social Security cards, or individuals who wish to change information in their SSN records, who use any of the modalities described above.

Type of Request: Revision of an OMB-approved information collection.

Application scenario	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office (minutes) **	Total annual opportunity cost (dollars) ***
EAB Modality							
Hospital staff who relay the State birth certificate information to the BVS and SSA through the EAB process	3,759,517	1	5	313,293	* \$24.49	** 0	*** \$7,672,546
iSSNRC Modality							
Adult U.S. Citizens requesting a replacement card with no changes through the iSSNRC	3,002,698	1	5	250,225	* 29.76	** 0	*** 7,447,589
Adult U.S. Citizens requesting a replacement card with a name change through iSSNRC	1,312	1	5	109	* 29.76	** 0	*** 3,244
oSSNAP Modality							
Adult U.S. Citizens providing information to receive a replacement card through the oSSNAP+	822,104	1	5	68,509	* 29.76	** 24	*** 11,825,136
Adult U.S. Citizens providing information to receive an original card through the oSSNAP+	37,323	1	5	3,110	* 29.76	** 24	*** 536,841
Adult Non-U.S. Citizens providing information to receive an original card through the oSSNAP+	204,081	1	5	17,007	* 29.76	** 24	*** 2,935,497
Adult Non-U.S. Citizens providing information to receive a replacement card through the oSSNAP+	84,635	1	5	7,053	* 29.76	** 24	*** 1,217,392
SSNAP/SS-5 Modality							
Respondents who do not have to provide parents' SSNs	6,973,505	1	9	1,046,026	* 29.76	** 24	*** 114,142,337
Respondents whom we ask to provide parents' SSNs (when applying for original SSN cards for children under age 12)	207,521	1	9	31,128	* 29.76	** 24	*** 3,396,717
Applicants age 12 or older who need to answer additional questions so SSA can determine whether we previously assigned an SSN	1,113,144	1	10	185,524	* 29.76	** 24	*** 18,772,072
Applicants asking for a replacement SSN card beyond the allowable limits (i.e., who must provide additional documentation to accompany the application)	6,703	1	60	6,703	* 29.76	** 24	*** 279,268
Enumeration Quality Review							
Authorization to SSA to obtain personal information cover letter	500	1	15	125	* 29.76	** 24	*** 9,672
Authorization to SSA to obtain personal information follow-up cover letter	500	1	15	125	* 29.76	** 24	*** 9,672
Grand Total							
Totals	16,213,543			1,928,937			*** 168,247,983

* The number of respondents for this modality is an estimate based on google analytics data for the SS-5 form downloads from SSA.Gov.

* We based this figure on average Hospital Records Clerks (<https://www.bls.gov/oes/current/oes292098.htm>), and average U.S. worker's hourly wages (https://www.bls.gov/oes/current/oes_nat.htm) as reported by the U.S. Bureau of Labor Statistics.

** We based this figure on the average FY 2023 wait times for field offices, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

2. Agreement to Sell Property—20 CFR 416.1240–416.1245—0960–0127.

Individuals or couples who are otherwise eligible for SSI payments, but whose resources exceed the allowable limit, may receive conditional payments

if they agree to dispose of the excess non-liquid resources and make repayments. SSA uses Form SSA–8060–U3 to document this agreement, and to ensure the individuals understand their obligations. Respondents are applicants

for and recipients of SSI payments who will be disposing of excess non-liquid resources.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office or for teleservice centers (minutes) **	Total annual opportunity cost (dollars) ***
SSA-8060-U3 (telephone interview)	10,000	1	20	3,333	* \$29.76	** 19	*** \$193,440
SSA-8060-U3 (paper)	10,000	1	20	3,333	* 29.76	** 24	*** 218,230
Total	20,000			6,666			*** 411,6710

* We based this figures on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (https://www.bls.gov/oes/current/oes_nat.htm).

** We based this figure on the average FY 2023 wait times for field offices and teleservice centers, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

3. *Work Activity Report (Self-Employment)*—20 CFR 404.1520(b), 404.1571–404.1576, 404.1584–404.1593, and 416.971–416.976—0960–0598. SSA uses Form SSA-820-BK to determine initial or continuing eligibility for: (1) Title II SSDI; or (2) Title XVI SSI payments. Under Titles II and XVI of the Social Security Act, recipients receive disability benefits and SSI payments based on their inability to engage in substantial gainful activity (SGA) due to a physical or mental condition. Therefore, when the recipients resume

work, they must report their work so SSA can evaluate and determine by law whether they continue to meet the disability requirements. SSA uses Form SSA-820-BK to obtain information on self-employment activities of Social Security Title II and XVI disability applicants and recipients. SSA uses the data we obtain to evaluate disability claims, and to help us determine if the claimant meets current disability provisions under Titles II and XVI. Since applicants for disability benefits or payments must prove an inability to

perform any kind of SGA generally available in the national economy for which we expect them to qualify based on age, education, and work experience, any work an applicant performed until, or subsequent to, the date the disability allegedly began, affects our disability determination. The respondents are applicants and claimants for SSI payments or SSDI benefits.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars) *	Average wait time in field office or for teleservice centers (minutes) **	Total annual opportunity cost (dollars) ***
SSA-820-BK (in Office)	12,144	1	30	6,072	* \$12.81	** 24	*** \$140,013
SSA-820-BK (phone)	36,428	1	30	18,214	* 12.81	** 19	*** 381,085
SSA-820-BK (paper)	48,571	1	30	24,286	* 12.81	0	*** 311,104
SSA-820-APP (online submission)	2,857	1	30	1,429	* 12.81	0	*** 18,305

* We based this figure on average DI payments, as reported in SSA's disability insurance payment data (<https://www.ssa.gov/legislation/2023factsheet.pdf>).

** We based this figure on the average FY 2023 wait times for field offices and teleservice centers, based on SSA's current management information data.

*** This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

4. *Social Security's Public Credentialing and Authentication Process*—20 CFR 401.45 and 402—0960–0789.

Background

Authentication is the foundation for secure, online transactions. Identity authentication is the process of determining, with confidence, that someone is who he or she claims to be during a remote, automated session. It comprises three distinct factors: something you know; something you have; and something you are. Single-factor authentication uses one of the factors, and multi-factor authentication uses two or more of the factors.

SSA's Public Credentialing and Authentication Process

SSA offers consistent authentication across SSA's secured online services. SSA allows our users to request and maintain only one User ID, consisting of

a self-selected username and password, to access multiple Social Security electronic services. Designed in accordance with the OMB Memorandum M-04-04 and the National Institute of Standards and Technology (NIST) Special Publication 800-63, this process provides the means of authenticating users of our secured electronic services and streamlines access to those services. SSA's public credentialing and authentication process:

- Issues a single User ID to anyone who wants to do business with the agency and meets the eligibility criteria;
- Partners with an external Identity Services Provider (ISP) to help us verify the identity of our online customers;
- Complies with relevant standards;
- Offers access to some of SSA's most pertinent, but more sensitive, workloads online while providing a high level of confidence in the identity of the person requesting access to these services;

- Offers an in-person process for those who are uncomfortable with or unable to use the internet process;
- Balances security with ease of use; and
- Provides a user-friendly way for the public to conduct extended business with us online instead of visiting local servicing offices or requesting information over the phone. Individuals have real-time access to their Social Security information in a safe and secure web environment.

Public Credentialing and Authentication Process Features

SSA collects and maintains the users' personally identifiable information (PII) in our Central Repository of Electronic Authentication Data Master File Privacy Act system of records, which we published in the **Federal Register** (75 FR 79065). The PII may include the users' name; address; date of birth; SSN; phone number; and other types of

identity information [e.g., address information of persons from the W-2 and Schedule Self Employed forms we receive electronically for our programmatic purposes as permitted by 26 U.S.C. 6103(l)(1)(A)]. SSA may also collect knowledge-based authentication data, which is information users establish with us or that we already maintain in our existing Privacy Act systems of records.

SSA retains the data necessary to administer and maintain our e-Authentication infrastructure. This includes management and profile information, such as blocked accounts; failed access data; effective date of passwords; and other data allowing us to evaluate the system's effectiveness. The data we maintain also may include archived transaction data and historical data. SSA uses the information from this collection to identity proof and authenticate our users online, and to allow them access to their personal information from our records. We also use this information to provide second factor authentication. SSA is committed to expanding and improving this process so we can grant access to additional online services in the future.

Offering online services is not only an important part of meeting SSA's goals, but is vital to good public service. In increasing numbers, the public expects to conduct complex business over the internet. Ensuring SSA's online services are both secure and user-friendly is our priority.

SSA awarded a competitively bid contract to an ISP, Equifax¹, to help us verify the identity of our online customers. SSA uses this ISP, in addition to our other authentication methods, to help us prove, or verify, the identity of our customers when they are completing online or electronic transactions with us.

Social Security's Authentication Strategy

SSA remains committed to enhancing our online services using authentication processes that balance usability and security. We will continue to research and develop new authentication tools while monitoring the emerging threats.

The following are key components of our authentication strategy:

- **Enrollment and Identity Verification**

Individuals who meet the following eligibility requirements may enroll:

- Must have a valid email address;
- Must have a valid SSN;

- Must have a domestic address of record (includes military addresses); and
- Must be at least 18 years of age.

We collect identifying data and use SSA and ISP records to verify an individual's identity. Individuals have the option of obtaining an enhanced, stronger, User ID by providing certain financial information (e.g., Medicare wages, self-employed earnings, or the last eight digits of a credit card number) for verification. We also ask individuals to answer out-of-wallet questions so we can further verify their identities. Individuals who are unable to complete the process online can present identification at a field office to obtain a User ID.

- **Establishing the User Profile**

The individual self-selects a username and password, both of which can be of variable length and alphanumeric. SSA provides a password strength indicator to help the individual select a strong password. We also ask the individual to choose challenge questions for use in restoring a lost or forgotten username or password.

- **Provide a Second Factor**

SSA asks the individual to provide a text message enabled cell phone number or an email address. We consider the cell phone number or email address the second factor of authentication. SSA sends a security code to the individual's selected second factor. We require the individual to confirm its receipt by entering the security code online. Subsequently, each time the individual attempts to sign in to his or her online account, we will also send a message with a one-time security code to the individual's selected second factor. The individual must enter the security code along with his or her username and password. The code is valid for only 10 minutes. If the individual does not enter the code within 10 minutes, the code expires, and the individual must request another code.

- **Enhancing the User ID**

If individuals opt to enhance or upgrade their User IDs, SSA requires them to provide certain financial information for verification. SSA mails a one-time-use upgrade code to the individual's verified residential address. When the individual receives the upgrade code in the mail, he or she can enter this code online to enhance the security of the account. With extra security, we continue to require the individuals to sign in using their username, password, and a one-time security code we send to their second factor email address or cell phone

number (whichever the users listed in their account).

- **Sign in and Use**

SSA's authentication process provides an individual with a User ID for access to our sensitive online Social Security services. Second factor authentication requires the individual to sign in with a username, password, and a one-time security code sent to the individual's selected second factor. SSA expanded its existing capabilities to require second factor authentication for every online sign in. We also allow for maintenance of the second factor options. An individual who forgets the password can reset it automatically without contacting SSA.

Social Security's Enrollment Process

The enrollment process is a one-time only activity. SSA requires the individuals to agree to the "Terms of Service" detailed on our website before we allow them to begin the enrollment process. The "Terms of Service" inform the individuals what we will and will not do with their personal information, and the privacy and security protections we provide on all data we collect. These terms also detail the consequences of misusing this service. To verify the individual's identity, we ask the individual to give us minimal personal information, which may include:

- Name;
- SSN;
- Date of birth;
- Address—mailing and residential;
- Telephone number;
- Email address;
- Financial information;
- Cell phone number; and
- Selecting and answering password reset questions.

We send a subset of this information to the ISP, who then generates a series of out-of-wallet questions back to the individual. The individual must answer all or most of the questions correctly before continuing in the process. The exact questions generated are unique to each individual.

This collection of information, or a subset of it, is mandatory for respondents who want to do business with SSA via the internet. We collect this information via the internet, on SSA's public-facing website. SSA also offers an in-person identification verification process for individuals who cannot, or are not willing, to register online. For this process, the individual must go to a local SSA field office and provide identifying information. SSA does not ask for financial information with the in-person process.

SSA only collects the identity verification information one time, when

¹ Equifax is a data aggregator, and that their data helps SSA mitigate fraud.

the individual registers for a credential. We ask for the User ID (username and password) every time an individual signs in to our automated services. If individuals opt for the enhanced or upgraded account, they also either

receive an email message or a text message on their cell phones (this serves as the second factor for authentication) each time they sign in.

The respondents are individuals who choose to use the internet or Automated

Telephone Response System to conduct business with SSA.

Type of Request: Revision of an OMB-approved information collection.

Modality of completion	Number of respondents	Frequency of response	Average burden per response (minutes)	Estimated total annual burden (hours)	Average theoretical hourly cost amount (dollars)*	Average wait time in field office (minutes)**	Total annual opportunity cost (dollars)***
Internet Registrations	11,788,914	1	8	1,571,855	*\$29.76		\$46,778,405
Internet Sign-Ins	124,989,089	1	1	2,083,151	* 29.76		*** 6,194,574
Intranet Registration (RCS)	54,908	1	8	7,321	* 29.76	** 24	*** 871,492
Totals	136,832,911			3,662,327			*** 53,844,471

*We based this figure on average U.S. citizen's hourly salary, as reported by Bureau of Labor Statistics data (https://www.bls.gov/oes/current/oes_nat.htm#00-0000).

**We based these figures on the average FY 2022 wait times for field offices, based on SSA's current management information data.

***This figure does not represent actual costs that SSA is imposing on recipients of Social Security payments to complete this application; rather, these are theoretical opportunity costs for the additional time respondents will spend to complete the application. *There is no actual charge to respondents to complete the application.*

Dated: November 9, 2023.

Naomi Sipple,

Reports Clearance Officer, Social Security Administration.

[FR Doc. 2023-25167 Filed 11-14-23; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA-2023-1739]

Policy on the Definition of Aeronautical Activities

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Proposed policy: request for comments.

SUMMARY: This notice announces a proposed update of the FAA's Office of Airports policy regarding the definition of "aeronautical activity" to include unmanned aircraft systems (UAS), advanced air mobility (AAM), and commercial space launch or re-entry vehicle operations. Under Federal law, an airport operator that has accepted Federal grants or certain Federal land conveyances is obligated to maintain the airport for public aviation use. This proposed update will add UAS, AAM, and commercial space operations to the existing definition of aeronautical activity that is included in FAA Order 5190.6B, *FAA Airport Compliance Manual*, Appendix Z, and subsequent revisions. This revised definition does not affect any international agreements or policies regarding commercial space operations. The FAA is seeking comments on the proposed statement of policy.

DATES: Send your comments on or before December 15, 2023.

ADDRESSES: You may send comments identified by Docket Number FAA-2023-1739 using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov> and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M-30; U.S. Department of Transportation, 1200 New Jersey Avenue SE, Room W12-140, West Building Ground Floor, Washington, DC 20590-0001.
- *Hand Delivery:* Deliver to mail address above between 9:00 a.m. and 5 p.m. EST, Monday through Friday, except Federal holidays;
- *Fax:* Fax comments to Docket Operations at 202-493-2251.

For more information, see the **SUPPLEMENTARY INFORMATION** section of this document.

Privacy: In accordance with 5 U.S.C. 553(c), the Department of Transportation (DOT) solicits comments from the public on its proposed Policy on the Definition of Aeronautical Activities. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

Docket: To read background documents or comments received, go to <http://www.regulations.gov> and follow the online instructions for accessing the docket. Or, go to the Docket Management Facility in Room W12-140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC, between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Availability of Documents: You can get an electronic copy of this Policy and all other documents in this docket using the internet by:

- (1) Searching the Federal eRulemaking portal (<http://www.faa.gov/regulations/search>);
- (2) Visiting FAA's Regulations and Policies web page at (https://www.faa.gov/regulations_policies) or
- (3) Accessing the Government Printing Office's web page at (<http://www.gpoaccess.gov/index.html>).

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Airport Compliance and Management Analysis, 800 Independence Avenue SW, Washington, DC 20591, or by calling (202) 267-3085. Make sure to identify the docket number, notice number, or amendment number of this proceeding.

Authority for the Policy: This notice is published under the authority described in Title 49 of the United States Code, Subtitle VII, part B, chapter 471, section 47122(a).

FOR FURTHER INFORMATION CONTACT:

Kevin C. Willis, Director, Office of Compliance and Management Analysis, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591, telephone (202) 267-3085; facsimile: (202) 267-5257; email: kevin.willis@faa.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Under Federal law, Airport owners/operators ("sponsors") that have accepted grants under the Airport Improvement Program (AIP) must comply with certain Federal policies included in each AIP grant agreement as sponsor assurances. In addition, sponsors who have acquired land from the Federal government using certain

conveyance instruments must abide by similar obligations included in property deeds. The Airport and Airway Improvement Act of 1982 (AIAA) (Pub. L. 97–248), as amended and recodified at 49 U.S.C. 47107(a)(1), as implemented by Sponsor Assurance 22, *Economic Nondiscrimination*, requires that “the airport will be made available for public use on reasonable conditions and without unjust discrimination to all types, kinds and classes of aeronautical activities, including commercial aeronautical activities offering services to the public at the airport.” The FAA defines aeronautical activities as any activity that involves, makes possible, is required for the operation of an aircraft/vehicle, or that contributes to or is required for the safety of such operations (FAA Order 5190.6B, *Airport Compliance Manual*, Appendix Z, (2009)). The order lists examples of aeronautical activities.

The FAA’s definition has evolved over time, primarily in response to emerging technologies and increased interest in locating certain activities at public use airports not previously contemplated or subject to FAA oversight. This updated definition serves to accommodate commercial space transportation, UAS, and AAM activities, as well as supports Congressional interest in integrating new technology into the array of services and capabilities offered by federally funded airports. As a result, the FAA believes that commercial space activities, UAS, and AAM operations should be considered aeronautical activities for the purposes of access to a federally-obligated airport.

However, some types of commercial space, UAS, or AAM operations may affect the safety of existing airport facilities, airport operations, or the efficiency of the airspace. Consistent with and in support of the airport sponsor’s obligation not to introduce or permit unsafe conditions at the airport, and to mitigate such conditions if they arise, the FAA uses its planning approval, safety review, and/or risk assessment processes to make a determination on (1) whether a particular activity can be safely accommodated at the airport and, if so, (2) the terms and conditions to mitigate risk to an acceptable level for that activity at the airport. In that regard, Congress has made the FAA the final arbiter regarding aviation safety (49 U.S.C. 40101 and 47101.)

II. The Proposed Policy

The updated definition of aeronautical activity in FAA Order 5190.6B, *FAA Airport Compliance*

Manual, Appendix Z will be the following:

Any activity that involves, makes possible, or is required for the operation of an aircraft, launch or reentry vehicle, or that contributes to or is required for the safety of such operations. It includes but is not limited to: general and corporate aviation, air taxi and charter operations, scheduled and nonscheduled air carrier operations, pilot training, aircraft rental and sightseeing, aerial photography, aerial application of agricultural agents, aerial advertising and surveying, aircraft sales and services, aircraft storage, sale of aviation fuel products, repair and maintenance of aircraft, repair and maintenance of launch or reentry vehicles, construction of amateur-built/recreational aircraft, sale of aircraft, sale of launch or reentry vehicle parts, parachute or ultralight activities, certain unmanned aircraft systems (UAS), advanced air mobility (AAM) operations, commercial space vehicle operations, and any other activities that because of their direct relationship to the operation of aircraft, UAS, or commercial space launch and re-entry vehicles can appropriately be regarded as aeronautical activities.

Activities such as aircraft and parts manufacturing and storage, aerospace design, research and development, flight simulation/training/management facilities, and/or engine testing facilities that are not associated with the final assembly of an aircraft or commercial space vehicle are not considered aeronautical activities for the purposes of airport access. Model rocket, model aircraft, and recreational UAS operations are not aeronautical activities for the purposes of airport access.

Issued in Washington, DC, on November 7, 2023.

Kevin C. Willis,

Director, Office of Airport Compliance and Management Analysis.

[FR Doc. 2023–25198 Filed 11–14–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2023–0043]

Qualification of Drivers; Exemption Applications; Implantable Cardioverter Defibrillator (ICD)

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT)

ACTION: Notice of denials.

SUMMARY: FMCSA announces its decision to deny the applications from two individuals treated with an Implantable Cardioverter Defibrillator (ICD) who requested an exemption from the Federal Motor Carrier Safety Regulations (FMCSRs) prohibiting operation of a commercial motor vehicle (CMV) in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope (transient loss of consciousness), dyspnea (shortness of breath), collapse, or congestive heart failure.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001, (202) 366–4001, fmcsamedical@dot.gov. Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing materials in the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number (FMCSA–2023–0043) in the keyword box and click “Search.” Next, sort the results by “Posted (Newer-Older),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov. As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>, the comments are searchable by the name of the submitter.

II. Background

On September 28, 2023, FMCSA published a notice announcing receipt of applications from two individuals treated with ICDs and requested comments from the public (88 FR 66932). The individuals requested an exemption from 49 CFR 391.41(b)(4) which prohibits operation of a CMV in interstate commerce by persons with a current clinical diagnosis of myocardial infarction, angina pectoris, coronary insufficiency, thrombosis, or any other cardiovascular disease of a variety known to be accompanied by syncope, dyspnea, collapse, or congestive heart failure. The public comment period ended on October 30, 2023, and no comments were received.

FMCSA has evaluated the eligibility of the applicants and concluded that granting an exemption would not provide a level of safety that would be equivalent to, or greater than, the level of safety that would be obtained by complying with § 391.41(b)(4). A summary of each applicant's medical history related to their ICD exemption request was discussed in the September 28, 2023 **Federal Register** notice (88 FR 66932) and will not be repeated here.

The Agency's decision regarding this exemption application is based on information from the Cardiovascular Medical Advisory Criteria, an April 2007 evidence report titled "Cardiovascular Disease and Commercial Motor Vehicle Driver Safety,"¹ and a December 2014 focused research report titled "Implantable Cardioverter Defibrillators and the Impact of a Shock in a Patient When Deployed." Copies of these reports are included in the docket.

FMCSA has published advisory criteria to assist medical examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.² The advisory criteria for § 391.41(b)(4) indicates that coronary artery bypass surgery and pacemaker implantation are remedial procedures and thus, not medically disqualifying. ICDs are disqualifying due to risk of syncope.

III. Discussion of Comments

FMCSA received no comments in this proceeding.

¹ The report is available on the internet at <https://rosap.ntl.bts.gov/view/dot/16462>.

² These criteria may be found in 49 CFR part 391, APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section D. *Cardiovascular: § 391.41(b)(4)*, paragraph 4, which is available on the internet at <https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf>.

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption.

The Agency's decision regarding these exemption applications is based on an individualized assessment of the applicants' medical information, available medical and scientific data concerning ICDs, and any relevant public comments received.

In the case of persons with ICDs, the underlying condition for which the ICD was implanted places the individual at high risk for syncope or other unpredictable events known to result in gradual or sudden incapacitation. ICDs may discharge, which could result in loss of ability to safely control a CMV. The December 2014 focused research report referenced previously upholds the findings of the April 2007 report and indicates that the available scientific data on persons with ICDs and CMV driving does not support that persons with ICDs who operate CMVs are able to meet an equal or greater level of safety.

V. Conclusion

The Agency has determined that the available medical and scientific literature and research provides insufficient data to enable the Agency to conclude that granting these exemptions would achieve a level of safety equivalent to, or greater than, the level of safety maintained without the exemption. Therefore, the following applicants have been denied an exemption from the physical qualification standards in § 391.41(b)(4):

Dean Cece (NC); and Donald Roach (KY).

The applicants have, prior to this notice, received a letter of final disposition regarding their exemption request. The decision letter fully outlined the basis for the denial and constitute final action by the Agency. The names of these individuals published today summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4).

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–25113 Filed 11–14–23; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2023–0186]

Hours of Service: Clym Environmental; Application for Exemption

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of application for exemption; request for comments.

SUMMARY: FMCSA announces that Clym Environmental Services LLC (Clym) has requested an exemption from the hours-of-service (HOS) regulations to allow its drivers up to 14 hours of drive time within the work shift or, in the alternative, up to 12 hours. Clym indicates that, due to the nature of its operations, complying with the 11-hour driving time limit in the HOS regulations places a strain on the company's drivers and its overall operating costs. Clym asserts that the exemption would allow additional flexibility while maintaining an equivalent level of safety. FMCSA requests public comment on the applicant's request for exemption.

DATES: Comments must be received on or before December 15, 2023.

ADDRESSES: You may submit comments identified by Federal Docket Management System (FDMS) Number FMCSA–2023–0186 by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. See the Public Participation and Request for Comments section below for further information.

- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Ground Floor, Washington, DC 20590–0001.

- *Hand Delivery or Courier:* West Building, Ground Floor, 1200 New Jersey Avenue SE, between 9 a.m. and 5 p.m. E.T., Monday through Friday, except Federal holidays.

- *Fax:* (202) 493–2251.

Each submission must include the Agency name and the docket number (FMCSA–2023–0186) for this notice. Note that DOT posts all comments received without change to www.regulations.gov, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to www.regulations.gov at any time or visit the ground level of the West Building, 1200 New Jersey Avenue

SE, Washington, DC, between 9 a.m. and 5 p.m., ET, Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-9317 or (202) 366-9826 before visiting Dockets Operations.

Privacy Act: In accordance with 49 U.S.C. 31315(b), DOT solicits comments from the public to better inform its exemption process. DOT posts these comments, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice DOT/ALL-14 FDMS, which can be reviewed under the "Department Wide System of Records Notices" at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices/DOT-ALL>. The comments are posted without edit and are searchable by the name of the submitter.

FOR FURTHER INFORMATION CONTACT: Mr. Richard Clemente, Driver and Carrier Operations Division; Office of Carrier, Driver and Vehicle Safety Standards, FMCSA; (202) 366-2722 or richard.clemente@dot.gov. If you have questions on viewing or submitting material to the docket, contact Dockets Operations at (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA-2023-0186), indicate the specific section of this document to which the comment applies, and provide a reason for suggestions or recommendations. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to www.regulations.gov and put the docket number "FMCSA-2023-0186" in the keyword box, and click "Search." Next, sort the results by "Posted (Newer-Older)," choose the first notice listed, click the "Comment" button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your

comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period.

II. Legal Basis

FMCSA has authority under 49 U.S.C. 31136(e) and 31315(b) to grant exemptions from Federal Motor Carrier Safety Regulations (FMCSRs). FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by the current regulation (49 CFR 381.305). The Agency must publish its decision in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption and the regulatory provision from which the exemption is granted. The notice must specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

III. Applicant's Request

Clym is a regulated medical waste pickup, transportation, and destruction company. Clym seeks an exemption from the requirement in 49 CFR 395.3(a)(3)(i) that a commercial motor vehicle (CMV) operator may drive a maximum of 11 hours within a 14-hour period before taking the required 10 consecutive hours off duty or the equivalent. Clym has specifically requested an exemption to extend the allotted driving time to 14 hours or, in the alternative, to extend the drive time to a maximum of 12 hours within the 14-hour period.

Clym makes this HOS exemption request for three contingencies: (1) when CDL A drivers are taking time off or calling off for illness or injury, in which case a relief driver is needed to transport the waste along the supply chain; (2) when there is an unexpected increase in material and a trailer needs

to be moved sooner than scheduled; and (3) when there is an upcoming issue with local and state health codes for the storage of regulated medical waste. If granted, the exemption would apply only to drivers operating on the long-haul route between Clym's office in New Castle, PA and its ozone destruction plant in Greenfield, IN. It would not apply to any drivers operating on the company's local routes.

Clym predicts a minimal impact on safety, as the exemption sought would allow its drivers to have more than the one mandatory 30-minute break after 8 consecutive hours of driving. Clym's internal policy provides a one-hour company lunch break and strongly encourages its drivers to take as many breaks as necessary. Clym further states that the round trip from the Greenfield office to the ozone destruction plant and back takes about 11 hours to complete without traffic, and it considers the run to be "very easy" as its commercial vehicles typically operate at approximately half of the 80,000-pound legal limit. Finally, Clym states that it takes safety very seriously because it transports regulated medical waste.

A copy of Clym's application for exemption is available for review in the docket for this notice.

IV. Request for Comments

In accordance with 49 U.S.C. 31315(b), FMCSA requests public comment from all interested persons on Clym Environmental Services LLC's application for an exemption from the requirement in 49 CFR 395.3(a)(3)(i) to operate a CMV in interstate commerce for a maximum of 11 hours of driving before taking 10 consecutive hours off duty or the equivalent. All comments received before the close of business on the comment closing date indicated at the beginning of this notice will be considered and will be available for examination in the docket at the location listed under the **ADDRESSES** section of this notice. Comments received after the comment closing date will be filed in the public docket and will be considered to the extent practicable. In addition to late comments, FMCSA will also continue to file, in the public docket, relevant information that becomes available after the comment closing date. Interested persons should continue to examine the public docket for new material.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023-25111 Filed 11-14-23; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration****[Docket No. FMCSA–2023–0023]****Qualification of Drivers; Exemption Applications; Hearing**

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt nine individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) to operate a commercial motor vehicle (CMV) in interstate commerce. The exemptions enable these hard of hearing and deaf individuals to operate CMVs in interstate commerce.

DATES: The exemptions are applicable on November 3, 2023. The exemptions expire on November 3, 2025.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001, (202) 366–4001, fmcsamedical@dot.gov. Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:**I. Public Participation****A. Viewing Comments**

To view comments go to www.regulations.gov. Insert the docket number (FMCSA–2023–0023) in the keyword box and click “Search.” Next, sort the results by “Posted (Older–Newer),” choose the first notice listed, and click “Browse Comments.” If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, without edit, including any personal

information the commenter provides, to www.regulations.gov. As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>, the comments are searchable by the name of the submitter.

II. Background

On September 27, 2023, FMCSA published a notice announcing receipt of applications from nine individuals requesting an exemption from the hearing requirement in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public (88 FR 66551). The public comment period ended on October 27, 2023, and one comment was received.

FMCSA has evaluated the eligibility of these applicants and determined that granting exemptions to these individuals would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing found in § 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5–1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid (35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 8, 1971), respectively).

III. Discussion of Comments

FMCSA received one comment in this proceeding. An individual anonymously commented stating that it is better for the person to take the hearing test with hearing aids in, rather than being exempt from that section of the test. The Federal hearing exemption does not exempt an individual from the hearing screening test during the physical qualification examination. It exempts an individual from needing to meet the requirement in 49 CFR 391.41(b)(11). FMCSA has evaluated each individual listed in this notice and determined they demonstrated that they do not pose a risk to public safety. Therefore,

granting an exemption from the hearing standard in § 391.41(b)(11) to each of the individuals listed in this notice would likely achieve a level of safety equal to that existing without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. However, FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The Agency's decision regarding these exemption applications is based on relevant scientific information and literature, and the 2008 Evidence Report, “Executive Summary on Hearing, Vestibular Function and Commercial Motor Driving Safety.” The evidence report reached two conclusions regarding the matter of hearing loss and CMV driver safety: (1) no studies that examined the relationship between hearing loss and crash risk exclusively among CMV drivers were identified; and (2) evidence from studies of the private driver's license holder population does not support the contention that individuals with hearing impairment are at an increased risk for a crash. In addition, the Agency reviewed each applicant's driving record found in the Commercial Driver's License Information System, for commercial driver's license (CDL) holders, and inspections recorded in the Motor Carrier Management Information System. For non-CDL holders, the Agency reviewed the driving records from the State Driver's Licensing Agency. Each applicant's record demonstrated a safe driving history. Based on an individual assessment of each applicant that focused on whether an equal or greater level of safety would likely be achieved by permitting each of these drivers to drive in interstate commerce, the Agency finds the drivers granted this exemption have demonstrated that they do not pose a risk to public safety.

Consequently, FMCSA finds further that in each case exempting these applicants from the hearing standard in § 391.41(b)(11) would likely achieve a level of safety equal to that existing

without the exemption, consistent with the applicable standard in 49 U.S.C. 31315(b)(1).

V. Conditions and Requirements

The terms and conditions of the exemption are provided to the applicants in the exemption document and include the following: (1) each driver must report any crashes or accidents as defined in § 390.5T; (2) each driver must report all citations and convictions for disqualifying offenses under 49 CFR parts 383 and 391 to FMCSA; and (3) each driver is prohibited from operating a motorcoach or bus with passengers in interstate commerce. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. In addition, the exemption does not exempt the individual from meeting the applicable CDL testing requirements.

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based upon its evaluation of the nine exemption applications, FMCSA exempts the following drivers from the hearing standard; in § 391.41(b)(11), subject to the requirements cited above:

Fred Dudley (TX)
Jonathan Garcia (AZ)
Juan Hernandez (TX)
Francisco Luna (TX)
Dylan Luttrell (MO)
Wanda Mack (FL)
Kevin Nadrowski (CT)
Kevin Prior (NH)
William Schoemig (UT)

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136, 49 U.S.C. chapter 313, or the FMCSRs.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023-25112 Filed 11-14-23; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2014-0387; Docket No. FMCSA-2018-0138; Docket No. FMCSA-2018-0139; Docket No. FMCSA-2019-0109; Docket No. FMCSA-2021-0014; Docket No. FMCSA-2021-0015]

Qualification of Drivers; Exemption Applications; Hearing

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to renew exemptions for 16 individuals from the hearing requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) for interstate commercial motor vehicle (CMV) drivers. The exemptions enable these hard of hearing and deaf individuals to continue to operate CMVs in interstate commerce.

DATES: Each group of renewed exemptions were applicable on the dates stated in the discussions below and will expire on the dates provided below.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64-224, Washington, DC 20590-0001, (202) 366-4001, fmcsamedical@dot.gov. Office hours are 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Viewing Comments

To view comments go to www.regulations.gov. Insert the docket number (FMCSA-2014-0387, FMCSA-2018-0138, FMCSA-2018-0139, FMCSA-2019-0109, FMCSA-2021-0014, or FMCSA-2021-0015) in the keyword box and click "Search." Next, sort the results by "Posted (Newer-Older)," choose the first notice listed, and click "Browse Comments." If you do not have access to the internet, you may view the docket online by visiting Dockets Operations on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590-0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366-

9317 or (202) 366-9826 before visiting Dockets Operations.

B. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption requests. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov. As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at <https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices>, the comments are searchable by the name of the submitter.

II. Background

On October 6, 2023, FMCSA published a notice announcing its decision to renew exemptions for 16 individuals from the hearing standard in 49 CFR 391.41(b)(11) to operate a CMV in interstate commerce and requested comments from the public (88 FR 69677). The public comment period ended on November 6, 2023, and no comments were received.

FMCSA has evaluated the eligibility of these applicants and determined that renewing these exemptions would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved by complying with § 391.41(b)(11).

The physical qualification standard for drivers regarding hearing found in § 391.41(b)(11) states that a person is physically qualified to drive a CMV if that person first perceives a forced whispered voice in the better ear at not less than 5 feet with or without the use of a hearing aid or, if tested by use of an audiometric device, does not have an average hearing loss in the better ear greater than 40 decibels at 500 Hz, 1,000 Hz, and 2,000 Hz with or without a hearing aid when the audiometric device is calibrated to American National Standard (formerly ASA Standard) Z24.5-1951.

This standard was adopted in 1970 and was revised in 1971 to allow drivers to be qualified under this standard while wearing a hearing aid (35 FR 6458, 6463 (Apr. 22, 1970) and 36 FR 12857 (July 8, 1971), respectively).

III. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based upon its evaluation of the 16 renewal exemption applications, FMCSA announces its decision to

exempt the following drivers from the hearing requirement in § 391.41 (b)(11).

As of October 1, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following five individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers (88 FR 69679): Azulita-Jane Camacho (CA)
Robert Culp (FL)
Charles Davis (AL)
Christopher Fisher (WA)
John Price (TX)

The drivers were included in docket number FMCSA–2018–0139. Their exemptions were applicable as of October 1, 2023 and will expire on October 1, 2025.

As of October 8, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following five individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers (88 FR 69679): Judith Badore (VT)
Dareous Glover (IL)
Delroy Hunt (FL)
John Norman (IL)
Kyle Voss (WI)

The drivers were included in docket number FMCSA–2021–0015. Their exemptions are applicable as of October 8, 2023 and will expire on October 8, 2025.

As of October 10, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following two individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers (88 FR 69679): Kurt Bernabei (IL); and Steven Robelia (TN).

The drivers were included in docket number FMCSA–2019–0109. Their exemptions are applicable as of October 10, 2023 and will expire on October 10, 2025.

As of October 22, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following four individuals have satisfied the renewal conditions for obtaining an exemption from the hearing requirement in the FMCSRs for interstate CMV drivers (88 FR 69679): Richard Carter (MD)
Clinton Homon (IL)
Pete Kujawa (WI)
Jonathan Muhm (KY)

The drivers were included in docket numbers FMCSA–2014–0387, FMCSA–2018–0138, or FMCSA–2021–0014. Their exemptions are applicable as of October 22, 2023 and will expire on October 22, 2025.

In accordance with 49 U.S.C. 31315(b), each exemption will be valid for 2 years from the effective date unless revoked earlier by FMCSA. The exemption will be revoked if the following occurs: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained prior to being granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136, 49 U.S.C. chapter 313, or the FMCSRs.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–25114 Filed 11–14–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2023–0153]

Agency Information Collection Activities; Request for OMB Approval To Renew an Information Collection Request: Truck and Bus Maintenance Requirements and Their Impact on Safety

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for review and approval. The Federal Motor Carrier Safety Administration (FMCSA) is authorized to study vehicle maintenance to determine the impact of vehicle maintenance requirements on overall motor carrier safety. FMCSA may fund research, development, and technology projects that improve the safety and efficiency of commercial motor vehicle operations through technological innovation and improvement.

DATES: Comments on this notice must be received on or before December 15, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this information collection by selecting “Currently under 30-day Review—Open for Public

Comments” or by using the search function.

FOR FURTHER INFORMATION CONTACT:

Mike Lukuc, Program Manager, Technology Division, DOT, FMCSA, West Building 6th Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 834–6180; mike.lukuc@dot.gov.

SUPPLEMENTARY INFORMATION: In this study, FMCSA will collect, via two surveys of freight motor carriers and passenger carrier maintenance managers, qualitative and quantitative data to assess the opinions of carrier representatives to develop an operational definition of “systematic maintenance” for trucks and buses, examine maintenance differences between vehicle classes, and identify industry maintenance norms. Survey results of those carriers with low crash and vehicle maintenance violation rates will be combined to provide guidance on recommended practices. Additionally, respondents from carriers with high rates of crashes and violations may provide useful feedback on the effect of the interventions within their maintenance programs or activities, and an evaluation of adequacy of current regulations. The information collected by the survey will be a critical input to the Recommended Practices Report, which is a required final product for the project. Three comments were received in response to the 60-day **Federal Register** notice.

Title: Truck and Bus Maintenance Requirements and Their Impact on Safety.

OMB Control Number: 2126–0069.

Type of Request: Renewal of a currently approved ICR.

Respondents: Freight motor carriers and passenger carriers.

Estimated Number of Respondents: 578 respondents [578 respondents will complete the Online Recruitment Survey. Of those 578 respondents, 289 will also complete the Carrier Maintenance Manager Survey].

Estimated Time per Response: Varies [Online Recruitment Survey: 5 minutes. Carrier Maintenance Manager Survey: 45 minutes].

Expiration Date: November 30, 2023.

Frequency of Response: Annually.

Estimated Total Annual Burden: 265 hours [Online Recruitment Survey: 578 respondents × (5 minutes ÷ 60 minutes) = 48 hours; Carrier Maintenance Manager Survey: 289 respondents × (45 minutes ÷ 60 minutes) = 217 hours].

Background: FMCSA’s core mission is to reduce crashes, injuries, and fatalities involving large trucks and buses. To aid in accomplishing this, the Agency uses

the Compliance, Safety, Accountability (CSA) enforcement program to prioritize and target interventions of those motor carriers who are most likely to be involved in a future crash. As part of the CSA program, the Agency deploys the Safety Measurement System (SMS). SMS uses inspection, crash, and investigation data captured in the Motor Carrier Management Information System to calculate a percentile for each motor carrier. A motor carrier's SMS percentile is based on its past compliance with a complete range of safety-based regulations (such as driver safety, hours of service, driver fitness, and vehicle maintenance, among others). The survey described in this notice focuses on the vehicle maintenance component of those safety regulations. The study goal is to determine what improvements, ranging from better compliance interventions to better vehicle maintenance requirements, would enhance motor carrier safety.

In 2014, the John A. Volpe National Transportation Systems Center conducted a study to assess the effectiveness of SMS in identifying the highest risk motor carriers to be targeted for interventions. One finding from the study was that motor carriers targeted for intervention due to "vehicle maintenance" issues (*i.e.*, violations) had a 65 percent higher crash rate compared to the national average. These violations are based on Federal and State inspections of components critical to the safe operation of the vehicle. It is important to recognize that proper and regular preventative maintenance (*i.e.*, systematic maintenance programs) among carriers—rather than Federal and State inspections, which are by nature limited to the most visible or obvious safety-related components—should be the primary activity applied to ensure safe equipment operation. While these initial findings are important, they raise additional questions. One such question is prompted by the stipulation in 49 CFR 396.3(a), which states that every carrier must have a program to "systematically inspect, repair, and maintain, or cause to be systematically inspected, repaired, and maintained, all motor vehicles and intermodal equipment subject to its control." Though this regulation provides some direction, there is no supporting definition of the word *systematic*, and because this term is subjective, it is likely to vary from one carrier to another. The lack of specificity regarding standard intervals for preventative maintenance makes it difficult for Federal and State personnel to evaluate the effectiveness of and

compliance with a carrier's maintenance program. Furthermore, the lack of specificity may make it difficult for carriers to ascertain and therefore comply with the regulation's intent.

The current research effort, augmented by the proposed survey, is necessary to improve FMCSA's understanding of the safety impact of preventative vehicle maintenance and to clarify the requirements of § 396.3(a). The study objectives are as follows:

1. Develop an operational definition of systematic maintenance.
2. Evaluate whether current regulations and the intervention process could be modified to improve compliance with vehicle maintenance requirements. Examples of such requirements are as follows: (i) Preventative maintenance intervals, (ii) preventative maintenance inspections with adequately trained/equipped mechanics, and (iii) adequacy of motor carriers' maintenance facilities. However, the results of the survey will be used only to explore what areas of rulemaking and/or other areas, such as policy guidance and training, might be useful in the future; the results of the survey will not be used for rulemaking, *per se*.
3. Gather information to assist in establishing minimum standards for inspection intervals, mechanic qualifications and training, and certification of maintenance facilities. FMCSA is authorized to conduct this research under 49 U.S.C. 31108, Motor Carrier Research and Technology Programs. Under section 31108(a)(3)(C), FMCSA may fund research, development, and technology projects that improve the safety and efficiency of commercial motor vehicle operations through technological innovation and improvement. This information collection supports the DOT strategic goal of Safety.

Under contract to FMCSA, the Virginia Tech Transportation Institute (VTI) at the Virginia Polytechnic Institute and State University will use online surveys to obtain the data required to address the study objectives. The information collection will be administered in two phases:

Phase I: Online Recruitment Survey. This voluntary, seven-question survey will screen carriers and verify their eligibility for Phase II participation. To be eligible for Phase II participation, carriers must fall into one of two groups: (a) The Recommended Practices (RP) Group, which includes carriers with the lowest Vehicle Maintenance and Crash Indicator Behavior Analysis and Safety Improvement Categories (BASIC) percentiles (*i.e.*, less than or equal to the

33rd percentile); or (b) the Intervention Effects (IE) Group, which includes carriers that have experienced Federal or State interventions in the last 24 months due to vehicle maintenance violations. The BASICs are Unsafe Driving, Crash Indicator, Hours-of-Service (HOS) compliance, Vehicle Maintenance, Controlled Substances/Alcohol, Hazardous Materials (HM) Compliance, and Driver Fitness. More information on the SMS methodology can be found at <https://csa.fmcsa.dot.gov/Documents/SMSMethodology.pdf>.

Phase II: Carrier Maintenance Management Survey. This voluntary, 108-question survey will include questions about demographics; maintenance practices, intervals, personnel, and facilities; and State and Federal inspections, among other things. The Phase II survey will employ branch logic; as such, carriers will be prompted to complete different sections based on their survey group (and for one section, carrier size). Consequently, no participating carrier will be asked to complete all 108 questions. In the Phase II survey, carriers (of all sizes) in the RP Group will be asked to provide additional information about maintenance personnel and facilities (*e.g.*, mechanic training levels, tools required for adequate inspection, and certification of facilities) and vehicle maintenance issues that may impact safety. Information from the RP Group will seek to address Objective 1, relating to development of an operational definition of systematic maintenance, Objective 2, relating to potential regulatory changes, and Objective 3, relating to establishment of minimum standards for inspection intervals, mechanic qualifications and training, and certification of maintenance facilities. Carriers in the IE Group will be asked to complete the section on intervention effects, which includes questions about the status of active interventions or investigations; results of closed interventions or investigations; interactions with State versus Federal agencies; intervention activities experienced; the accuracy of violations leading to interventions; actions taken in response to interventions; changes in carrier vehicle maintenance practices as a result of an intervention; significant benefits of interventions; and ways the intervention process could be improved. Information provided by the IE Group will also address the portion of Objective 2 regarding sufficiency of regulations and where interventions need to be improved to facilitate complying with these regulations.

Survey responses will be summarized and reported using plots, tables, content analysis, and calculated summary statistics. Plots and tables will provide a visual comparison of multiple choice and checkbox survey responses for successful carriers (*i.e.*, carriers in the RP Group) and those receiving interventions in the last 24 months (*i.e.*, carriers in the IE Group). These methods will also allow researchers to summarize responses by carrier operation type (*i.e.*, truck or bus) and size. Bar charts will be used to plot responses to many survey questions. Some survey responses may be summarized with tables with rows for each of the carrier operation types (truck or bus) and each carrier-size subgroup. To explore and summarize responses to open-ended survey questions, researchers will use content analysis methods. An illustration of an open-ended question in the survey is "List examples of critical safety-related maintenance activities for trailer vehicle milestones." The goal of content analysis of open-ended questions will be to identify common answers.

The results of this information collection will be documented in a technical report to be delivered to and published by FMCSA. In addition, the results will be used to create a "recommended best practices" report that will outline minimum standards for inspection intervals, mechanic qualifications and training, and certification of maintenance facilities. Finally, VTTI is required under the contract with FMCSA to compile and analyze the collected information and develop a public-use data set.

If this data collection does not take place, the truck and bus industry would continue to operate with the uncertainty of what a "systematic maintenance" program, as currently worded in § 396.3(a), consists of. This term's ambiguous definition makes it difficult for Federal and State inspectors to evaluate the effectiveness of a carrier's maintenance program or its compliance with this provision. Furthermore, this uncertainty may make it difficult for carriers to ascertain and therefore comply with the regulation's intent.

The 60-day notice for this collection was published on August 24, 2023 (88 FR 58057). The Agency received three comments.

The first comment was anonymous and asserted that fraud within the industry affected the industry's ability to perform maintenance that could enhance safety. Through the research enabled by this survey, the Agency seeks to assess the degree to which maintenance enhances safety.

The second comment was from a maintenance trainer who stated that 49 CFR 396.17 requires that periodic inspections beyond visual observation are required on an annual basis to certify that each vehicle passes maintenance requirements. The Agency agrees that periodic maintenance inspections that go beyond roadside visual inspections are an important part of a systematic maintenance program, and the research is taking into consideration the elements of periodic maintenance that impact carrier preventative maintenance programs.

The third comment was from the National Waste and Recycling Association (NWRA). NWRA suggests that the survey should recruit carriers that operate vocational short-haul trucks (*e.g.*, refuse hauler) because of the differences in duty cycles that affect maintenance. In particular, waste and recycling vehicles brake frequently as part of their duty cycle, which may have implications for maintenance and safety. The Agency agrees that a variety of highway and vocational truck and bus carriers will be recruited for the survey, but the recruitment and collection will be constrained to identifying carriers based on the recommended practices group and intervention effects group criteria.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information.

Issued under the authority of 49 CFR 1.87.

Thomas P. Keane,

Associate Administrator, Office of Research and Registration.

[FR Doc. 2023-25196 Filed 11-14-23; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

[FTA Docket No. FTA 2023-0026]

Agency Information Collection Activity Under OMB Review: Charter Service Operations

AGENCY: Federal Transit Administration, Department of Transportation.

ACTION: Notice of request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the intention of the Federal Transit Administration (FTA) to request the Office of Management and Budget (OMB) to approve the extension of a currently approved information collection: Charter Service Operations.

DATES: Comments must be submitted before January 16, 2024.

ADDRESSES: To ensure that your comments are not entered more than once into the docket, submit comments identified by the docket number by only one of the following methods:

1. **Website:** www.regulations.gov. Follow the instructions for submitting comments on the U.S. Government electronic docket site. (Note: The U.S. Department of Transportation's (DOT's) electronic docket is no longer accepting electronic comments.) All electronic submissions must be made to the U.S. Government electronic docket site at www.regulations.gov. Commenters should follow the directions below for mailed and hand-delivered comments.

2. **Fax:** 202-366-7951.

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

4. **Hand Delivery:** U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: You must include the agency name and docket number for this notice at the beginning of your comments. Submit two copies of your comments if you submit them by mail. For confirmation that FTA has received your comments, include a self-addressed stamped postcard. Note that all comments received, including any personal information, will be posted and will be available to internet users, without change, to www.regulations.gov. You may review DOT's complete Privacy Act Statement in the **Federal Register** published April 11, 2000, (65 FR 19477), or you may visit www.regulations.gov. Docket: For access to the docket to read background documents and comments received, go to www.regulations.gov at any time. Background documents and comments received may also be viewed at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, Docket Operations, M-30, West Building, Ground Floor, Room W12-140, Washington, DC 20590-0001 between

9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Micah Miller at (404) 865-5474, or email: Micah.Miller@dot.gov.

SUPPLEMENTARY INFORMATION: Interested parties are invited to send comments regarding any aspect of this information collection, including: (1) the necessity and utility of the information collection for the proper performance of the functions of the FTA; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the collected information; and (4) ways to minimize the collection burden without reducing the quality of the collected information. Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection.

Title: Charter Service Operations.
OMB Number: 2132-0543.

Background: FTA's Charter Service Regulations protects private charter operators from unauthorized competition from FTA grant recipients. In essence, the charter regulations were implemented to ensure that transit agencies, subsidized with federal money, do not unfairly compete with privately owned bus companies. Under the charter rules, with limited exceptions, local transit agencies are restricted from operating chartered services.

Charter service means, but does not include demand response service to individuals:

- Transportation provided by a recipient at the request of a third party for the exclusive use of a bus or van for a negotiated price. The following features may be characteristic of charter service:
 - A third party pays the transit provider a negotiated price for the group,
 - Any fares charged to individual members of the group are collected by a third party,
 - The service is not part of the transit provider's regularly scheduled service, or is offered for a limited period of time, or
 - A third party determines the origin and destination of the trip as well as scheduling; or
 - Transportation provided by a recipient to the public for events or functions that occur on an irregular basis or for a limited duration and:
 - A premium fare is charged that is greater than the usual or customary fixed route fare; or
 - The service is paid for in whole or in part by a third party.

There are limited exceptions when a grantee may provide charter service, including:

- Official government business,
 - Qualified Human Service Organizations (elderly, persons with disabilities, and low-income individuals),
 - When no registered charter provider responds to a notice sent by a recipient,
 - Leasing (must exhaust all available vehicles first),
 - By agreement with all registered charter providers,
 - Petitions to the Administrator:
- Events of regional or national significance, or hardship.
- Respondents:* Transit Agencies and Private Operators.
- Estimated Annual Responses:* 1,810 respondents.
- Estimated Total Annual Burden:* 359 hours.
- Frequency:* Annually, bi-annually, quarterly, and as required.

Nadine Pembleton,

Deputy Associate Administrator, Office of Administration.

[FR Doc. 2023-25184 Filed 11-14-23; 8:45 am]

BILLING CODE 4910-57-P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Fiscal Year 2024 Competitive Funding Opportunity: Innovative Coordinated Access and Mobility (ICAM) Pilot Program

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Notice of funding opportunity (NOFO).

SUMMARY: The Federal Transit Administration (FTA) announces the opportunity to apply for \$4.7 million in Fiscal Year (FY) 2023 funding under the Innovative Coordinated Access and Mobility (ICAM) pilot program. This funding opportunity seeks to improve coordination to enhance access and mobility to vital community services for older adults, people with disabilities, and people of low income. As required by Federal public transportation law, funds will be awarded competitively as grants to finance innovative mobility management capital projects that will improve the coordination of transportation services and Non-Emergency Medical Transportation (NEMT) services. An additional \$4.8 million is authorized for FY 2024 and FTA may award additional funding that is made available to the program prior

to the announcement of project selections.

DATES: Applicants must submit completed proposals for each funding opportunity through the *GRANTS.GOV* "APPLY" function by 11:59 p.m. Eastern Time February 13, 2024. Prospective applicants should register as soon as possible on the *GRANTS.GOV* website to ensure they can complete the application process before the submission deadline.

ADDRESSES: Application instructions are available on FTA's website at <https://www.transit.dot.gov/funding/grants/grant-programs/access-and-mobility-partnership-grants> and in the "FIND" module of *GRANTS.GOV*. The *GRANTS.GOV* funding opportunity ID for the ICAM is FTA-2024-006-TPM-ICAM. Mail and fax submissions will not be accepted.

FOR FURTHER INFORMATION CONTACT: Destiny Buchanan, FTA Office of Program Management; Phone: (202) 493-8018; Email: Destiny.Buchanan@dot.gov.

SUPPLEMENTARY INFORMATION:

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A. Program Description

Section 3006(b) of the Fixing America's Surface Transportation (FAST) Act (Pub. L. 114-94) authorizes FTA to award grants for ICAM pilot projects that improve the coordination of transportation services and NEMT services for transportation disadvantaged populations. The Infrastructure Investment and Jobs Act (the "Bipartisan Infrastructure Law" or "BIL") (Pub. L. 117-58) authorized funding for FY 2022 through FY 2026. Transportation disadvantaged populations include older adults, people with disabilities, and people of low income.

In the FY 2024 program, FTA intends to target funding for regional and statewide mobility management capital projects that support coordination and enable comprehensive community access, including access to NEMT, for underserved groups. In accordance with Performance Measure 3.1.9 in the Coordinating Council on Access and Mobility (CCAM)'s 2023-2026 Strategic Plan (<https://www.transit.dot.gov/>

regulations-and-programs/access/ccam/about/2023-2026-coordinating-council-access-and-mobility), FTA has collaborated with the Centers for Medicare and Medicaid Services (CMS) to ensure that this Notice of Funding Opportunity (NOFO) includes a link to the 2023 CMS sub-regulatory guidance [Assurance of Transportation: A Medicaid Transportation Coverage Guide (<https://www.medicaid.gov/sites/default/files/2023-09/smd23006.pdf>)] to help inform potential applicants about flexibilities within Medicaid NEMT. Applicants are encouraged to coordinate with and engage their State Medicaid office (<https://www.medicaid.gov/state-overviews/state-profiles/index.html>) to best understand and navigate the Medicaid NEMT rules and regulations to develop a successful ICAM pilot program application.

The CCAM consists of 11 Federal agencies and coordinates 130 Federal programs that may fund transportation (find the CCAM Program Inventory at <https://www.transit.dot.gov/regulations-and-guidance/ccam/about/ccam-program-inventory>). The CCAM's mission is to improve the availability, accessibility, and efficiency of transportation for targeted populations. The benefits of successful coordinated transportation systems include providing greater access to funding and enabling more cost-effective use of resources; reducing duplication and overlap in human service agency transportation services; filling service gaps in a community or geographic area; serving additional individuals within existing budgets; and providing more centralized management of existing resources.

The ICAM pilot program (Federal Assistance Listing 20.513) supports FTA's strategic goals of improving equity and connecting communities by providing funding for deployment of coordination technology, mobility management, and other capital projects that: improve access and mobility, positively affect social determinants of health, and improve quality of life for disadvantaged communities.

The Department seeks to award projects under the ICAM pilot program that will create proportional impacts to all populations in a project area, remove transportation related disparities to all populations in a project area, and increase equitable access to project benefits, consistent with Executive Order 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (86 FR 7009). The Department also seeks to award projects that address equity and environmental

justice, particularly for communities that have experienced decades of underinvestment and are most impacted by climate change, pollution, and environmental hazards, consistent with Executive Order 14008, Tackling the Climate Crisis at Home and Abroad (86 FR 7619).

The ICAM pilot program will improve State and regional coordination by funding regional and statewide mobility management capital projects that enable comprehensive community access, including NEMT, for underserved groups. Successful projects will prioritize coordination, including coordination with recipients of funding from Federal agencies that are members of the CCAM (<https://www.transit.dot.gov/coordinating-council-access-and-mobility>), that enhances access and mobility to vital community services for older adults, people with disabilities, and people of low income.

Agencies often restrict their transportation services to clients of a specific program and do not permit the vehicles or services to be used by other programs or riders. This practice leads to inefficient use of resources and unused capacity. These restrictions are often attributed to Federal requirements but compliance with Federal requirements can be achieved without such restrictions. Federally funded vehicles and transportation resources can be shared with other agencies that have a transportation role, as long as costs can be allocated appropriately. The ICAM pilot program seeks to help promote this coordination.

B. Federal Award Information

Federal public transportation law (49 U.S.C. 5338(a)(2)(E)) authorized \$4,701,218 in FY 2023 funds for competitive grants under the ICAM pilot program. FTA may cap the amount a single recipient or State may receive as part of the selection process. There is no minimum or maximum grant award amount; however, FTA intends to fund as many meritorious projects as possible. An additional \$4,823,972 is authorized for FY 2024 and FTA may award additional funding made available to the program prior to the announcement of the project selections.

Due to funding limitations, projects selected for funding may receive less than the amount originally requested. In those cases, applicants must be able to demonstrate that the proposed projects are still viable, meet all eligibility requirements, and can be completed with the amount awarded.

FTA will grant pre-award authority to incur costs for selected projects

beginning on the date project selections are announced on FTA's website. Funds are available for obligation for two fiscal years after the fiscal year in which the competitive awards are announced. Funds are available only for eligible costs incurred after the date project selections are announced. FTA intends to fund as many meritorious projects as possible.

C. Eligibility Information

1. Eligible Applicants

Eligible applicants are entities eligible as direct or designated recipients under the Section 5310 program, including: State departments of transportation, designated recipients for Section 5310 funds, or local governmental entities that operate a public transportation service, or their eligible subrecipients that have the authority and technical capacity to implement a regional or statewide cost allocation pilot. Private entities that provide shared-ride on-demand service to the general public on a regular basis are operators of public transportation and are therefore eligible subrecipients. Organizations that do not operate public transportation are not eligible applicants.

Applicants must serve as the lead agency of a regional or statewide consortium that includes stakeholders from the transportation, healthcare, human service, or other sectors. Applicants are encouraged to coordinate with and engage their State Medicaid office (<https://www.medicaid.gov/state-overviews/state-profiles/index.html>) to best understand and navigate the Medicaid NEMT rules and regulations to develop a successful ICAM pilot program application. Recently updated Medicaid sub-regulatory guidance can be found in the aforementioned Assurance of Transportation: A Medicaid Transportation Coverage Guide. Members of this consortium are eligible as subrecipients if they would otherwise be eligible subrecipients of Section 5310 funds. Further, applicants must demonstrate that the proposed project was planned through an inclusive process with the involvement of the transportation, healthcare, and human service sectors. An implementation plan and schedule must be submitted as part of the proposal.

2. Cost Sharing or Matching

The maximum Federal share of projects selected under the ICAM pilot program is 80 percent. The applicant must provide a non-Federal share of at least 20 percent of the project cost and must document the source of the non-Federal match in the grant application.

Federal funds may not be used as match for this program unless the Federal program providing the funds expressly authorizes its funds to fulfill the match requirement of another Federal program. Per 49 U.S.C. 5323(i), the Federal share may exceed 80 percent for certain projects related to the Americans with Disabilities Act (ADA) of 1990 and Clean Air Act (CAA) compliance as follows:

(1) *Vehicles*. The Federal share is 85 percent of the net project cost of the acquisition of vehicles (including clean-fuel or alternative fuel vehicles) for purposes of complying with or maintaining compliance with the ADA or CAA.

(2) *Vehicle-Related Equipment and Facilities*. The Federal share is 90 percent of the net project cost for acquiring vehicle-related equipment or facilities (including clean fuel or alternative fuel vehicle-related equipment or facilities) for purposes of complying or maintaining compliance with the ADA or CAA. FTA considers vehicle-related equipment to be equipment on and attached to the vehicle. The award recipient must itemize the cost of specific, discrete, vehicle-related equipment associated with compliance with the ADA or CAA to be eligible for the maximum 90 percent Federal share for these costs.

Eligible sources of non-Federal matching funds include:

- i. Cash from non-governmental sources other than revenues from providing transit services (such as fare revenues);
- ii. Non-farebox revenues from the operation of public transportation service, such as the sale of advertising and concession;
- iii. Monies received under a service agreement with a State or local social service agency or private social service organization;
- iv. Undistributed cash surpluses, replacement, or depreciation cash funds, reserves available in cash, or new capital;
- v. In-kind contributions integral to the project;
- vi. Revenue bond proceeds for a capital project, with prior FTA approval; and
- vii. Transportation Development Credits (formerly referred to as Toll Revenue Credits).

3. Eligible Projects

Eligible projects are capital projects, as defined in 49 U.S.C. 5302(4). FTA intends to make grants to assist in financing innovative projects for the transportation disadvantaged that improve the coordination of

transportation services and NEMT services, including: regional or statewide mobility management projects; deployment of coordination technology; and regional or statewide projects that create or increase access to one-call/one-click centers. For purposes of this NOFO, regional is defined as projects that cover more than one community or area such as multiple cities, counties, or tribal areas. FTA's goal for these pilot program grants is to identify and test promising, innovative, coordinated mobility strategies other communities can replicate. Only one project may be included in each application. The ICAM grants will operate as pilots for up to 24 months. Within the first year, projects must be able to demonstrate significant progress toward increased State interagency coordination. ICAM funds must be used to implement a regional or statewide pilot of coordinated service delivery, to demonstrate the benefits of coordinated transportation. Projects funded under previous ICAM NOFOs are not eligible.

D. Application and Submission Information

1. Address To Request Application Package

Applications must be submitted through *GRANTS.GOV*. Applicants can find general information for submitting applications at *GRANTS.GOV*. Mail and fax submissions will not be accepted. Applicants may also attach additional supporting information. Failure to submit the information as requested may delay or prevent review of the application.

2. Content and Form of Application Submission

i. Proposal Submission

A complete proposal submission consists of at least two forms, the SF-424 Mandatory Form and the Supplemental Form for the FY 2024 Innovative Coordinated Access and Mobility Pilot Program (downloaded from *GRANTS.GOV* or the FTA website at <https://www.transit.dot.gov/funding/grants/grant-programs/access-and-mobility-partnership-grants>). The application must include responses to all sections of the SF-424 Mandatory Form and the Supplemental Form unless a section is indicated as optional. FTA will use the information on the Supplemental Form to determine applicant and project eligibility for the program and to evaluate the proposal against the selection criteria described in part E of this notice. FTA will accept only one Supplemental Form per SF-424 submission. FTA encourages States

and other applicants to consider submitting a single Supplemental Form that includes multiple activities to be evaluated as a consolidated proposal. If States or other applicants choose to submit separate proposals for individual consideration by FTA, they must submit each proposal with a separate SF-424 and Supplemental Form.

Applicants may attach additional supporting information to the SF-424 submission, including, but not limited to the following examples: letters of support, memorandums of understanding, interagency agreements, coordinated plans, project budgets, fleet status reports, or excerpts from relevant planning documents. Supporting documentation must be described and referenced by file name in the appropriate response section of the Supplemental Form, or it may not be reviewed.

Information such as applicant name, Federal amount requested, local match amount, or description of areas served, may be requested in varying degrees of detail on both the SF-424 Form and Supplemental Form. Applicants must fill in all fields unless stated otherwise on the forms. If applicants copy information into the Supplemental Form from another source, they should verify that the Supplemental Form has fully captured pasted text and that it has not truncated the text due to character limits built into the form. Applicants should use both the "Check Package for Errors" and the "Validate Form" buttons on both forms to check all required fields. Applicants should also ensure that the Federal and local amounts specified are consistent.

ii. Application Content

The SF-424 Mandatory Form and the Supplemental Form will prompt applicants for the required information, including:

- a. Applicant Name
- b. Unique Entity Identifier
- c. Key contact information (including contact name, address, email address, and phone)
- d. Congressional district(s) where project will take place
- e. Project Information (including title, an executive summary, and type)
- f. A detailed description of the project
- g. A detailed description of the need for the project
- h. A detailed description of how the project will support the ICAM pilot program goals to improve access to coordinated transportation services; reduce duplication of service; and enhance efficiency of the 130 Federal programs (<https://www.transit.dot.gov/regulations-and-guidance/ccam/about/>)

ccam-program-inventory) that may fund human service transportation.

i. Evidence that the project is consistent with State and regional planning documents including consistency with the Coordinated Public Transportation-Human Services Transportation Plan

j. A detailed description of all project partners and their specific role in the eligible project

k. Specific performance measures the project will use to quantify actual outcomes against expected outcomes

l. Evidence that the applicant can provide the non-Federal cost share and details on the non-Federal match

m. A description of the technical, legal, and financial capacity of the applicant

n. A detailed project budget (up to 24 months). The project budget should show how different funding sources will share in each activity and present those data in dollars and percentages. The budget should identify other Federal funds the applicant is applying for or has been awarded, if any, that the applicant intends to use. Funding sources should be grouped into three categories: non-Federal, ICAM (Federal), and other Federal with specific amounts from each funding source

o. An explanation of the scalability of the project (if applicable)—Applicants are encouraged to identify scaled funding options in case insufficient funding is available to fund a project at the full requested amount. If an applicant indicates that a project is scalable, the applicant must provide an appropriate minimum funding amount that will fund an eligible project that achieves the objectives of the program and meets all relevant program requirements. The applicant must provide a clear explanation of how the project budget would be affected by a reduced award.

p. A detailed project timeline

q. Address all the applicable criteria and priority considerations identified in Section E.

3. Unique Entity Identifier and System for Award Management (SAM)

Each applicant is required to: (1) be registered in SAM before submitting an application; (2) provide a valid unique entity identifier in its application; and (3) continue to maintain an active SAM registration with current information during which the applicant has an active Federal award or an application or plan under consideration by FTA. FTA may not make an award until the applicant has complied with all applicable unique entity identifier and SAM requirements. If an applicant has

not fully complied with the requirements by the time FTA is ready to make an award, FTA may determine that the applicant is not qualified to receive an award and use that determination as a basis for making a Federal award to another applicant. These requirements do not apply if the applicant has an exception approved by FTA under 2 CFR 25.110(c) or (d). SAM registration takes approximately 3–5 business days, but FTA recommends allowing ample time, up to several weeks, for completion of all steps. For additional information on obtaining a unique entity identifier, please visit <https://www.sam.gov>.

FTA will provide further instructions on registration through an introductory applicant training session. Dates and times for the training session will be posted on FTA's website.

4. Submission Dates and Times

Project proposals must be submitted electronically through *GRANTS.GOV* by 11:59 p.m. Eastern Time February 13, 2024. Late applications will not be accepted. Mail and fax submissions will not be accepted.

FTA urges applicants to submit applications at least 72 hours prior to the due date to allow time to correct any problems that may have caused either *GRANTS.GOV* or FTA systems to reject the submission. Deadlines will not be extended due to scheduled website maintenance. *GRANTS.GOV* scheduled maintenance and outage times are announced on the *GRANTS.GOV* website.

Within 48 hours after submitting an electronic application, the applicant should receive an email message from *GRANTS.GOV* with confirmation of successful transmission to *GRANTS.GOV*. If a notice of failed validation or incomplete materials is received, the applicant must address the reason for the failed validation, as described in the email notice, and resubmit before the submission deadline. If making a resubmission for any reason, include all original attachments regardless of which attachments were updated and check the box on the supplemental form indicating this is a resubmission.

Applicants are encouraged to begin the process of registration on the *GRANTS.GOV* site well in advance of the submission deadline. Registration is a multi-step process, which may take several weeks to complete before an application can be submitted. Registered applicants may still be required to update their registration before submitting an application. Registration in SAM is renewed annually and

persons making submissions on behalf of the Authorized Organization Representative (AOR) must be authorized in *GRANTS.GOV* by the AOR to make submissions.

5. Funding Restrictions

Funds made available under the ICAM pilot program may only be used for capital expenditures, including mobility management, that are included in the State Transportation Improvement Plan/Transportation Improvement Plan. Eligible projects are capital projects, as defined in 49 U.S.C. 5302(4). Allowable direct and indirect expenses must be consistent with the Government-wide Uniform Administrative Requirements and Cost Principles (2 CFR part 200) and FTA Circular 5010.1E.

Funds awarded under this notice cannot be used to reimburse recipients for expenses incurred prior to FTA issuing pre-award authority. FTA intends to issue pre-award authority pursuant to 2 CFR 200.458 to incur costs for selected projects beginning on the date FTA announces recipients of the FY 2024 awards on FTA's website. Funds are only available for projects that have not incurred costs prior to the announcement of project selections on FTA's website and the corresponding issuance of pre-award authority.

6. Other Submission Requirements

FTA encourages applicants to identify scaled funding options in the event that insufficient funding is available to fund a project at the fully requested amount. If an applicant indicates that a project is scalable, the applicant must provide an appropriate minimum funding amount that will fund an eligible project that achieves the objectives of the program and meets all relevant program requirements. The applicant must provide a clear explanation of how a reduced award would affect the project. FTA may award a lesser amount regardless of whether the applicant provides a scalable option.

E. Application Review Information

1. Criteria

FTA will evaluate proposals submitted according to the following criteria: (a) demonstration of need; (b) demonstration of benefits; (c) planning and partnerships; (d) local financial commitment; (e) project implementation strategy; and (f) technical, legal, and financial capacity. Each applicant is encouraged to provide a succinct, logical, and orderly response to all criteria referenced in this NOFO. Additional information may be

provided to support the responses; however, any additional documentation must be directly referenced on the Supplemental Form, including the file name where the additional information can be found.

a. Demonstration of Need

FTA will evaluate proposals based on how the proposed project will address the need for a regional or statewide capital project that enables comprehensive community access, including NEMT access, for underserved groups. FTA will consider the scope of the overall need or challenge as described. Applications should address how the need is related to one or both of the following goals:

- (1) A need to coordinate multiple funding sources that can fund transportation (*i.e.* CCAM Program Inventory (<https://www.transit.dot.gov/regulations-and-guidance/ccam/about/ccam-program-inventory>) which includes aging/disability programs (<https://acl.gov/programs>), Temporary Assistance for Needy Families (TANF) (<https://www.acf.hhs.gov/ofa/programs/temporary-assistance-needy-families-tanf>), Medicaid (<https://www.medicaid.gov/about-us/learn-how-apply-for-coverage/index.html>), etc.);
- (2) A need to improve transportation services for the targeted disadvantaged community.

b. Demonstration of Benefits

FTA will evaluate proposals on the benefits provided by the proposed project. Benefits will be tied to the ICAM pilot program goals and project elements:

Goals:

- (1) Improve access to coordinated transportation services;
- (2) Reduce duplication of service; and
- (3) Enhance efficiency of the 130 Federal programs that may fund human service transportation.

Project Elements:

- (1) Develop an inter-agency transportation coordinating work group at the regional or state-level;
- (2) The adoption of:
 - a. Consistent driver and vehicle standards,
 - b. Cost allocation rate(s) when clients of different programs use a single transportation service, (increasing efficiency by using the same vehicles to transport passengers whose trips are funded via different Federal programs),
 - c. Rate-setting methodology based on the cost allocation rate of providing transportation (allows costs to be billed or allocated appropriately to the transportation user, facilitating a more efficient use of transportation resources), and

d. Cost allocation technology (enables costs to be shared equitably among participating agencies who receive funding from a variety of Federal agencies); and

(3) Implementation of a regional or statewide pilot of coordinated service delivery to demonstrate the benefits of coordinated transportation.

Proposals for projects that will not directly address the ICAM objectives or project elements should describe how the ICAM objectives or project elements are already met in the state or region.

c. Planning and Partnerships

Applicants must describe the eligible project and identify project partners and their specific role in the project (*e.g.*, vendor, subrecipient, state agency). Successful projects will work collaboratively and leverage partnerships with agencies that are funding recipients of the Federal agencies that are members of the CCAM, such as the Department of Health and Human Services' Administration for Community Living, Health Resources and Services Administration, and the Centers for Medicare and Medicaid Services. A full list of CCAM agencies may be accessed by going to <https://www.transit.dot.gov/ccam/about/agencies>. Partners also may include transportation providers as well as private and nonprofit entities involved in the coordination of NEMT for the transportation disadvantaged.

Applicants should provide evidence of strong commitment from key partners, including memoranda of agreement or letters of support from relevant State agency stakeholders and partner organizations. Any changes to the proposed partnerships will require FTA's advance approval and must be consistent with the scope of the approved project. Projects may be derived from a locally developed, coordinated public transit-human services transportation plan. Inclusion in the locally developed coordinated public transit-human service transportation plan, local and/or regional long range planning documents, and/or local government priorities will demonstrate local/regional prioritization.

FTA will evaluate the project based on the extent to which it was developed inclusively, incorporating meaningful involvement from key stakeholders including consumer representatives of the target groups and providers from the healthcare, transportation, and human services sectors, among others. The applicant must show significant, ongoing involvement of the project's target population.

d. Local Financial Commitment

Applicants must identify the source of the non-Federal share and describe whether such funds are currently available for the project or will need to be secured if the project is selected for funding. FTA will consider the availability of the non-Federal share as evidence of local financial commitment to the project.

e. Project Implementation Strategy

FTA will evaluate the project on the proposed schedule, the applicant's demonstrated ability to implement the proposed project, and the applicant's ability to provide impact data during and after the pilot project. Applicants should indicate the short-term, mid-term, and long-term goals for the project. Proposals must provide specific performance measures the eligible project will use to quantify actual outcomes against expected outcomes.

FTA requires each successful applicant to report progress toward meeting project objectives on a quarterly basis and a final report at the end of the project. FTA will use this data to produce the required Annual Report to Congress that contains a detailed description of the activities carried out under the pilot program, and an evaluation of the program, including an evaluation of the performance measures described.

f. Technical, Legal and Financial Capacity

FTA will evaluate proposals on the capacity of the lead agency and any partners to successfully execute the pilot effort. The lead agency must have the authority and technical capacity to implement a regional or statewide cost allocation pilot project. The applicant should have no outstanding legal, technical, or financial issues that would make this a high-risk project. FTA will evaluate each proposal (including the business plan, financial projections, and other relevant data) for feasibility and longer-term sustainability of both the pilot project as well as the proposed project at full deployment. Applicants should discuss and include any supporting information demonstrating the lead agency has successfully executed a similar project or grant. FTA intends to select projects with a high likelihood of long-term success and sustainability.

2. Review and Selection Process

A technical evaluation committee made up of Federal staff will evaluate proposals based on the published evaluation criteria. FTA may request additional information from applicants,

if necessary. Based on the review of the technical evaluation committee, the FTA Administrator will determine the final selection of projects for program funding. In determining the allocation of program funds, FTA may also consider geographic diversity, diversity in the size of the transit systems receiving funding, and the applicant's receipt of other competitive awards.

After applying the above criteria, FTA will give priority consideration to projects that support the Justice40 initiative, <https://www.transportation.gov/equity-Justice40>. In support of Executive Order 14008, DOT has been developing a geographic definition of Historically Disadvantaged Communities as part of its implementation of the Justice40 Initiative. Consistent with the Interim Guidance for the Justice40 Initiative, Historically Disadvantaged Communities include (a) certain qualifying census tracts identified as disadvantaged due to categories of environmental, climate, and socioeconomic burdens, as identified by the Climate and Economic Justice Screening Tool, and (b) any Federally Recognized Tribes or Tribal entities, whether or not they have land.¹ Applicants should use the Climate & Economic Justice Screening Tool (CEJST), a new tool by the White House Council on Environmental Quality (CEQ), that aims to help Federal agencies identify disadvantaged communities as part of the Justice40 initiative to accomplish the goal that 40 percent of overall benefits from certain Federal investments reach disadvantaged communities. Applicants should use CEJST as the primary tool to identify disadvantaged communities (Justice40 communities). Applicants are strongly encouraged to supplement their use of the CEJST by employing the USDOT Equitable Transportation Community (ETC) Explorer to understand how their community or project area is experiencing disadvantage related to lack of transportation investments or opportunities. Through understanding how a community or project area is experiencing transportation-related disadvantage, applicants are able to address how the benefits of a project will reverse or mitigate the burdens of disadvantage and demonstrate how the project will address challenges and accrued benefits. <https://www.transportation.gov/priorities/equity/justice40/etc-explorer>. Additionally, in support of the Justice40

Initiative, the applicant also should provide evidence of any strategies that the applicant has used in the planning process to seek out and consider the needs of those historically disadvantaged and underserved by existing transportation systems. For technical assistance using either mapping tool, please contact GMO@dot.gov.²

If an applicant is proposing to implement autonomous vehicles or other innovative motor vehicle technology, the application should demonstrate that all vehicles will comply with applicable safety requirements, including those administered by the National Highway Traffic Safety Administration (NHTSA) and Federal Motor Carrier Safety Administration (FMCSA). Specifically, the application should show that vehicles acquired for the proposed project will comply with applicable Federal Motor Vehicle Safety Standards (FMVSS) and Federal Motor Carrier Safety Regulations (FMCSR). If the vehicles may not comply, the application should either (1) show that the vehicles and their proposed operations are within the scope of an exemption or waiver that has already been granted by NHTSA, FMCSA, or both agencies or (2) directly address whether the project will require exemptions or waivers from the FMVSS, FMCSR, or any other regulation and, if the project will require exemptions or waivers, present a plan for obtaining them. If applicable, FTA will also consider the extent to which the application presents a plan to address workforce impacts of autonomous vehicles or other innovative motor vehicle technology.

3. Integrity and Performance Review

Prior to making an award, FTA is required to review and consider any information about the applicant that is in the Federal Awardee Performance and Integrity Information Systems (FAPIIS) accessible through SAM. An applicant may review and comment on information about itself that a Federal awarding agency previously entered. FTA will consider any comments by the applicant, in addition to the other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 2

CFR 200.206, Federal Awarding Agency Review of Risk Posed by Applicants.

F. Federal Award Administration Information

1. Federal Award Notices

FTA will announce the final project selections on the FTA website. Project recipients should contact their FTA Regional Office for additional information regarding allocations for projects under each program. At the time the project selections are announced, FTA expects to extend pre-award authority for the selected projects. There is no pre-award authority for these projects before announcement.

2. Administrative and National Policy Requirements

i. Grant Requirements

Selected applicants will submit a grant application through FTA's Transit Award Management System (TrAMS) and adhere to FTA grant requirements. All competitive grants will be subject to the congressional notification and release process. All ICAM awards are subject to the requirements of the Formula Grants for the Enhanced Mobility of Seniors and Individuals with Disabilities (49 U.S.C. 5310), including those of FTA Circular "Enhanced Mobility of Seniors and Individuals with Disabilities Program Guidance and Application Instructions" (FTA.C.9070.1). All recipients must accept the FTA Master Agreement and follow the Award Management Requirements (FTA.C.5010.1E) and the labor protections required by Federal public transportation law (49 U.S.C. 5333(b)). Technical assistance regarding these requirements is available from each FTA Regional Office.

By submitting a grant application, the applicant assures that it will comply with all applicable Federal statutes, regulations, Executive orders, directives, FTA circulars and other Federal administrative requirements in carrying out any project supported by the FTA grant, including the Davis-Bacon Act (40 U.S.C. 3141–3144, and 3146–3148) as supplemented by Department of Labor regulations (29 CFR part 5, "Labor Standards Provisions Applicable to Contracts Covering Federally Financed and Assisted Construction"). Further, the applicant acknowledges that it is under a continuing obligation to comply with the terms and conditions of the grant agreement issued for its project with FTA. The applicant understands that Federal laws, regulations, policies, and administrative practices might be modified from time to time and may

² See also <https://static-data-screeningtool.geoplatform.gov/data-versions/1.0/data/score/downloadable/CEQ-CEJST-Instructions.pdf>.

¹ https://whitehouse.gov/wp-content/uploads/2023/01/M-23-09_Signed_CEQ_CPO.pdf.

affect the implementation of the project. The applicant agrees that the most recent Federal requirements will apply to the project unless FTA issues a written determination otherwise. The applicant must submit the Certifications and Assurances before receiving a grant if it does not have current certifications on file.

As authorized by Section 25019 of the BIL, applicants are encouraged to implement a local or other geographical or economic hiring preference relating to the use of labor for construction of a project funded by the grant, including pre-hire agreements, subject to any applicable State and local laws, policies, and procedures.

ii. Made in America

A project funded under this NOFO must comply with FTA's Buy America (49 U.S.C. 5323(j)) and the Build America, Buy America Act's domestic preference requirements for infrastructure projects (§§ 70901–70927 of the Infrastructure Investment and Jobs Act, Pub. L. 117–58), which together require that all iron, steel, manufactured goods, and construction materials used in the project be produced in the United States and set minimum domestic content and final assembly requirements for rolling stock.

Any proposal that will require a waiver of any domestic preference standard must identify the items for which a waiver will be sought in the application. Applicants should not proceed with the expectation that waivers will be granted.

iii. Civil Rights Requirements

Applications should demonstrate that the recipient has a plan for compliance with civil rights obligations and nondiscrimination laws, including Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act (ADA), and Section 504 of the Rehabilitation Act, and accompanying regulations. This should include a current Title VI Program Plan and a completed Community Participation Plan (alternatively called a Public Participation Plan and often part of the overall Title VI program plan), if applicable. Applicants who have not sufficiently demonstrated the conditions of compliance with civil rights requirements will be required to do so before receiving funds.

Recipients of Federal transportation funding will be required to comply fully with the DOT's regulations and guidance for the ADA and all relevant civil rights requirements. The Department's and FTA's Office of Civil Rights will work with awarded grant

recipients to ensure full compliance with Federal civil rights requirements.

iv. Disadvantaged Business Enterprise

Recipients of planning or capital assistance that will award prime contracts, the cumulative total of which exceeds \$250,000 in FTA funds in a Federal fiscal year, must have a Disadvantaged Business Enterprise (DBE) program that complies with the U.S. Department of Transportation's DBE regulation (49 CFR part 26).

To be eligible to bid on any FTA-assisted vehicle procurement, entities that manufacture transit vehicles or perform post-production alterations or retrofitting must be certified Transit Vehicle Manufacturers (TVM). If a vehicle remanufacturer is responding to a solicitation for new or remanufactured vehicles with a vehicle to which the remanufacturer has provided post-production alterations or retrofitting (e.g., replacing major components such as engine to provide a "like new" vehicle), the vehicle remanufacturer must be a certified TVM.

v. Critical Infrastructure Security and Resilience

It is the policy of the United States to strengthen the security and resilience of its critical infrastructure against both physical and cyber threats. TSA issued Security Directive 1582–21–01B, "Enhancing Public Transportation and Passenger Railroad Cybersecurity" on October 23, 2023. The Security Directive, which applies to all public passenger rail owners and operators identified in 49 CFR 1582.101 and other TSA-designated owner/operators, requires four critical actions:

1. Designate a cybersecurity coordinator who is required to be available to TSA and the DHS's CISA at all times (all hours/all days) to coordinate implementation of cybersecurity practices, and manage of security incidents, and serve as a principal point of contact with TSA and CISA for cybersecurity-related matters;

2. Report cybersecurity incidents to CISA;

3. Develop a Cybersecurity Incident Response Plan to reduce the risk of operational disruption should their Information and/or operational technology systems be affected by a cybersecurity incident; and

4. Conduct a cybersecurity vulnerability assessment using the form provided by TSA and submit the form to TSA. The vulnerability assessment will include an assessment of current practices and activities to address cyber risks to information and operational technology systems, identify gaps in

current cybersecurity measures, and identify remediation measures and a plan for the owner/operator to implement the remediation measures to address any vulnerabilities and gaps.

TSA issued IC–2021–01, "Enhancing Surface Transportation Cybersecurity", dated December 31, 2021, which applies to each passenger railroad, public transportation agency, or rail transit system owner/operator not specifically covered under Security Directive 1582–21–01. This circular provides the same four recommendations for enhancing cybersecurity practices listed above. While this document is guidance and does not impose any mandatory requirements, TSA strongly recommends the adoption of the measures set forth in the circular.

vi. Planning

FTA encourages applicants to engage the appropriate State departments of transportation, Regional Transportation Planning Organizations, or Metropolitan Planning Organizations in areas to be served by the project funds available under these programs.

vii. Reporting

Post-award reporting requirements include submission of Federal Financial Reports and Milestone Progress Reports in FTA's electronic grants management system. An independent evaluation of the pilot program may occur at various points in the deployment process and at the end of the pilot project. In addition, FTA is responsible for producing an annual report to Congress evaluating the program, including an evaluation of the performance and outcome measures identified by the applicants. All applicants must develop a final report evaluating their performance measures and measuring the success or failure of their projects. FTA will provide successful applicants with technical assistance through the National Aging and Disability Transportation Center. The technical assistance will focus on the detailed development of project performance measures that are linked to project outcomes. FTA may request data and reports to support the independent evaluation and annual report. Applicants should also include any goals, targets, and indicators referenced in their application to the project in the Executive Summary of the TrAMS application.

FTA is committed to making evidence-based decisions guided by the best available science and data. In accordance with the Foundations for Evidence-based Policymaking Act of 2018 (Evidence Act), FTA may use information submitted in discretionary

funding applications; information in FTA's Transit Award Management System (TrAMS), including grant applications, Milestone Progress Reports (MPRs), Federal Financial Reports (FFRs); transit service, ridership and operational data submitted in FTA's National Transit Database; documentation and results of FTA oversight reviews, including triennial and state management reviews; and other publicly available sources of data to build evidence to support policy, budget, operational, regulatory, and management processes and decisions affecting FTA's grant programs.

As part of completing the annual certifications and assurances required of FTA grant recipients, a successful applicant must report on the suspension or debarment status of itself and its principals. If the award recipient's active grants, cooperative agreements, and procurement contracts from all Federal awarding agencies exceeds \$10,000,000 for any period of time during the period of performance of an award made pursuant to this notice, the recipient must comply with the Recipient Integrity and Performance Matters reporting requirements described in Appendix XII to 2 CFR part 200.

G. Federal Awarding Agency Contact

For questions about applying to the pilot program outlined in this notice, please contact the FTA Program Manager, Destiny Buchanan, phone: (202) 493-8018, or email, Destiny.Buchanan@dot.gov. A TDD is available at 1-800-877-8339 (TDDFIRS). Additionally, you may visit FTA's website for this program at <https://www.transit.dot.gov/funding/grant-programs/access-and-mobility-partnership-grants>.

To ensure that applicants receive accurate information about eligibility or the program, applicants are encouraged to contact FTA directly with questions, rather than through intermediaries or third parties. FTA staff also may conduct briefings on the FY 2024 competitive grants selection and award process upon request. Contact information for FTA's regional offices can be found on FTA's website at <https://www.transit.dot.gov/>.

H. Other Information

This program is not subject to Executive Order 12372, *Intergovernmental Review of Federal Programs*.

All information submitted as part of or in support of any application shall use publicly available data or data that can be made public and methodologies that are accepted by industry practice and standards, to the extent possible. The Department may share application information within the Department or with other Federal agencies if the Department determines that sharing is relevant to the respective program's objectives. If an applicant submits information the applicant considers to be a trade secret or confidential commercial or financial information, the applicant must provide that information in a separate document, which the applicant may reference from the application narrative or other portions of the application. For the separate document containing confidential information, the applicant must do the following: (1) state on the cover of that document that it "Contains Confidential Business Information (CBI);" (2) mark each page that contains confidential information with "CBI;" (3) highlight or otherwise denote the confidential content on each page; and (4) at the end of the document, explain how disclosure of the confidential information would cause substantial competitive harm. FTA will protect confidential information complying with these requirements to the extent required under applicable law. If FTA receives a Freedom of Information Act (FOIA) request for the information that the applicant has marked in accordance with this section, FTA will follow the procedures described in DOT's FOIA regulations at 49 CFR 7.29. Only information that is in the separate document, marked in accordance with this section, and ultimately determined to be confidential will be exempt from disclosure under FOIA.

Nuria I. Fernandez,

Administrator.

[FR Doc. 2023-25181 Filed 11-14-23; 8:45 am]

BILLING CODE 4910-57-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Actions on Special Permits

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of actions on special permit applications.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before December 15, 2023.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

SUPPLEMENTARY INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH-13, 1200 New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 3, 2023.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA—GRANTED

Application number	Applicant	Regulation(s) affected	Nature of the special permits thereof
11911-M	Transfer Flow, Inc	177.834(h), 178.700(c)(1)	To modify the special permit to revise the "safe zone" definition.

SPECIAL PERMITS DATA—GRANTED—Continued

Application number	Applicant	Regulation(s) affected	Nature of the special permits thereof
14232-M	Luxfer Inc	173.302(a), 173.304(a), 180.205.	To modify the special permit to authorize Modal Acoustic Emission testing of cylinders.
15642-M	Linde Gas & Equipment Inc	172.203(a), 180.205(c), 180.209(a), 180.209(b), 180.209(b)(1)(iv).	To modify the special permit to extend the initial periodic re-qualification period of DOT 3AL and DOT-SP 12440 cylinders from 5 years to 10 years and to authorize certain newly manufactured DOT 3AL cylinders to be used in dedicated dry-gas service.
20351-M	Roeder Cartage Company, Incorporated.	180.407(c), 180.407(e), 180.407(f).	To modify the special permit to remove unit numbers 7145 and 7133.
21139-M	KULR Technology Corporation	172.600, 172.200, 172.300, 172.700(a), 172.400, 172.500, 173.185(b).	To modify the special permit to authorize an alternative shipping document, to remove the reference to ferry vessel operations, and to clarify the requirement in paragraph 7.b.(2).
21460-M	Amerex Corporation	173.309(c)	To modify the special permit to authorize an additional extinguisher model.
21542-N	Samsung SDI Co., Ltd	172.101(j)	To authorize the transportation in commerce of lithium batteries exceeding 35 kg by cargo-only aircraft.
21582-N	ABG Bag, Inc	172.102, 173.36(b)(2), 173.241(e)(1).	To authorize the manufacture, mark, sale, and use of UN 51H large packagings for the purpose of transporting polychlorinated biphenyls by motor vehicle.
21651-N	Australian Federal Police	172.700(a), 172.400, 172.200, 172.300, 175.75(b).	To authorize the transportation in commerce of Division 6.1 hazardous materials in the cabin of a passenger-carrying aircraft.
21653-N	Environmental Protection Agency.	172.400, 172.101, 173.27, 178.2.	To authorize the transportation in commerce of unclassified waste materials to a staging area where the materials will be classified and brought into compliance with the Hazardous Materials Regulations (HMR).

SPECIAL PERMITS DATA—GRANTED

Application number	Applicant	Regulation(s) affected	Nature of the special permits thereof
15882-M	Ryan Air, Inc	172.101, 173.27, 173.243	To modify the special permit to add a C-208 to carry bulk fuel in a 476-gallon BATT Tank.

SPECIAL PERMITS DATA—GRANTED

Application number	Applicant	Regulation(s) affected	Nature of the special permits thereof
20245-M	Jaguar Texas Valve & Instruments, LLC.	173.302(a), 173.304(a)	To modify the special permit to authorize a cylinder with an increased length.
20251-M	Salco Products Inc	172.203(a), 178.345-1, 180.413 ..	To modify the special permit to authorize additional manway configurations. (mode 1).
21555-N	Hach Company	172.301(c), 172.315	To authorize the transportation in commerce of certain Division 5.1, Class 8, and Class 9 materials between Hach Company facilities without having to apply the limited quantity marking each individual package when consolidated into an overpack displaying the limited quantity mark.
21620-N	3rd Light, LLC	172.200(a), 172.400(a), 173.60(a), 173.63(b), 172.320(a), 172.500(a),	To authorize the transportation in commerce of Ultimate Match life-saving devices as limited quantities.
21645-N	Flint Hills Resources, LLC	172.203(a), 173.120(c)(1)(ii)(A)	To authorize the transportation in commerce of flammable liquids and combustible liquids classed using an alternative test method (ASTM D7094-17a) that is not currently authorized in § 173.120(c) for determining a liquid's flash point.
21647-N	Airbus U.S. Space & Defense, Inc	172.101(j)(1), 173.301(f), 173.302a(a)(1), 173.302a(a)(3), 173.304a(a)(2).	To authorize the transportation in commerce of certain non-DOT specification containers containing certain Division 2.2 and 2.3 hazardous materials identified in paragraph 6 of this special permit for the use in satellites.

[FR Doc. 2023–25170 Filed 11–14–23; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration****Hazardous Materials: Notice of Applications for Modification to Special Permits**

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for modification of special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety

has received the application described herein.

DATES: Comments must be received on or before November 30, 2023.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT: Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington, DC 20590–0001, (202) 366–4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the “Nature of Application” portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH–13, 1200 New Jersey Avenue Southeast, Washington DC or at <http://regulations.gov>.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 3, 2023.

Donald P. Burger,
Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application number	Applicant	Regulation(s) affected	Nature of the special permits thereof
14201–M	National Air Cargo Group, Inc	172.204(c)(3), 172.101(j)(1), 173.27(b)(2), 173.27(b)(3), 175.30(a)(1).	To modify the special permit to authorize more than 2,000 pounds new explosives to be transported aboard the aircraft and to authorize UN1005, UN3543, and UN3549 to be transported. (mode 4).
20677–M	Department of Defense (Military Surface Deployment & Distribution Command).	173.302(a)(1)	To modify the special permit to authorize additional packagings. (modes 1, 2, 3, 4).
20936–M	Co2 Exchange LLC	171.2(k), 172.200, 172.300, 172.700(a), 172.400, 172.500.	To modify the special permit to authorize a different marking and hazard communication information on a package and different reoffering provisions in paragraph 8.b. (modes 1, 2).
21193–M	KULR Technology Corporation	172.200, 172.300, 172.700(a), 172.400, 172.500, 172.600, 173.185(f).	To modify the special permit to authorize the transportation of end of life lithium ion cells and batteries and lithium metal cells and batteries and to authorize alternative packaging. (modes 1, 2).
21403–M	Northrop Grumman Systems Corporation.	173.185(a)(1), 173.185(a)(2)	To modify the special permit to remove paragraphs 7.b.(2) and (4). (modes 1, 4).
21490–M	Myers Industries, Inc	173.28(b)(2), 178.509(b)(7), 178.601(h).	To modify the special permit to authorize testing variations 3 and 5 under 49 CFR 178.601(g)(3) and (5). (modes 1, 2).
21539–M	Rivian Automotive, LLC	172.301(c), 173.185(c)(1)(iii)	To modify the special permit to authorize party status to entities under contract with the grantee. (mode 1).

[FR Doc. 2023–25169 Filed 11–14–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION**Pipeline and Hazardous Materials Safety Administration****Hazardous Materials: Notice of Applications for New Special Permits**

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of applications for special permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations, notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein.

DATES: Comments must be received on or before December 15, 2023.

ADDRESSES: Record Center, Pipeline and Hazardous Materials Safety

Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT:

Donald Burger, Chief, Office of Hazardous Materials Safety General Approvals and Permits Branch, Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, East Building, PHH-13,

1200 New Jersey Avenue Southeast, Washington, DC 20590-0001, (202) 366-4535.

SUPPLEMENTARY INFORMATION: Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

Copies of the applications are available for inspection in the Records Center, East Building, PHH-13, 1200

New Jersey Avenue Southeast, Washington, DC.

This notice of receipt of applications for special permit is published in accordance with part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on November 3, 2023.

Donald P. Burger,

Chief, General Approvals and Permits Branch.

SPECIAL PERMITS DATA

Application number	Applicant	Regulation(s) affected	Nature of the special permits thereof
21656-N	Rawhide Leasing Company LLC.	173.302a(b)	To authorize the requalification of 3A, 3AA, 3AX, 3AAx and 3T cylinders by proof pressure testing in accordance with CGA Pamphlet C-1 in lieu of hydrostatic or direct expansion testing. (modes 1, 3).
21658-N	Veolia ES Technical Solutions LLC.	173.21(b), 173.51, 173.54(a), 173.56(b).	To authorize the one-time, one-way transportation in commerce of unapproved explosives for the purpose of disposal. (mode 1).
21659-N	Siller Helicopters, Inc	172.400, 172.101, 172.200, 172.204(c)(3), 172.204(c)(3), 172.300, 173.27(b)(2), 175.30(a)(1).	To authorize the transportation in commerce of certain hazardous materials by 14 CFR Part 133 cargo-only aircraft (rotorcraft external load operations) transporting hazardous materials attached to or suspended from the aircraft, and Part 135, as applicable, in remote areas of the US only, without being subject to certain hazard communication requirements, quantity limitations and certain loading and stowage requirements. (mode 4).
21661-N	Thermavant Technologies, LLC.	173.301(f), 173.302a(a)(1), 173.304a(a)(2).	To authorize the transportation in commerce of certain non-DOT specification containers containing anhydrous ammonia for use in specialty cooling applications in the DoD and Aerospace industry. (mode 1).
21662-N	Tank Traders Missouri	180.215	To authorize the transportation in commerce of propane cylinders where the visual inspection record is created in an alternative manner.
21663-N	Orbion Space Technology, Inc.	173.301(f)(1), 173.302a	To authorize the transportation in commerce of non-DOT specification cylinders intended for use in spacecraft. (mode 1).
21664-N	Champion Container Corporation.	173.158(f)(3)	To authorize the transportation in commerce of nitric acid in combination packaging where the inner packagings are not further individually overpacked in tightly closed metal packagings. (modes 1, 2, 3).
21665-N	Weilert Enterprises, Inc	178.935(c)(1)	To authorize the manufacture, mark, sale, and use of UN 50D large packagings with a volumetric capacity exceeding 3000 L.
21666-N	CMC Materials, Inc	173.22(a)(2), 173.24(c)(1)(i)	To authorize the transportation in commerce of certain oxidizing liquids in alternative packaging. (mode 1).
21667-N	Hanwha Cimarron LLC	173.302(a)	To authorize the manufacture, mark, sale, and use of non-DOT specification fiber reinforced composite cylinders with non-load sharing plastic liners in compliance with UN/ISO11515: 2013, Type 4. (modes 1, 2, 3).

[FR Doc. 2023-25168 Filed 11-14-23; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Docket No. DOT-OST-2023-0108]

Privacy Act of 1974; System of Records

AGENCY: Office of the Departmental Chief Information Officer, Office of the Secretary of Transportation, DOT.

ACTION: Notice of a new system of records.

SUMMARY: In accordance with the Privacy Act of 1974, the United States Department of Transportation (DOT), Federal Aviation Administration (FAA), proposes a new system of records titled, "DOT/FAA 858 Adjudication Docket Records in Aviation Litigation Proceedings under 14 Code of Federal

Regulations (CFR) part 13, subparts D and G and Acquisition Dispute Proceedings under 14 CFR part 17". This system of records allows DOT to collect and maintain case records for in-house administrative adjudications and mediations ("adjudicative records") in accordance with FAA procedures and regulations that support its mission of aviation safety.

DATES: Submit comments on or before December 15, 2023. The Department may publish an amended Systems of Records Notice considering any comments received. This new system will be effective immediately upon publication. The routine uses will be effective December 15, 2023.

ADDRESSES: You may submit comments identified by docket number DOT-OST-2023-0108 by any of the following methods:

- *Federal e-Rulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments.

- *Mail:* Docket Management Facility, U.S. Department of Transportation, 1200 New Jersey Ave. SE, West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.

- *Hand Delivery or Courier:* West Building Ground Floor, Room W12-140, 1200 New Jersey Ave. SE, between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal Holidays.

- *Fax:* (202) 493-2251.

Instructions: You must include the agency name and docket number DOT-OST-2023-0108. All comments received will be posted without change to <https://www.regulations.gov>, including any personal information provided.

Privacy Act: Anyone is able to search the electronic form of all comments received in any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

Docket: For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> or to the street address listed above. Follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: For questions, please contact: Karyn Gorman, Departmental Chief Privacy Officer, Privacy Office, Department of Transportation, Washington, DC 20590; privacy@dot.gov; or 202-366-3140.

SUPPLEMENTARY INFORMATION: The adjudicative records consist of two categories of records, namely: adjudications resulting from actions in which individuals request a hearing under 14 CFR part 13, subparts D or G;

and acquisition adjudications, such as bid protests, contract disputes and pre-disputes filed under 14 CFR part 17. The adjudicative records in both categories include any associated applications for attorney fees under 14 CFR part 14. The information maintained in this system of records depends on the nature of the case and includes but is not limited to: a party's name; date of birth; tax identification number (TIN) and/or social security number (SSN); certificate number, business and personal contact information (e.g., address and phone number); medical information; drug test results; penalty history; docket number or order number; financial (e.g., tax returns, pay stubs or bank statements) and employment-related information; as well as other personally identifiable information (PII) in exhibits and other artifacts, which vary depending on the nature of the case.

Background

In accordance with the Privacy Act of 1974, the United States DOT/FAA is proposing a new system of records notice titled, "DOT/FAA 858 Adjudication Docket Records in Aviation Litigation Proceedings under 14 CFR part 13, subparts D and G and Acquisition Dispute Proceedings under 14 CFR part 17." The records covered by this Notice were previously covered by two separate Notices: SORN DOT/FAA 847, Aviation Records on Individuals, and SORN DOT/ALL 14, Federal Docket Management System (FDMS). To ensure consistent handling of records maintained by FAA's Office of Adjudication, DOT is proposing to consolidate adjudication docket records maintained by the Office of Adjudication into a single SORN.

This system of records covers all facets of in-house administrative adjudications and mediations ("adjudicative records"). The adjudicative records consist of two categories of records, namely: adjudications resulting from certain actions in which individuals request a hearing under 14 CFR part 13, subparts D or G ("subparts D or G records"), and acquisition adjudications ("acquisition adjudication records"), such as bid protests, contract disputes and pre-disputes filed by individuals under 14 CFR part 17. Both of these categories include any related applications for attorney fees under 14 CFR part 14.

Subparts D or G Records

Subparts D or G records are records that are generated in connection with a request for hearing and proceedings related to such a request under 14 CFR

part 13, subparts D and G. FAA actions that result in the creation of records following a request for a hearing under subpart D are referenced in 14 CFR 13.20 and include orders of compliance, cease and desist orders, and orders of denial. FAA actions that result in the creation of records following a request for a hearing under subpart G are referenced in that subpart. Requests for hearings under subparts D and G are filed with the Office of Adjudication. This Notice does not cover the underlying enforcement investigative records maintained in FAA's investigative files for actions described in 14 CFR 13.16 and 13.20; those files are maintained in accordance with System of Records Notice DOT/FAA 847, Aviation Records on Individuals, to the extent they pertain to investigations pertaining to an individual.

The individual's request for a hearing initiates in-house administrative adjudication by the FAA. During the adjudication process, the individual and the FAA make arguments and submit into the case record information in connection with the litigation and their positions. This case record information often contains PII that includes but is not limited to: the individual's name; date of birth; TIN and/or SSN; certificate number, business and personal contact information (e.g., address and phone number); medical information; drug test results; penalty history; docket number or order number; financial (e.g., tax returns, pay stubs or bank statements) and employment-related information; as well as other PII in exhibits and other artifacts, which vary depending on the nature of the case. These records are generated under the provisions of 14 CFR part 13, subparts D and G. Associated records pertaining to requests for attorney fees are generated as a result of the requirements under 14 CFR part 14.

Subparts D or G records that are the subject of this notice are those created under 14 CFR part 13, subparts D and G, following an individual's request for a hearing under those subparts. These individuals consist of any members of the public who are subject to FAA statutes and regulations those who fall within the ambit of §§ 13.16 and 13.20, who request a hearing under those sections, and who are the subject of documents generated through litigation under those sections.

Acquisition Adjudication Records

Acquisition adjudication records pertain to acquisition actions filed by a party who does, or seeks to do, business with the FAA; this Notice applies to those actions filed by parties who

conduct, or seek to conduct business with the FAA in their personal capacity. It does not apply to actions filed by businesses or other non-person entities. An acquisition matter could involve a contract dispute between a party and the FAA over rental payments. A bid protest filed by a party against an adverse evaluation by the FAA of their financial capability to perform a contract is another possible acquisition matter. These parties submit records to support their contract dispute or bid protest, that includes but is not limited to: a party's name, date of birth, TIN and/or SSN; business and personal contact information (address and phone number); docket number or order number; financial (e.g., tax returns, pay stubs or bank statements) and employment-related information; as well as other PII in exhibits and other artifacts, which vary depending on the nature of the case.

Acquisition adjudication records cover: parties who file, and are the subjects of, bid protests, contract disputes, pre-disputes and any associated application for attorney fees, pursuant to 14 CFR parts 17 and 14 (respectively), with the Office of Adjudication's Office of Dispute Resolution for Acquisition (ODRA). These parties can include:

Individuals who are contractors, lessors, offerors, and members of the public who do, or seek to do business with the FAA in their personal capacity.

Privacy Act

The Privacy Act (5 U.S.C. 552a) governs the means by which the Federal Government collects, maintains, and uses personally identifiable information (PII) in a System of Records. A "System of Records" is a group of any records under the control of a Federal agency from which information about individuals is retrieved by name or other personal identifier. The Privacy Act requires each agency to publish in the **Federal Register** a System of Records Notice (SORN) identifying and describing each System of Records the agency maintains, including the purposes for which the agency uses PII in the system, the routine uses for which the agency discloses such information outside the agency, and how individuals to whom a Privacy Act record pertains can exercise their rights under the Privacy Act (e.g., to determine if the system contains information about them and to contest inaccurate information). In accordance with 5 U.S.C. 552a(r), DOT has provided a report of this system of records to the Office of Management and Budget and to Congress.

SYSTEM NAME AND NUMBER:

Department of Transportation, Federal Aviation Administration, DOT/FAA 858 Adjudication Docket Records in Aviation Litigation Proceedings under 14 CFR part 13, subparts D and G and Acquisition Dispute Proceedings under 14 CFR part 17.

SECURITY CLASSIFICATION:

Unclassified

SYSTEM LOCATION:

System records are maintained at FAA headquarters in the Office of Adjudication. Address: 800 Independence Avenue SW, Washington, DC 20591.

SYSTEM MANAGER(S):

For adjudication records in pending cases: Director, Office of Adjudication, AGC-70, 800 Independence Ave. SW, Washington, DC 20591. *9-AGC-FAA-HearingDocket@faa.gov* [for Subparts D or G adjudication records] or *9-AGC-ODRA@faa.gov* [for acquisition adjudication records].

For finalized adjudication records in closed cases stored in the Case and Document Management System (CDMS): Director, Administrative Division, AGC-10, 800 Independence Ave. SW, Washington, DC 20591.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

49 U.S.C. 106, 44701, 40113-40114, and 46101-46110; 14 CFR part 13, subparts D and G; 14 CFR parts 14 and 17.

PURPOSE(S) OF THE SYSTEM:

The purpose of the system is to allow DOT to collect and maintain case records for in-house administrative adjudications and mediations ("adjudicative records") in accordance with FAA procedures and regulations that support its mission of aviation safety. The adjudicative records consist of two categories of records, namely: legal proceedings resulting from adjudications resulting from certain actions in which individuals request a hearing under 14 CFR part 13, subparts D or G; and acquisition adjudications, such as bid protests, contract disputes and pre-disputes filed under 14 CFR part 17. The adjudicative records in both categories include any associated applications for attorney fees under 14 CFR part 14.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

This system of records contains information on individual members of the public who are parties in aviation litigation adjudication proceedings under 14 CFR part 13, subparts D and

G or acquisition adjudication proceedings under 14 CFR part 17.

Subparts D or G Records: Individuals who request a hearing under 14 CFR part 13, subparts D and G, resulting from an FAA-initiated action described in 14 CFR 13.16 and 13.20: These individuals consist of those who fall within the ambit of §§ 13.16 and 13.20, who request a hearing under those sections, and who are the subject of documents generated through litigation under those sections.

Acquisition Adjudication Records: Parties who file, and are the subjects of, bid protests, contract claims, pre-disputes and associated applications for attorney fees, pursuant to 14 CFR parts 17 and 14 (respectively), with the ODRA relative to contracts competed or awarded under the FAA's acquisition policies and procedures. These parties can include:

Individuals who are contractors, lessors, offerors, and members of the public who do, or seek to do business with the FAA in their personal capacity.

CATEGORIES OF RECORDS IN THE SYSTEM:

The types of PII contained within the categories of records in this system of records depend on the nature of the case, and include but are not limited to:

Subparts D or G Records: Subparts D or G records are records that are generated as a result of a request for a hearing under 14 CFR part 13, subparts D and G, resulting from an FAA-initiated legal enforcement action described in 14 CFR 13.16 and 13.20. Such records may include a party's name, date of birth; TIN and/or SSN; certificate number, business and personal contact information (e.g., address and phone number); medical information; drug test results; penalty history; docket number or order number; financial (e.g., tax returns, pay stubs or bank statements) and employment-related information; as well as other PII in exhibits and other artifacts, which vary depending on the nature of the case. These records are generated as a result of the provisions of 14 CFR part 13, subparts D and G.

Acquisition Adjudication Records: A party's name, date of birth, TIN and/or SSN; business and personal contact information (address and phone number); docket number or order number; financial (e.g., tax returns, pay stubs or bank statements) and employment-related information; as well as other PII in exhibits and other artifacts, which vary depending on the nature of the case.

RECORD SOURCE CATEGORIES:

Subparts D or G Records: Subparts D or G records that are the subject of this notice are those created under 14 CFR part 13, subparts D and G, following an individual's request for a hearing under those subparts. These individuals consist of: those individuals who fall within the ambit of §§ 13.16 and 13.20, who request a hearing under those sections, and who are the subject of documents generated through litigation under those sections.

Acquisition Adjudication Records: Parties who file, and are the subjects of, bid protests, contract claims, pre-disputes and associated applications for attorney fees, pursuant to 14 CR parts 17 and 14 (respectively), with the ODRA relative to contracts competed or awarded under the FAA's acquisition policies and procedures.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to other disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DOT as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

System Specific Routine Use

1. The FAA may provide public versions of decisions and orders, which have been sanitized to remove any sensitive PII, proprietary, source-selection or other confidential information, as a routine use, to commercial publishers of legal materials for inclusion in print editions and online services for the same reasons. Public versions of decisions and orders published on the FAA website or by commercial publishers such as Westlaw or LexisNexis may contain the names of parties, attorneys, legal representatives, witnesses, and other individuals involved in the case.

Departmental Routine Uses

2. In the event that a system of records maintained by DOT to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or particular program pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, or rule, regulation, or order issued pursuant thereto.

3. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a DOT decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant or other benefit.

4. A record from this system of records may be disclosed, as a routine use, to a Federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

5a. Routine Use for Disclosure for Use in Litigation. It shall be a routine use of the records in this system of records to disclose them to the Department of Justice, or other Federal agencies conducting litigation when (a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof in their official capacity, or (c) Any employee of DOT or any agency thereof, in their individual capacity, where the Department of Justice has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that litigation likely to affect the United States, is a party to litigation or has an interest in such litigation, and the use of such records by the Department of Justice or other Federal agency conducting the litigation is deemed by DOT to be relevant and necessary in the litigation, provided, however, that in each case, DOT determines that disclosure of the records in the litigation is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

5b. Routine Use for Agency Disclosure in Other Proceedings. It shall be a routine use of records in this system to disclose them in proceedings before any court or adjudicative or administrative body before which DOT or any agency thereof appears when (a) DOT, or any agency thereof, or (b) Any employee of DOT or any agency thereof in their official capacity, or (c) Any employee of DOT or any agency thereof in their individual capacity where DOT has agreed to represent the employee, or (d) The United States or any agency thereof, where DOT determines that the

proceeding is likely to affect the United States, is a party to the proceeding, or has an interest in such proceeding, and DOT determines that use of such records is relevant and necessary in the proceeding, provided, however, that in each case, DOT determines that disclosure of the records in the proceeding is a use of the information contained in the records that is compatible with the purpose for which the records were collected.

6. The information contained in this system of records will be disclosed to the Office of Management and Budget, OMB in connection with the review of private relief legislation as set forth in OMB Circular No. A-19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

7. Disclosure may be made to a Congressional office from the record of an individual in response to an inquiry from the Congressional office made at the request of that individual. In such cases, however, the congressional office does not have greater rights to records than the individual. Thus, the disclosure may be withheld from delivery to the individual where the file contains investigative or actual information or other materials which are being used, or are expected to be used, to support prosecution or fines against the individual for violations of a statute, or of regulations of the Department based on statutory authority. No such limitations apply to records requested for Congressional oversight or legislative purposes; release is authorized under 49 CFR 10.35(9).

8. One or more records from a system of records may be disclosed routinely to the National Archives and Records Administration (NARA) in records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

9. Routine Use for disclosure to the Coast Guard and to Transportation Security Administration. A record from this system of records may be disclosed as a routine use to the Coast Guard and to the Transportation Security Administration if information from this system was shared with either agency when that agency was a component of the Department of Transportation before its transfer to the Department of Homeland Security and such disclosure is necessary to accomplish a DOT, TSA or Coast Guard function related to this system of records.

10. DOT may make available to another agency or instrumentality of any government jurisdiction, including State and local governments, listings of names from any system of records in DOT for

use in law enforcement activities, either civil or criminal, or to expose fraudulent claims, regardless of the stated purpose for the collection of the information in the system of records. These enforcement activities are generally referred to as matching programs because two lists of names are checked for match using automated assistance. This routine use is advisory in nature and does not offer unrestricted access to systems of records for such law enforcement and related antifraud activities. Each request will be considered on the basis of its purpose, merits, cost effectiveness and alternatives using Instructions on reporting computer matching programs to the Office of Management and Budget, OMB, Congress, and the public, published by the Director, OMB, dated September 20, 1989.

11. It shall be a routine use of the information in any DOT system of records to provide to the Attorney General of the United States, or his/her designee, information indicating that a person meets any of the disqualifications for receipt, possession, shipment, or transport of a firearm under the Brady Handgun Violence Prevention Act. In case of a dispute concerning the validity of the information provided by DOT to the Attorney General, or his/her designee, it shall be a routine use of the information in any DOT system of records to make any disclosures of such information to the National Background Information Check System, established by the Brady Handgun Violence Prevention Act, as may be necessary to resolve such dispute.

12a. DOT may disclose records from this system, as a routine use, to appropriate agencies, entities, and persons when: (1) DOT suspects or has confirmed that there has been a breach of the system of records; (2) DOT has determined that as a result of the suspected or confirmed breach there is a risk of harm to individuals, DOT (including its information systems, programs, and operations), the Federal Government, or national security; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with DOT's efforts to respond to the suspected or confirmed breach or to prevent, minimize or remedy such harm.

12b. To another Federal agency or Federal entity, when DOT determines that information from this system of records is reasonably necessary to assist the recipient agency or entity in (1) responding to a suspected or confirmed breach or (2) preventing, minimizing, or

remediating the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the Federal Government, or national security, resulting from a suspected or confirmed breach.

13. DOT may disclose records from this system, as a routine use, to the Office of Government Information Services for the purpose of (a) resolving disputes between FOIA requesters and Federal agencies and (b) reviewing agencies policies, procedures and compliance in order to recommend policy changes to Congress and the President.

14. DOT may disclose records from this system, as a routine use, to contractors and their agents, experts, consultants, and other performing or working on a contract, service, cooperative agreement, or other assignment for DOT, when necessary to accomplish an agency function related to this system of records.

15. DOT may disclose records from this system, as a routine use, to an agency, organization or individual for the purpose of performing audit or oversight operations related to this system of records, but only such records as are necessary and relevant to the audit or oversight activity. This routine use does not apply to intra-agency sharing authorized under Section (b)(1) of the Privacy Act.

16. DOT may disclose from this system, as a routine use, records consisting of, or relating to, terrorism information (6 U.S.C. 485(a)(5)), homeland security information (6 U.S.C. 482(f)(1)), or Law enforcement information (Guideline 2 Report attached to White House Memorandum, "Information Sharing Environment," November 22, 2006) to a Federal, State, local, Tribal, Territorial, foreign government and/or multinational agency, either in response to its request or upon the initiative of the component for purposes of sharing such information as is necessary and relevant for the agencies to detect, prevent, disrupt, preempt, and mitigate the effects of terrorist activities against the territory, people and interests of the United States of America, as contemplated by the Intelligence Reform and Terrorism Prevention Act of 2004 (Pub. L. 108-458) and Executive Order 13388 (October 25, 2005).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records are initially stored electronically on a shared drive and then are migrated to CDMS, once the case is finalized.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

All records are primarily retrieved by personal identifiers, such as party name, docket number, or order number.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The FAA is drafting a retention and disposition schedule for adjudicative records; currently all records retention schedules are pending. Unscheduled records are retained indefinitely pending the agency's submission, and (National Archives and Records Administration) NARA's approval, of a disposition schedule. FAA anticipates proposing to NARA the following retention periods:

1. In-house administrative adjudication final orders and decisions are precedential, permanently retained, and transferred to NARA 15 years after the case closes.

2. In-house adjudicative records, excluding final orders and decisions, in adjudications not appealed to and litigated in federal court are destroyed 5 years after the case closes.

3. In-house adjudicative records in adjudications appealed to and litigated in federal court are permanently retained, and transferred to NARA 15 years after the case closes.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Records in this system are safeguarded in accordance with applicable rules and policies, including all applicable DOT FAA automated systems security and access policies. Strict controls have been imposed to minimize the risk of compromising the information that is being stored. Access to the computer system containing the records in this system is limited to individuals who have a need to know the information for the performance of their official duties and who have appropriate clearances or permissions.

RECORD ACCESS PROCEDURES:

Individuals seeking notification of whether this system of records contains information about them may contact the System Manager at the address provided in the section "System Manager". When seeking records about yourself from this system of records or any other Departmental system of records your request must conform to the Privacy Act regulations set forth in 49 CFR part 10. You must sign your request and your signature must either be notarized or submitted under 28 U.S.C. 1746, a law that permits statements to be made under penalty of perjury as a substitute for notarization. If your request is

seeking records pertaining to another living individual, you must include a statement from that individual certifying his/her agreement for you to access his/her records.

CONTESTING RECORD PROCEDURES:

See "Record Access Procedures" above.

NOTIFICATION PROCEDURES:

See "Record Access Procedures" above.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

None.

Issued in Washington, DC.

Karyn Gorman,

Departmental Chief Privacy Officer.

[FR Doc. 2023-24940 Filed 11-14-23; 8:45 am]

BILLING CODE 4910-9X-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1041-N

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning U.S. Income Tax Return for Electing Alaska Native Settlement Trusts.

DATES: Written comments should be received on or before January 16, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Include "OMB Number 1545-1776—U.S. Income Tax Return for Electing Alaska Native Settlement Trusts" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Martha R. Brinson, at (202)317-5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at Martha.R.Brinson@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: U.S. Income Tax Return for Electing Alaska Native Settlement Trusts.

OMB Number: 1545-1776.

Form Number: 1041-N.

Abstract: An Alaska Native Settlement Trust (ANST) may elect under section 646 to have the special income tax treatment of that section apply to the trust and its beneficiaries. This one-time election is made by filing Form 1041-N which is used by the ANST to report its income, etc., and to compute and pay any income tax. Form 1041-N is also used for the special information reporting requirements that apply to ANSTs.

Current Actions: IRS is revising Form 1041-N, Part II, to allow the elective payment election amount to be entered from Form 3800.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 20.

Estimated Time per Response: 39 minutes.

Estimated Total Annual Burden Hours: 788.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 7, 2023.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2023-25149 Filed 11-14-23; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8881

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service (IRS), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning the Form 8881—Credit for Small Employer Pension Plan Startup Costs, Auto-Enrollment, and Military Spouse Retirement Plan, as amended to include changes by the SECURE 2.0 Act.

DATES: Written comments should be received on or before January 16, 2024 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to pra.comments@irs.gov. Include "OMB Number 1545-1810—Form 8881—Credit for Small Employer Pension Plan Startup Costs, Auto-Enrollment, and Military Spouse Retirement Plan" in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of this collection should be directed to Martha R. Brinson, at (202)317-5753, or at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet at Martha.R.Brinson@irs.gov.

SUPPLEMENTARY INFORMATION:

Title: Credit for Small Employer Pension Plan Startup Costs, Auto-Enrollment, and Military Spouse Retirement Plan.

OMB Number: 1545-1810.

Form Number: 8881.

Abstract: Qualified small employers use Form 8881 to claim a credit for start-up costs and auto-enrollment arrangements related to eligible retirement plans. Form 8881 implements section 45E of the Internal

Revenue Code (IRC), which provides a credit based on costs incurred by an employer in establishing or administering an eligible employer plan or for the retirement-related education of employees with respect to the plan.

Form 8881 also implements IRC section 45T, which provides a credit for including an eligible automatic contribution arrangement (as defined in section 414(w)(3)) in a qualified employer plan sponsored by the employer. For an eligible employer, the section 45E credit is 50% of the qualified start-up costs for a tax year, up to \$500 for the tax year in which the plan is established or becomes effective and each of the two subsequent tax years. For an eligible employer, the section 45T credit is \$500 for the first tax year in which the automatic contribution arrangement is included in the plan and for each of the two subsequent tax years.

Current Actions: The Secure 2.0 Act of 2022 added new IRC section 45AA, Military Spouse Retirement Plan Eligibility Credit for Small Employers. Section 45AA provides a general business tax credit to eligible small employers who offer defined contribution plans with specific features that benefit military spouses. The section 45AA credit is, for a tax year during which a military spouse participates in the plan, up to 3 tax years beginning with the tax year during which the military spouse began participating in the plan, \$200, plus the amount of employer contributions (other than elective deferrals) made on behalf of the military spouse for any of the 3 tax years, up to \$300 for a tax year. The Form 8881 is being revised to add the Section 45AA credit. Additionally, the Secure 2.0 Act amended section 45E to permit eligible employers, with 1–50 employees, an increased start-up costs credit of 100% of the qualified start-up costs for a tax year, up to \$500 for the tax year in which the plan is established or becomes effective and each of the two subsequent tax years. The Secure 2.0 Act also amended section 45E to permit an additional credit for employer contributions by certain eligible employers, in an amount equal to an applicable percentage of eligible employer contributions to a defined contribution plan, for up to 5 tax years beginning with the tax year in which the plan is established. The Form 8881 is being revised to include these additions under section 45E.

Type of Review: Revision of a currently approved collection.

Affected Public: Businesses or other for-profit organizations.

Estimated Number of Respondents: 66,667.

Estimated Time per Respondent: 8 hours, 38 minutes.

Estimated Total Annual Burden Hours: 575,337.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments will be of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: November 7, 2023.

Martha R. Brinson,

Tax Analyst.

[FR Doc. 2023–25148 Filed 11–14–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Departmental offices, U.S. Department of the Treasury.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other federal agencies to comment on the proposed information collections

listed below, in accordance with the Paperwork Reduction Act of 1995.

DATES: Written comments must be received on or before January 16, 2024.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestions for reducing the burden, to Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW, Suite 8100, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT:

Copies of the submissions may be obtained from Spencer W. Clark by emailing PRA@treasury.gov, calling (202) 927–5331, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Control Number: 1505–0231.

Type of Review: Extension without change of a currently approved collection.

Description: The collection of information is necessary for the Department to solicit customer and stakeholder feedback with respect to timeliness, appropriateness, accuracy of information, courtesy, efficiency of service delivery, and resolution of issues with service delivery. Responses will be assessed to plan and inform efforts to improve or maintain the quality of service offered to the public.

Form: None.

Affected Public: Businesses or other for-profits; Non-profit institutions, State and Local Governments; Individuals and Households.

Estimated Number of Respondents: 14,000.

Frequency of Response: On Occasion.

Estimated Total Number of Annual Responses: 14,000.

Estimated Time Per Response: 15 minutes.

Estimated Total Annual Burden Hours: 3,500 hours.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d)

ways to minimize the burden of the collection of information on respondents, including through the use of technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services required to provide information.

Authority: 44 U.S.C. 3501 *et seq.*

Spencer W. Clark,

Treasury PRA Clearance Officer.

[FR Doc. 2023-25127 Filed 11-14-23; 8:45 am]

BILLING CODE 4810&ndashAK&mdashP

**DEPARTMENT OF VETERANS
AFFAIRS**

[OMB Control No. 2900-0706]

Agency Information Collection Activity Under OMB Review: Application for Reimbursement of National Exam Fee

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act (PRA) of 1995, this notice announces that the Veterans Benefits Administration (VBA), Department of Veterans Affairs, will submit the collection of information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden, and it includes the actual data collection instrument.

DATES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice by clicking on the following link www.reginfo.gov/public/do/PRAMain, select “Currently under Review—Open for Public Comments”, then search the list for the information collection by Title or “OMB Control No. 2900–0706.”

FOR FURTHER INFORMATION CONTACT:
Maribel Aponte, Office of Enterprise
and Integration, Data Governance
Analytics (008), 810 Vermont Ave. NW,
Washington, DC 20420, (202) 266-4688
or email Maribel.aponte@va.gov. Please
refer to “OMB Control No. 2900-0706”
in any correspondence.

SUPPLEMENTARY INFORMATION:

Authority: Public Law 108–454 and Public Law 111–377; 38 U.S.C. 5101 and CFR 21.1030.

Title: Application for Reimbursement
of National Exam Fee, VA Form 22-
0810.

OMB Control Number: 2900-0706.

Type of Review: Revision of a currently approved collection.

Abstract: VA will use the information collected to determine whether the claimant qualifies to receive reimbursement for a claimed national test, and if so, the amount of the reimbursement of the fee charged.

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 **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 88 FR 60743 on Tuesday, September 5, 2023, Page 60743.

Affected Public: Individuals and Households.

Estimated Annual Burden: 57 hours.

Estimated Average Burden Time per

Respondent: 15 minutes.

Frequency of Response: Once.

Estimated Number of Respondents:
230.

By direction of the Secretary:

Maribel Aponte,

*VA PRA Clearance Officer, Office of
Enterprise and Integration, Data Governance
Analytics, Department of Veterans Affairs.*

[FR Doc. 2023-25179 Filed 11-14-23; 8:45 am]

BILLING CODE 8320-01-P

**DEPARTMENT OF VETERANS
AFFAIRS**

National Research Advisory Council, 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 National Research Advisory Council will hold a meeting on Wednesday, December 6, 2023, by Teams. The teleconference number is 1-872-701-0185, Phone Conference ID: 830 018 956# or the meeting link is https://teams.microsoft.com/l/meetup-join/19%3ameeting_NGYzZDdiN2MtYWYwOC00ZDE0LThmNjctZTUzNjkoYzRlMmJm%40thread.v2/0?context=%7b%22Tid%22%3a%22

e95f1b23-abaf-45ee-821d-
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%2c%22Oid%22%3a%227a4935a6-
e7e0-4f23-b7e9-443546f09fa8%22%7d.

The meeting will convene at 11:00 a.m. and end at 2:00 p.m. Eastern Standard Time. This meeting is open to the public and will include time reserved for public comment at the end of the meeting. The public comment period will be 30 minutes. Individual stakeholders will be afforded three to five minutes to express their comments.

The purpose of the National Research Advisory Council (NRAC) is to advise the Secretary on research conducted by the Veterans Health Administration, including policies and programs targeting the high priority of Veterans' health care needs.

On December 6, 2023, the agenda will include remarks from the Assistant Undersecretary of Health, Discovery, Education, and Affiliate Networks (DEAN); The NRAC vision for supporting the VA Research Enterprise; VA Office of Research and Development policy updates; Sensitive Species Subcommittee and Diversity and Inclusion Subcommittee annual updates; updates on Pathology Specimen Storage and an overview of the National Academic Affiliations Council (NAAC) and opportunities for collaboration with the NRAC.

No time will be allocated at this meeting for receiving oral presentations from the public. Members of the public may submit written statements for review by the NRAC in advance of the meeting. Public comments may be received no later than *close of business November 24, 2023*, for inclusion in the official meeting record. Please send statements to Rashelle Robinson, Designated Federal Officer, Office of Research and Development (14RD), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, at 202-443-5768, or Rashelle.robinson@va.gov. Any member of the public seeking additional information should contact Rashelle Robinson at the above phone number or email address noted above.

Dated: November 9, 2023.

LaTonya L. Small,

Federal Advisory Committee Management Officer.

[FR Doc. 2023-25229 Filed 11-14-23; 8:45 am]

BILLING CODE P



FEDERAL REGISTER

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Wednesday,

No. 219

November 15, 2023

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 401, et al.

45 CFR Part 170

Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 401, 405, 417, 422, 423, 455, and 460

Office of the Secretary

45 CFR Part 170

[CMS–4205–P]

RIN 0938–AV24

Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

AGENCY: Centers for Medicare & Medicaid Services (CMS), Office of the National Coordinator for Health Information Technology (ONC), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, marketing and communications, agent/broker compensation, health equity, dual eligible special needs plans (D–SNPs), utilization management, network adequacy, and other programmatic areas. This proposed rule also includes proposals to codify existing sub-regulatory guidance in the Part C and Part D programs.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 5, 2024.

ADDRESSES: In commenting, please refer to file code CMS–4205–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the “Submit a comment” instructions.

2. *By regular mail.* You may mail written comments to the following

address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4205–P, P.O. Box 8013, Baltimore, MD 21244.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–4205–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Carly Medosch, (410) 786–8633—General Questions.

Naseem Tarmohamed, (410) 786–0814—Part C and Cost Plan Issues.

Lucia Patrone, (410) 786–8621—Part D Issues.

Kristy Nishimoto, (206) 615–2367—Beneficiary Enrollment and Appeal Issues.

Kelley Ordonio, (410) 786–3453—Parts C and D Payment Issues.

Hunter Coohill, (720) 853–2804—Enforcement Issues.

Lauren Brandow, (410) 786–9765—PACE Issues.

Sara Klotz, (410) 786–1984—D–SNP Issues.

Joe Strazzire, (410) 786–2775—RADV Audit Appeals Issues.

Alexander Baker, (202) 260–2048—Health IT Standards.

PartCandDStarRatings@cms.hhs.gov—Parts C and D Star Ratings Issues.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is

identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this proposed rule may be found at <https://www.regulations.gov/>.

I. Executive Summary

A. Purpose

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicare cost plan program, and Programs of All-Inclusive Care for the Elderly (PACE). This proposed rule includes a number of new policies that would improve these programs beginning with contract year 2025 and proposes to codify existing Part C and Part D sub-regulatory guidance. Please note that the new marketing and communications policies in this rule are proposed to be applicable for all contract year 2025 marketing and communications, beginning September 30, 2024. This proposed rule also includes revisions to existing regulations in the Risk Adjustment Data Validation (RADV) audit appeals process and the appeals process for quality bonus payment determination that would take effect and apply 60 days after publication of a final rule. Revisions to existing regulations for the use and release of risk adjustment data would also take effect and apply 60 days after publication of a final rule. A limited number of the provisions in this rule are proposed to be applicable beginning with coverage on and after January 1, 2026.

Additionally, this proposed rule would implement certain sections of the following Federal laws related to the Parts C and D programs:

- The Bipartisan Budget Act (BBA) of 2018.
- The Consolidated Appropriations Act (CAA), 2023.

B. Summary of the Major Provisions

1. Improving Access to Behavioral Health Care Providers

We propose regulatory changes that would improve access to behavioral health care by adding certain behavioral health provider specialties to our MA network adequacy standards. Specifically, we propose to add a new facility-specialty type to the existing list of facility-specialty types evaluated as part of our network adequacy reviews. The new facility-specialty type, “Outpatient Behavioral Health,” would be included in network adequacy

evaluations and can include: Marriage and Family Therapists (MFTs), Mental Health Counselors (MHCs), Opioid Treatment Program (OTP) providers, Community Mental Health Centers or other behavioral health and addiction medicine specialists and facilities. MFTs and MHCs will be eligible to enroll in Medicare and start billing for services beginning January 1, 2024, due to the new statutory benefit category established by the Consolidated Appropriations Act (CAA) 2023. We aim to strengthen network adequacy requirements and improve beneficiary access to behavioral health services and providers by expanding our network adequacy requirements for MA organizations.

2. Special Supplemental Benefits for the Chronically Ill (SSBCI)

We are proposing regulatory changes that would help ensure that SSBCI items and services offered are appropriate and improve or maintain the health or overall function of chronically ill enrollees. First, we are proposing to require that an MA organization must be able to demonstrate through relevant acceptable evidence that an item or service offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee, and must, by the date on which it submits its bid to CMS, establish a bibliography of this evidence. Second, we are proposing to clarify that an MA plan must follow its written policies based on objective criteria for determining an enrollee's eligibility for an SSBCI when making such eligibility determinations. Third, we are proposing to require that the MA plan document its denials of SSBCI eligibility rather than its approvals. Additionally, we are proposing to codify CMS's authority to review and deny approval of an MA organization's bid if the MA organization has not demonstrated, through relevant acceptable evidence, that its proposed SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. Finally, we propose to codify CMS's authority to review SSBCI offerings annually for compliance, considering the evidence available at the time. These proposals, if implemented, would better ensure that the benefits offered as SSBCI are reasonably expected to improve health or overall function of the chronically ill enrollee while also guarding against the use of MA rebate dollars for SSBCI that are not supported by evidence.

In addition, we are proposing new policies to protect beneficiaries and

improve transparency regarding SSBCI so that beneficiaries are aware that SSBCI are only available to enrollees who meet specific eligibility criteria. We propose to modify and strengthen the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned. Specifically, we propose that the SSBCI disclaimer list the relevant chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the MA organization. We propose that the MA organization must convey in its SSBCI disclaimer that even if the enrollee has a listed chronic condition, the enrollee may not receive the benefit because other coverage criteria also apply. We also propose to establish specific font and reading pace parameters for the SSBCI disclaimer in print, television, online, social media, radio, other voice-based ads, and outdoor advertising (including billboards). Finally, we propose to clarify that MA organizations must include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. We believe that imposing these new SSBCI disclaimer requirements will help to ensure that the marketing of and communication about these benefits is not misleading or potentially confusing to enrollees who rely on these materials to make enrollment decisions.

3. Mid-Year Enrollee Notification of Available Supplemental Benefits

In addition, over the past several years, the number of MA plans offering supplemental benefits has increased. The benefits offered are broader in scope and variety and we are seeing an increasing amount of MA rebate dollars directed towards these benefits. At the same time, plans have reported that enrollee utilization of many of these benefits is low. It is not clear whether MA plans are actively encouraging utilization of these benefits by their enrollees. We propose requiring MA plans to notify enrollees mid-year of the unused supplemental benefits available to them. The notice would list any supplemental benefits not utilized by the beneficiary during the first 6 months of the year (1/1 to 6/30). Currently, MA plans are not required to send any communication specific to an enrollee's usage of supplemental benefits which could be an important part of a plan's overall care coordination efforts. This policy aims to educate enrollees on their access to supplemental benefits to encourage greater utilization of these benefits and ensure MA plans are better stewards of the rebate dollars directed towards these benefits.

4. Enhance Guardrails for Agent and Broker Compensation

Section 1851(j) of the Act requires that CMS develop guidelines to ensure that compensation to agents and brokers creates incentives to enroll individuals in MA plans that are intended to best meet their health care needs. To that end, for many years CMS has set upper limits on the amount of compensation agents and brokers can receive for enrolling Medicare beneficiaries into MA and PDP plans. We have learned, however, that many MA and PDP plans, as well as third-party entities with which they contract (such as Field Marketing Organizations (FMOs)) have structured payments to agents and brokers that have the effect of circumventing compensation caps. We also note that that these additional payments appear to be increasing. In this rule, we are proposing to generally prohibit contract terms between MA organizations and agents, brokers or other third party marketing organizations (TPMOs) that may interfere with the agent's or broker's ability to objectively assess and recommend the plan that best fits a beneficiary's health care needs; set a single compensation rate for all plans; revise the scope of items and services included within agent and broker compensation; and eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. We are also proposing to make conforming edits to the Part D agent broker compensation rules at § 423.2274. Collectively, we believe the impact of these proposed changes will better align with statutory requirements and intent: to ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the plan that best fits a beneficiary's health care needs. Further, such changes align with the Biden-Harris Administration's commitment to promoting fair, open, and competitive markets and ensuring beneficiaries can make fully informed choices among a robust set of health insurance options.

5. Annual Health Equity Analysis of Utilization Management Policies and Procedures

We are proposing regulatory changes to the composition and responsibilities of the Utilization Management (UM) committee. We propose to require that a member of the UM committee have expertise in health equity. We also propose that the UM committee conduct an annual health equity analysis of the use of prior authorization. The proposed

analysis would examine the impact of prior authorization on enrollees with one or more of the following social risk factors (SRFs): (i) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (ii) having a disability. To enable a more comprehensive understanding of the impact of prior authorization practices on enrollees with the specified SRFs, the proposed analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. Finally, we propose to require MA organizations to make the results of the analysis publicly available on their website in a manner that is easily accessible and without barriers.

6. Amendments to Part C and Part D Reporting Requirements

We are proposing to affirm our authority to collect detailed information from MA organizations and Part D plan sponsors under current regulations, in keeping with the Biden-Harris administration's focus on improving transparency and data in Medicare Advantage and Part D. This proposal would lay the groundwork for new data collection to be established through the Paperwork Reduction Act (PRA) process, which would provide advance notice to interested parties and be subject to public comment. An example of increased data collection could be service level data for all initial coverage decisions and plan level appeals, such as decision rationales for items, services, or diagnosis codes to have better line of sight on utilization management and prior authorization practices, among many other issues.

7. Enhance Enrollees' Right To Appeal an MA Plan's Decision To Terminate Coverage for Non-Hospital Provider Services

Beneficiaries enrolled in Traditional Medicare and MA plans have the right to a fast-track appeal by an Independent Review Entity (IRE) when their covered skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility (CORF) services are being terminated. Currently, Quality Improvement Organizations (QIO) act as the IRE and conduct these reviews. Under current regulations, MA enrollees do not have the same access to QIO review of a fast-track appeal as Traditional Medicare beneficiaries. We are proposing to (1) require the QIO, instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) fully eliminate provision requiring the

forfeiture of an enrollee's right to appeal a termination of services decision when they leave the facility. These proposals would bring MA regulations in line with the parallel reviews available to beneficiaries in Traditional Medicare and expand the rights of MA beneficiaries to access the fast-track appeals process.

8. Additional Changes to an Approved Formulary—Substituting Biosimilar Biological Products

Under current policy, Part D sponsors must obtain explicit approval from CMS prior to making a midyear formulary change that removes a reference product and replaces it with a biosimilar biological product other than an interchangeable biological product. If such a change is approved, the Part D sponsor may apply the change only to enrollees who begin therapy after the effective date of the change. In other words, enrollees currently taking the reference product can remain on the reference product until the end of the plan year without having to obtain an exception. To increase access to biosimilar biological products, including interchangeable biological products, in the Part D program, consistent with the Biden-Harris Administration's commitment to competition as outlined in Executive Order (E.O.) 14036: "Promoting Competition in the American Economy," we previously proposed to permit Part D sponsors either to immediately substitute interchangeable biological products for their reference products and/or to treat such substitutions as changes applicable to all enrollees following 30 days' notice.¹ As we continue to consider comments received on that proposal, we are now also proposing to add substitutions of biosimilar biological products other than interchangeable biological products to the type of formulary changes that apply to all enrollees (including those already taking the reference product prior to the effective date of the change) following a 30-day notice. This proposed policy regarding formulary substitution of biosimilar biological products would parallel our

current notice policy for formulary changes that cannot take place immediately. Under current § 423.120(b)(5)(i), Part D sponsors must give 30 days' advance notice to affected enrollees before removing or changing the tiered cost-sharing status of a Part D drug, unless, for instance, the formulary change qualifies for an immediate substitution. This proposal would not permit immediate formulary substitution of biosimilar biological products other than interchangeable biological products.

9. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization

We are proposing interconnected proposals to (a) replace the current quarterly special enrollment period (SEP) with a one-time-per month SEP for dually eligible individuals and others enrolled in the Part D low-income subsidy program to elect a standalone PDP, (b) create a new integrated care SEP to allow dually eligible individuals to elect an integrated D-SNP on a monthly basis, (c) limit enrollment in certain D-SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and (d) limit the number of D-SNP plan benefit packages an MA organization, its parent organization, or entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO. This proposed rule would increase the percentage of dually eligible MA enrollees who are in plans that are also contracted to cover Medicaid benefits, thereby expanding access to integrated materials, unified appeal processes across Medicare and Medicaid, and continued Medicare services during an appeal. It would also reduce the number of plans overall that can enroll dually eligible individuals outside the annual coordinated election period, thereby reducing the number of plans deploying aggressive marketing tactics toward dually eligible individuals throughout the year.

10. For D-SNP PPOs, Limit Out-of-Network Cost Sharing

We are proposing to limit out-of-network cost sharing for D-SNP preferred provider organizations (PPOs) for specific services. The proposed rule would reduce cost shifting to Medicaid, increase payments to safety net providers, expand dually eligible enrollees' access to providers, and protect dually eligible enrollees from unaffordable costs.

¹ See section III.Q., Changes to an Approved Formulary, of the proposed rule titled "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications," which appeared in the December 27, 2022 *Federal Register* (87 FR 79452) (hereinafter referred to as the December 2022 proposed rule).

11. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes

Under existing regulations, CMS does not contract with and will not renew the contract of a D-SNP look-alike—that is, an MA plan that is not a SNP but in which dually eligible enrollees account for 80 percent or more of total enrollment. We are proposing to lower the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026. This proposal would help address the continued proliferation of MA plans that are serving high percentages of dually eligible individuals without meeting the requirements to be a D-SNP.

12. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation Appeals Process

We propose regulatory language to address gaps and operational constraints included in existing RADV appeal regulations. Currently, if MA organizations appeal both medical record review determinations and payment error calculations resulting from RADV audits, both issues must be appealed and move through the appeals process concurrently, which we foresee could result in inconsistent appeal adjudications at different levels of appeal that impact recalculations of the payment error. This has the potential to cause burden, confuse MA organizations, and negatively impact the operations and efficiency of CMS's

appeals processes. This proposal would standardize and simplify the RADV appeals process for CMS and MA organizations, as well as address operational concerns at all three levels of appeal. We are proposing that MA organizations must exhaust all three levels of appeal for medical record review determinations before beginning the payment error calculation appeals process. This will ensure adjudication of medical record review determinations are final before a recalculation of the payment error is completed and subject to appeal. We also propose several other revisions to our regulatory appeals process to conform with these proposed changes to our procedures.

C. Summary of Costs and Benefits**BILLING CODE 4120-01-P**

TABLE A1

Provision	Description	Financial Impact
1. Improving Access to Behavioral Health Care Providers	We propose to add a new facility-specialty type called “Outpatient Behavioral Health” to the network adequacy standards under § 422.116(b)(2). For purposes of the network adequacy requirements, the new facility-specialty type would be evaluated using time and distance and minimum number standards proposed here. The new facility type would include MFTs, MHCs, OTP or other behavioral health and addiction medicine specialists and facilities.	The new provision adds requirements for a new facility specialty type, which include providers some of which we have data for and some which are new and for which we lack data. Therefore, we cannot quantify the effects of this provision though we expect it may increase access which may qualitatively increase utilization.
2. Special Supplemental Benefits for the Chronically Ill (SSBCI)	We propose to require MA organizations to establish bibliographies for each SSBCI they include in their bid to demonstrate that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. This would shift the burden from CMS to the MA organizations to demonstrate compliance with this standard and help ensure that SSBCI items and services are offered based on current, reliable evidence. In addition, we are proposing new policies to protect beneficiaries and improve transparency regarding SSBCI so that beneficiaries are aware that SSBCI are only available to enrollees who meet specific eligibility criteria. We propose to modify and strengthen the current requirements for the SSBCI disclaimer that MA organizations offering SSBCI must use whenever SSBCI are mentioned.	The proposed requirements for SSBCI are not expected to have any economic impact on the Medicare Trust Fund.
3. Mid-Year Enrollee Notification of Available Supplemental Benefits	We propose to require MA plans to issue notices to enrollees who, by June 30 th of a given year, have not utilized supplemental benefits, to ensure enrollees are aware of the availability of such benefits and ensure appropriate utilization.	Although the intent is to increase utilization and ultimately create a savings to the Medicare Trust Fund, we cannot currently quantify this provision because it is new, and we lack data. See the Regulatory Impact Analysis for further discussion.

Provision	Description	Financial Impact
4. Enhance Guardrails for Agent/Broker Compensation	We propose modifications to agent/broker compensation requirements to further ensure payment arrangements and structure are aligned with CMS's statutory obligation to set limits on compensation to ensure that the use of compensation creates incentives for agents and brokers to enroll prospective enrollees in plans that best fit their needs.	There is a paperwork burden of about \$31 million annually. Other effects cannot be analyzed at this time because of uncertainty; however, we expect any impact would be minimal. See the Regulatory Impact Analysis for further discussion.
5. Annual Health Equity Analysis of Utilization Management Policies and Procedures	We propose changes to the composition and responsibilities for the Utilization Management committee, to require: a member of the UM committee have expertise in health equity; the UM committee conduct an annual health equity analysis of prior authorization used by the MA organization using specified metrics; and require MA organizations to make the results of the analysis publicly available on its website.	We do not expect any cost impact to the Medicare Trust Fund.
6. Amendments to Part C and Part D Reporting Requirements	We propose to affirm our authority to collect detailed data from MA organizations and Part D plan sponsors under the Part C and D reporting requirements.	We do not expect any cost impact to the Medicare Trust Fund.
7. Enhance Enrollees' Right to Appeal an MA Plan's Decision to Terminate Coverage for Non-Hospital Provider Services	We propose to (1) require QIOs to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF and (2) eliminate the provision requiring the forfeiture of an enrollee's right to appeal to the QIO a termination of services decision when they leave the facility.	We do not expect any cost impact to the Medicare Trust Fund.
8. Additional Changes to an Approved Formulary—Substituting Biosimilar Biological Products	We propose to permit biosimilar biological products other than interchangeable biological products ² to be substituted for their reference products without requiring that enrollees currently taking the reference product be exempt from the change for the remainder of the contract year.	We do not expect any cost impact to the Medicare Trust Fund.
9. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services from the Same Organization	We propose to (a) replace the current dual/LIS quarterly SEP, (b) create a new integrated care SEP, (c) limit enrollment in certain D-SNPs to those individuals who are also enrolled in an affiliated Medicaid MCO, and (d) limit the number of D-SNPs an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO.	Over a 10-year horizon, we estimate a \$1.3 billion savings to the Trust Fund for Part D plans and an additional \$1 billion savings to the Trust Fund for Part C plans.
10. For D-SNP PPOs, Limit Out-of-Network Cost Sharing	We propose to limit D-SNP PPOs' out-of-network cost sharing for certain Part A and Part B benefits, on an individual service level.	We do not expect any cost impact to the Medicare Trust Fund.

Provision	Description	Financial Impact
11. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes	We propose to lower the D-SNP look-alike threshold from 80 percent to 70 percent for plan year 2025 and 60 percent for plan year 2026.	We estimate this provision would have an average annual impact of less than \$1M for plan years 2025-2027 due to non-SNP MA plans meeting the lower D-SNP look-alike threshold transitioning enrollees into other plans. We also estimate this provision would have an average annual impact of less than \$1M on MA plan enrollees for plan years 2025-2027 due to enrollees choosing a different plan. We expect cumulative annual costs to non-SNP MA plans and MA plan enrollees beyond plan year 2027 to also be less than \$1M per year.
12. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process	Revising when a medical record review determination and a payment error calculation appeal can be requested and adjudicated is necessary because RADV payment error calculations are based upon the outcomes of medical record review determinations. We are also proposing other revisions to our regulatory appeals process to conform with these proposed changes. The proposed changes could reduce burden on some MA organizations that, absent these revisions, would have otherwise potentially submitted payment error calculation appeals that could have been rendered moot by certain types of medical record appeals decisions. The potential reduction in burden to MA organizations cannot be quantified prior to the implementation and execution of the appeals process pursuant to these changes. While the MA RADV appeals regulations have been in place for a period of years, CMS did not issue RADV overpayment findings to MA organizations as we worked to finalize a regulation on our long-term RADV methodology. Therefore, any impact of these proposed policies on MA organization behavior is further unquantifiable. The proposed changes do not impose any new information collection requirements.	The potential reduction in burden to MA organizations cannot be quantified prior to the implementation and execution of the appeals process pursuant to these changes.

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II. Strengthening Current Medicare Advantage and Medicare Prescription Drug Benefit Program Policies: Past Performance

We established at §§ 422.502(b) and 423.503(b) that we may deny an

² We previously proposed that would provide Part D sponsors (choosing not to or unable to qualify to make immediate substitutions as proposed) the option to treat substitutions of interchangeable biological products for their reference products as changes applicable to all enrollees requiring 30 days' notice for those currently taking a related reference product. See

application submitted by MA organizations and Part D sponsors that failed to comply with the requirements of a previous MA or Part D contract, which we refer to as “past performance.” We are proposing several technical changes to the regulation text related to past performance. These changes are intended to clarify the basis for application denials due to past performance and to ensure that the

section III.Q. of the December 2022 proposed rule. These and other proposals discussed in section III.Q. of the December 2022 proposed rule have not been finalized and remain under consideration.

factors adequately account for financial difficulties that should prevent an organization from receiving a new or expanded MA or Part D contract.

One factor we consider regarding the past performance of MA organizations and Part D sponsors is their record of imposition of intermediate sanctions, because intermediate sanctions represent significant non-compliance with MA or Part D contract requirements. To clarify the basis for application denials due to intermediate sanctions, at §§ 422.502(b)(1)(i)(A) and 423.503(b)(1)(i)(A) we propose to

change “Was subject to the imposition of an intermediate sanction” to “Was under an intermediate sanction.” We are proposing this revision because MA organizations and Part D sponsors may have a sanction imposed in one 12-month past performance review period and effective for all or part of the subsequent 12-month review period. For instance, CMS could impose a sanction in December 2022 that remains in effect until September 2023. The sanction would be in effect for the past performance review period that runs from March 2022 through February 2023 (for Contract Year 2024 MA and Part D applications filed in February 2023) and for the past performance review period that runs from March 2023 through February 2024 (for Contract Year MA and Part D applications filed in February 2024). Our proposal reflects our stated intent to deny applications from MA organizations and Part D sponsors when an active sanction existed during the relevant 12-month review period when we previously codified that intermediate sanctions are a basis for denial of an application from an MA organization or Part D sponsor in “Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly,” final rule which appeared in the **Federal Register** on January 19, 2021 (86 FR 5864) hereinafter referred to as the “January 2021 final rule.” When we codified this requirement, a commenter requested that sanctions lifted during the 12 months prior to the application denial be excluded from past performance. We responded that “The applying organization will receive credit for resolving the non-compliance that warranted the sanction during the next past performance review period, when, presumably, the organization will not have an active sanction in place at any time during the applicable 12-month review period” (86 FR 6000 through 6001). Since an intermediate sanction may be active during multiple consecutive review periods, our proposed language clarifies that an organization’s application may be denied as long as the organization is under sanction, not just during the 12-month review period when the sanction was imposed.

An additional factor we consider regarding the past performance of MA organizations and Part D sponsors is involvement in bankruptcy proceedings.

At §§ 422.502(b)(1)(i)(C) and 423.503(b)(1)(i)(C) we propose to incorporate Federal bankruptcy as a basis for application denials due to past performance and to conform the two paragraphs by changing the text to “Filed for or is currently in Federal or State bankruptcy proceedings” from “Filed for or is currently in State bankruptcy proceedings,” at § 422.502(b)(1)(i)(C) and “Filed for or is currently under State bankruptcy proceedings” at § 423.503(b)(1)(i)(C). We codified State bankruptcy as a basis for an application denial for the past performance of an MA or Part D Sponsor in “Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency” which appeared in the **Federal Register** on May 9, 2022 (87 FR 27704). We codified that requirement because bankruptcy may result in the closure of an organization’s operations and entering into a new or expanded contract with such an organization is not in the best interest of the MA or Prescription Drug program or the beneficiaries they serve. This concern is equally applicable to both Federal and State bankruptcy, so we propose to revise the regulation so that applications from MA organizations or Part D sponsors that have filed for or are in State or Federal bankruptcy proceedings may be denied on the basis of past performance.

In addition, we are also proposing to correct two technical issues identified since the final rule was published in May 2022. At § 422.502(b)(1)(i)(B), we propose to change the reference to the requirement to maintain fiscally sound operations from § 422.504(b)(14) to the correct reference at § 422.504(a)(14). We also propose to remove the duplication of § 422.502(b)(1)(i)(A) and (B).

III. Enhancements to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Expanding Network Adequacy Requirements for Behavioral Health

Section 1852(d)(1) of the Act allows an MA organization to select the providers from which an enrollee may receive covered benefits, provided that the MA organization, in addition to meeting other requirements, makes such benefits available and accessible in the service area with promptness and assures continuity in the provision of

benefits. Further, our regulation at § 422.112(a), requires that a coordinated care plan maintain a network of appropriate providers that is sufficient to provide adequate access to covered services to meet the needs of the population served. To establish standards for these requirements, CMS codified network adequacy criteria and access standards in the “Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program” final rule, which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796), hereinafter referred to as the “June 2020 final rule.” In that final rule, we codified, at § 422.116(b), the list of 27 provider specialty types and 13 facility specialty types subject to CMS network adequacy standards. Further, as part of the “Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs” published in the **Federal Register** January 12, 2022 (87 FR 1842) proposed rule, hereinafter referred to as the “January 2022 proposed rule,” we solicited comments through a Request for Information (RFI), regarding challenges in building MA behavioral health networks and opportunities for improving access to services. In response to the RFI, stakeholders commented on the importance of ensuring adequate access to behavioral health services for enrollees and suggested expanding network adequacy requirements to include additional behavioral health specialty types. As a result, in the “Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” final rule, which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120) hereinafter referred to as the “April 2023 final rule,” CMS finalized the addition of two new specialty types to the provider-specialty types list at § 422.116(b)(1), Clinical Psychology and Clinical Social Work, to be subject to the specific time and distance and minimum provider number requirements used in CMS’s network adequacy evaluation.

While our regulation at § 422.116(b)(3) authorizes the removal of a specialty or facility type from the network evaluation criteria for a specific year without rulemaking, CMS did not implement a process in § 422.116 to add

new provider types without rulemaking. In a continued effort to address access to behavioral health services within MA networks, we are proposing to add to the list of provider specialties at § 422.116(b) and add corresponding time and distance standards at § 422.116(d)(2).

In addition to meeting the network adequacy evaluation requirements, MA organizations are required at § 422.112(a) to maintain and consistently monitor their provider networks to ensure they are sufficient to provide adequate access to covered services that meet the needs of enrollees. This also helps MA organizations maintain a complete and accurate health plan provider directory as required under §§ 422.111(b)(3) and 422.120(b). The Health Plan Management System (HPMS) provides MA organizations with access to the “Evaluate my Network” functionality, which allows MA organizations the opportunity to test their provider networks against the evaluation standards in § 422.116 outside of a formal network review. The “Evaluate my Network” functionality provides MA organizations the ability to test their networks using the standards in § 422.116(a)(2) in different scenarios, including at the Plan Benefit Package (PBP) level, to consistently monitor whether their provider networks are meeting the current network adequacy standards. We encourage MA organizations to utilize the HPMS “Evaluate my Network” tool to monitor their PBP-level active provider networks and keep abreast of any network issues that could hinder access to care for enrollees. We also remind MA organizations to report any compliance issues or significant changes in their provider network to their CMS Account Manager.

With the revisions applicable beginning January 1, 2024, MA organizations are required to demonstrate that they meet network adequacy for four behavioral health specialty types: psychiatry, clinical psychology, clinical social work, and inpatient psychiatric facility services. The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328) amended the Act to authorize payment under Medicare Part B for services furnished by a Marriage and Family Therapist (MFT) and by a Mental Health Counselor (MHC), effective January 1, 2024. Specifically, section 4121 of the CAA amends section 1861(s)(2) of the Act by adding a new subparagraph (II) that establishes a new benefit category under Part B for MFT services (as defined in section 1861(III) of the Act)

and MHC services (as defined in section 1861(III) of the Act). MA organizations are required to cover virtually all Part B covered services. As such, these new services must be covered as defined and furnished, respectively, by MFTs, as defined in section 1861(III)(2) of the Act, and MHCs, as defined in section 1861(III)(4) of the Act. As a practical matter, MA organizations need to ensure access to these new Medicare-covered services that can only be provided by these types of individual providers and therefore must contract with these types of providers in order to furnish basic benefits as required by section 1852 of the Act (when furnished by different providers, the services would be supplemental benefits covered by the MA plan.)

In addition, we discussed in the April 2023 final rule, that the responses CMS received to the January 2022 proposed rule RFI emphasized the importance of expanding network adequacy standards to include other outpatient behavioral health physicians and health professionals that treat substance use disorders (SUDs) to better meet behavioral health care needs of enrollees. Medicare fee-for-service claims data for 2020 shows that Opioid Treatment Program (OTP) providers had the largest number of claims for SUD services during that timeframe. At the time of publishing our April 2023 final rule, we indicated that while we were not able to finalize adding a combined specialty type called “Prescribers of Medication for Opioid Use Disorder,” which included OTPs and Medication for Opioid Use Disorder (MOUD) waived providers to the facility-specialty type list in § 422.116(b)(2) as proposed, we would consider the appropriateness of setting network adequacy standards for OTPs in future rulemaking.

Considering the statutory changes to section 1861 of the Act as mentioned, and our interest in establishing network adequacy standards for SUD providers, CMS is proposing to amend the MA network adequacy requirements to address the new provider types and SUD provider types through a combined behavioral health specialty type to include MFTs, MHCs, OTPs, Community Mental Health Centers and other behavioral health and addiction medicine specialty providers that will help us enhance behavioral health access for enrollees. This is consistent with the explanation in our April 2023 final rule that setting a meaningful access standard for the OTP specialty type would be possible under a combined behavioral health specialty type.

CMS is committed to improving access to behavioral health care services for enrollees in the MA program. The CMS Behavioral Health Strategy,³ aims to improve access and quality of mental health care and services, including, access to substance use disorder prevention and treatment services. We propose to extend network adequacy requirements to additional behavioral health and substance use disorder providers and facilities by adding time and distance and minimum provider number requirements for a combined provider category. Specifically, we are proposing to add Outpatient Behavioral Health as a new type of facility-specialty in § 422.116(b)(2) and to add Outpatient Behavioral Health to the time and distance requirements in

§ 422.116(d)(2). For purposes of network adequacy evaluations under § 422.116, Outpatient Behavioral Health can include, MFTs (as defined in section 1861(III) of the Act), MHCs (as defined in section 1861(III) of the Act), OTPs (as defined in section 1861(jjj) of the Act), Community Mental Health Centers (as defined in section 1861(ff)(3)(B) of the Act), or those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services, including, but not limited to, psychotherapy or prescription of medication for substance use disorders: physician assistants, nurse practitioners, and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities. Per § 422.2, the term “provider” means (1) any individual who is engaged in the delivery of health care services in a State and is licensed or certified by the State to engage in that activity in the State; and (2) any entity that is engaged in the delivery of health care services in a State and is licensed or certified to deliver those services if such licensing or certification is required by State law or regulation. Although we are not using the term “provider” specifically here in listing the type of healthcare professionals that we expect to be available to furnish services in order to count for purposes of the proposed new network evaluation standard, all applicable laws about the practice of medicine and delivery of health care services must be met and specific healthcare professionals must be appropriately licensed or certified to furnish the applicable services.

We are proposing to add this combined facility-specialty type instead

³ <https://www.cms.gov/cms-behavioral-health-strategy>.

of adding individual provider-specialty types for a few reasons. First, data from the U.S. Department of Labor, Bureau of Labor Statistics show that currently MFTs and MHCs are generally providing services in outpatient behavioral health settings, such as community mental health centers, substance abuse treatment centers, hospitals, and some private practices.^{4 5} These types of clinical settings offer a fuller range of services and usually provide access to additional providers, such as advanced practice nurses and physician assistants who provide counseling and other therapeutic services to individuals with behavioral health conditions; our review of the Place of Service codes recorded on professional claims for behavioral health services in the Medicare FFS program illustrates this. In addition, currently, there are a limited number (if any) claims in the Medicare FFS program from MFTs and MHCs; combining the MFT and MHC provider types into the “Outpatient Behavioral Health” facility type provides time for CMS to develop additional data as FFS claims are submitted by MFTs and MHCs to show patterns of access to these provider types across the country. CMS needs such claims and utilization data to support the development of time and distance standards for these particular provider-specialty types.

Finally, categorizing these provider specialties as a facility type is consistent with our practice, under § 422.116, wherein physical therapy (PT), occupational therapy (OT), and speech therapy (ST) providers have traditionally been categorized as facility types, even though care is typically furnished by individual health care providers. These provider types (that is, PT, OT, ST) are reported for network adequacy purposes under facility specialty types on Health Service Delivery (HSD) tables.

As mentioned previously, the statutory change under the CAA will allow MFTs and MHCs to bill Medicare directly for services provided beginning January 1, 2024. We acknowledge that these provider types may not always be located in facilities and provide facility-based services. As such, we will continue to monitor the appropriateness of maintaining this proposed new behavioral health specialty type as a facility-specialty type (that is, under § 422.116(b)(2)) for network adequacy review purposes. Similarly, as the list⁶ of OTPs enrolled in Medicare continues to expand, we will continue to monitor whether network adequacy for OTPs is best measured under a combined facility type for the purpose of network adequacy reviews. Thus, we may engage in future rulemaking to revise this requirement if the landscape of

providers changes such that access would be best evaluated separately for MFTs, MHCs, or OTPs instead of under the one facility-specialty type we are proposing in this rule. Any related changes would be proposed in future rulemaking. At this time, we are proposing that MA organizations are allowed to include on their facility HSD tables the following: contracted individual practitioners, group practices, or facilities that are applicable under this specialty type. Under this proposal, MA organizations may not submit a single provider, for purposes of meeting more than one of our provider network requirements, for example, they cannot submit a single provider as a psychiatry, clinical social work, or clinical psychologist provider specialty and also as an Outpatient Behavioral Health facility.

Our current regulations, at § 422.116(a)(2), specify that an MA plan must meet maximum time and distance standards and contract with a specified minimum number of each provider and facility-specialty type. Therefore, as part of the proposed changes to our list of facility specialty types under § 422.116(b)(2), we are proposing base time and distance standards in each county type for the new specialty type as follows:

TABLE CA-1: MAXIMUM TIME AND DISTANCE STANDARDS:

Provider/ Facility type	Large Metro		Metro		Micro		Rural		Counties with Extreme Access Considerations (CEAC)	
	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance	Max Time	Max Distance
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100

In the proposed rule titled “Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002) (hereinafter referred to as the “February 2020 proposed rule”), we

explained how CMS developed the base time and distance standards and the minimum provider requirements used in § 422.116 (85 FR 9094 through 9103). Further, we explained in the February 2020 proposed rule how CMS determines the minimum number requirement for all provider and facility specialty types, which is now codified in § 422.116(e). We codified at § 422.116(e)(2)(iii) that all facilities, except for acute inpatient hospitals

facilities, have a minimum number requirement of one. Because we had previously established paragraph (e)(2)(iii) to refer to all facility types listed in paragraphs (b)(2)(ii) through (xiv) and are proposing to add Outpatient Behavioral Health as a facility type at paragraph (b)(2)(xiv), we are not proposing any revisions to paragraph (e)(2)(iii). We followed the analysis and methodology described in the February 2020 proposed rule to

⁴ Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Marriage and Family Therapists, at <https://www.bls.gov/ooh/community-and-social-service/marriage-and-family-therapists.htm> (visited July 03, 2023).

⁵ Bureau of Labor Statistics, U.S. Department of Labor, *Occupational Outlook Handbook*, Substance Abuse, Behavioral Disorder, and Mental Health Counselors, at [https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-](https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-disorder-and-mental-health-counselors.htm)

[disorder-and-mental-health-counselors.htm](https://www.bls.gov/ooh/community-and-social-service/substance-abuse-behavioral-disorder-and-mental-health-counselors.htm) (visited July 06, 2023).

⁶ <https://data.cms.gov/provider-characteristics/medicare-provider-supplier-enrollment/opioid-treatment-program-providers>.

develop the time and distance standards that we propose to apply to the new behavioral health facility-specialty type described here. However, we utilized updated data, including outpatient facility and professional Part B claims data from August 1, 2021, through July 31, 2022, to inform our proposed standard.

Finally, as we indicated in the April 2023 final rule, Medicare FFS claims data shows that telehealth was the second most common place of service for claims with a primary behavioral health diagnosis in 2020 (88 FR 22170). Per § 422.116(d)(5), MA plans may receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards for certain providers when the plan includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. Currently, § 422.116(d)(5) specifies 14 specialty types for which the 10-percentage point credit is available. Because we understand from stakeholders who commented on our April 2023 final rule that they were supportive of usage of the 10-percentage point credit for behavioral health specialty types, we also propose to add the new Outpatient Behavioral Health facility-specialty type to the list at § 422.116(d)(5) of the specialty types that that will receive the credit if the MA organization's contracted network of providers includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, for covered services.

We welcome comment on this proposal.

B. Standards for Electronic Prescribing (§ 423.160)

1. Legislative Background

Section 1860D–4(e) of the Act requires the adoption of Part D e-prescribing standards. Part D sponsors are required to establish electronic prescription drug programs that comply with the e-prescribing standards that are adopted under this authority. For a further discussion of the statutory requirements at section 1860D–4(e) of the Act, refer to the proposed rule titled “Medicare Program; E-Prescribing and the Prescription Drug Program,” which appeared in the February 4, 2005 **Federal Register** (70 FR 6255). Section 6062 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271),

hereinafter referred to as the SUPPORT Act, amended section 1860D–4(e)(2) of the Act to require the electronic transmission of ePA requests and responses for the Part D e-prescribing program to ensure secure ePA request and response transactions between prescribers and Part D sponsors for covered Part D drugs prescribed to Part D-eligible individuals. Such electronic transmissions must comply with technical standards adopted by the Secretary. There is generally no requirement that Part D prescribers or dispensers implement e-prescribing, with the exception of required electronic prescribing of Schedule II, III, IV, and V controlled substances that are Part D drugs, consistent with section 2003 of the SUPPORT Act and as specified at § 423.160(a)(5). However, prescribers and dispensers who electronically transmit and receive prescription and certain other information regarding covered Part D drugs prescribed for Medicare Part D eligible beneficiaries, directly or through an intermediary, are required to comply with any applicable standards that are in effect.

2. Regulatory History

As specified at § 423.160(a)(1), Part D sponsors are required to support the Part D e-prescribing program transaction standards as part of their electronic prescription drug programs. Likewise, as specified at § 423.160(a)(2), prescribers and dispensers that conduct electronic transactions for covered Part D drugs for Part D eligible individuals for which a program standard has been adopted must do so using the adopted standard. Transaction standards are periodically updated to take new knowledge, technology, and other considerations into account. As CMS adopted specific versions of the standards when it initially adopted the foundation and final e-prescribing standards, there was a need to establish a process by which the standards could be updated or replaced over time to ensure that the standards did not hold back progress in the healthcare industry. CMS discussed these processes in the final rule titled “Medicare Program; E-Prescribing and the Prescription Drug Program,” (hereinafter referred to as “the November 2005 final rule”) which appeared in the November 7, 2005 **Federal Register** (70 FR 67579). An account of successive adoption of new and retirement of previous versions of various e-prescribing standards is described in the final rule titled “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee

Schedule & Other Revisions to Part B for CY 2014,” which appeared in the December 10, 2013 **Federal Register** (78 FR 74229); the proposed rule titled “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program,” which appeared in the November 28, 2017 **Federal Register** (82 FR 56336); and the corresponding final rule (83 FR 16440), which appeared in the April 16, 2018 **Federal Register**. The final rule titled “Medicare Program; Secure Electronic Prior Authorization For Medicare Part D,” which appeared in the December 31, 2020 **Federal Register** (85 FR 86824), codified the requirement that Part D sponsors support the use of NCPDP SCRIPT standard version 2017071 for certain ePA transactions (85 FR 86832).

The final rule titled “Modernizing Part D and Medicare Advantage To Lower Drug Prices and Reduce Out-of-Pocket Expenses,” which appeared in the May 23, 2019 **Federal Register** (84 FR 23832), codified at § 423.160(b)(7) the requirement that Part D sponsors adopt an electronic RTBT capable of integrating with at least one prescriber's electronic prescribing or electronic health record (EHR) system, but did not name a standard since no standard had been identified as the industry standard at the time (84 FR 23851). The electronic standards for eligibility transactions were codified in the final rule titled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,” which appeared in the May 16, 2012 **Federal Register** (77 FR 29001), to align with the applicable Health Insurance Portability and Accountability Act of 1996 (HIPAA) standards.

The Part D program has historically adopted electronic prescribing standards independently of other HHS components that may adopt electronic prescribing standards under separate authorities; however, past experience has demonstrated that duplicative adoption of health IT standards by other agencies within HHS under separate authorities can create significant burden on the healthcare industry as well as HHS when those standards impact the same technology systems. Notably, independent adoption of the NCPDP SCRIPT standard version 2017071 by CMS in various subsections of § 423.160 (83 FR 16638) in 2018, which required use of the standard beginning in 2020, led to a period where ONC had to exercise special enforcement discretion

in its Health Information Technology (IT) Certification Program until the same version was incorporated into regulation at 45 CFR 170.205(b)(1) through the final rule titled “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,” which appeared in the May 1, 2020 **Federal Register** (85 FR 25679). This resulted in significant impact on both ONC and CMS program resources. See section III.C. of this proposed rule for additional discussion of ONC’s proposal and authority. Similarly, the final rule titled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,” which appeared in the May 16, 2012 **Federal Register** (77 FR 29002), noted that, in instances in which an e-prescribing standard has also been adopted as a HIPAA transaction standard in 45 CFR part 162, the process for updating the e-prescribing standard would have to be coordinated with the maintenance and modification of the applicable HIPAA transaction standard (77 FR 29018).

3. Withdrawal of Previous Proposals and Summary of New Proposals

CMS published a proposed rule, “Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications” (hereinafter referred to as “the December 2022 proposed rule”), which appeared in the **Federal Register** December 27, 2022 (87 FR 79452), in which we proposed updates to the standards to be used by Medicare Part D prescription drug plans for electronic prescribing (e-prescribing). The proposals in the December 2022 proposed rule included a novel approach to updating e-prescribing standards by proposing to cross-reference Part D requirements with standards adopted by the Office of the National Coordinator for Health Information Technology (ONC) and the standards adopted by HHS for electronic transactions under HIPAA⁷ rather than

the historical approach of adopting e-prescribing standards in the Part D regulations independently or making conforming amendments to the Part D regulations in response to updated HIPAA standards for eligibility transactions. We proposed this approach in concert with ONC in order to mitigate potential compliance challenges for the healthcare industry and enforcement challenges for HHS that could result from independent adoption of such standards.⁸

In summary, the proposals in the December 2022 proposed rule included the following:

- Requiring the National Council for Prescription Drug Plans (NCPDP) SCRIPT standard version 2022011, proposed for adoption at 45 CFR 170.205(b), and retiring the current NCPDP SCRIPT standard version 2017071, as the e-prescribing standard for transmitting prescriptions and prescription-related information, medication history, and electronic prior authorization (ePA) transactions using electronic media for covered Part D drugs for Part D eligible individuals. This proposal included a transition period from July 1, 2023 up to January 1, 2025, when either version of the NCPDP SCRIPT standard could be used. The cross citation to 45 CFR 170.205(b) included an expiration date of January 1, 2025 for NCPDP SCRIPT standard version 2017071 meaning that this version would expire for the purposes of HHS use and entities named at § 423.160(a)(1) and (2) could use only NCPDP SCRIPT standard version 2022011 as of that date;
- Requiring the NCPDP Real-Time Prescription Benefit (RTPB) standard version 12, proposed for adoption at 45 CFR 170.205(c), as the standard for prescriber real-time benefit tools (RTBTs) supported by Part D sponsors beginning January 1, 2025; and
- Revising regulatory text referring to standards for eligibility transactions (87 FR 79548) to cross reference standards adopted for electronic eligibility transactions in the HIPAA regulations at 45 CFR 162.1202.

We received 24 comments related to these proposals by the close of the comment period on February 13, 2023. Commenters largely supported the proposals; however, several commenters, including NCPDP, recommended that CMS require use of

NCPDP SCRIPT standard version 2023011, rather than NCPDP SCRIPT standard version 2022011. Similarly, NCPDP and other commenters recommended that CMS require NCPDP RTPB standard version 13, rather than NCPDP RTPB standard version 12.

Several commenters expressed concerns about being able to successfully transition to NCPDP SCRIPT standard version 2022011 by January 1, 2025, and requested at least 2 years from publication of a final rule to sunset NCPDP SCRIPT standard version 2017071. Several commenters noted that if the implementation of NCPDP SCRIPT standard version 2022011 (or NCPDP SCRIPT standard version 2023011, as recommended by some commenters) is delayed, the January 1, 2025 compliance deadline for electronic prescribing of controlled substances (EPCS) in long-term care (LTC) facilities, as codified at § 423.160(a)(5), should also be delayed accordingly, since the new versions of the NCPDP SCRIPT standard permit 3-way communication between the prescriber, LTC pharmacy, and LTC facility, enabling EPCS to occur reliably in the LTC setting.

A commenter expressed concern that requiring use of the NCPDP SCRIPT standard imposes a financial barrier for independent pharmacies since NCPDP membership is required to access standards. CMS’s requirements at § 423.160(a)(2) do not require that all pharmacies transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media for Part D drugs for Part D-eligible individuals, but (subject to exemptions in § 423.160(a)(3)) § 423.160(a)(2) does require that when pharmacies do so, they must comply with the Part D electronic prescribing standards. CMS’s understanding is that a pharmacy management system vendor or software developer is the entity that incurs the direct costs associated with accessing the code and implementation guide associated with updating standards, not the pharmacy itself. We acknowledge that these costs may be passed on through license fees that the vendor charges to the pharmacy as normal costs of doing business. We are not aware of any open-source standards that could replace the NCPDP standards in the Part D program, but we invite comments on this topic. We also note in section III.C.10. of this proposed rule that interested parties may view materials proposed for incorporation by reference for free by following the instructions provided.

CMS has considered these comments, reviewed NCPDP SCRIPT standard

⁷ HIPAA mandated the adoption of standards for electronically conducting certain health care administrative transactions between certain entities. HIPAA administrative requirements are codified at 45 CFR part 162. See also: <https://www.cms.gov/about-cms/what-we-do/administrative-simplification>.

⁸ Due to discrepancies between prior regulatory timelines, adoption of the NCPDP SCRIPT standard version 2017071 in different rules led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program. See section III.C.5. for additional discussion.

version 2023011 and NCPDP RTPB standard version 13, and identified areas where we can reorganize the regulatory text in § 423.160.

Consequently, CMS is withdrawing all proposals contained in section III.S. Standards for Electronic Prescribing (87 FR 79548) of the December 2022 proposed rule. This approach will allow CMS to incorporate the feedback we received on prior proposals, seek comment on concerns raised in response to prior proposals, add new proposals, reorganize and make technical changes to the electronic prescribing regulations at § 423.160, and allow the public to comment on all Medicare Part D electronic prescribing-related proposals simultaneously.

In sections III.B.4. through III.B.9. of this proposed rule, the new proposals related to standards for electronic prescribing that we are putting forth encompass the following:

- Requiring use of NCPDP SCRIPT standard version 2023011, proposed for adoption at 45 CFR 170.205(b)(2), and retiring use of NCPDP SCRIPT standard version 2017071 for communication of a prescription or prescription-related information supported by Part D sponsors. This proposal includes a transition period beginning on the effective date of the final rule during which either version of the NCPDP SCRIPT standard may be used. The transition period would end on January 1, 2027, which is the date that ONC has proposed that NCPDP SCRIPT standard version 2017071 would expire for the purposes of HHS use, as described in section III.C.8.a. of this proposed rule. If finalized as proposed, starting January 1, 2027, NCPDP SCRIPT standard version 2023011 would be the only version of the NCPDP SCRIPT standard available for HHS use and for purposes of the Medicare Part D electronic prescribing program;

- Requiring use of NCPDP RTPB standard version 13 for prescriber RTBTs implemented by Part D sponsors beginning January 1, 2027;

- Requiring use of NCPDP Formulary and Benefit (F&B) standard version 60, proposed for adoption at 45 CFR 170.205(u), and retiring use of NCPDP F&B version 3.0 for transmitting formulary and benefit information between prescribers and Part D sponsors. This proposal includes a transition period beginning on the effective date of the final rule and ending January 1, 2027, during which entities would be permitted to use either NCPDP F&B version 3.0 (currently named in regulation at § 423.160(b)(5)(iii) and proposed to be named at § 423.160(b)(3) consistent with

the proposed technical changes in this rule) or NCPDP F&B standard version 60, proposed for adoption at 45 CFR 170.205(u). If finalized as proposed, starting January 1, 2027, only a version of the standard adopted for HHS use at 45 CFR 170.205(u) would be permitted for use in Part D electronic prescription drug program, which would be NCPDP F&B standard version 60 if the proposal in section III.C.8.c. of this rule is finalized as proposed;

- Cross-referencing standards adopted for eligibility transactions in HIPAA regulations at 45 CFR 162.1202 for requirements related to eligibility inquiries; and
- Making multiple technical changes to the regulation text throughout § 423.160 by removing requirements and incorporations by reference that are no longer applicable, re-organizing existing requirements, and correcting a technical error.

In these proposals, we propose a novel approach to updating e-prescribing standards by cross-referencing Part D e-prescribing requirements with standards, including any expiration dates, adopted by ONC, as discussed in section III.C.5. of this proposed rule, and the standards adopted by HHS for electronic transactions under HIPAA. This approach differs from our historical approach of adopting e-prescribing standards in the Part D regulations independently or undertaking rulemaking to make conforming amendments to the Part D regulations in response to updated HIPAA standards for eligibility transactions.⁹ As ONC notes in section III.C.5., independent adoption of the NCPDP SCRIPT standard version 2017071 in different rules¹⁰ led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT

⁹ HIPAA eligibility transaction standards were updated in final rule titled “Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards,” which appeared in the January 16, 2009 **Federal Register** (74 FR 3296). Conforming amendments to the Part D regulation were made in the final rule titled “Medicare and Medicaid Program; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction,” which appeared in the May 16, 2012 **Federal Register** (77 FR 29002).

¹⁰ 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule, which appeared in the May 1, 2020 **Federal Register** (85 FR 25642), and the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program final rule, which appeared in the April 16, 2018 **Federal Register** (83 FR 16440).

Certification Program. We believe the proposed approach would mitigate potential compliance challenges for the healthcare industry and enforcement challenges for HHS that could result from independent adoption of such standards or asynchronous rulemaking cycles across programs. CMS invites comment on all aspects of these proposals. We also solicit comment on our proposals to cross-reference ONC regulations adopting NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60. We solicit comment on the effect of the proposals that, taken together, would require use of these standards by January 1, 2027, as a result of ONC’s proposals to adopt these standards and retire previous versions, as well as our proposal to require use NCPDP F&B standard version 60 by that date.

The NCPDP SCRIPT standards are used to exchange information among prescribers, dispensers, intermediaries, and Medicare prescription drug plans (PDPs). NCPDP has requested that CMS adopt NCPDP SCRIPT standard version 2023011 because this version provides a number of enhancements to support electronic prescribing and transmission of prescription-related information.¹¹ Accordingly, we propose to update § 423.160 to specify where transactions for electronic prescribing, medication history, and ePA are required to utilize the NCPDP SCRIPT standard. The proposal, in conjunction with ONC’s proposal as described in section III.C.8.a. of this proposed rule, will allow for a transition period where either NCPDP SCRIPT standard version 2017071 or 2023011 can be used, with exclusive use of NCPDP SCRIPT standard version 2023011 required by January 1, 2027. As described in section III.B.7., we solicit comment on the date by which use of the updated version of this and other standards proposed in this proposed rule would be required, if finalized as proposed.

The NCPDP RTPB standard enables the real-time exchange of patient-specific eligibility, product coverage (including any restrictions and alternatives), and estimated cost sharing so prescribers have access to this information through a RTBT application

¹¹ National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011, April 2023. NCPDP SCRIPT standard implementation guides are available to NCPDP members for free and to non-members for a fee at ncdp.org. The NCPDP SCRIPT standard version 2023011 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

at the point-of-prescribing.^{12 13} As discussed in section III.B.5. of this proposed rule, as currently codified at § 423.160(b)(7), CMS requires that Part D sponsors implement one or more electronic RTBTs that are capable of integrating with at least one prescriber's electronic prescribing system or electronic health record, as of January 1, 2021; however, at the time CMS established this requirement, no single industry RTPB standard was available. NCPDP has since developed an RTPB standard. We propose to require the most current version, NCPDP RTPB standard version 13, as the standard for prescriber RTBTs at § 423.160(b)(5) starting January 1, 2027.

The NCPDP F&B standard is a batch standard that provides formulary and benefit information at the plan level rather than at the patient level. The NCPDP F&B standard complements other standards utilized for electronic prescribing, electronic prior authorization, and real-time prescription benefit applications.^{14 15} We propose to require use of NCPDP F&B standard version 60, and retire NCPDP F&B standard version 3.0, beginning January 1, 2027, and after a transition period during which either version may be used.

Eligibility inquiries utilize the NCPDP Telecommunication standard or Accredited Standards Committee X12N 270/271 inquiry and response transaction for pharmacy or other health benefits, respectively. The Part D program has adopted standards based on the HIPAA electronic transaction

standards, which have not been updated for more than a decade. HHS has proposed updates to the HIPAA electronic transaction standards for retail pharmacies (87 FR 67638) in the proposed rule titled “Administrative Simplification: Modifications of Health Insurance Portability and Accountability Act of 1996 (HIPAA) National Council for Prescription Drug Programs (NCPDP) Retail Pharmacy Standards; and Adoption of Pharmacy Subrogation Standard,” (hereinafter referred to as “the November 2022 Administrative Simplification proposed rule”), which appeared in the **Federal Register** November 9, 2022 (87 FR 67634). We propose to update the Part D regulation at § 423.160(b)(3) to require that eligibility transactions utilize the applicable standard named as the HIPAA standard for electronic eligibility transactions at 45 CFR 162.1202. Since 45 CFR 162.1202 currently identifies the same standards that are named at § 423.160(b)(3)(i) and (ii), we anticipate no immediate impact from this proposed change in regulatory language. Our proposal, however, would ensure that Part D electronic prescribing requirements for eligibility transactions align with the HIPAA standard for electronic eligibility transactions should a newer version of the NCPDP Telecommunication (or other) standards be adopted as the HIPAA standard for these types of electronic transactions, if HHS’ proposals in the November 2022 Administrative Simplification proposed rule are finalized or as a result of any future HHS rules.

4. Requiring NCPDP SCRIPT Standard Version 2023011 as the Part D Electronic Prescribing Standard, Retirement of NCPDP SCRIPT Standard Version 2017071, and Related Conforming Changes in § 423.160

The NCPDP SCRIPT standard has been the adopted electronic prescribing standard for transmitting prescriptions and prescription-related information using electronic media for covered Part D drugs for Part D eligible individuals since foundation standards were named in the final rule titled “Medicare Program; E-Prescribing and the Prescription Drug Program,” which appeared in the November 7, 2005 **Federal Register** (70 FR 67568), at the start of the Part D program. The NCPDP SCRIPT standard is used to exchange information among prescribers, dispensers, intermediaries, and Medicare prescription drug plans. In addition to electronic prescribing, the NCPDP SCRIPT standard is used in electronic prior authorization (ePA) and medication history transactions.

Although electronic prescribing is optional for physicians, except as to Schedule II, III, IV, and V controlled substances that are Part D drugs prescribed under Part D, and pharmacies, the Medicare Part D statute and regulations require drug plans participating in the prescription benefit to support electronic prescribing, and physicians and pharmacies who elect to transmit prescriptions and related communications electronically must utilize the adopted standards except in limited circumstances, as codified at § 423.160(a)(3).

NCPDP’s standards development process involves a consensus-based approach to solve emerging needs of the pharmacy industry or to adapt NCPDP standards to changes made by other standards development organizations.¹⁶ Emerging needs of the pharmacy industry may be the result of legislative or regulatory changes, health IT innovations, patient safety issues, claims processing issues, or electronic prescribing-related process automation.¹⁷ Changes to standards are consensus-based and driven by the NCPDP membership, which includes broad representation from pharmacies, insurers, pharmacy benefit managers, Federal and State government agencies, and vendors serving all the stakeholders.^{18 19}

In a letter to CMS dated January 14, 2022, NCPDP requested that CMS adopt NCPDP SCRIPT standard version 2022011, given the number of updates and enhancements that had been added to the standard since NCPDP SCRIPT standard version 2017071 was adopted.²⁰ NCPDP summarized the major enhancements in NCPDP SCRIPT standard version 2022011 relative to the currently required NCPDP SCRIPT standard version 2017071. Those summarized enhancements include—

- General extensibility;²¹
- Redesign of the Product/Drug groupings requiring National Drug Code

¹⁶ <https://standards.ncdp.org/Our-Process.aspx>.

¹⁷ NCPDP University. How Industry Needs Drive Changes in Standards. Accessed August 15, 2023, from [https://member.ncdp.org/\(member-only-content\)](https://member.ncdp.org/(member-only-content)).

¹⁸ NCPDP University. Voting: The Life Cycle of Standards Approval. Accessed August 15, 2023, from [https://member.ncdp.org/\(member-only-content\)](https://member.ncdp.org/(member-only-content)).

¹⁹ <https://www.ncdp.org/Membership-diversity.aspx>.

²⁰ <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf>.

²¹ Extensibility is a term in software engineering that is defined as the quality of being designed to allow the addition of new capabilities or functionality. See: Ashaolu B. What is Extensibility? Converged. February 17, 2021. Available from: <https://converged.propelsoftware.com/blogs/what-is-extensibility>.

¹² National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, July 2023. NCPDP RTPB standard implementation guides are available to NCPDP members for free and to non-members for a fee at ncdp.org. The NCPDP RTPB standard version 13 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

¹³ Bhardwaj S, Miller SD, Bertram A, Smith K, Merrey J, Davison A. Implementation and cost validation of a real-time benefit tool. *Am J Manag Care*. 2022 Oct 1;28(10):e363–e369. doi: 10.37765/ajmc.2022.89254.

¹⁴ National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard, Implementation Guide, Version 60, April 2023. NCPDP F&B standard implementation guides are available to NCPDP members for free and to non-members for a fee at ncdp.org. The NCPDP F&B standard version 60 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

¹⁵ Babbrah P, Solomon MR, Stember L, Hill JW, Weiker M. Formulary & Benefit and Real-Time Pharmacy Benefit: Electronic standards delivering value to prescribers and pharmacists. *J Am Pharm Assoc*. 2023 May–June;63(3):725–730. <https://doi.org/10.1016/j.japh.2023.01.016>.

(NDC) for DrugCoded element, but not for NonDrugCoded element;

- Addition of Observation elements to Risk Evaluation and Mitigation Strategies (REMS) transactions;

- Addition of

ProhibitRenewalRequest to RxChangeResponse and RxRenewalResponse;

- Modification of Structured and Codified Sig Structure format; and

- Additional support related to dental procedure codes, RxBarCode, PatientConditions, patient gender and pronouns, TherapeuticSubstitutionIndicator, multi-party communications, and withdrawal/retracting of a previous sent message using the MessageIndicatorFlag.

Subsequently, in the December 2022 proposed rule, CMS proposed to require NCPDP SCRIPT standard version 2022011 and retire NCPDP SCRIPT standard version 2017071, after a transition period, by cross referencing the standards as proposed for adoption by ONC. In response to this proposal, NCPDP and many other commenters recommended that CMS instead adopt the more current NCPDP SCRIPT standard version 2023011. NCPDP SCRIPT standard version 2023011, like NCPDP SCRIPT standard version 2022011, includes the functionality that supports a 3-way transaction (that is, multi-party communication) among prescriber, facility, and pharmacy, which will enable EPCS in the LTC setting.²² In its comments on the December 2022 proposed rule,²³ NCPDP highlighted specific enhancements within NCPDP SCRIPT standard version 2023011 that are not present in NCPDP SCRIPT standard version 2022011, which include:

- Addition of an optional element in the header for OtherReferenceNumber for multi-party communication transactions, such as those in LTC;
- Addition of a response type of Pending for RxChangeResponse and RxRenewalResponse for communicating when to expect an approval or denial of the request or delays in approval or denial of requests;

- Addition of a new RequestExpirationDate element to NewRxRequest, RxChangeRequest, and RxRenewalRequest to notify the prescriber to not send a response after this date;

- Addition of a new element NoneChoiceID to PASElectType so that a “none of the above” answer can be selected by the provider and allow branching to the next question in a series;

- Addition of a new element for REMSReproductivePotential replacing REMSPatientRiskCategory in the prescribed medication element group in the NewRx and RxChangeRequest message and in the replace medication element group for the RxRenewalResponse;

- Addition of a new element group of ReviewingProvider to the Resupply and Recertification messages to allow for the reporting of the provider who reviewed the chart and certified continued need of a specific medication; and

- Revised guidance in the SCRIPT Implementation Guide.

NCPDP SCRIPT standard version 2023011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071. This allows for a less burdensome implementation process and flexible adoption timeline for pharmacies, payers, prescribers, health IT vendors, and intermediaries involved in electronic prescribing, since backwards compatibility permits a transition period where both versions of the NCPDP SCRIPT standards may be used simultaneously without the need for entities involved to utilize a translator program.

Even though we are withdrawing the proposals contained in section III.S. Standards for Electronic Prescribing in the December 2022 proposed rule (87 FR 79548), we have considered comments we received on the December 2022 proposed rule when crafting our proposals for this proposed rule. For instance, several commenters asked that CMS clearly indicate that the proposed version of the NCPDP SCRIPT standard will apply to medication history functions. Several commenters noted that the regulation text at § 423.160(b)(4)(ii) does not list the NCPDP SCRIPT standard-specific medication history transactions. Commenters asked that CMS list the corresponding medication history transactions (RxHistoryRequest and RxHistoryResponse) in the regulation text so as to minimize ambiguity. After considering these comments, we propose to list the RxHistoryRequest and RxHistoryResponse transactions at § 423.160(b)(1)(i)(U) subsequent to our

technical reorganization of the section proposed in section III.B.9. of this rule, rather than list the transactions under § 423.160(b)(4).

With respect to ePA transactions in the NCPDP SCRIPT standard currently listed at § 423.160(b)(8)(i)(A) through (D) (PAInitiationRequest, PAInitiationResponse, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse) and a new ePA transaction (PANotification) available in NCPDP SCRIPT standard version 2023011, we propose to list all transactions at § 423.160(b)(1)(i)(V) through (Z). We are proposing new language at § 423.160(b)(1) to indicate that the transactions listed must comply with a standard in proposed 45 CFR 170.205(b) “as applicable to the version of the standard in use” since an older version of a standard may not support the same transactions as the newer version of the standard. For example, during the proposed transition period where either NCPDP SCRIPT version 2017071 or NCPDP SCRIPT standard version 2023011 may be used, entities that are still using NCPDP SCRIPT standard version 2017071 would not be expected to use the PANotification transaction because the PANotification transaction is only supported in the NCPDP SCRIPT standard version 2023011.

Since the NCPDP SCRIPT standard version 2023011 is fully backwards compatible with NCPDP SCRIPT standard version 2017071, the pharmacies, payers, prescribers, health IT vendors, and intermediaries involved in electronic prescribing can accommodate a transition period when either version may be used. That is, during a transition period, transactions taking place between entities using different versions of the same standard maintain interoperability without the need for entities to utilize (that is, purchase) a translator software program. The cross reference to proposed 45 CFR 170.205(b) permits a transition period starting as of the effective date of a final rule during which either NCPDP SCRIPT standard version 2017071 or NCPDP SCRIPT standard version 2023011 may be used. If finalized as proposed, the transition period will end and exclusive use of NCPDP SCRIPT standard version 2023011 will be required starting January 1, 2027, when NCPDP SCRIPT standard version 2017071 will expire for the purposes of HHS use.

Instead of independently naming the NCPDP SCRIPT standard version 2023011 and incorporating the corresponding implementation guide by

²² National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011, April 2023. NCPDP SCRIPT standard implementation guides are available to NCPDP members for free and to non-members for a fee at ncdpdp.org. The NCPDP SCRIPT standard version 2023011 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

²³ https://standards.ncdpdp.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf.

reference at § 423.160(c), we propose at § 423.160(b)(1) to cross reference a standard in 45 CFR 170.205(b). ONC proposes to adopt NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2) as described in section III.C.8.a. of this proposed rule. The proposed approach would enable CMS and ONC to avoid misalignment from independent adoption of NCPDP SCRIPT standard version 2023011 for their respective programs. Updates to the standard would impact requirements for both programs at the

same time, ensure consistency, and promote alignment for providers, payers, and health IT developers participating in and supporting the same prescription transactions. See section III.C.5. of this proposed rule for additional discussion of this coordination effort.

In its letter to CMS requesting CMS to adopt NCPDP SCRIPT standard version 2022011, NCPDP requested that CMS identify certain transactions for prescriptions for which use of the standard is mandatory.²⁴ As previously mentioned in this preamble, in response

to the December 2022 proposed rule, NCPDP and other commenters requested additional transactions be named in regulation. As part of our proposed reorganization of § 423.160, we propose to list all transactions associated with the NCPDP SCRIPT standard requirements in one place in the regulation. We propose the transactions for prescriptions, ePA, and medication history for which use of the standard is mandatory at § 423.160(b)(1)(i)(A) through (Z), as described in Table C–C1.

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TABLE C-C1: PROPOSED TRANSACTIONS FOR COMMUNICATION OF PRESCRIPTION AND PRESCRIPTION RELATED INFORMATION USING THE NCPDP SCRIPT STANDARD

Transaction	Function Supported by Transaction ²⁵
GetMessage	Requests from a mailbox, a renewal prescription request, prescription change request, new prescription request, prescription fill status notification, verification, transfer request, transfer response, transfer confirmation or an error or other transactions that have been sent by a pharmacy or prescriber system.
Status	Relays acceptance of a transaction back to the sender.
Error	Indicates an error has occurred indicating the request was terminated.
RxChangeRequest and RxChangeResponse	Request from a pharmacy to a prescriber asking for a change in a new or "fillable" prescription; additional usage includes verification of prescriber credentials and request on a prior authorization from the payer. Response is sent from a prescriber to the requesting pharmacy to either approve, approve with change, validate, or deny the request.
RxRenewalRequest and RxRenewalResponse	Request from the pharmacy to the prescriber requesting additional refills. Response is sent from the prescriber to the requesting pharmacy to allow pharmacist to provide a patient with additional refills, a new prescription, or decline to do either.

²⁴ <https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf>.

Transaction	Function Supported by Transaction ²⁵
Resupply	Request from a Long Term or Post-Acute Care (LTPAC) organization to a pharmacy to send an additional supply of medication for an existing order.
Verify	Response to a pharmacy or prescriber indicating that a transaction requesting a return receipt has been received.
CancelRx and CancelRxResponse	Request from the prescriber to the pharmacy to inactivate a previously sent prescription. Response is sent from the pharmacy to the prescriber to acknowledge a cancel request.
RxFill	Indicates the dispensing or activity status. It is the notification from one entity to another conveying the status of dispensing activities or other clinical activities.
DrugAdministration	Communicates drug administration events from a prescriber/care facility to the pharmacy or other entity. It is a notification from a prescriber/care facility to a pharmacy or other entity that a drug administration event has occurred.
NewRxRequest	Request from a pharmacy to a prescriber for a new prescription for a patient. If approved, a NewRx transaction would be sent.
NewRx	New prescription is sent from the prescriber to the pharmacy electronically so it can be dispensed to a patient.
NewRxResponseDenied	Denied response to a previously sent NewRxRequest.
RxTransferInitiationRequest (previously named RxTransferRequest in NCPDP SCRIPT standard version 2017071)	Used when the destination pharmacy is asking for a transfer of one or more prescriptions for a specific patient from the source pharmacy.
RxTransfer (previously named RxTransferResponse NCPDP SCRIPT standard version 2017071)	In the solicited model, it is the response to the RxTransferInitiationRequest which includes the prescription(s) being transferred from the source pharmacy to the destination pharmacy or a rejection of the transfer request. In the unsolicited model, it is a push of the prescription(s) being transferred from the source pharmacy to the destination pharmacy.
RxTransferConfirm	Used by the destination pharmacy to confirm the transfer prescription has been received and the transfer is complete.
RxFillIndicatorChange	Sent to the receiver to indicate the sender is changing the types of RxFill responses that were previously requested. The sender may modify the fill status notification of transactions previously selected or cancel future RxFill transactions.
Recertification	Notification on behalf of a reviewing provider to a pharmacy recertifying the continued administration of a medication order. Used in LTPAC only.
REMSInitiationRequest and REMSInitiationResponse	Request to the REMS Administrator for the information required to submit a REMS request (REMSRequest) for a specified patient and drug. Response is from the REMS Administrator with the information required to submit a REMS request (REMSRequest) for a specified patient and drug.

Transaction	Function Supported by Transaction ²⁵
REMSRequest and REMSResponse	Request to the REMS Administrator with information (answers to question set; clinical documents) to make a REMS determination (approved, denied, pended, etc.). Response is the determination from the REMS administrator whether dispensing authorization can be granted.
RxHistoryRequest and RxHistoryResponse	Request from one entity to another for a list of medications that have been prescribed, dispensed, claimed or indicated by the patient. Response includes the medications that were dispensed or obtained within a certain timeframe, optionally including the prescriber that prescribed them.
PAInitiationRequest and PAInitiationResponse	Request from the submitter to a payer for the information required to submit a prior authorization request (PAREquest) for a specified patient and product. Response is from a payer to the submitter with the information required to submit a prior authorization request (PAREquest) for a specified patient and product.
PAREquest and PAResponse	Request from the submitter to the payer with information (answers to question set; clinical documents) for the payer to make a PA determination (approved, denied, pended, etc.). Response from the payer to the submitter indicates the status of a PAREquest. Response could be a PA determination, notice that the request is in process, or specify that more information is required.
PAAppealRequest and PAAppealResponse;	Request from the submitter to the payer to appeal a PA determination. Response from the payer to the submitter indicates what information is needed for an appeal or the status or outcome of a PAAppealRequest.
PACancelRequest and PACancelResponse	Request from the submitter to the payer to notify the payer that the PA request is no longer needed. Response from the payer to the submitter indicates the if the PA request was cancelled or not.
PANotification	Alerts the pharmacist or prescriber when a PA has been requested, or when a PA determination has been received.

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The transactions specific to electronic prescribing remain the same as those required for NCPDP SCRIPT standard version 2017071 (currently codified at § 423.160(b)(2)(iv)(A) through (Z)), except where renamed as noted in Table C–C1. The transactions specific to ePA are also the same as those required with NCPDP SCRIPT standard version 2017071, with one additional transaction (PA Notification), which was incorporated into the standard after NCPDP SCRIPT standard version 2017071. As discussed in section III.C.8.a. of this proposed rule, NCPDP SCRIPT standard version 2023011 is proposed for adoption at 45 CFR 170.205(b)(2), and NCPDP SCRIPT

standard version 2017071 is proposed to expire January 1, 2027, at 45 CFR 170.205(b)(1). Consequently, should we finalize our proposal, use of NCPDP SCRIPT standard version 2023011 for the transactions related to electronic prescribing, medication history, and ePA (proposed at § 423.160(b)(1)(i)(A) through (Z)) will be mandatory starting January 1, 2027, if ONC's proposed adoption of NCPDP SCRIPT version 2023011 and proposed expiration date for NCPDP SCRIPT version 2017071 are adopted as proposed.

²⁵ Section 4. Business Functions, and Section 5. Transactions. National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011, April 2023. NCPDP SCRIPT standard implementation

As stated previously, in response to the December 2022 proposed rule, several commenters pointed out that if mandatory use of an updated version of the NCPDP SCRIPT standard is delayed, then the EPCS requirement in LTC facilities should also be delayed accordingly, since NCPDP SCRIPT standard version 2017071 lacks appropriate guidance for LTC facilities. CMS was aware of this limitation in the NCPDP SCRIPT standard version

guides are available to NCPDP members for free and to non-members for a fee at ncdp.org. The NCPDP SCRIPT standard version 2023011 implementation guide proposed for incorporation by reference in section III.C.10. of this proposed rule can be viewed by interested parties for free by following the instructions provided in that section.

2017071, and acknowledged the challenges to EPCS faced by LTC facilities in the proposed rule “Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements” (hereinafter referred to as “the July 2022 proposed rule”), which appeared in the **Federal Register** July 23, 2021 (86 FR 39104). However, in the July 2022 proposed rule, CMS also stated that we understood that NCPDP was in the process of creating specific guidance for LTC facilities within the NCPDP SCRIPT standard version 2017071, which would allow willing partners to enable 3-way communication between the prescriber, LTC facility, and pharmacy to bridge any outstanding gaps that impede adoption of the NCPDP SCRIPT standard version 2017071 in the LTC setting (86 FR 39329).

Similarly, in the “Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; and Provider and Supplier Prepayment and Post-Payment Medical Review Requirements” final rule (hereinafter referred to as “the November 2021 final rule”), which appeared in the **Federal Register** November 19, 2021 (86 FR 64996), CMS acknowledged that although 3-way communication is not as seamless in NCPDP SCRIPT standard version 2017071 as it was expected to be in later versions, EPCS was still possible with some modifications (86 FR 65364). CMS delayed EPCS compliance for prescribers’ prescriptions written for beneficiaries in a LTC facility from January 1, 2022, to no earlier than January 1, 2025, in order to give prescribers additional time to make the necessary changes to conduct electronic prescribing of covered Part D controlled substance prescriptions for Part D beneficiaries in LTC facilities using NCPDP SCRIPT standard version 2017071 (86 FR 65365). We are not proposing a change in the EPCS compliance date for covered Part D controlled substance prescriptions for Part D beneficiaries in LTC on the basis of the proposed adoption of NCPDP SCRIPT standard version 2023011; however, we invite comment on the status of EPCS in LTC and the degree to which LTC facilities have been able to

implement guidance from NCPDP to meet the EPCS requirement.

As proposed, § 423.160(b)(1) would require use of the version or versions of the NCPDP SCRIPT standard adopted in 45 CFR 170.205(b) to carry out the transactions listed in § 423.160(b)(1)(i)(A) through (Z). However, it would not require that all transactions be utilized if they are not needed or are not relevant to the entity. We refer readers to ONC’s Interoperability Standards Advisory (ISA) website for descriptions and adoption level of transactions in the NCPDP SCRIPT standard.²⁶ For example, we have been informed that the “GetMessage” transaction described in Table C–C1 is not widely used among prescribers. For this reason, we are reiterating guidance²⁷ that the NCPDP SCRIPT standard transactions named are not themselves mandatory, but rather they are to be used as applicable to the entities specified at § 423.160(a)(1) and (2) when they are completing or supporting the transmission of information related to electronic prescriptions, electronic prior authorization, or medication history. We believe the pharmacies, payers, prescribers, health IT vendors, and intermediaries involved in electronic prescribing have been utilizing the standards in this manner, based on discussions with NCPDP.

In summary, with respect to changes related to adopting, via cross-reference to ONC proposals in section III.C.8.a., NCPDP SCRIPT standard version 2023011 and retiring NCPDP SCRIPT standard version 2017071, we propose a revised paragraph § 423.160(b)(1) to:

- Consolidate all transactions for electronic prescribing, ePA, and medication history for which use of the NCPDP SCRIPT standard is mandatory at § 423.160(b)(1)(i)(A) through (Z); and
- Indicate that communication of prescriptions and prescription-related transactions listed must comply with a standard in 45 CFR 170.205(b). In conjunction with ONC proposals in section III.C.8.a., this cross-reference would permit a transition period when either NCPDP SCRIPT standard versions 2017071 or 2023011 may be used beginning as of the effective date of a final rule and ending January 1, 2027, because, as ONC has proposed at 45 CFR 170.205(b)(1), the NCPDP SCRIPT standard version 2017071 would expire January 1, 2027, after which only

NCPDP SCRIPT standard version 2023011 would be available for HHS use.

We solicit comment on these proposals.

5. Requiring NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13

In the May 2019 final rule (84 FR 23832), which implemented the statutory provision at section 1860D–4(e)(2)(D) of the Act, CMS required at § 423.160(b)(7) that Part D plan sponsors implement, by January 1, 2021, one or more electronic real-time benefit tools (RTBT) capable of integrating with at least one prescriber’s e-prescribing system or electronic health record (EHR) to provide prescribers with complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information. CMS indicated that the formulary and benefit information provided by the tool should include cost, clinically appropriate formulary alternatives, and utilization management requirements because, at that time, an industry standard for RTBTs had not been identified (84 FR 23833). NCPDP has since developed and tested an RTPB standard for use with RTBT applications. The NCPDP RTPB standard enables the real-time exchange of information about patient eligibility and patient-specific formulary and benefit information. For a submitted drug product, the RTPB standard will indicate coverage status, coverage restrictions, and estimated patient financial responsibility. “Estimated” financial responsibility accounts for the fact that the RTPB transaction transmits the patient’s cost sharing at that particular moment in time, which could later change if the claim is processed at a later date or in a different sequence relative to other claims (for example, an RTPB transaction could show a cost sharing that reflects a deductible or particular stage in the Part D benefit which could be different from when the prescription claim is actually processed by the pharmacy if other claims were processed in the interim). The RTPB standard also supports providing information on alternative pharmacies and products. In an August 20, 2021 letter to CMS, NCPDP described these features and recommended adoption of RTPB standard version 12.²⁸ Subsequently, in the December 2022 proposed rule, CMS proposed that Part D sponsors’ RTBTs comply with NCPDP RTPB standard version 12. In response

²⁶ <https://www.healthit.gov/isa/section/pharmacyinteroperability>.

²⁷ Supporting Electronic Prescribing Under Medicare Part D. September 19, 2008. <https://www.hhs.gov/guidance/document/supporting-electronic-prescribing-under-medicare-part-d>.

²⁸ https://standards.ncdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBAndFandBStandardsAdoptionRequest.pdf.

to that proposal, NCPDP and many other interested parties provided comments to CMS recommending that CMS instead require NCPDP RTPB standard version 13. In their comments on the December 2022 proposed rule,²⁹ NCPDP listed enhancements in NCPDP RTPB standard version 13 that improve the information communicated between the payer and the prescriber. These enhancements include:

- Addition of a Coverage Status Message to enable the payer to communicate at the product level additional clarifying coverage information which is not codified;
- Addition of values to the Coverage Restriction Code and data elements to codify information communicated in the Message to reduce the number of free text messages on the response;
- Addition of a next available fill date to communicate when the patient is eligible to receive a prescription refill in a discrete field instead of via a free text message;
- Addition of fields to communicate formulary status and preference level of both submitted and alternative products in order to clarify pricing; and
- Addition of data elements on the request transaction to convey the patient's address, State/province, zip/postal code and country to aid in coverage determinations.

Even though we are withdrawing the proposals contained in section III.S. Standards for Electronic Prescribing in the December 2022 proposed rule (87 FR 79548), we have considered comments we received on the December 2022 proposed rule when crafting our proposals related to RTBTs for this proposed rule. A commenter on the December 2022 proposed rule requested that CMS specify that adoption of the NCPDP RTPB standard should not impede what the commenter refers to as the industry standard of sending 4 drugs or 4 pharmacies for pricing in a single transaction. We understand that each transaction between a prescriber EHR and the payer or processor is associated with a degree of latency (that is, the amount of time it takes for the RTBT request to travel from the electronic prescribing system to the payer or processor and return a response with the patient's cost sharing and formulary status information for the submitted drug). In order to populate information on alternative formulary drugs or alternative pharmacies, if one alternative is submitted per transaction, then the latency associated with each

transaction becomes additive. If the total latency is too long, then either the RTBT request may "time out" and a response may never be presented to the prescriber, or the prescriber may simply not wait long enough for the RTBT response before moving on through the electronic prescribing process. To illustrate the concept at the center of this issue, if each RTBT transaction is associated with 1 second of latency, then 1 transaction containing the submitted drug, plus 3 alternatives should return the patient-specific cost and formulary status information for all 4 drugs within 1 second. However, if the submitted drug and each alternative are sent as separate transactions, then the total time to return the RTBT response becomes 4 seconds (1 second $\times$ 4 transactions). This longer response time increases the likelihood that the prescriber will not wait for the information to populate or that that EHR system will cause the transaction to time out, meaning the patient-specific cost and formulary status information are not presented to the prescriber. CMS takes interest in how adoption of the proposed NCPDP RTPB standard version 13 could alter functionality of RTBTs already in use. CMS created requirements for RTBTs in the absence of an industry-wide standard because of their potential to increase drug price transparency and lower out-of-pocket costs for Medicare Part D enrollees. The impact of RTBTs is contingent on prescribers actually receiving the patient-specific information in the response from the payer. CMS appreciates that this is relatively new technology and that there are multiple factors that contribute to the overall impact of RTBTs in real-world settings.^{30 31 32} Nevertheless, we seek comment on the issue raised by the commenter. We ask interested parties for their perspective on whether requiring the NCPDP RTPB standard version 13 would limit the ability to send more than one drug or pharmacy per RTBT transaction, and if so, whether the benefit of adopting a standard for

prescriber RTBTs in order to enable widespread integration across EHRs and payers outweighs such limitation.

The NCPDP RTPB standard version 13 standard is designed for prescriber, not beneficiary (that is, consumer), RTBTs. CMS emphasizes that we are not proposing a required standard for beneficiary RTBTs. Beneficiary RTBTs are made available directly to Part D plan enrollees by the Part D sponsor; therefore, beneficiary RTBT applications do not necessarily interface with an electronic prescribing system or EHR, as prescriber RTBTs must. Consequently, CMS believes that Part D sponsors can retain the flexibility to use beneficiary RTBTs that are based on an available standard or a custom application, as long as the information presented to enrollees meets CMS's requirements codified at § 423.128(d)(4). The requirements for the beneficiary RTBT are discussed in the final rule titled "Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," which appeared in the January 19, 2021 **Federal Register** (86 FR 5864). We decline to propose a standard for beneficiary RTBTs at this time, however we welcome comments on this topic which we may consider for future rulemaking.

As discussed in section III.C.8.b. of this proposed rule, ONC proposes to adopt the NCPDP RTPB standard version 13 at 45 CFR 170.205(c)(1). We therefore propose at § 423.160(b)(5) to require that beginning January 1, 2027, Part D sponsors' prescriber RTBT must comply with a standard in 45 CFR 170.205(c).

We solicit comment on these proposals and the related issues raised.

6. Requiring NCPDP Formulary and Benefit Standard Version 60 and Retirement of NCPDP Formulary and Benefit Standard Version 3.0

The NCPDP Formulary and Benefit (F&B) standard provides a uniform means for prescription drug plan sponsors to communicate plan-level formulary and benefit information to prescribers through electronic prescribing/EHR systems. The NCPDP F&B standard transmits, on a batch basis, data on the formulary status of drugs, preferred alternatives, coverage restrictions (that is, utilization management requirements), and cost sharing consistent with the benefit design (for example, cost sharing for drugs on a particular tier). The NCPDP

³⁰ Everson J, Dusetzina SB. Real-time Prescription Benefit Tools—The Promise and Peril. *JAMA Intern Med.* 2022;182(11):1137–1138. Doi:10.1001/jamainternmed.2022.3962.

³¹ Real-Time Benefit Check: Key Insights and Challenges. May 2021. Accessed January 1, 2023. Available at: <https://www.hmpgloballearningnetwork.com/site/frmc/cover-story/real-time-benefit-check-key-insights-and-challenges>.

³² American Medical Association. Council on Medical Service. Access to Health Plan Information Regarding Lower-Cost Prescription Options (Resolution 213–NOV–20). Available from https://councilreports.ama-assn.org/councilreports/downloadreport?url=/councilreports/n21_cms_report_2.pdf.

²⁹ https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf.

F&B standard serves as a foundation for other electronic prescribing functions including ePA, real-time benefit check, and specialty medication eligibility when used in conjunction with other standards.³³ NCPDP F&B standard version 3.0 is required for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors, consistent with the existing text of § 423.160(b)(1)(v) and (b)(5)(iii). In an April 4, 2023 letter to CMS, NCPDP requested that CMS adopt NCPDP F&B standard version 60 to replace NCPDP F&B standard version 3.0.³⁴ A detailed change log was attached to the letter and is available at the link in the footnote. As described in the letter, compared with NCPDP F&B standard version 3.0, NCPDP F&B standard version 60 includes all of the following major enhancements:

- Normalization of all files (lists), which allows for smaller files and reusability.
- All files have expiration dates.
- Redesigned alternative and step medication files to reduce file sizes and to include support for reason for use (that is, diagnosis).
- Step medication files support a more complex step medication program.
- Updated coverage files to include support for electronic prior authorization and specialty drugs.
- Updated copay files to allow a minimum and maximum copay range without a percent copay and to support deductibles and pharmacy networks.

In its letter to CMS, NCPDP requested mandatory use of NCPDP F&B version 60 24 months after the effective date of a final rule adopting the standard. NCPDP F&B standard version 60 is backwards compatible with NCPDP F&B standard version 3.0, permitting a transition period where both versions of the NCPDP F&B standard may be used simultaneously without the need for entities involved to utilize a translator program.

Following an approach similar to those proposed in sections III.B.4. and III.B.5. of this proposed rule, CMS proposes at § 423.160(b)(3) that transmitting formulary and benefit information between prescribers and Medicare Part D sponsors must either utilize NCPDP F&B standard version 3.0 or comply with a standard in 45 CFR

170.205(u), where ONC proposes to adopt, at 45 CFR 170.205(u)(1), NCPDP F&B standard version 60 as described in section III.C.8.c. of this proposed rule. After January 1, 2027, entities transmitting formulary and benefit information would be required to comply with a standard in 45 CFR 170.205(u) exclusively, if finalized as proposed. Since ONC did not previously adopt NCPDP F&B standard version 3.0, we are maintaining the incorporation by reference of that version in the Part D regulation at § 423.160(c)(1)(i) to permit a transition period where either NCPDP F&B standard version 3.0 or NCPDP F&B version 60 could be used until January 1, 2027.

We solicit comment on these proposals.

7. Date for Required Use of NCPDP SCRIPT Standard Version 2023011, NCPDP RTPB Standard Version 13, and NCPDP F&B Standard Version 60

CMS has received feedback on a number of practical considerations for determining a realistic timeframe to implement new or update existing electronic prescribing standards. We have been informed that organizations generally do not budget for new requirements until a final rule has been published establishing a particular new requirement and, therefore, the timing of when a final rule is finalized relative to budget approval cycles can determine if a requirement can be accounted for in the organization's next annual budget. The health IT industry has indicated to CMS that it requires at least 2 years to design, develop, test, and certify software with trading partners; perform DEA audits for EPCS compliance; and roll out updated software to provider organizations and partners who then must train end users before a transition to a new or updated version of a standard is complete. This account is consistent with NCPDP's requests for up to 24-month implementation timeframes for new standards.³⁵ A commenter on the December 2022 proposed rule requested that CMS either permit 3 years from a final rule before requiring use of a new or updated version of a standard, or use enforcement discretion if requiring use of a new or updated version of a standard less than 3 years from a final rule. CMS will generally aim to provide entities with at least 2 years from when a final rule is finalized; however, we qualify that in some cases

less time may be provided if determined to be necessary.

CMS routinely receives feedback requesting that we do not require the use of new or updated electronic prescribing standards starting on January 1 due to end-of-year "code freezes," which prohibit updates to internal systems and plan enrollment changes that contribute to a general high workload at the start of a new plan year. CMS reminds entities impacted by the proposed regulatory changes that, consistent with § 423.516, CMS is prohibited from imposing new, significant regulatory requirements on Part D sponsors midyear. If the approach proposed in this proposed rule to align CMS's requirements for certain Part D electronic prescribing standards by cross-referencing standards adopted in ONC regulations is finalized, CMS and ONC will coordinate to establish appropriate timeframes for updating adopted standards and expiration dates for prior versions of adopted standards. CMS, working with ONC, will consider transition periods longer than 24 months following publication of a final rule to permit a sufficient transition period prior to January 1. Since a new, significant requirement must be effective January 1, a new or updated version of a standard could be required January 1 of the year following 24 months after a final rule is effective. For example, if a final rule containing a provision to update an electronic prescribing standard to a new version were effective May 30, 2024, then CMS would anticipate requiring the new version of the standard by January 1, 2027. This would allow for a 31-month transition period during which either version of a required standard could be used. Part D sponsors would need to plan accordingly to completely transition to the updated version of the standard ahead of the January 1 date to meet their internal production calendars. Using the prior example, we would assume that to avoid implementing the updated version of a standard on January 1, 2027, Part D sponsors would transition to the updated version of the standard by approximately May 30, 2026.

ONC is proposing January 1, 2027, as the date NCPDP SCRIPT standard version 2023011 would be the required version of this standard, as a product of the proposed expiration for NCPDP SCRIPT standard version 2017071 and our proposed cross-reference, in § 423.160(b)(1), to a standard in 45 CFR 170.205(b). We are proposing the required use of NCPDP F&B standard version 60 and NCPDP RTPB standard version 13 by January 1, 2027, in the

³³ Babrah P, Solomon MR, Stember LA, Hill JW, Weiker M. Formulary & benefit and real-time pharmacy Benefit: Electronic standards delivering value to prescribers and pharmacists. *J Am Pharm Assoc* (2003). 2023 May–Jun;63(3):725–730. doi: 10.1016/j.japh.2023.01.016.

³⁴ <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2023/20230404-to-CMS-Formulary-and-Benefit-V60-Request.pdf>.

³⁵ https://standards.ncdp.org/Standards/media/pdf/Correspondence/2021/20210820_To_CMS_RTPBAndFandBStandardsAdoptionRequest.pdf.

³⁶ <https://standards.ncdp.org/Standards/media/pdf/Correspondence/2022/202201NCPDP-SCRIPTNextVersionLetter.pdf>.

text of § 423.160(b)(3) and (5), respectively, as previously discussed. We are also aware that Part D sponsors and the health IT industry are awaiting HHS' final rule on the proposals to update the NCPDP Telecommunication standard from version D.0 to version F6 (87 FR 67638), update the equivalent NCPDP Batch Standard version 15 (87 FR 67639), and implement the NCPDP Batch Standard Pharmacy Subrogation version 10 (87 FR 67640) proposed in the November 2022 Administrative Simplification proposed rule.

Taking all of these proposals into consideration, we ask interested parties to comment on the proposed January 1, 2027, date for the required use of NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60. It is expressly outside the scope of this proposed rule, and we do not seek comment on, the compliance date for the proposals in HHS' November 2022 Administrative Simplification proposed rule; however, we ask for comments on the feasibility of updating multiple standards simultaneously.

8. Standards for Eligibility Transactions

We propose to revise the Part D requirements to indicate that eligibility transactions must comply with 45 CFR 162.1202. The requirements for eligibility transactions currently codified at § 423.160(b)(3)(i) and (ii) name the Accredited Standards Committee X12N 270/271-Health Care Eligibility Benefit Inquiry and Response, Version 5010, April 2008, ASC X12N/005010x279 and the NCPDP Telecommunication Standard Specification, Version D, Release 0 (Version D.0), August 2007, and equivalent NCPDP Batch Standard Batch Implementation Guide, Version 1, Release 2 (Version 1.2), January 2006 supporting Telecommunications Standard Implementation Guide, Version D, Release 0 (Version D.0), August 2007. We adopted these standards to align with those adopted at 45 CFR 162.1202, pursuant to the final rule titled "Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA) Electronic Transaction Standards," which appeared in the January 16, 2009, **Federal Register** (74 FR 3326).

The November 2022 Administrative Simplification proposed rule proposes to update the HIPAA standards used for eligibility transactions (87 FR 67638). We therefore propose to update the Part D regulation by proposing, at § 423.160(b)(2), that eligibility inquiries and responses between the Part D

sponsor and prescribers and between the Part D sponsor and dispensers must comply with the applicable HIPAA regulation in 45 CFR 162.1202, as opposed to naming standards independently, which would ensure, should the HIPAA standards for eligibility transactions be updated as a result of HHS rulemaking or in the future, that the Part D regulation would be synchronized with the required HIPAA standards. We foresee no immediate impact of this proposed change since the HIPAA regulation at 45 CFR 162.1202 currently identifies the same standards as those named in the Part D regulation at § 423.160(b)(3)(i) and (ii), but we believe establishing a cross-reference would help avoid potential future conflicts and mitigate potential compliance challenges for the healthcare industry and enforcement challenges for HHS.

Thus, we propose to delete existing § 423.160(b)(3)(i) and (ii) and modify § 423.160(b)(2) (as renumbered per the technical proposals in section III.B.9. of this proposed rule) to require that eligibility transactions must comply with 45 CFR 162.1202.

We solicit comment on these proposals.

9. Technical Changes Throughout § 423.160

In the spirit of alignment with ONC's approach to adopting standards, we reviewed § 423.160 in its entirety and identified areas where we can reorganize text throughout this section. We do not believe we should continue to list historical requirements that are no longer relevant and have resulted in repetitive content being added to the regulation. We propose removing reference to old effective dates (for example, "After January 1, 2009 . . ." at § 423.160(a)(3)(ii)). Additionally, certain exemptions have long since expired. For example, at § 423.160(a)(3)(iv), entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider (such as a nursing facility) that in turn forwards the prescription to a dispenser have not been exempt from using the SCRIPT standard since November 1, 2014.

We are proposing a correction at § 423.160(a)(3)(iii), where regulation text refers to prescriptions and prescription-related information transmitted "internally when the sender and the beneficiary are part of the same legal entity." The exemption currently at § 423.160(a)(3)(iii) was previously codified at § 423.160(a)(3)(ii) as "Entities may use either HL7 messages

or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity . . ." as finalized in the November 2005 final rule, which codified the foundation standards for Medicare Part D electronic prescription drug programs (70 FR 67594). Section 423.160(a)(3)(ii) was redesignated as § 423.160(a)(3)(iii) subsequent to changes made in the final rule titled "Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, and Other Part B Payment Policies for CY 2008; Revisions to the Payment Policies of Ambulance Services Under the Ambulance Fee Schedule for CY 2008; and the Amendment of the E-Prescribing Exemption for Computer Generated Facsimile Transmissions," (hereinafter referred to as "the November 2007 final rule") which appeared in the November 27, 2007 **Federal Register** (72 FR 66222). There is no indication of intent in the November 2007 final rule to change the wording in § 423.160(a)(3)(iii) when it was redesignated, nor can we find evidence of when this paragraph may have been altered in subsequent rules. Therefore, we believe the word "recipient" was inadvertently changed to "beneficiary" in the distant past and we are proposing to change this back to "recipient."

Section 423.160(a)(1) and (2) already indicate that the entities listed must comply with the applicable standards in § 423.160(b); therefore, the language currently at § 423.160(b)(1), "Entities described in paragraph (a) of this section must comply with the following adopted standards for transactions under this section," is redundant. We propose to remove it from the text of § 423.160(b)(1). Moreover, § 423.160(b)(1)(i) through (iv) and (b)(2)(i) through (iii) contain long-outdated requirements going back to the start of the electronic prescribing program in Medicare Part D. We propose to delete references to outdated requirements so that the regulation text will include only relevant and applicable requirements. Transition periods would no longer be specifically spelled out as starting at a particular date (historically, 6 months after the effective date of a final rule). Rather, the transition period would begin as of the effective date of a final rule effectuating a change from one version of a standard to a new version and would last until the prior version of the standard is expired, as proposed to be codified in ONC regulation, or until the date specified in Part D regulation. For

versions of standards adopted by ONC, CMS would consider the necessary transition period when working with ONC to establish the appropriate expiration date for prior versions of standards in rulemaking. This would align the Part D approach with the approach that ONC has used in its own regulations.

As currently organized, separate sections for “Prescription” at § 423.160(b)(2), “Medication history” at § 423.160(b)(4), and “Electronic prior authorization” at § 423.160(b)(8) has resulted in multiple versions of the NCPDP SCRIPT standard, and relevant transactions, being repeated in these sections. Because § 423.160(a)(1) and (2) state that the entities listed must comply “with the applicable standards in paragraph (b),” we believe that we can group the functions in paragraph (b) according to the standard used for those functions to avoid repetition. Therefore, we propose to combine “Prescriptions, electronic prior authorization, and medication history” at § 423.160(b)(1), which will require the use of the NCPDP SCRIPT standard version or versions as proposed via cross-reference to ONC regulations. We propose to delete § 423.160(b)(4) and (8). The ePA transactions previously listed at § 423.160(b)(8)(i)(A) through (D) are proposed at § 423.160(b)(1)(i)(V) through (Y). We are proposing to delete reference to versions of the NCPDP F&B standard, currently codified at § 423.160(b)(5) introductory text and (b)(5)(i) and (ii), that are no longer applicable. The remaining paragraphs in § 423.160(b) are renumbered such that § 423.160(b)(2) refers to eligibility, § 423.160(b)(3) refers to formulary and benefits, § 423.160(b)(4) refers to provider identifier, and § 423.160(b)(5) refers to real-time benefit tools.

We are proposing to delete standards incorporated by reference at § 423.160(c) that are: no longer applicable (that is, were associated with outdated requirements that we have proposed to delete); are being proposed for incorporation by reference by ONC at 45 CFR 170.299; or are already incorporated by reference by HHS at 45 CFR 162.920. The standards incorporated by reference at § 423.160(c)(1)(i), (ii), and (v) are no longer applicable, and we propose to delete them. The standards for eligibility transactions currently incorporated by reference at § 423.160(c)(1)(iii) and (c)(2)(i) and (ii) have already been incorporated by reference by HHS at 45 CFR 162.920. We propose to delete these specified § 423.160(c)(1) and (2) incorporations by reference in light of our proposals in

section III.B.8. of this proposed rule to indicate that entities must comply with 45 CFR 162.1202 for eligibility transactions. In section III.B.11. of this proposed rule, we discuss how we propose to renumber the applicable standards currently incorporated by reference and where we propose to incorporate by reference the proposed new versions of standards as discussed in sections III.B.4., III.B.5., and III.B.6. of this proposed rule.

We believe these changes improve the overall readability of the section. With the exception of proposed changes described in sections III.B.4., III.B.5., III.B.6., and III.B.8., we do not intend for technical changes to alter current requirements.

We solicit comment on these proposals.

10. Summary of Standards for Electronic Prescribing Proposals

Sections III.B.4. through III.B.9. of this proposed rule include the following proposals:

- Requiring, via cross-reference to a standard in 45 CFR 170.205(b), use of NCPDP SCRIPT standard version 2023011, which ONC proposes for adoption at 45 CFR 170.205(b)(2), and retiring use of NCPDP SCRIPT standard version 2017071, via the same proposed cross-reference, for communication of a prescription or prescription-related information supported by Part D sponsors. This proposal includes a transition period beginning on the effective date of the final rule when either version of the NCPDP SCRIPT standard may be used. The transition period would end on January 1, 2027, which is the date that ONC has proposed that NCPDP SCRIPT standard version 2017071 would expire for the purposes of HHS use, as described in section III.C.8.a. of this proposed rule. If finalized as proposed, starting January 1, 2027, NCPDP SCRIPT standard version 2023011 would be the only version of the NCPDP SCRIPT standard available for HHS use and for purposes of the Medicare Part D electronic prescribing program;

- Requiring, beginning January 1, 2027, prescriber RTBTs implemented by Part D sponsors to comply with a standard in 45 CFR 170.205(c), where ONC proposes to adopt NCPDP RTPB standard version 13;

- Requiring transmission of formulary and benefit information between prescribers and Medicare Part D sponsors to comply with a standard in 45 CFR 170.205(u), where ONC proposes to adopt NCPDP F&B standard version 60, and retiring use of NCPDP F&B version 3.0 for transmitting

formulary and benefit information between prescribers and Part D sponsors. This proposal includes a transition period beginning on the effective date of the final rule and ending January 1, 2027, where entities would be permitted to use either NCPDP F&B version 3.0 (currently named in regulation at § 423.160(b)(5)(iii) and proposed to be named at § 423.160(b)(3) consistent with the proposed technical changes in this rule) or NCPDP F&B standard version 60, proposed for adoption at 45 CFR 170.205(u). If finalized as proposed, starting January 1, 2027, only a version of the standard adopted for HHS use at 45 CFR 170.205(u) would be permitted for use in Part D electronic prescription drug program, which would be NCPDP F&B standard version 60 if the proposal in section III.C.8.c. of this rule is finalized as proposed;

- Cross-referencing standards adopted for eligibility transactions in HIPAA regulations at 45 CFR 162.1202 for requirements related to eligibility inquiries; and

- Making multiple technical changes to the regulation text throughout § 423.160 for clarity by removing requirements and incorporations by reference that are no longer applicable or redundant, re-organizing existing requirements, and correcting a technical error. CMS invites comment on all aspects of these proposals, including the proposed date of January 1, 2027, for required use of NCPDP SCRIPT standard version 2023011, NCPDP RTPB standard version 13, and NCPDP F&B standard version 60.

11. Incorporation by Reference and Availability of Incorporation by Reference Materials

The Office of the Federal Register (OFR) has regulations concerning incorporation by reference (IBR) at 1 CFR part 51. If the regulations reference a standard, either in general or by name, in another section, IBR approval is required. In order for CMS to require use of standards in § 423.160 by cross citation to 45 CFR 170.205(b), those standards must be published in full in the **Federal Register** or CFR. Therefore, CMS must incorporate by reference the materials referenced in the proposals in sections III.B.4., III.B.5., and III.B.6. of this proposed rule which cross cite standards in ONC regulations.

For a proposed rule, agencies must discuss in the preamble to the proposed rule ways that the materials the agency proposes to incorporate by reference are reasonably available to interested parties or how the agency worked to make the materials reasonably available.

Additionally, the preamble to the proposed rule must summarize the materials. See also section III.C.10. of this proposed rule for summaries of the standards proposed for incorporation by reference by ONC.

Consistent with those requirements CMS has established procedures to ensure that interested parties can review and inspect relevant materials. The proposals related to the Part D electronic prescribing standards have relied on the following materials which we propose to incorporate by reference where specified:

- NCPDP SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017, which is currently incorporated by reference at § 423.160(c)(1)(vii). We propose to renumber this incorporation by reference as § 423.160(c)(2);

- NCPDP SCRIPT Standard, Implementation Guide Version 2023011, published April 2023, (Approval Date for American National Standards Institute [ANSI]: January 17, 2023). We propose to incorporate by reference at § 423.160(c)(3);

- NCPDP Real-Time Prescription Benefit Standard, Implementation Guide Version 13, published July 2023 (Approval Date for ANSI: May 19, 2022). We propose to incorporate by reference at § 423.160(c);

- NCPDP Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), published April 2012, which is currently incorporated by reference at § 423.160(c)(1)(vi). We propose to renumber this incorporation by reference at § 423.160(c)(1); and

- NCPDP Formulary and Benefit Standard, Implementation Guide Version 60, published April 2023 (Approval Date for ANSI: April 12, 2023). We propose to incorporate by reference at § 423.160(c)(5).

NCPDP members may access these materials through the member portal at www.ncdp.org. Non-NCPDP members may obtain these materials for information purposes by contacting the CMS at 7500 Security Boulevard, Baltimore, Maryland 21244 by calling (410) 786-4132 or (877) 267-2323 (toll free), or emailing PartDPolicy@cms.hhs.gov.

C. Adoption of Health IT Standards and Incorporation by Reference (45 CFR 170.205 and 170.299)

1. Overview

In this section, ONC proposes to adopt standards for electronic prescribing and related activities on behalf of HHS under the authority in

section 3004 of the Public Health Service Act (42 U.S.C. 300jj-14). ONC is proposing these standards for adoption by HHS as part of a nationwide health information technology infrastructure that supports reducing burden and health care costs and improving patient care. ONC proposes to adopt these standards on behalf of HHS in one location within the Code of Federal Regulations for HHS use, including by the Part D Program as proposed in section III.B. of this proposed rule. These proposals reflect a unified approach across the Department to adopt standards for electronic prescribing (e-prescribing) activities that have previously been adopted separately by CMS and ONC under independent authorities. This approach is intended to increase alignment across HHS and reduce regulatory burden for interested parties subject to program requirements that incorporate these standards.

In the Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications” (December 2022 proposed rule), which appeared in the **Federal Register** December 27, 2022 (87 FR 79552 through 79557), we proposed the adoption of NCPDP SCRIPT standard version 2022011 and NCPDP Real-Time Prescription Benefit standard version 13, as well as related proposals. We considered whether to issue a final rule based on that proposed rule, but considering the concerns raised by the commenters regarding which version of the standards to use, we have opted not to do so. Specifically, some commenters recommended adoption of NCPDP SCRIPT standard version 2023011, rather than the proposed NCPDP SCRIPT standard version 2022011. Other commenters recommended adoption of NCPDP RTPB standard version 13, rather than the proposed NCPDP RTPB standard version 12. See additional discussion in section III.B.5. of this rule. Therefore, we are withdrawing the proposals in sections III.T. and III.U. of the December 2022 proposed rule (87 FR 79552 through 79557). We are issuing a series of new proposals in this proposed rule that take into consideration the feedback we received from commenters on the December 2022 proposed rule and

further build on these proposals. Additionally, summaries of the standards we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations can be found below in section III.C.10. of this rule.

2. Statutory Authority

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (the Recovery Act) (Pub. L. 111-5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created “Title XXX—Health Information Technology and Quality” (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health IT and exchange of electronic health information (EHI). Subsequently, Title IV of the 21st Century Cures Act (Pub. L. 114-255) (Cures Act) amended portions of the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

3. Adoption of Standards and Implementation Specifications

Section 3001 of the PHSA directs the National Coordinator for Health Information Technology (National Coordinator) to perform duties in a manner consistent with the development of a nationwide health information technology infrastructure that allows for the electronic use and exchange of information. Section 3001(b) of the PHSA establishes a series of core goals for development of a nationwide health information technology infrastructure that—

- Ensures that each patient’s health information is secure and protected, in accordance with applicable law;
- Improves health care quality, reduces medical errors, reduces health disparities, and advances the delivery of patient-centered medical care;
- Reduces health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care, and incomplete information;
- Provides appropriate information to help guide medical decisions at the time and place of care;
- Ensures the inclusion of meaningful public input in such development of such infrastructure;
- Improves the coordination of care and information among hospitals, laboratories, physician offices, and other entities through an effective infrastructure for the secure and authorized exchange of health care information;

- Improves public health activities and facilitates the early identification and rapid response to public health threats and emergencies, including bioterror events and infectious disease outbreaks;
- Facilitates health and clinical research and health care quality;
- Promotes early detection, prevention, and management of chronic diseases;
- Promotes a more effective marketplace, greater competition, greater systems analysis, increased consumer choice, and improved outcomes in health care services; and
- Improves efforts to reduce health disparities.

Section 3004 of the PHSA identifies a process for the adoption of health IT standards, implementation specifications, and certification criteria, and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1) of the PHSA, the Secretary is required, in consultation with representatives of other relevant Federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) of the PHSA and subsequently determine whether to propose the adoption of any grouping of such standards, implementation specifications, or certification criteria. The Secretary is required to publish all determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA, which is titled “Subsequent Standards Activity,” provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the Health IT Advisory Committee (HITAC). As noted in the final rule, “2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications,” which appeared in the October 16, 2015 **Federal Register**, we consider this provision in the broader context of the HITECH Act and the Cures Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria (80 FR 62606).

Under the authority outlined in section 3004(b)(3) of the PHSA, the Secretary may adopt standards, implementation specifications, and certification criteria as necessary even if those standards have not been recommended and endorsed through the process established for the HITAC under section 3002(b)(2) and (3) of the PHSA. Moreover, while HHS has traditionally adopted standards and implementation specifications at the same time as adopting certification criteria that reference those standards, the Secretary’s authority under section 3004(b)(3) of the PHSA is not limited to adopting standards or implementation specifications at the same time certification criteria are adopted.

Finally, the Cures Act amended the PHSA by adding section 3004(c), which specifies that in adopting and implementing standards under section 3004, the Secretary shall give deference to standards published by standards development organizations and voluntary consensus-based standards bodies.

4. Alignment With Federal Advisory Committee Activities

The HITECH Act established two Federal advisory committees, the HIT Policy Committee (HITPC) and the HIT Standards Committee (HITSC). Each was responsible for advising the National Coordinator on different aspects of health IT policy, standards, implementation specifications, and certification criteria.

Section 4003(e) of the Cures Act amended section 3002 of the PHSA and replaced the HITPC and HITSC with one committee, the HITAC. After that change, section 3002(a) of the PHSA establishes that the HITAC advises and recommends to the National Coordinator standards, implementation specifications, and certification criteria relating to the implementation of a health IT infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. The Cures Act specifically directed the HITAC to advise on two areas: (1) A policy framework to advance an interoperable health information technology infrastructure (section 3002(b)(1) of the PHSA); and (2) priority target areas for standards, implementation specifications, and certification criteria (section 3002(b)(2) of the PHSA).

For the policy framework, as described in section 3002(b)(1)(A) of the PHSA, the Cures Act tasked the HITAC with providing recommendations to the National Coordinator on a policy framework for adoption by the Secretary

consistent with the Federal Health IT Strategic Plan under section 3001(c)(3) of the PHSA. In February of 2018, the HITAC made recommendations to the National Coordinator for the initial policy framework³⁷ and subsequently published a schedule in the **Federal Register** and an annual report on the work of the HITAC and ONC to implement and evolve that framework.³⁸ For the priority target areas for standards, implementation specifications, and certification criteria, section 3002(b)(2)(A) of the PHSA identified that in general, the HITAC would recommend to the National Coordinator, for purposes of adoption under section 3004 of the PHSA, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. In October of 2019, the HITAC finalized recommendations on priority target areas for standards, implementation specifications, and certification criteria.³⁹

5. Aligned Approach to Standards Adoption

Historically, the ONC Health IT Certification Program and the Part D Program have maintained complementary policies of aligning health IT certification criteria and associated standards related to electronic prescribing, medication history, and electronic prior authorization for prescriptions. While CMS and ONC have worked closely together to ensure consistent adoption of standards through regulatory actions, we recognize that the practice of different HHS components conducting parallel adoption of the same standards may result in additional regulatory burden and confusion for interested parties. For instance, due to discrepancies between regulatory timelines, adoption of the NCPDP SCRIPT standard version 2017071 in different rules (respectively, 21st Century Cures Act: Interoperability, Information Blocking, and the ONC

³⁷ HITAC Policy Framework Recommendations, February 21, 2018: https://www.healthit.gov/sites/default/files/page/2019-07/2018-02-21_HITAC_Policy-Framework_FINAL_508-signed.pdf.

³⁸ Health Information Technology Advisory Committee (HITAC) Annual Report for Fiscal Year 2019 published March 2, 2020: https://www.healthit.gov/sites/default/files/page/2020-03/HITAC%20Annual%20Report%20for%20FY19_508.pdf.

³⁹ HITAC recommendations on priority target areas, October 16, 2019: https://www.healthit.gov/sites/default/files/page/2019-12/2019-10-16_ISP_TF_Final_Report_signed_508.pdf.

Health IT Certification Program final rule (85 FR 25642) and the Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program final rule which appeared in the April 16, 2018 **Federal Register** (83 FR 16440)) led to a period where ONC had to exercise special enforcement discretion in the ONC Health IT Certification Program.⁴⁰ Given these concerns, ONC and CMS proposals in the December 2022 proposed rule (87 FR 79552 through 79557) reflected a new approach to alignment of standards under which ONC proposed to adopt and incorporate by reference, on behalf of HHS, the NCPDP SCRIPT standard version 2022011 and the NCPDP RTPB standard version 12 in a single Code of Federal Regulations location at 45 CFR 170.205, where CMS proposed to cross-reference these standards for requirements in the Part D program.

For additional discussion of this approach see the December 2022 proposed rule (87 FR 79552 through 79557) and CMS's discussion in sections III.B.3 through III.B.7. of this proposed rule. We note that the proposals in this rule continue to reflect an aligned approach with CMS to adoption of health IT standards for e-prescribing and related purposes. We believe our proposed adoption of these standards in a single CFR location for HHS use will help to address concerns around alignment across HHS programs.

6. Regulatory History

For a summary of past standards adoption activities under section 3004 of the PHSA intended to ensure alignment for electronic prescribing and related activities across the ONC Health IT Certification Program and the Part D Program, we refer readers to the December 2022 proposed rule (87 FR 79553). In this proposed rule, we also propose to adopt the NCPDP Formulary and Benefit (F&B) standard version 60, which was not previously discussed in the December 2022 proposed rule (87 FR 79553). For a summary of previous notice-and-comment rulemaking related to formulary and benefit management capabilities in the ONC Health IT Certification Program, we refer readers to the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and

Information Sharing" proposed rule (HTI-1 Proposed Rule) (88 FR 23853 through 23854).

7. Interoperability Standards Advisory

ONC's Interoperability Standards Advisory (ISA) supports the identification, assessment, and public awareness of interoperability standards and implementation specifications that can be used by the health care industry to address specific interoperability needs.⁴¹ The ISA is updated on an annual basis based on recommendations received from public comments and subject matter expert feedback. This public comment process reflects ongoing dialogue, debate, and consensus among industry interested parties when more than one standard or implementation specification could be used to address a specific interoperability need.

ONC currently identifies the standards proposed for adoption in this section within the ISA as available standards for a variety of potential use cases. The NCPDP SCRIPT standard version 2023011, the NCPDP Real-Time Prescription Benefit standard version 13, and the NCPDP Formulary and Benefits standard version 60 are currently identified in sections of the ISA including the "Pharmacy Interoperability"⁴² and "Administrative Transactions—Non-Claims."⁴³ We encourage interested parties to review the ISA to better understand key applications for the implementation specifications proposed for adoption in this proposed rule.

8. Proposal To Adopt Standards for Use by HHS

Consistent with section 3004(b)(3) of the PHSA and the efforts, as previously described, to evaluate and identify standards for adoption, we propose to adopt the following implementation specifications in 45 CFR 170.205(b)(2), (c)(1), and (u)(1), on behalf of the Secretary, to support the continued development of a nationwide health information technology infrastructure as described under section 3001(b) of the PHSA, and to support Federal alignment of standards for interoperability and health information exchange. Specifically, we propose to adopt the following standards:

- NCPDP SCRIPT Standard, Implementation Guide, Version 2023011.

- NCPDP Real-Time Prescription Benefit (RTPB) Standard, Implementation Guide, Version 13.
- NCPDP Formulary and Benefits (F&B) Standard, Implementation Guide, Version 60.

In addition to comments on the individual proposals below, we invite comments on whether there are alternative versions, including any newer versions, of these or other standards that we should consider for adoption for HHS use. In particular, we would be interested in, and would consider for adoption in a final rule, any newer version of the proposed standard(s) that may correct any unidentified errors or clarify ambiguities that would support successful implementation of the standard(s) and the interoperability of health IT.

a. NCPDP SCRIPT Standard Version 2023011 (45 CFR 170.205(b))

ONC has previously adopted three versions of the NCPDP SCRIPT standard in 45 CFR 170.205. Most recently, we adopted NCPDP SCRIPT standard version 2017071 in the ONC 21st Century Cures Act final rule to facilitate the transfer of prescription data among pharmacies, prescribers, and payers (85 FR 25678).

The updated NCPDP SCRIPT standard version 2023011 includes important enhancements relative to NCPDP SCRIPT standard version 2017071. Enhancements have been added to support electronic prior authorization functions as well as electronic transfer of prescriptions between pharmacies. NCPDP SCRIPT standard version 2023011 also includes functionality that supports a 3-way transaction among prescriber, facility, and pharmacy, which will enable electronic prescribing of controlled substances in the long-term care (LTC) setting.⁴⁴

We propose to adopt NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2), replacing NCPDP SCRIPT standard version 10.6 which is currently in 170.205(b)(2). We propose to incorporate NCPDP SCRIPT standard version 2023011 by reference in 45 CFR 170.299. Regarding NCPDP SCRIPT standard version 2017071, we propose to revise the regulatory text in 45 CFR 170.205(b)(1) to specify that adoption of this standard will expire on January 1, 2027. If these proposals are finalized, this would mean that both the 2017071 and 2023011 versions of the NCPDP SCRIPT standard would be available for

⁴⁰ See the archived version of the Certification Companion Guide for the "electronic prescribing" certification criterion in 45 CFR 170.315(b)(3): https://www.healthit.gov/sites/default/files/page/2020-12/b3_ccg.pdf.

⁴¹ See <https://www.healthit.gov/isa>.

⁴² See <https://www.healthit.gov/isa/section/pharmacyinteroperability>.

⁴³ See <https://www.healthit.gov/isa/section/administrative-transactions-non-claims>.

⁴⁴ See https://standards.ncdpd.org/Standards/media/pdf/Correspondence/2023/20230213_To_CMS_CMS_4201_P_NPRM.pdf.

HHS use from the effective date of a final rule until January 1, 2027. On and after January 1, 2027, only the 2023011 version of the NCPDP SCRIPT standard would be available for HHS use, for instance, where use of a standard in 45 CFR 170.205(b) is required. We refer readers to section III.B.4. of this proposed rule, where CMS discusses its proposal at § 423.160(b)(1) to require use of a standard in 45 CFR 170.205(b) for communication of a prescription or prescription-related information to fulfill the requirements for prescriptions, electronic prior authorization, and medication history.

We request comment on these proposals.

b. NCPDP Real-Time Prescription Benefit (RTPB) Standard Version 13 (45 CFR 170.205(c))

The NCPDP Real-Time Prescription Benefit standard version 13 enables the exchange of coverage status and estimated patient financial responsibility for a submitted product and pharmacy, and identifies coverage restrictions and alternatives when they exist. See section III.B.5. of this proposed rule for a description of Real-Time Prescription Benefit standard functionality and enhancements of NCPDP Real-Time Prescription Benefit standard version 13 relative to NCPDP Real-Time Prescription Benefit standard version 12.

Our proposal to adopt this standard supports the requirements of Division CC, Title I, Subtitle B, section 119 of the Consolidated Appropriations Act, 2021 (CAA), Public Law 116–260, which required sponsors of Medicare prescription drug plans to implement a real-time benefit tool that meets technical standards named by the Secretary, in consultation with ONC. In addition, section 119(b) of the CAA amended the definition of a “qualified electronic health record” in section 3000(13) of the PHSA to specify that a “qualified electronic health record” must include or be capable of including a real-time benefit tool. ONC intends to address this provision in future rulemaking for the ONC Health IT Certification Program and will ensure alignment with the proposed NCPDP Real-Time Prescription Benefit standard version 13, if finalized, and related proposals in the Part D program where appropriate.

We also note that the HITAC has previously addressed real-time prescription benefit standards, consistent with its statutory role to recommend standards. In 2019, the HITAC accepted the recommendations included in the 2018 report of the

Interoperability Priorities Task Force, including recommendations to continue to monitor standards then being developed for real-time prescription benefit transactions, and, when the standards are sufficiently validated, to require EHR vendors to provide functionality that integrates real time patient-specific prescription benefit checking into the prescribing workflow.⁹ In early 2020, the National Committee on Vital and Health Statistics (NCVHS) and HITAC convened another task force, the Intersection of Clinical and Administrative Data (ICAD) Task Force, which was charged with convening industry experts and producing recommendations related to electronic prior authorizations. The task force report was presented to HITAC in November 2020¹⁰ and discussed the NCPDP Real-Time Prescription Benefit standard as an important tool for addressing administrative transactions around prescribing.

We are proposing in 45 CFR 170.205(c) to add a new section heading “Real-Time Prescription Benefit.” We are also proposing to adopt the NCPDP Real-Time Prescription Benefit standard version 13⁴⁵ in 45 CFR 170.205(c)(1) and to incorporate this standard by reference in 45 CFR 170.299. We refer readers to section III.B.5. of this rule, where CMS proposes at § 423.160(b)(5) to require Part D sponsors’ RTBTs to comply with a standard in 45 CFR 170.205(c) by January 1, 2027, to fulfill the requirements for real-time benefit tools. As previously noted, ONC will consider proposals to require use of this standard to support real-time benefit tool functionality in the ONC Health IT Certification Program, consistent with section 119 of the CAA, in future rulemaking.

We request comment on these proposals.

c. NCPDP Formulary and Benefit (F&B) Standard Version 60 (45 CFR 170.205(u))

The NCPDP Formulary and Benefit (F&B) standard version 60⁴⁶ provides a uniform means for prescription drug plan sponsors to communicate plan-level formulary and benefit information to prescribers through electronic prescribing/EHR systems. The NCPDP F&B standard transmits, on a batch basis, data on the formulary status of drugs, preferred alternatives, coverage restrictions (that is., utilization

management requirements), and cost sharing consistent with the benefit design for example, cost sharing for drugs on a particular tier). The NCPDP F&B standard serves as a foundation for other electronic prescribing transactions including ePA, real-time benefit check, and specialty medication eligibility when used in conjunction with other standards.

We propose to add a new paragraph heading at 45 CFR 170.205(u), “Formulary and benefit.” We propose to adopt the NCPDP Formulary and Benefit standard version 60 at 45 CFR 170.205(u)(1) and to incorporate this standard by reference in 45 CFR 170.299. We refer readers to section III.B.6. of this proposed rule, where CMS proposes at § 423.160(b)(3) to require, by January 1, 2027, use of a standard in 45 CFR 170.205(u) by Part D plan sponsors to fulfill the requirements for exchange of formulary and benefit information with prescribers.

9. ONC Health IT Certification Program

We are not proposing new or revised certification criteria based on the proposed adoption of standards within this rulemaking. We note that section 119 of the CAA does not require ONC to adopt certification criteria for real-time prescription benefit capabilities at the same time as a standard is adopted by HHS. We are therefore proposing to adopt the standard for HHS use and, as previously discussed, ONC would address new or revised certification criteria referencing the standard, if finalized, in separate rulemaking. ONC recently published a Request for Information in the HTI–1 Proposed Rule seeking information related to a real-time prescription benefit criterion (88 FR 23853 through 23854). ONC will continue to collaborate with CMS to ensure that any future proposals in the ONC Health IT Certification Program continue to advance alignment with program requirements under the Part D Program.

We believe the approach reflected in the standards proposals in this proposed rule will support Federal alignment and coordination of Federal activities with adopted standards and implementation specifications for a wide range of systems, use cases, and data types within the broad scope of health information exchange. Historically, State, Federal, and local partners have leveraged the standards adopted by ONC on behalf of HHS to inform program requirements, technical requirements for grants and funding opportunities, and systems implementation for health information

⁴⁵ See <https://standards.ncdpd.org/Access-to-Standards.aspx>.

⁴⁶ See <https://standards.ncdpd.org/Access-to-Standards.aspx>.

exchange. We believe the adoption of these standards will support HHS partners in setting technical requirements and advancing the use of innovative health IT solutions for electronic prescribing and related activities.

10. Incorporation by Reference (45 CFR 170.299)

The Office of the Federal Register has established requirements for materials (for example, standards and implementation specifications) that agencies propose to incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5(a)). Specifically, 1 CFR 51.5(a) requires agencies to discuss, in the preamble of a proposed rule, the ways that the materials it proposes to incorporate by reference are reasonably available to interested parties or how it worked to make those materials reasonably available to interested parties; and summarize, in the preamble of the proposed rule, the material it proposes to incorporate by reference.

To make the materials we intend to incorporate by reference reasonably available, we provide a uniform resource locator (URL) for the standards and implementation specifications. In many cases, these standards and implementation specifications are directly accessible through the URLs provided. In instances where they are not directly available, we note the steps and requirements necessary to gain access to the standard or implementation specification. In most of these instances, access to the standard or implementation specification can be gained through no-cost (monetary) participation, subscription, or membership with the applicable standards developing organization (SDO) or custodial organization. In certain instances, where noted, access requires a fee or paid membership. As an alternative, a copy of the standards may be viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201. Please call (202) 690-7171 in advance to arrange inspection.

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A-119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA

and OMB Circular A-119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. We have followed the NTTAA and OMB Circular A-119 in proposing standards and implementation specifications for adoption, and note that the technical standards proposed for adoption in 45 CFR 170.205 in this proposed rule were developed by NCPDP, which is an ANSI-accredited, not-for-profit membership organization using a consensus-based process for standards development.

As required by 1 CFR 51.5(a), we provide summaries of the standards we propose to adopt and subsequently incorporate by reference in the Code of Federal Regulations. We also provide relevant information about these standards and implementation specifications in the preamble where these standards are proposed for adoption. We propose to revise § 170.299(k) with the following updated standards:

- National Council for Prescription Drug Programs (NCPDP) SCRIPT Standard, Implementation Guide, Version 2023011, April 2023 (Approval Date for ANSI: January 17, 2023)

URL: <https://standards.ncdpd.org/Access-to-Standards.aspx>.

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

Summary: SCRIPT is a standard created to facilitate the transfer of prescription data between pharmacies, prescribers, and payers. The current standard supports transactions regarding new prescriptions, prescription changes, renewal requests, prescription fill status notification, and prescription cancellation. Enhancements have been added for drug utilization review/use (DUR/DUE) alerts and formulary information as well as transactions to relay medication history and for a facility to notify a pharmacy of resident information. Enhancements have been added to support electronic prior authorization functions as well as electronic transfer of prescriptions between pharmacies.

- National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, July 2023 (Approval Date for ANSI: May 19, 2022)

URL: <https://standards.ncdpd.org/Access-to-Standards.aspx>.

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

Summary: The NCPDP Real-Time Prescription Benefit Standard Implementation Guide is intended to meet the industry need within the pharmacy services sector to facilitate the ability for pharmacy benefit payers/processors to communicate to providers and to ensure a consistent implementation of the standard throughout the industry. The Real-Time Prescription Benefit (RTPB) Standard enables the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions, and alternatives when they exist.

- National Council for Prescription Drug Programs (NCPDP) Formulary and Benefit Standard, Implementation Guide, Version 60, April 2023 (Approval Date for ANSI: April 12, 2023)

URL: <https://standards.ncdpd.org/Access-to-Standards.aspx>.

Access requires registration, a membership fee, a user account, and a license agreement to obtain a copy of the standard.

Summary: The NCPDP Formulary and Benefit Standard Implementation Guide is intended to provide a standard means for pharmacy benefit payers (including health plans and Pharmacy Benefit Managers) to communicate formulary and benefit information to prescribers via technology vendor systems.

D. Improvements to Drug Management Programs (§§ 423.100 and 423.153)

Section 1860D-4(c)(5)(A) of the Social Security Act (the Act) requires that Part D sponsors have a drug management program (DMP) for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs), currently defined by CMS as opioids and benzodiazepines. CMS codified the framework for DMPs at § 423.153(f) in the April 16, 2018 final rule “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Programs, and the PACE Program” (83 FR 16440),

hereafter referred to as the April 2018 final rule.

Under current DMP policy, CMS identifies potential at-risk beneficiaries (PARBs) who meet the clinical guidelines described at § 423.153(f)(16), which CMS refers to as the minimum Overutilization Monitoring System (OMS) criteria. CMS, through the OMS, reports such beneficiaries to their Part D plans for case management under their DMP. There are also supplemental clinical guidelines, or supplemental OMS criteria, which Part D sponsors can apply themselves to identify additional PARBs. Under § 423.153(f)(2), sponsors are required to conduct case management for PARBs, which must include informing the beneficiary's prescribers of their potential risk for misuse or abuse of FADs and requesting information from the prescribers relevant to evaluating the beneficiary's risk, including whether they meet the regulatory definition of exempted beneficiary.

If the sponsor determines through case management that the enrollee is an at-risk beneficiary (ARB), after notifying the beneficiary in writing, the sponsor may limit their access to opioids and/or benzodiazepines to a selected prescriber and/or network pharmacy(ies) and/or through a beneficiary-specific point-of-sale claim edit, in accordance with the requirements at § 423.153(f)(3). CMS regulations at § 423.100 define exempted beneficiary, at-risk beneficiary, potential at-risk beneficiary, and frequently abused drug.

1. Definition of Exempted Beneficiary § 423.100

Section 1860D–4(c)(5)(C)(ii) of the Act defines an exempted individual as one who receives hospice care, who is a resident of a long-term care facility for which frequently abused drugs are dispensed for residents through a contract with a single pharmacy, or who the Secretary elects to treat as an exempted individual. At § 423.100 CMS defines an exempted beneficiary as an enrollee being treated for active cancer-related pain, or has sickle-cell disease, residing in a long-term care facility, has elected to receive hospice care, or is receiving palliative or end-of-life care.

The OMS criteria finalized in the April 2018 final rule were developed to align with available information and guidelines, such as the Centers for Disease Control and Prevention (CDC) Guideline for Prescribing Opioids for Chronic Pain (2016 CDC Guideline) issued in March 2016.⁴⁷ The current

policy to exempt beneficiaries with cancer from DMPs was developed through feedback from interested parties and alignment with the 2016 CDC Guideline's active cancer treatment exclusion. Patients within the scope of the 2016 CDC Guideline included cancer survivors with chronic pain who have completed cancer treatment, were in clinical remission, and were under cancer surveillance only. The 2022 CDC Clinical Practice Guideline for Prescribing Opioids for Pain (2022 CDC Guideline)⁴⁸ expands and updates the 2016 CDC Guideline to provide evidence-based recommendations for prescribing opioid pain medication for acute, subacute, and chronic pain for outpatients aged ≥18 years, excluding pain management related to sickle cell disease, cancer-related pain treatment, palliative care, and end-of-life care.

In the interest of alignment with the 2022 CDC Guideline regarding applicability in individuals with cancer, we are proposing to amend the regulatory definition of “exempted beneficiary” at § 423.100 by replacing the reference to “active cancer-related pain” with “cancer-related pain.” With this proposal we expand the definition of exempted beneficiary to more broadly refer to enrollees being treated for cancer-related pain to include beneficiaries undergoing active cancer treatment, as well as cancer survivors with chronic pain who have completed cancer treatment, are in clinical remission, or are under cancer surveillance only.

2. Drug Management Program Notices: Timing and Exceptions § 423.153(f)(8)

As discussed above, sponsors must provide case management for any PARB that meets the OMS criteria to determine whether the individual is an ARB and whether to implement a limitation on their access to FADs. Under section 1860D–4(c)(5)(B)(i)(I) of the Act, a sponsor must send an initial and second notice to such beneficiary prior to imposing such limitation. In the April 2018 final rule (83 FR 16440), CMS adopted requirements for the initial and second notices at § 423.153(f)(5) and (6). The initial notice must inform the beneficiary that they have been identified as a PARB and must include information outlined in § 423.153(f)(5)(ii). The second notice must inform the beneficiary that they have been identified as an ARB and of the limitations on the beneficiary's coverage of FADs, as specified in § 423.153(f)(6)(ii). In the event that, after

sending an initial notice, a sponsor determines that a PARB is not an ARB, a second notice would not be sent; instead, an alternate second notice would be sent. Though not required by the Act, CMS codified a requirement at § 423.153(f)(7) to provide an alternate second notice for the purpose of informing the beneficiary that they are not an ARB and that no limitation on their coverage of FADs will be implemented under the DMP.

Section 1860D–4(c)(5)(B)(iv) of the Act establishes that sponsors must send a second notice on a date that is not less than 30 days after the initial notice. The 30 days allow sufficient time for the beneficiary to provide information relevant to the sponsor's determination, including their preferred prescribers and pharmacies. CMS codified at § 423.153(f)(8) the timing for providing both the second notice and alternate second notice. Currently, CMS requires sponsors to send either the second or alternate second notice on a date not less than 30 days from the date of the initial notice and not more than the earlier of the date the sponsor makes the determination or 60 days after the date of the initial notice.

Based on program experience during the first several years of DMPs, we propose to change the timeframe within which a sponsor must provide an alternate second notice to a beneficiary who is determined to be exempt from the DMP subsequent to receiving an initial notice. Specifically, we propose to redesignate existing § 423.153(f)(8)(ii) as § 423.153(f)(8)(iii), and to revise the text at § 423.153(f)(8)(ii) to specify that, for such exempted beneficiaries, the sponsor must provide the alternate second notice within 3 days of determining the beneficiary is exempt, even if that occurs less than 30 days from the date of the initial notice. In other words, we propose to remove the requirement that sponsors wait at least 30 days from the date of the initial notice to send the alternate second notice to exempted beneficiaries.

Through program oversight, including audits of Part D sponsors, CMS has observed that initial notices are sometimes sent to Part D enrollees who meet the definition of an exempted beneficiary at § 423.100, often because the sponsor does not have the necessary information—for example, that the enrollee has a cancer diagnosis or is receiving palliative care or end-of-life care—at the time the sponsor sends the initial notice. However, this information may be provided later by the enrollee or their prescriber in response to the initial notice. In some cases, sponsors identify exemptions very quickly after issuing

⁴⁷ <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>.

⁴⁸ <https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm>.

the initial notice, prior to 30 days elapsing. Under current CMS regulations, if a beneficiary meets the definition of an exempted beneficiary, the beneficiary does not meet the definition of a PARB. For this reason, exempted beneficiaries cannot be placed in a Part D sponsor's DMP. Therefore, as stated in the preamble to the April 2018 final rule (83 FR 16455), a sponsor must remove an exempted beneficiary from a DMP as soon as it reliably learns that the beneficiary is exempt (whether that be via the beneficiary, their representative, the facility, a pharmacy, a prescriber, or an internal or external data source, including an internal claims system). CMS understands that sponsors may have already been sending alternate second notices after determining that a beneficiary is exempt, without waiting for 30 days to elapse. This proposed change would specify that it is required to send such notices to exempted beneficiaries sooner than 30 days after the provision of the initial notice.

CMS reminds Part D sponsors that, during their review and during case management, they are expected to use all available information to identify whether a PARB is exempt in advance of sending an initial notice to protect these vulnerable beneficiaries from unnecessary burden, anxiety, and disruptions in medically necessary drug therapy. Thorough review of plan records and robust outreach efforts to prescribers during case management help to minimize the risk that an exempted beneficiary would receive an initial notice.

On April 20, 2023, CMS released updated DMP guidance.⁴⁹ Sections 8.1 and 8.2.2 of the guidance state that if a sponsor learns that a beneficiary is exempt after sending an initial notice, the sponsor should inform the beneficiary that the initial notice is rescinded. If less than 30 days have passed since the initial notice, a sponsor should send a Part D Drug Management Program Retraction Notice for Exempted Beneficiaries. The model retraction notice addresses the required 30-day timing issue in the current regulation. If this proposal to require sponsors to provide an alternate second notice to a beneficiary who is determined to be exempt from the DMP prior to the required 30 days elapsing since the initial notice is finalized, the Part D Drug Management Program Retraction Notice for Exempted Beneficiaries would no longer be used because sponsors would instead send the

alternate second notice. We are not estimating any reduction of burden for sponsors no longer using the Retraction Notice. The Retraction Notice was implemented as a temporary solution for Part D sponsors to use for exempted beneficiaries in place of the alternate second notice, which had been accounted for in the latest version of CMS-10141 (OMB control number 0938-0964).

We note that sponsors may determine that a PARB is not an ARB prior to 30 days elapsing for reasons other than the beneficiary being exempted. However, we believe the current 30-day requirement before a sponsor may send an alternate second notice in such situations is important to maintain because it allows the beneficiary and other prescribers enough time to provide the sponsor with information that may influence the sponsor's determination.

We propose an additional technical change related to the timeframe for providing second and alternate second notices. The current regulation at § 423.153(f)(8)(i) requires that a sponsor provide a second or alternate second notice not more than the earlier of the date the sponsor makes the relevant determination or 60 days after the date of the initial notice. It is critical that beneficiaries receive timely written notice about changes to their access to Part D drugs, as well as information about appeal rights, and the second and alternate second notices are tied to the date of the plan's determination. However, CMS understands that sponsors may not always be able to issue printed notices on the exact day they make a determination for a variety of reasons, such as they made the determination on a day when there is no USPS mail service, or later in the day after files have been sent to a print vendor.

Specifically, we propose to add at § 423.153(f)(8)(i)(A) a window of up to 3 days to allow for printing and mailing the second notice or alternate second notice. We note a 3-day window would align with requirements for providing written notice of a standard or expedited Part D coverage determination after initial oral notice, as described at §§ 423.568(d) and (f) and 423.572(b), respectively, and is therefore familiar to sponsors. However, unlike the circumstances covered by those regulatory provisions, sponsors would not be providing an initial oral notice, as it would be impracticable to verbally convey the details of a second notice or alternate second notice to an enrollee. This proposed change would provide sponsors sufficient time to print and

mail the notices while ensuring that beneficiaries receive timely information about DMP limitations. Sponsors must continue to issue these notices as soon as possible when a determination is made, and CMS does not expect that sponsors will routinely take the maximum amount of time.

We are not proposing to change the requirement in § 423.153(f)(8)(i)(B) that the second notice or alternate second notice must be provided no later than 60 days from the date of the initial notice. This is because sponsors have ample time to account in advance for the days needed to print and mail these notices.

3. OMS Criteria Request for Feedback

CMS regulations at § 423.153(f)(16) specify that PARBs and ARBs are identified using clinical guidelines that are developed with stakeholder consultation, derived from expert opinion backed by analysis of Medicare data, and include a program size estimate. In addition, the clinical guidelines (also referred to as the "OMS criteria") are based on the acquisition of FADs from multiple prescribers, multiple pharmacies, the level of FADs used, or any combination of these factors, or a history of opioid-related overdose.

PARBs are the Part D beneficiaries whom CMS believes are potentially at the highest risk of opioid-related adverse events or overdose. The current minimum OMS criteria⁵⁰ identifies PARBs who (1) use opioids with an average daily morphine milligram equivalents (MME) of greater or equal to 90 mg for any duration during the most recent six months, who have received opioids from 3 or more opioid prescribers and 3 or more opioid dispensing pharmacies, or from 5 or more opioid prescribers regardless of the number of dispensing pharmacies (also referred to as "MIN1" minimum OMS criteria), or (2) have a history of opioid-related overdose, with a medical claim with a primary diagnosis of opioid-related overdose within the most recent 12 months and a Part D opioid prescription (not including Medication for Opioid Use Disorder⁵¹ (MOUD)) within the most recent 6 months (also referred to as "MIN2" minimum OMS criteria). The current supplemental OMS criteria are for sponsors to address plan members who are receiving opioids from a large number of prescribers or

⁴⁹ April 20, 2023 HPMS memorandum, CORRECTION—Contact Year 2023 Drug Management Program Guidance available at: <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/rxutilization>.

⁵¹ Referred to as medication-assisted treatment (MAT) in past guidance.

⁴⁹ <https://www.cms.gov/files/zip/cy-2023-part-d-dmp-guidance-april-20-2023.zip>.

pharmacies, but who do not meet a particular MME threshold. These are (1) use of opioids (regardless of average daily MME) during the most recent 6 months; AND (2) 7 or more opioid prescribers OR 7 or more opioid dispensing pharmacies.

In 2019, CMS assigned the Health Federally Funded Research and Development Center (FFRDC) to develop evidence-based recommendations for improving the OMS criteria for the future. The Health FFRDC conducted a literature review, facilitated a Technical Expert Panel (TEP), and performed data analyses. All three activities served as inputs into the evidence-based recommendations. The Health FFRDC recommended that the results of the literature review and data analysis support the continued inclusion of average MME, number of opioid dispensing pharmacies, and number of opioids prescribers as indicators for PARBs. In addition, they recommended that further data analysis would be necessary to determine which additional criteria would be appropriate to potentially adopt. CMS conducted subsequent literature reviews and analysis.

In recent years, there has been a marked decrease in Medicare Part D prescription opioid overutilization, but opioid-related overdose deaths continue to be a growing problem throughout the United States.⁵² While the CDC found synthetic opioids (other than methadone) to be the main driver of opioid overdose deaths, accounting for 82 percent of all opioid-involved deaths in 2020,⁵³ we must remain vigilant regarding the risks of prescription opioids including misuse, opioid use disorder (OUD), overdoses, and death. CMS tracks prevalence rates for Medicare Part D beneficiaries with an OUD⁵⁴ diagnosis and beneficiaries with an opioid poisoning (overdose). While overall opioid-related overdose prevalence rates among Medicare Part D enrollees have declined over the period from contract year 2017 through 2021 at about 6.5 percent per annum, overall opioid-related overdose prevalence rates increased by 1.0 percent between 2020 and 2021. Furthermore, about 1.6 percent of all Part D enrollees had a provider diagnosed OUD in contract

year 2021 and the OUD prevalence rate has grown by 3.2 percent per annum since contract year 2017.

A past overdose is the risk factor most predictive for another overdose or suicide-related event.⁵⁵ CMS finalized regulations to implement section 2004 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act to include beneficiaries with a history of opioid-related overdose as PARBs in DMPs. While the implementation of the SUPPORT ACT enables identification of beneficiaries with a history of opioid-related overdose and continues to identify PARBs who receive high levels of opioids through multiple providers who may be more likely to misuse prescription opioids,⁵⁶ CMS is working on models that can identify beneficiaries potentially at risk before their risk level is diagnosed as an OUD or the person experiences an opioid-related overdose.

A recently published article that evaluated the use of machine learning algorithms for predicting opioid overdose risk among Medicare beneficiaries taking at least one opioid prescription concluded that the machine learning algorithms appear to perform well for risk prediction and stratification of opioid overdose especially in identifying low-risk groups having minimal risk of overdose.⁵⁷ Machine learning is a method of data analysis that automates analytical model building, based on the idea that systems can learn from data, identify patterns and make decisions with minimal human intervention.

While we are not proposing changes to the clinical guidelines or OMS criteria in this proposed rule, we provide information on our data analysis to date and welcome feedback for future changes. Using predictor variables identified through the literature reviews, CMS performed a

data analysis to determine the top risk factors for Part D enrollees at high-risk for one of two outcomes: (1) having a new opioid poisoning (overdose) or (2) developing newly diagnosed OUD. Since Part D enrollees with a known opioid-related overdose are already identified in OMS, CMS focused on individuals at high risk for a new opioid-related overdose or OUD. We anticipate no burden since, as indicated, we are not proposing regulatory changes and are soliciting feedback.

In this analysis, we utilize Medicare data and traditional logistic regression as well as machine learning models like Random Forest, Least Absolute Shrinkage and Selection Operator (LASSO), and Extreme Gradient Boosting (XGBoost)⁵⁸ Cross Validation (CV) to examine and evaluate performance in predicting risk of opioid overdose and OUD. The models were compared based on the following criteria: Area Under the Curve (AUC), sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and number needed to examine (NNE). An XGBoost model with CV performed best according to the specified criteria and was selected as the model of choice for predicting a beneficiary with a new opioid overdose or OUD diagnosis.

The model population included 6,756,152 Medicare beneficiaries contemporaneously enrolled in Part D and Parts A, B, or C during the period from January to June 2019, who were prescribed at least one non-MOUD prescription opioid during the measurement period and did not have a DMP exemption (that is, cancer, sickle cell disease, hospice, LTC facility resident, palliative care, or end-of-life care). We excluded beneficiaries with a prior opioid-related overdose or an OUD diagnosis in the year prior to the prediction period. The training dataset used to build the model consisted of a random 75 percent sample of the study population (5,067,114). The remaining 25 percent of the population (1,689,038) was used for validating the prediction performance of the model. The measurement period to obtain information for the predictor variables (for example, opioid use patterns, demographics, comorbidities, etc.) was from January 1 to June 30, 2019, and the prediction period we used to identify beneficiaries with a new opioid

⁵² Spencer, Merianne R. et al. (2022). Drug Overdose Deaths in the United States, 2001–2021. (457).

⁵³ <https://www.cdc.gov/drugoverdose/deaths/synthetic/index.html>.

⁵⁴ CMS used a modified version of the Chronic Condition Warehouse (CCW) definition that excludes undiagnosed OUD beneficiaries such as those with an opioid OD event and also limits analysis to the particular measurement period instead of the prior two years.

⁵⁵ Bohnert K.M., Ilgen M.A., Louzon S., McCarthy J.F., Katz I.R., Substance use disorders and the risk of suicide mortality among men and women in the U.S. Veterans Health Administration. *Addiction*. 2017 Jul;112(7):1193–1201. doi: 10.1111/add.13774.

⁵⁶ Over 30,000 Part D enrollees met the minimum OMS criteria and were reported to sponsors through OMS reports in 2022 (18 percent met the level of opioid use though multiple provider criteria, and 82 percent met the history of history of opioid-related overdose criteria).

⁵⁷ Lo-Ciganic WH, Huang J.L., Zhang H.H., Weiss J.C., Wu Y., Kwok C.K., Donohue J.M., Cochran G., Gordon A.J., Malone D.C., Kuza C.C., Gellad W.F. Evaluation of Machine-Learning Algorithms for Predicting Opioid Overdose Risk Among Medicare Beneficiaries With Opioid Prescriptions. *JAMA Netw Open*. 2019 Mar 1;2(3):e190968. doi: 10.1001/jamanetworkopen.2019.0968. Erratum in: *JAMA Netw Open*. 2019 Jul 3;2(7):e197610. PMID: 30901048; PMCID: PMC6583312.

⁵⁸ Extreme Gradient Boosting (XGBoost) model—data mining technique that is similar to Random Forest that combines multiple decision trees into a single strong prediction model, but it differs in doing so in an iterative manner by building one tree at a time and optimizing a differentiable loss function.

overdose event or new OUD diagnosis was from July 1 to December 31, 2019.

The following risk factors⁵⁹ were incorporated into the XGBoost model:
BILLING CODE 4120-01-P

Risk Factor Flag	Description
Age	Beneficiary age in years
Sex	Female or Male sex
Race	White, Black, Asian, Hispanic, Native American, Other or Unknown race/ethnicity
LIS	Beneficiary low-income subsidy status
Dual	Beneficiary dual-eligibility status
Current Medicare Entitlement	Beneficiary current Medicare entitlement: ESRD (1) / non-ESRD (2)
MME	Average daily morphine milligram equivalents (MME)
Number of Opioid Pharmacies	Number of different pharmacies with an opioid prescription drug event (PDE) claim
Number of Opioid Prescribers	Number of different opioid prescribers
Number of Short-Acting Opioid Fills	Number of short-acting opioid PDEs
Number of Long-Acting Opioid Fills	Number of long-acting opioid PDEs
Number of Different Prescription Opioids	Number of different opioids prescribed (GPI-14 ⁶⁰)
Number of MOUD Days	Number of Medication-Assisted Treatment (MOUD) days
Hepatitis	Hepatitis diagnosis
Cervical nerve injury	Cervical nerve injury diagnosis

⁵⁹ Multicollinearity tests were undertaken in order to ensure that there was no collinearity among the explanatory variables used in the model.

⁶⁰ The Generic Product Identifier (GPI) designates any or all of a drug's group, class, sub-class, name, dosage form, and strength.

Risk Factor Flag	Description
Lumbar nerve injury	Lumbar nerve injury diagnosis
Thoracic nerve injury	Thoracic nerve injury diagnosis
Neuropathy	Neuropathy diagnosis
Other chronic pain	Other chronic pain diagnosis
Number of Mental Health Conditions	Number of mental health conditions (ADHD, anxiety, bipolar, depression, PTSD, personality disorder, schizophrenia) diagnosed
Number of Substance Use Disorders	Number of substance use disorders (alcohol, cannabis, hallucinogen, inhalant, non-psychoactive, psychoactive, sedative, stimulant) diagnosed
Antianxiety Drug Fill	PDE claim for antianxiety drug
Antipsychotic Drug Fill	PDE claim for antipsychotic drug
Anticonvulsant Drug Fill	PDE claim for anticonvulsant drug
Concurrent use of opioid and benzodiazepine (1 or more days)	Concurrent PDE for opioid and benzodiazepine (1+ day overlap)
Concurrent use of opioid and benzodiazepine (30 or more days)	Concurrent PDE for opioid and benzodiazepine (30+ day overlap)
Codeine Fill	PDE opioid claim for codeine (GPI-10)
Fentanyl Fill	PDE opioid claim for fentanyl (GPI-10)
Methadone Fill	PDE opioid claim for methadone (GPI-10)
Morphine Fill	PDE opioid claim for morphine (GPI-10)
Oxycodone Fill	PDE opioid claim for oxycodone (GPI-10)
Oxymorphone Fill	PDE opioid claim for oxymorphone (GPI-10)
Tramadol Fill	PDE opioid claim for tramadol (GPI-10)
Hydrocodone Fill	PDE opioid claim for hydrocodone (GPI-10)
Hydromorphone Fill	PDE opioid claim for hydromorphone (GPI-10)
Other Opioid Fill	PDE opioid claim for other opioid (GPI-10)

We evaluated the performance of the model using the confusion matrix

generated by applying the prediction

model to the validation dataset to calculate various metrics.

Confusion Matrix and Performance
Metrics for the XGBoost model:

Actual New OUD or Opioid-Related Overdose Diagnosis:	Predicted New OUD or Opioid- Related Overdose Diagnosis: No	Predicted New OUD or Opioid- Related Overdose Diagnosis: Yes	Total
No	1,154,395	513,551	1,667,946
Yes	3,920	17,172	21,092
Total	1,158,315	530,732	1,689,038

Criteria	Result
AUC	0.8253
Sensitivity	81.41 Percent
Specificity	69.21 Percent
PPV	3.24 Percent
NPV	99.66 Percent
NNE	31
Probability Threshold	0.474

The top 15 risk factors that were
highly associated with a new OUD or
opioid-related overdose diagnosis were:

Rank	Risk Factor Variable	Gain
1	Number of Short-Acting Opioid Fills	0.3853
2	MME*	0.1256
3	Age	0.0882
4	Number of Long-Acting Opioid Fills	0.0729
5	Number of Mental Health Conditions	0.0539
6	Number of Substance Use Disorders	0.0298
7	Anticonvulsant Drug Fill	0.0294
8	Number of Different Prescription Opioids	0.0234
9	Oxycodone Fill	0.0230
10	Other Opioid Fill	0.0227
11	Dual	0.0200
12	Number of Opioid Prescribers*	0.0148
13	Concurrent use of opioid and benzodiazepine (30 or more days)	0.0134
14	Morphine Fill	0.0112
15	LIS	0.0102

*Part of current minimum OMS criteria.

The number of short-acting prescription opioid fills and the average daily MME were found to contribute most to XGBoost model predictions of a new OUD or opioid-related overdose diagnosis. Risk was present across a range of MME levels and increased with higher MME levels. The risk of developing a new OUD or opioid-related overdose diagnosis also increased with the number of diagnosed mental health

or substance use disorders. Utilization of opioids with other high-risk medications like anticonvulsants, benzodiazepines, anti-psychotics, and anti-anxiety medications were positively associated with higher risk. Also, utilization of opioids like oxycodone and morphine were positively associated with higher risk, while utilization of codeine, tramadol,

and opioids in the other category were positively associated with lower risk.

Lastly, we applied our finalized model to data from October 1, 2021, through March 31, 2022, to predict future new opioid-related overdose events and OUD diagnoses during the period from April 1, 2022, to September 30, 2022, to understand program size estimates and NNE values.

Risk Probability Threshold	Number of Beneficiaries with Predicted New OUD or Opioid-Related Overdose Diagnosis	Number of True Positives*	PPV (Percent)	NNE
Top 1 percent** (Validation Data)	16,862	1,860	11.01	9
Top 1 percent	62,571	5,445	8.70	11
Top 50,000	50,000	4,562	9.12	11
Top 40,000	40,000	3,792	9.48	11
Top 30,000	30,000	2,996	9.99	10
Top 20,000	20,000	2,168	10.84	9
Top 10,000	10,000	1,219	12.19	8
Top 5,000	5,000	679	13.58	7
Top 1,000	1,000	150	15.00	7

*True Positives are beneficiaries that were categorized into the given risk probability threshold group based on data from the October 1, 2021, to March 31, 2022, measurement period, then were subsequently found to have experienced a new opioid OD/OD during the April 1, 2022, to September 30, 2022, prediction period.

**Validation data: random 25 percent sample of total population: January 1, 2019, to June 30, 2019, measurement period, and July 1, 2019, to December 31, 2019, prediction period.

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Between 9 percent and 15 percent of the beneficiaries with a predicted new opioid-related overdose/OD actually experienced a new overdose or OD diagnosis during the evaluation period (April 1, 2022, through September 30, 2022) depending on the Risk Probability Threshold. The Top 1 percent threshold (n = 62,571) reported the lowest precision score, while the Top 1,000 threshold showed the highest precision. Among those who had a new opioid-related overdose/OD in the evaluation period, about 92 percent developed a new OD; the proportion with a new opioid overdose increased from 10 percent to 17 percent as the risk probability threshold increased from the Top 1 percent to the Top 1,000; and, as the risk probability threshold increased, about 2 percent to 8 percent had both a new opioid overdose and were identified as having a newly diagnosed OD. Among the different Risk Probability Thresholds, between 93 to 98 percent of the correctly predicted

new overdoses/ODs do not meet the current OMS criteria. The percentage that meets the current OMS criteria decreases as the Risk Probability Threshold becomes more restrictive. Thus, our analysis shows that there is very little overlap between the population identified through this model and beneficiaries already identified through the OMS.⁶¹ Furthermore, our analysis confirms that machine learning models can analyze large datasets and identify complex patterns that are not easily discernible by current non-statistical approaches. This makes them a powerful tool for identifying new opioid-related overdose or OD risk and capturing an additional population of potential at-risk beneficiaries who have not been identified through our current OMS criteria.

⁶¹ CMS also notes that historically, only about 1.6 percent of the beneficiaries meeting the history of opioid-related overdose (MIN2) OMS criteria also meet the (MIN1) minimum OMS criteria.

CMS next plans to assess risk in the model, validate the stability of the model as new data become available, and develop guidelines on how to feasibly implement the model into the existing DMP and OMS processes. We solicit feedback on the following:

- Potentially using such a model to enhance the minimum or supplemental OMS criteria in the future (either in addition to the current criteria or as a replacement).
- How to avoid the stigma and/or misapplication of identification of a PARB at high risk for a new opioid-related overdose or OD using the variables in the model.
- Implementation considerations, such as effectively conducting case management, as described in § 423.153(f)(2), with prescribers of PARBs identified by the model; opportunities to promote MOUD, co-prescribing of naloxone, or care coordination; or potential unintended consequences for access to needed medications.

- Other factors to consider.

E. Codification of Complaints Resolution Timelines and Other Requirements Related to the Complaints Tracking Module (CTM) (42 CFR 417.472(l), 422.125, 423.129, and 460.119)

CMS maintains the CTM in the Health Plan Management System (HPMS) as the central repository for complaints received by CMS from various sources, including, but not limited to the Medicare Ombudsman, CMS contractors, 1–800–MEDICARE, and CMS websites. The CTM was developed in 2006 and is the system used to comply with the requirement of section 3311 of the Affordable Care Act for the Secretary to develop and maintain a system for tracking complaints about MA and Part D plans received by CMS, CMS contractors, the Medicare Ombudsman, and others. Complaints from beneficiaries, providers, and their representatives regarding their Medicare Advantage (MA) organizations, Cost plans, Programs of All-inclusive Care for the Elderly (PACE) organizations, and Part D sponsors are recorded in the CTM and assigned to the appropriate MA organization, Cost plan, PACE organization, and Part D sponsor if CMS determines the plan, organization, or sponsor is responsible for resolving the complaint. Unless otherwise noted, “plans” applies to Medicare Advantage (MA) organizations, Part D sponsors, Cost plans, and PACE organizations for purposes of this proposal.

We are proposing to codify existing guidance for the timeliness of complaint resolution by plans in the CTM. Currently, §§ 422.504(a)(15) and 423.505(b)(22) require MA organizations and Part D sponsors to address and resolve complaints received by CMS against the MA organization and Part D sponsor through the CTM; we are proposing to codify the expectation in guidance that Cost plans and PACE organizations also address and resolve complaints in the CTM. We are proposing to codify the existing priority levels for complaints based on how quickly a beneficiary needs to access care or services and to codify a new requirement for plans to make first contact with individuals filing non-immediate need complaints within three (3) calendar days. This time frame would not apply to immediate need complaints because those complaints need to be resolved within two calendar days.

CMS codified the requirement for MA organizations and Part D sponsors to address and resolve complaints in the CTM at §§ 422.504(a)(15) and

423.505(b)(22) in the “Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes” (76 FR 21431), which appeared in the April 15, 2011 **Federal Register** (hereafter referred to as the “April 2011 final rule”). As described in the April 2011 final rule, the regulation requires that MA organizations and Part D sponsors provide a summary of the resolution in the CTM when a complaint is resolved. (76 FR 21470)

As Part D sponsors, Cost plans and PACE organizations that offer Part D coverage have been required to comply with § 423.505(b)(22). We are proposing to add language to §§ 417.472(l) and 460.119 to codify in the Cost plan regulations and PACE regulations, respectively, the requirement that Cost plans and PACE organizations address and resolve complaints in the CTM. This proposed new requirement would apply to all complaints in the CTM for Cost plans and PACE organizations, not just complaints about Part D.

In addition, CMS has issued guidance describing our expectations for how complaints should be handled. In the Complaints Tracking Module Plan Standard Operational Procedures (CTM SOP), the most recent version of which was released on May 10, 2019, via HPMS memo,⁶² CMS provides detailed procedures for plans to use when accessing and using the CTM to resolve complaints. This includes describing the criteria CMS uses in designating certain complaints as “immediate need” or “urgent” (all other complaints are categorized “No Issue Level” in the CTM), setting forth our expectation that plans should review all complaints at intake, and documentation requirements for entering complaint resolutions in the CTM. The CTM SOP defines an “immediate need complaint” for MA organizations, Cost plans, and PACE organizations as “a complaint where a beneficiary has no access to care and an immediate need exists.” For Part D sponsors, “an immediate need complaint is defined as a complaint that is related to a beneficiary’s need for medication where the beneficiary has two or less days of medication remaining.” The CTM SOP defines an “urgent complaint” for MA organizations, Cost plans, and PACE organizations as a complaint that “involves a situation where the beneficiary has no access to care, but no immediate need exists.” For Part D

sponsors, “an urgent complaint is defined as a complaint that is related to the beneficiary’s need for medication where the beneficiary has 3 to 14 days of medication left.”

In chapter 7, section 70.1 of the Prescription Drug Benefit Manual, “Medication Therapy Management and Quality Improvement Program,”⁶³ CMS requires Part D sponsors to resolve any “immediate need” complaints within two (2) calendar days of receipt into the CTM and any “urgent” complaints within seven (7) calendar days of receipt into the CTM. Chapter 7, section 70.1 also sets forth CMS’s expectation that Part D sponsors promptly review CTM complaints and notify the enrollee of the plan’s action as expeditiously as the case requires based on the enrollee’s health status.

Requirements for resolution of complaints received in the CTM do not override requirements related to the handling of appeals and grievances set forth in 42 CFR part 422, subpart M (which apply to cost plans as well as MA organizations per § 417.600), part 423, subpart M, for Part D sponsors, and §§ 460.120 through 460.124 for PACE organizations. Rather, CTM requirements supplement the appeals and grievance requirements by specifying how organizations must handle complaints received by CMS in the CTM and passed along to the plan. The requirement for organizations to enter information on the resolution of complaints in the CTM within specified time periods allows CMS to track and ensure accountability for complaints CMS itself received, either directly from beneficiaries or via entries in the CTM from the Medicare ombudsman, CMS contractors, or others. A beneficiary who filed a complaint directly with CMS may later contact CMS to find out the status of the complaint and the plan’s use of the system would allow CMS to answer the beneficiaries inquiries more expeditiously. In order to comply with the applicable regulations, plans must handle any CTM complaint that is also an appeal or grievance within the meaning of the regulation in such a way that complies with the notice, timeliness, procedural, and other requirements of the regulations governing appeals and grievances.

We are proposing to codify the timeliness requirements for MA organizations and Part D plans at new §§ 422.125 and 423.129, both titled “Resolution of Complaints in Complaints Tracking Module.” We are

⁶² Available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/ctm%20plan%20sop%20eff053019.pdf>.

⁶³ Available at <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/dwnlds/chapter7pdf>.

proposing to codify these requirements for Cost plans and PACE organizations at §§ 417.472(l) and 460.119 by incorporating §§ 422.504(a)(15) and 422.125 by reference into the requirements for Cost plans and PACE organizations, respectively.

Specifically, we propose to codify at §§ 422.125(a) and 423.129(a) the definitions of “immediate need” and “urgent” complaints in substantially the same way as they are currently defined in guidance for MA and Part D-related complaints. However, we propose to specify that immediate need and urgent complaints for MA plans (as well as Cost plans, and PACE) also include situations where a beneficiary has access to enough of a drug or supply to last fewer than 2 days or from 3 to 14 days, respectively, as part of the definition that these complaints are about situations that prevent the beneficiary from accessing care or a service. This proposed change recognizes that some complaints to an MA organization (or Cost plan or PACE organization) may overlap with Part D access, such as when a beneficiary reports a problem with their enrollment in an MA–PD plan that is blocking access to Part D coverage. The change also recognizes that non-Part D MA, Cost plan, and PACE complaints relate not just to access to physician services but to drugs and supplies that may be covered by the MA plan, Cost plan, or PACE organization’s non-Part D benefit (for example, Part B drugs or diabetic test strips covered under the medical benefit of an MA plan). Further, MA plans, Cost plans, and PACE also cover Part B drugs.

We also propose to codify at §§ 422.125(b) and 423.129(b) the current timeframes reflected in section 70.2 of chapter 7 of the Prescription Drug Benefit Manual for resolving immediate need and urgent complaints. A two (2) calendar day deadline for resolving plan-related immediate need complaints is both consistent with current practice by plans and logically follows from the definition of an “immediate need” complaint. By its nature, an immediate need complaint requires swift action. Because we define immediate need, in part, as a situation where a beneficiary has access to two or fewer days’ worth of a drug or supply they need, a timeline greater than two calendar days for resolving a complaint would represent an unacceptable risk to beneficiaries.

Similarly, a seven (7) calendar day deadline for “urgent” complaints reflects the importance of not delaying resolution of a situation that is preventing access to care or services a beneficiary needs. Because we define

“urgent” in part as a situation where a beneficiary has 3 to 14 days’ worth of a drug or supply they need, allowing more than a week to elapse before resolving the complaint would put beneficiaries at unacceptable risk of not receiving replacement drugs or supplies timely.

For all other Part D and non-Part D complaints in the CTM, we propose requiring resolution within 30 days of receipt. This is consistent with current practice and the guidance in section 70.2 of chapter 7 of the Prescription Drug Benefit Manual, and we believe would prevent complaints from lingering for months without resolution in the CTM. Further, a 30-day timeframe for resolving complaints in the CTM aligns with the 30-day period provided in §§ 422.564(e) and 423.564(e) for resolution of grievances. Although those regulations permit an extension of up to 14 days for resolving the grievance if the enrollee requests the extension or if the organization justifies a need for additional information and documents how the delay is in the interest of the enrollee, we do not believe that including the authority to extend the deadline to resolve complaints in the CTM is appropriate because complaints received into the CTM are often the result of failed attempts to resolve issues directly with the plan. Allowing plans to further extend the time to resolve the complaint only allows further delays in addressing beneficiary concerns. Moreover, recent evidence indicates that the vast majority of non-immediate need or urgent complaints are resolved within 30 days—98% of such complaints were resolved by plans within 30 days in 2022.

All timeframes for resolution would continue to be measured from the date a complaint is assigned to a plan in the CTM, rather than the date the plan retrieves the complaint from the CTM. This is consistent with current guidance and practice. Measuring the timeframe in this manner is the best way to protect beneficiaries from delayed resolution of complaints and encourages organizations to continue retrieving CTM complaints in a timely manner so that they have sufficient time to resolve complaints.

We do not anticipate that plans will have difficulty meeting these timeframes. The vast majority of complaints are currently resolved in the timelines specified for the priority level of the complaint. For example, in 2022, plans resolved 97 percent of complaints within the required time frames for the level of complaint. Plans resolved 94 percent of immediate need complaints within 2 calendar days, 97 percent of

urgent complaints within 7 calendar days, and 98 percent of complaints with no issue level designated within 30 calendar days. Codifying the timeframes as proposed merely formalizes CMS’s current expectations and the level of responsiveness currently practiced by plans.

We are also proposing to create a new requirement for plans to contact individuals filing non-immediate need complaints. At §§ 422.125(c) and 423.129(c), we propose to require plans to contact the individual filing a complaint within three (3) calendar days of the complaint being assigned to a plan. While current guidance generally includes the expectation that organizations inform individuals of the progress of their complaint, CMS has never specified a timeframe for reaching out to a complainant. CMS has observed that, particularly for complaints that are not assigned a priority level, plans sometimes wait until the timeframe for resolution has almost elapsed to contact the complainant. Because the timeframe for resolving uncategorized complaints is 30 days, an individual who files a complaint may wait weeks to hear back from the plan responsible for resolving it. We believe that such delays cause unnecessary frustration for beneficiaries and are inconsistent with the customer service we expect from plans.

We acknowledge that our proposed timeframe for reaching out to the complainant concerning a CTM complaint is more specific than our requirement at §§ 422.564(b) and 423.564(b) for plans to “promptly inform the enrollee whether the complaint is subject to its grievance procedures or its appeals procedures.” We are proposing a specific timeframe for contacting the beneficiary regarding a CTM complaint because, unlike with complaints received by the plans outside the CTM, the complainant has not reached out directly to the plan and may not know that their complaint has been passed on to the plan by CMS via the CTM. Moreover, as previously noted, CMS monitors the handling of complaints it receives through the CTM in real time. Part of handling CTM complaints through the CTM, as required by §§ 422.504(a)(15) and 423.505(b)(22), is entering information into the CTM when the plan reaches out to the complainant. CMS would therefore be able to monitor whether a plan has reached out to a beneficiary within the required timeframe and follow up with the plan well before timeframe for resolving the complaint has elapsed.

We are proposing a 3 calendar day timeframe for reaching out to the

individual filing the complaint because it would provide a timely update to individuals filing both urgent and uncategorized complaints without delaying resolution of immediate need complaints. We expect that a plan would indicate in this communication that the plan has received and is working on the complaint, and that they provide contact information that the individual filing the complaint could use to follow up with the plan regarding the complaint. We solicit comment on whether this timeframe is appropriate and whether a longer or shorter timeframe would better balance the needs of beneficiaries with the capacity of plans to respond to complaints.

We are also proposing conforming changes to §§ 422.504(a)(15) and 423.505(b)(22) to incorporate the proposed new requirements into the existing contractual requirements for MA organizations and Part D sponsors. The proposed revisions to §§ 417.472(l) and 460.119 incorporate both the requirements in proposed § 422.125 and the requirement for a contract term for resolving complaints received by CMS through the CTM for Cost plans and PACE organizations and their contracts with CMS.

F. Additional Changes to an Approved Formulary—Biosimilar Biological Product Maintenance Changes and Timing of Substitutions (§§ 423.4, 423.100, and 423.120(e)(2))

1. Introduction

Section 1860D–11(e)(2) of the Act provides that the Secretary may only approve Part D plans if certain requirements are met, including the provision of qualified prescription drug coverage. Section 1860D–11(e)(2)(D) of the Act specifically permits approval only if the Secretary does not find that the design of the plan and its benefits, including any formulary and tiered formulary structure, are likely to substantially discourage enrollment by certain Part D eligible individuals. Section 1860D–4(c)(1)(A) of the Act requires “a cost-effective drug utilization management program, including incentives to reduce costs when medically appropriate.” Lastly, section 1860D–4(b)(3)(E) of the Act requires Part D sponsors to provide “appropriate notice” to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists before removing a covered Part D drug from a formulary or changing the preferred or tiered cost-sharing status of such a drug.

In section III.Q., Changes to an Approved Formulary, of the proposed rule titled “Medicare Program; Contract

Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications,” which appeared in the December 27, 2022 **Federal Register** (hereinafter referred to as the December 2022 proposed rule), we proposed regulations related to (1) Part D sponsors obtaining approval to make changes to a formulary already approved by CMS, including extending the scope of immediate formulary substitutions (also generally referred to as immediate substitutions herein);⁶⁴ and (2) Part D sponsors providing notice of such changes.

The December 2022 proposed rule proposed to reorganize current regulatory text to incorporate and as necessary conform with longstanding sub-regulatory guidance and operations with respect to changes to an approved formulary and associated notice provisions. For example, § 423.120(b)(5)(iv) currently permits a plan sponsor to immediately remove a brand name drug from its formulary when adding a therapeutically equivalent generic drug, subject to certain requirements. If finalized, the December 2022 proposed rule would expand immediate substitutions in a new § 423.120(e)(2)(i) to allow plan sponsors to substitute an authorized generic for a brand name drug, an interchangeable biological product for a reference product, or an unbranded biological product for its corresponding brand name biological product under the same biologics license application (BLA).

These and other proposals discussed in section III.Q., Changes to an Approved Formulary, of the December 2022 proposed rule have not been finalized and remain under consideration. As we noted in the April 2023 final rule, CMS intends to address remaining proposals from the December

2022 proposed rule in subsequent rulemaking, which would be effective no earlier than January 1, 2025. As we continue to consider comments we received in response to the December 2022 proposed rule, we identified a limited number of changes that we would like to make to the proposed regulatory text relating to section III.Q. of the December 2022 proposed rule. Accordingly, this proposed rule reflects our intent to consider section III.Q. of the December 2022 proposed rule, as updated by the limited proposed changes discussed herein, for inclusion in future rulemaking. While we discuss below certain comments regarding the December 2022 proposed rule that informed the limited proposed changes herein, we will respond to comments received in response to section III.Q. of the December 2022 proposed rule, as well as comments received in response to the changes proposed below, if we decide to move forward with such proposals in future rulemaking.

Commenters on section III.Q. of the December 2022 proposed rule did not agree on the requirements that should apply to formularies substituting Food and Drug Administration (FDA) approved and licensed biosimilar biological products. Different commenters submitted divergent requests that substitutions of biosimilar biological products other than interchangeable biological products be treated as immediate substitutions, be treated as maintenance changes, or not be permitted whatsoever. Our proposed regulatory text in the December 2022 proposed rule only addressed substitution of interchangeable biological products and did not specify how Part D sponsors could treat substitution of biosimilar biological products other than interchangeable biological products, and we believe, in part because of the interest in the topic, that it would be appropriate to propose to do so now in order to solicit comment directly on the subject.

Accordingly, we are proposing to update the regulatory text we proposed in the December 2022 proposed rule to the extent necessary to permit Part D sponsors to treat substitutions of biosimilar biological products other than interchangeable biological products as “maintenance changes,” as defined in the December 2022 proposed rule, for the reasons discussed below. We are also proposing to define a new term, “biosimilar biological product,” distinct from our previously proposed term “interchangeable biological products.” (We propose some technical changes to the latter term as well.)

⁶⁴ We note the distinction between formulary substitutions made by a plan sponsor and product substitutions made by a pharmacist at the point-of-dispensing. As we describe in section III.F.2.a.(2) of this proposed rule, State laws govern the ability of pharmacists to substitute biological products at the point-of-dispensing. By contrast, the Secretary’s statutory authority under section 1860D–11(e)(2) of the Act governs approval of, and by extension any changes to, Part D formularies. The provisions we describe throughout section III.F. of this proposed rule strictly apply to changes to Part D formularies made by plan sponsors, and do not apply to substitutions made by pharmacists at the point-of-dispensing.

We propose to define biosimilar biological products consistent with sections 351(i) and (k) of the Public Health Service Act to include interchangeable biological products. In section III.Q (87 FR 79536) of the December 2022 proposed rule, we proposed to permit maintenance changes and immediate substitutions involving interchangeable biological products, and that proposal is still under consideration. In this proposed rule, we are also proposing to allow substitution of biosimilar biological products other than interchangeable biological products for reference products as a maintenance change. To ensure clarity, we are proposing to address the application of these policies to interchangeable biological products and to biosimilar biological products other than interchangeable biological products in separate paragraphs of the proposed definition of maintenance change in § 423.100.

Further, in considering a comment on immediate formulary substitutions, we also determined it would be appropriate to propose providing Part D sponsors with additional flexibility with respect to maintenance changes and immediate substitutions than as originally proposed in the December 2022 proposed rule. Rather than requiring a Part D sponsor to add a “corresponding drug” and make a “negative formulary change” (as both such terms are defined in the December 2022 proposed rule) to its related drug “at the same time,” we are proposing additional flexibility. Specifically, we propose to allow Part D sponsors to make a negative formulary change to the related drug within a certain period of time following the addition of the corresponding drug—rather than at the same time they add the corresponding drug.

Additionally, we propose a technical change to our proposed definition of “corresponding drug” in § 423.100 included in the December 2022 proposed rule to specify that the reference to an “unbranded biological product of a biological product” is intended to be a reference to “an unbranded biological product marketed under the same BLA as a brand name biological product.”

Lastly, we are taking this opportunity to address a technical change to the regulatory text proposed in the December 2022 proposed rule to specify in introductory language to the § 423.100 proposed definition of “maintenance change” that changes apply with respect to “a covered Part D drug.”

Our goal in this proposed rule is to focus only on these specific changes to

the original proposals in the December 2022 proposed rule that remain under consideration, but as updated below. We are re-proposing in this proposed rule only the regulatory text in the December 2022 proposed rule necessary to address new policy considerations and, therefore, we include only the updated parts of the three following sections of proposed regulatory text in the December 2022 proposed rule: §§ 423.4; 423.100; and 423.120(e)(2). Section III.F.2.a. of this proposed rule includes both language and synopses of the preamble to the December 2022 proposed rule as necessary to provide context for the updates we are proposing in this proposed rule. Except as specified in this proposed rule, stakeholders should assume, as does the discussion in this proposed rule, that the proposals for regulatory text regarding changes to approved formularies otherwise remain under consideration as proposed in the December 2022 proposed rule. If any provisions regarding this topic are finalized, the final rule would include the provisions proposed in the December 2022 proposed rule, as revised by the proposed changes in this proposed rule and taking into consideration any potential changes in response to comments.

We received numerous comments on section III.Q. of the December 2022 proposed rule on changes to an approved formulary, comments which we have carefully reviewed and continue to consider (and some of which are discussed in this proposed rule). We solicit comments on any aspects regarding the changes we are proposing in this rule to the December 2022 proposed rule’s provisions.

2. Substituting Biosimilar Biological Products for Their Reference Products as Maintenance Changes

a. Previously Proposed Provisions

(1) Certain Previously Proposed Provisions Related to Maintenance and Non-Maintenance Changes

In section III.Q.2.b., Proposed Provisions for Approval of Formulary Changes, of the December 2022 proposed rule, we proposed to define terms such as “negative formulary change” and “affected enrollee.” In categorizing negative formulary changes, we discussed the fact that chapter 6 of the Prescription Drug Benefit Manual also classifies negative formulary changes as either maintenance or non-maintenance changes. Maintenance changes are changes generally expected to pose a minimal risk of disrupting drug therapy

or are warranted to address safety concerns or administrative needs (for example, drug availability due to shortages and determining appropriate payment such as coverage under Part B or Part D). We noted that in our experience the vast majority of negative formulary changes are “maintenance” changes that CMS routinely approves, and the vast majority of maintenance changes are generic substitutions, in which the Part D sponsor removes a brand name drug and adds its generic equivalent.

We then noted that consistent with our current manual policy and operations, we were proposing at § 423.100 to define “maintenance changes” to mean the following negative formulary changes: (1) making any negative formulary changes to a drug and at the same time adding a corresponding drug at the same or lower cost-sharing tier and with the same or less restrictive prior authorization (PA), step therapy (ST), or quantity limits (QL) requirements (other than those meeting the requirements of immediate substitutions currently permitted and that we proposed to permit in the December 2022 proposed rule); (2) removing a non-Part D drug; (3) adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning; (4) removing a drug deemed unsafe by FDA or withdrawn from sale by the manufacturer if the Part D sponsor chooses not to treat it as an immediate negative formulary change; (5) removing a drug based on long-term shortage and market availability; (6) making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization; or (7) adding PA to help determine Part B versus Part D coverage. We additionally stated that we intended through the use of the plural tense to clarify that Part D sponsors may request to apply more than one negative formulary change simultaneously to that drug.

We noted that non-maintenance changes, which are infrequently warranted, are negative formulary changes that limit access to a specific drug without implementing a corresponding offset (such as adding an equivalent drug) or addressing safety or administrative needs. We proposed to define “non-maintenance change” at § 423.100 to mean a negative formulary change that is not a maintenance change or (as discussed in the next paragraph) an immediate negative formulary change.

We also introduced a third category of negative formulary changes in § 423.100 to capture negative formulary changes

that fall within certain parameters and that may be made immediately. We proposed to define “immediate negative formulary changes” as those which meet the requirements as either an immediate substitution or market withdrawal under § 423.120(e)(2)(i) or (ii) respectively. We noted, however, that while such changes may be made immediately, Part D sponsors retain the option to implement such changes as maintenance changes. This means that those Part D sponsors that can meet all applicable requirements would have a choice as to whether to make such changes immediately and thereafter provide notice of specific changes or submit a negative change request and provide specific notice of such changes to affected enrollees at least 30 days before they occur.

We also proposed to define “corresponding drug” in § 423.100 to mean, respectively, a generic or authorized generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product of a biological product and to move and retain our current regulatory description of “other specified entities” currently in § 423.120(b)(5)(i) to be a standalone definition of the term in § 423.100.

We proposed in § 423.120(e) that Part D sponsors may not make any negative formulary changes to the CMS-approved formulary except as specified in the regulation.

We proposed to codify our existing policy with respect to maintenance changes, which would, at proposed § 423.120(e)(3)(i), permit Part D sponsors that have submitted a maintenance change request to assume that CMS has approved their negative change request if they do not hear back from CMS within 30 days of submission. We proposed to codify our existing policy with respect to non-maintenance changes as well, which would specify at § 423.120(e)(3)(ii) that Part D sponsors must not implement non-maintenance changes until they receive notice of approval from CMS. We also proposed to codify our longstanding policy that affected enrollees are exempt from approved non-maintenance changes for the remainder of the contract year at § 423.120(e)(3)(ii).

In section III.Q.3.b., Alignment of Approval and Notice Policy, of the December 2022 proposed rule, we noted in relevant part that: we first proposed in § 423.120(f)(1) to specify that only maintenance and non-maintenance negative formulary changes would require 30 days’ advance notice to CMS and other specified entities, and in

writing to affected enrollees. We also proposed to retain at § 423.120(f)(1) an alternative option for Part D sponsors to provide an affected enrollee who requests a refill of an approved month’s supply of the Part D drug under the same terms as previously allowed, as well as written notice of the change. We further proposed in § 423.120(f)(5)(i) to require Part D sponsors to provide advance general notice of other formulary changes to all current and prospective enrollees and other specified entities, in formulary and other applicable beneficiary communication materials, advising that the formulary may change subject to CMS requirements; providing information about how to access the plan’s online formulary and contact the plan; and stating that the written notice of any change made when provided would describe the specific drugs involved. For immediate substitutions, we indicated we would require information on the steps that enrollees may take to request coverage determinations and exceptions. We noted that our current model documents already largely provide advance general notice of such changes. Section 423.120(f)(5)(ii) as proposed in the December 2022 proposed rule would further require that Part D sponsors provide enrollees and other specified entities notice of specific formulary changes by complying with § 423.128(d)(2) and provide CMS with notice of specific changes through formulary updates.

We proposed to revise and renumber the existing regulation to specify that, except for immediate negative formulary changes, negative formulary changes require at least 30 days advance notice. Consistent with our proposal for approval of maintenance changes, we proposed that a Part D sponsor could submit the negative change request, which would constitute its notice to CMS, and notice to other specified entities at the same time. We explained this would permit the Part D sponsor to implement the maintenance change once it is deemed approved under proposed § 423.120(e)(3)(i)—although facing the risk of sending notice of a change that is subsequently disapproved by CMS.

We also noted that Part D sponsors currently submit negative change requests to CMS via HPMS that specify the negative change’s intended effective date, which under our proposed approach, would have to be at least 30 days after submission for a maintenance change. However, consistent with our previous proposal under § 423.120(f)(3)(ii) to prohibit Part D

sponsors from implementing non-maintenance changes until they receive notice of approval from CMS, Part D sponsors would not be permitted to provide notice to other specified entities or affected enrollees, or to otherwise update formularies or other materials, until CMS has approved the non-maintenance change. We also discussed updating online notice of negative formulary changes at § 423.128(d)(2)(iii).

(2) Certain Previously Proposed Provisions Related to Interchangeable Biological Products as Immediate Negative Formulary Changes

In section III.Q.2.b.(3), Immediate Negative Formulary Changes, of the December 2022 proposed rule, we proposed to permit immediate substitutions of interchangeable biological products for their reference products. In our preamble, we reviewed how, under the current § 423.120(b)(5)(iv), we permit immediately substituting new generic drugs for brand name drugs, and that current § 423.120(b)(5)(iii) permits the immediate removal of drugs deemed unsafe by FDA or withdrawn from sale by their manufacturers. We then discussed our proposal to broaden the scope of permitted immediate substitutions at § 423.120(e)(2)(i) to include authorized generics as defined at § 423.4.

We noted that when we first adopted the immediate substitution policy, we stated that the regulation would not apply to biological products, but that we would reconsider the issue when interchangeable biological products became available in Part D. In the December 2022 proposed rule, we noted there was at least one interchangeable biological product and also an unbranded biological product marketed under the same license, and that other licensed interchangeable biological products may become available in Part D in the future.⁶⁵ Accordingly, we stated we believed it appropriate to expand our policy to include interchangeable biological products and unbranded biological products marketed under the same license as the brand name biological products when immediate substitution would not disrupt existing therapy. We noted that as discussed in the preamble to the proposed rule titled, “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the

⁶⁵ The December 2022 proposed rule cited Semglee® (insulin glargine-yfgn). Other interchangeable biological products now available include Cyltezo® (adalimumab-adbm) and Rezvoglar™ (insulin glargine-aglr).

Medicare Prescription Drug Benefit Programs, and the PACE Program,” which appeared in the November 28, 2017 **Federal Register** (82 FR 56413), in deciding to permit immediate generic substitutions without advance direct notice of specific changes to affected enrollees, CMS, or other specified entities, we weighed the need to maintain the continuity of a plan’s formulary for beneficiaries who enroll in plans based on the drugs offered at the time of enrollment against the need to provide Part D sponsors more flexibility to facilitate the use of new generics. We stated that key to our decision to permit such substitutions was the fact that the rule would apply only to therapeutically equivalent generics of the affected brand name drug because such generics are the same as an existing approved brand name drug in dosage form, safety, strength, route of administration, and quality. Congress, we noted, defined “interchangeable” in reference to biological products, stating that interchangeable biological products “may be substituted for the reference product without the intervention of the health care professional who prescribed the reference product.”⁶⁶ We also explained that FDA reports that this is similar to how generic drugs are routinely substituted for brand name drugs.⁶⁷

We then noted that all 50 States now permit or require pharmacists to substitute interchangeable biological products when available, for prescribed reference products at the point-of-dispensing, subject to varying requirements regarding patient and prescriber notice, documentation of the substitution, and patient savings as a result of the substitution, among other safeguards.⁶⁸ In the context of a growing market for interchangeable biological products, to follow the lead of FDA in encouraging uptake of these products, and to provide flexibility that could lead to better management of the Part D benefit that does not impede State pharmacy practices, we proposed at § 423.120(e)(2)(i) to permit Part D sponsors meeting the applicable requirements to immediately substitute an interchangeable biological product for the reference product on its

formulary. In support of that proposal, we also proposed the following definitions at § 423.4: An “interchangeable biological product” would mean a product licensed under section 351(k) of the Public Health Service Act (PHSA) (42 U.S.C. 262(k)) that FDA has determined to be interchangeable with a reference product in accordance with sections 351(i)(3) and 351(k)(4) of the PHSA (42 U.S.C. 262(i)(3) and 262(k)(4)).⁶⁹ We stated that a “biological product” would mean a product licensed under section 351 of the PHSA, and a “reference biological product” would mean a product as defined in section 351(i)(4) of the PHSA.

We also noted that in addition to interchangeable biological products, unbranded biological products have recently been marketed. We explained that in the frequently asked questions of FDA’s “Purple Book Database of Licensed Biological Products,” available at <https://purplebooksearch.fda.gov/faqs#11>, FDA describes an “unbranded biologic” or “unbranded biological product” as an approved brand name biological product that is marketed under its approved BLA without its brand name on its label. Thus, like an authorized generic, an unbranded biological product is the same product as the brand name biological product. Accordingly, since we proposed in the December 2022 proposed rule to permit Part D sponsors to immediately substitute an authorized generic for a brand name drug, we similarly proposed at § 423.120(e)(2)(i) in that proposed rule to permit immediately substituting, as specified, unbranded biological products for corresponding brand name biological products. We further proposed at § 423.4 to define “brand name biological products” to mean biological products licensed under section 351(a) or 351(k) of the PHSA and marketed under a brand name. We also proposed at § 423.4 to define “unbranded biological products” as biological products licensed under a BLA under section 351(a) or 351(k) of the PHSA and marketed without a brand name.

We also noted we were not proposing to permit Part D sponsors to immediately substitute all “biosimilar products” (87 FR 79539) because not all biosimilar biological products have met additional requirements to support a demonstration of interchangeability, as outlined by the Biologics Price Competition and Innovation (BPCI) Act of 2009.⁷⁰ Nevertheless, we encouraged Part D plan sponsors to offer such products on their formularies.

The remainder of the section covered a variety of topics including proposed changes to terminology; use of plural tense for negative formulary changes to reflect the possibility of concurrent changes; exemption of immediate negative formulary changes from negative change request and approval processes and inclusion in formulary updates; market withdrawals including renumbering; and exemption of all immediate negative formulary changes from transition requirements.

In section III.Q.3.c., Notice of Negative Immediate Changes, of the December 2022 proposed rule, we noted that, consistent with our existing requirements for immediate generic substitutions (which we proposed to broaden to include other corresponding drugs), we were proposing to require advance general notice of immediate substitutions and market withdrawals at § 423.120(f)(2), followed by written notice to affected enrollees as soon as possible under § 423.120(f)(3), but by no later than the end of the month following any month in which a change takes effect. We provided details on the content of the direct written notice at § 423.120(f)(4), noted it could be provided for both maintenance and non-maintenance changes, and noted that we were renumbering some current regulatory requirements.

b. Current Proposals

(1) Substituting Biosimilar Biological Products for Their Reference Products as Maintenance Changes

In the December 2022 proposed rule, we indicated that biosimilar biological products⁷¹ other than interchangeable

⁶⁶ Public Health Service Act section 351(i)(3) (42 U.S.C. 262(i)(3)).

⁶⁷ “Biosimilar and Interchangeable Biologics: More Treatment Choices” at the following FDA website: <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices>. Accessed April 26, 2022.

⁶⁸ Cardinal Health. Biosimilar Interchangeability Laws by State. Updated July 2021. Available from: <https://www.cardinalhealth.com/content/dam/corp/web/documents/publication/Cardinal-Health-Biosimilar-Interchangeability-Laws-by-State.pdf>.

⁶⁹ See section 351(k)(4) of the PHSA (42 U.S.C. 262(k)(4)). We cited as current at the time, “Considerations in Demonstrating Interchangeability With a Reference Product Guidance for Industry” at the following FDA website: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/considerations-demonstrating-interchangeability-reference-product-guidance-industry>. Accessed September 2, 2022. See also section 351(i)(3) of the PHSA (42 U.S.C. 262(i)(3)) for the statutory definition of the term “interchangeable” or “interchangeability.”

⁷⁰ We note that in the December 2022 proposed rule, the actual statement read: “Biosimilar products have not met additional requirements to support a demonstration of interchangeability based on further evaluation and testing of the product, as outlined by the Biologics Price Competition and Innovation (BPCI) Act.” This statement failed to capture the nuances that the definition of a biosimilar biological product includes interchangeable biological products, and that a determination of interchangeability may not require additional testing.

⁷¹ We propose a definition of “biosimilar biological product” later in this section.

biological products did not qualify for immediate substitutions but nonetheless encouraged their inclusion on formularies. However, neither the preamble at section III.Q., Changes to an Approved Formulary, in the December 2022 proposed rule, nor the accompanying proposed regulatory text, explicitly discussed whether we would treat the substitution of biosimilar biological products other than interchangeable biological products for their reference products as non-maintenance changes or as maintenance changes, as respectively proposed to be defined in section § 423.100 in the December 2022 proposed rule. Our current guidance treats such substitutions as non-maintenance changes.

Nevertheless, we received multiple comments regarding this issue with a range of views. Commenters asking CMS to treat substitutions of reference products with biosimilar biological products, including interchangeable biological products, as immediate formulary changes or maintenance changes noted, for example, that FDA states that biosimilar biological products, including interchangeable biological products, are as safe and effective as the reference product they were compared to,⁷² and that beneficiaries could benefit from additional treatment options and the potential for savings. Commenters asking CMS to restrict immediate substitutions to interchangeable biological products noted, among other things, that the PHSa distinguishes between biosimilar biological products based on interchangeability. Commenters asking us not to permit immediate substitutions, or even any substitutions, of biosimilar biological products, including interchangeable biological products, for reference products noted, for instance, that established drug therapies should not be changed for non-clinical reasons to avoid risk to patient safety and that prescribers need to be consulted before changing medications.

We appreciate all the comments we received. In response thereto, and after further consideration of these issues, we have revisited our current policy, which treats substitutions of biosimilar biological products for reference products as non-maintenance changes, as well as our proposal in the December 2022 proposed rule. Upon further consideration, we are now proposing in this rule to include substitutions of

biosimilar biological products other than interchangeable biological products⁷³ for their reference products as maintenance changes. All FDA-licensed biosimilar biological products, including FDA-licensed interchangeable biological products, must be highly similar to and have no clinically meaningful differences from the reference product in terms of safety and effectiveness notwithstanding minor differences in clinically inactive components. Thus, based on FDA's standards for approval, health care providers and patients can be confident in the safety and effectiveness of all biosimilar biological products, just as they would be for their reference products. The FDA has noted that all biosimilar biological products are as safe and effective as their reference product:

Both are rigorously and thoroughly evaluated by the FDA before approval. For [biosimilar biological products] to be approved by the FDA, manufacturers must show that patients taking [biosimilar biological products] do not have any new or worsening side effects as compared to people taking the [reference products].

As it does with all medication approvals, the FDA carefully reviews the data provided by manufacturers and takes several steps to ensure that all [biosimilar biologic products] meet standards for patient use. The FDA's thorough evaluation makes sure that all [biosimilar biological products] are as safe and effective as their [reference products] and meet the FDA's high standards for approval. This means [consumers] can expect the same safety and effectiveness from the [biosimilar biological product] over the course of treatment as [they] would from the original product.

In addition, the FDA closely regulates the manufacturing of [biosimilar biological products]. The same quality manufacturing standards that apply to the [reference product] also apply to the

[biosimilar biological product]. It must be manufactured in accordance with Current Good Manufacturing Practice⁷⁴ requirements, which cover: Methods, Facilities, and Controls for the manufacturing, processing, packaging, or holding of a medication. This helps to prevent manufacturing mistakes or unacceptable impurities, and to ensure consistent product quality.

* * * * *

[All biosimilar biological products, not just interchangeable biological products,] are as safe and effective as the [reference product] they were compared to, and they can both be used in its place. This means that health care professionals can prescribe either a biosimilar [biological product] or interchangeable [biological] product instead of the [reference product].⁷⁵

However, we note that under the PHSa an FDA determination that a biological product is interchangeable with the reference product means that the interchangeable biological product may be substituted without the intervention of the health care provider who prescribed the reference product. A manufacturer of a proposed interchangeable biological product must show that the product is biosimilar to its reference product and that it can be expected to produce the same clinical results as the reference product in any given patient and there are no greater risks in terms of safety or diminished efficacy with alternating or switching between the reference product and the interchangeable biological product.⁷⁶ We appreciate the importance of provider and patient education to advance uptake and acceptance as the development and market for biosimilar biological products, including interchangeable biological products, continues to grow.

We believe that including substitutions of biosimilar biological products other than interchangeable biological products for their reference products as maintenance changes would strike the right balance between promoting utilization of more biosimilar biological products and providing enrollees with sufficient advance notice

⁷³ We would note that in our December 2022 proposed rule, we already proposed the option for Part D sponsors to treat substitution of interchangeable biological products for their reference products as maintenance changes: We proposed in paragraph (1) of the proposed definition of "maintenance change" in § 423.100 to mean, in part, making any negative formulary changes to a drug and at the same time adding a corresponding drug as specified. In turn, we proposed to define "corresponding drug" in § 423.100 to include an interchangeable biological product of a reference product. In this proposed rule, we are proposing to add a new paragraph (2) to the proposed definition of "maintenance change" in § 423.100 to treat substitution of biosimilar biological products other than interchangeable biological products for their reference products as maintenance changes.

⁷⁴ <https://www.fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations>. Accessed October 18, 2023.

⁷⁵ See FDA website entitled "Biosimilar and Interchangeable Biologics: More Treatment Choices" at: <https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices#:~:text=Biosimilars%20are%20a%20type%20of,macular%20degeneration%2C%20and%20some%20cancers>. Accessed October 18, 2023.

⁷⁶ See 42 U.S.C. 262(i)(3) and (k)(4).

⁷² FDA. Overview of Biosimilar Products. Available from: <https://www.fda.gov/media/151058/download?attachment>.

of such changes. This proposal would provide Part D sponsors with more flexibility than the current policy of treating such changes as non-maintenance changes (which do not apply to enrollees who are currently taking a reference product when the change takes effect⁷⁷) but would not extend the flexibility to what is permitted for immediate substitutions (which apply to all enrollees, including those currently taking a reference product, but only require direct notice of specific changes made to affected enrollees after the fact⁷⁸). We realize now that not addressing in the December 2022 proposed rule the treatment of biosimilar biological products other than interchangeable biological products suggested that we wanted to continue our sub-regulatory policy of treating substitution of reference products by biosimilar biological products other than interchangeable biological products as non-maintenance changes. However, continuing to treat such changes as non-maintenance would not support our goal to encourage greater use of biosimilar biological products.

At the same time, we are not convinced that it is appropriate at this time to propose to permit immediate substitutions of reference products for biosimilar biological products other than interchangeable biological products without 30 days advance notice. In this regard, we would note that, pharmacists generally cannot substitute a biosimilar biological product other than an interchangeable biological product for its reference product without first consulting the prescribing health care provider, subject to State pharmacy laws. If a biosimilar biological product other than an interchangeable biological product were able to be immediately substituted, the result is that any enrollee seeking a refill on their prescription for a reference product after a Part D sponsor has substituted a biosimilar biological product for that reference product (regardless of whether such a formulary change were permitted to take place as an immediate substitution or a maintenance change) would be told that their plan no longer covers the reference product. And, subject to State pharmacy laws, a pharmacist in most cases would not be able to provide the corresponding biosimilar biological product to the

enrollee unless they receive a new prescription from a prescriber.

The above would mean that, were we to treat substitutions of biosimilar biological products other than interchangeable biological products as immediate substitutions, enrollees currently taking a reference product would receive no direct advance notice of specific changes made and would likely find themselves at the pharmacy counter unable to obtain coverage for their reference product and needing to either request an exception or obtain a new prescription for the biosimilar biological product. Such enrollees would receive a notice at the point of sale telling them what they or their prescriber would need to do to request an exception to stay on the reference product and that they can call their plan for more information. To avoid a situation in which the enrollee might not have medication on hand and need to take quick action, but at the same time still encourage the use of all biosimilar biological products, we are proposing to treat such substitutions as maintenance changes. Given that maintenance changes would apply to all enrollees under proposed

§ 423.120(e)(3) in the December 2022 proposed rule, permitting Part D sponsors to substitute such biosimilar biological products for their reference products as maintenance changes would presumably result in more widespread use of such products than continuing our current sub-regulatory policy that treats such substitutions as non-maintenance changes. Further, under current sub-regulatory policy and proposed § 423.120(e)(3)(i) in the December 2022 proposed rule, Part D sponsors that submit a maintenance change request are able to assume that CMS has approved their negative change request if they do not hear back from CMS within 30 days of submission, which could result in changes that take place more quickly.

Additionally, we believe that the 30-day notice period is appropriate for a variety of reasons. We have applied the 30-day time frame in other contexts (such as notice of changes required under current § 423.120(b)(5)(i)(A) and for changes proposed in our December 2022 proposed rule) and are hesitant to create more confusion by carving out certain biosimilar biological products. We understand the nature of the change is different from, for instance, substituting generic drugs for brand name drugs, in that in most states the enrollees that are prescribed reference products must at this time obtain new prescriptions for biosimilar biological products other than interchangeable

biological products. However, this would not be the only time an enrollee has 30 days' notice within which to obtain a new prescription. For instance, in the final rule titled "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program," which appeared in the April 16, 2018 **Federal Register**, we reduced the time for advance direct notice of certain formulary changes from 60 to 30 days and since its effective date, § 423.120(b)(5)(i)(A) has required only 30 days' notice of changes to the formulary that are not immediate. A similar period applies to the transition process for enrollees prescribed Part D drugs that are not on the Part D plan's formulary: under § 423.120(b)(3)(iii), enrollees receive a month's supply of a drug after which they must obtain a new prescription for an alternate drug or apply for an exception. If we required Part D sponsors to issue notice earlier, for instance to provide advance notice 90 days prior to the formulary change, the lengthened notice period would provide Part D sponsors less time within a year for a change to be effective and might unintentionally motivate them to wait until the next plan year—which would defeat the goal of this proposal to encourage uptake of biosimilar biological products other than interchangeable biological products sooner than would otherwise be the case.

If a Part D sponsor were to implement a maintenance change for a biosimilar biological product other than an interchangeable biological product under our proposal, then it would work as follows: Part D sponsors removing or making any negative changes to a reference product would be required to add a biosimilar biological product other than an interchangeable biological product at the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements as the reference product. Part D sponsors adding a biosimilar biological product other than an interchangeable biological product would also be required to provide 30 days' advance written notice before making any negative change to the reference product. The written notice under proposed § 423.120(f)(4) would include details regarding the change, including the specific biosimilar biological product to be added to the formulary; whether the sponsor will be removing the related reference product, subjecting it to a new or more restrictive PA, ST,

⁷⁷ See proposed § 423.120(e)(3)(ii), of the December 2022 proposed rule, which would codify longstanding policy regarding non-maintenance changes.

⁷⁸ See § 423.120(b)(5)(iv).

or QL, or moving it to a higher cost-sharing tier; and identification of whether appropriate alternatives, other than the biosimilar biological product that is the subject of the notice, are available on the formulary at the same or lower cost-sharing tier as the reference product. The written notice would also include the means by which the affected enrollee can request a coverage determination under § 423.566 or an exception to a coverage rule under § 423.578. Specifically, under § 423.566, the enrollee can always ask for a coverage determination, including an exception to a coverage rule, and might choose to do so after receiving their notice of a specific change due to occur within 30 days. Furthermore, the enrollee can also request an expedited determination if their health requires. Again, treating the change as a maintenance change would mean enrollees have 30 days to take action before the change becomes effective.

We would note that the Part D transition policy does not apply to midyear maintenance changes. An enrollee is only entitled to a transition supply under § 423.120(b)(3)(i)(A) if the enrollee is new to the plan or stayed in the plan until the next contract year and a drug they are taking is affected by formulary changes in the next contract year. Formulary changes from one contract year to the next do not constitute changes to an approved formulary since formularies are submitted for review and approval annually as part of the Part D bid submission process. Rather, the advance direct notice of changes currently required under § 423.120(b)(5)(i), and which we proposed to require in the December 2022 proposed rule at the proposed § 423.120(f)(1), provides an affected enrollee with time to obtain a new prescription for that biosimilar biological product other than an interchangeable biological product or to seek an exception, before the reference product comes off the formulary.

We assume that in most cases, substituting a biosimilar biological product other than an interchangeable biological product for the reference product on the formulary will be more financially favorable to enrollees since biosimilar biological products are generally lower cost than reference products and must be added to the same or lower cost-sharing tier as the reference product. However, differences in plan benefit designs make it challenging to predict the degree of savings an enrollee may experience. For example, if a Part D sponsor removes a reference product from the formulary and adds a biosimilar biological product

other than an interchangeable biological product to the formulary on the same tier, the affected enrollee likely would experience savings if the cost sharing for the tier is based on a percent coinsurance, but not if the cost sharing for the tier is a fixed copay. If an affected enrollee pursues a formulary exception to continue to take the non-formulary reference product, these enrollees may be faced with higher out-of-pocket costs, depending on the tier that the Part D sponsor designates for Part D drugs obtained through formulary exceptions and the tier that the reference product was originally on. If the reference product was on a preferred tier, but the formulary exception tier designated in the plan benefit package is the non-preferred tier, then affected enrollees who obtain a formulary exception may be subject to higher cost sharing than previously.

For the reasons discussed above, we are now proposing to update the proposed definition of “maintenance changes” at § 423.100 in the December 2022 proposed rule to include a new paragraph (2) on making any negative formulary changes to a reference product when adding a biosimilar biological product other than an interchangeable biological product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements. We would renumber the remaining maintenance changes listed in the proposed definition in the December 2022 proposed rule.

We are also proposing in this proposed rule at § 423.4 to define “biosimilar biological product” to mean a biological product licensed under section 351(k) of the PHSA that, in accordance with section 351(i)(2) of the PHSA, is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and has no clinically meaningful differences between the biological product and the reference product, in terms of the safety, purity, and potency of the product. The proposed term, biosimilar biological product, includes interchangeable biological products as we proposed to define them in our December 2022 proposed rule. We are also proposing a technical correction to the proposed definition of an interchangeable biological product to mean a product licensed under section 351(k) of the PHSA (42 U.S.C. 262(k)) that FDA has determined meets the standards described in section 351(k)(4) of the PHSA (42 U.S.C. 262(k)(4)).

We solicit comment on our proposal to treat formulary substitutions of

biosimilar biological products other than interchangeable biological products for reference products as maintenance changes, as well as our proposed definition of biosimilar biological product. We also would be interested in any comments on our proposal that enrollees taking a reference product would receive 30 days’ notice before the change is made and whether that is sufficient time to obtain a new prescription for the biosimilar biological product other than an interchangeable biological product, as well as how that 30-day notice period relates to the timing of other notice requirements. We also solicit comment on our proposal that the biosimilar biological product other than the interchangeable biological product be placed on the same or a lower cost-sharing tier as the reference product it replaces or that is subject to negative formulary changes.

(2) Updated Proposal Related to Timing of Substitutions

In reexamining our proposed definition of “maintenance changes” in § 423.100 in the December 2022 proposed rule to add a new category for biosimilar biological products other than interchangeable biological products in paragraph (2), as discussed above, we also revisited paragraph (1) of the proposed definition, in which we proposed to require Part D sponsors making a negative formulary change to a drug to “at the same time” add a corresponding drug at the same or lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements (excluding immediate substitutions permitted under the proposed § 423.120(e)(2)(i) of the December 2022 proposed rule). Considering that our current sub-regulatory guidance does not require maintenance substitutions to occur “at the same time,” we have reconsidered and do not believe it is necessary to propose imposing such strict timing requirements for a maintenance change—whether it be related to plan sponsors removing or making negative changes (1) to a brand name or reference product when adding a corresponding drug that is not an immediate substitution, or (2) to a reference product when adding a biosimilar biological product other than an interchangeable biological product. We would like to encourage plans to offer more choices by adding corresponding drugs (the proposed definition of which in the December 2022 proposed rule includes interchangeable biological products) and biosimilar biological products other than interchangeable

biological products to their formularies as soon as possible. We are concerned that requiring such an addition to occur “at the same time” as the negative formulary change to the brand name drug or reference product could cause a Part D sponsor to delay adding a corresponding drug or biosimilar biological product other than an interchangeable biological product until the Part D sponsor has taken the steps it deems necessary to operationalize the negative changes that would be made to the brand name drug or reference product currently on the formulary, which in turn would delay enrollee access to the corresponding drug or biosimilar biological product other than an interchangeable biological product.

Therefore, we propose to remove the requirement to have changes take place “at the same time” in the December 2022 proposed rule’s definition of “maintenance change” at proposed § 423.100, and will not add that modifier for the change for biosimilar biological products other than interchangeable biological products that we are proposing in this proposed rule, with the understanding that the addition of the corresponding drug or biosimilar biological product other than an interchangeable biological product would need to come before the negative change is applied to the brand name drug or reference product. Further, this proposed update to the definition of a maintenance change does not alter other proposed requirements for maintenance changes in the December 2022 proposed rule, including that CMS must be provided a 30-day opportunity to review any such changes and in all cases enrollees will receive at least 30 days’ notice before a drug is removed or subject to any other negative formulary change.

At the same time, we are not proposing an unlimited window in which to make a negative formulary change to the related drug after adding a corresponding drug under paragraph (1) or adding a biosimilar biological product other than an interchangeable biological product under paragraph (2) of the proposed § 423.100 definition of a “maintenance change.” We believe Part D sponsors should make such negative changes within a reasonable amount of time after adding corresponding drugs and biosimilar biological products other than interchangeable biological products as specified in order to best achieve the goal of increasing their utilization. We understand that Part D sponsors may be eager to add, for example, a newly approved generic drug or biosimilar biological product to their formularies,

but may need additional time to operationalize the negative formulary change to the brand name or reference product, respectively; however, we do not believe that Part D sponsors should have an unlimited amount of time to effectuate the negative formulary change because this presents challenges for CMS to monitor and deviates from the idea that such formulary changes are in many cases substitutions of one drug for another. In other words, the addition of a corresponding drug or a biosimilar biological product other than an interchangeable biological product justifies the negative formulary change to the brand name or reference product. Nevertheless, we do not want to establish too short a timeframe requirement to make the negative change to the brand name drug or reference product because it could increase the chance that Part D sponsors will miss the formulary update opportunity, resulting in more continued utilization of the brand name drug or reference product and less utilization of the corresponding drug or biosimilar biological product other than an interchangeable biological product than otherwise could be achieved. To strike a balance, we are proposing to codify our longstanding operational limitation of a 90-day timeframe for a Part D sponsor to remove a brand name drug from the formulary when a generic drug is added. Our experience suggests that this timeframe would provide Part D sponsors with sufficient time to implement the negative formulary change for a brand name drug or reference product after adding a corresponding drug or biosimilar biological product other than an interchangeable biological product, but still ensure the removal of the brand name drug or reference product is timely enough to help increase utilization of the corresponding drug or biosimilar biological product other than an interchangeable biological product. Accordingly, we believe negative formulary changes to the brand name drug or reference product should have to take effect within 90 days after a generic or other corresponding drug, or biosimilar biological product other than an interchangeable biological product, is added as specified to the formulary.

To provide Part D sponsors with more flexibility, we propose to remove from paragraph (1) of the proposed definition of “maintenance change” in § 423.100 of the December 2022 proposed rule the requirement that the corresponding drug be added and the related drug be subject to negative formulary changes “at the same time.” Rather, we now propose to

revise paragraph (1) to require Part D sponsors to make any negative formulary changes “within 90 days of” adding a corresponding drug. Similarly, the newly proposed paragraph (2) of the proposed definition of “maintenance change” in § 423.100, as discussed above, would require Part D sponsors to make negative formulary changes to a reference product “within 90 days of” adding a biosimilar biological product other than an interchangeable biological product.

In this vein, we note that a commenter on the December 2022 proposed rule requested that we remove the requirement in the proposed § 423.120(e)(2)(i) of the December 2022 proposed rule (currently appearing at § 423.120(b)(5)(iv)(A)) that Part D sponsors making immediate substitutions remove or make any other negative formulary changes to a related drug “at the same time” they add its corresponding drug. The commenter suggested that this requirement might discourage them from adding new corresponding drugs, which could be lower in cost than related drugs, as soon as possible because they often need more time to implement the changes with respect to the related drug. For instance, they suggested it takes time to evaluate new products; check their availability; communicate changes; update operations; and assess suitability for substitution among interchangeable biological products. We appreciate the comment and reiterate that we favor expeditious access for enrollees to Part D drugs that could be lower in cost. The purpose of the immediate substitutions policy is to encourage quick action with respect to immediately placing a corresponding drug on the formulary after it is released.

Accordingly, with respect to the proposed § 423.120(e)(2)(i) in the December 2022 proposed rule, we now propose to remove the requirement that immediate substitutions occur “at the same time” and instead state that negative formulary changes may still qualify as immediate substitutions if made within 30 days of adding a corresponding drug to a formulary. As proposed in the December 2022 proposed rule, for immediate substitutions, Part D sponsors would be required to submit such changes to CMS, in a form and manner specified by CMS, in their next required or scheduled formulary update.

We note that we are proposing different windows of time in which Part D sponsors can make negative formulary changes to the related drug based on whether there is an immediate substitution (that is, within 30 days after

adding the corresponding drug) or a maintenance change (that is, within 90 days after adding the corresponding drug). The different requirements reflect a distinction in the nature of the changes themselves. As noted earlier, the entire purpose of immediate substitutions is quick action, such that Part D sponsors can put a newer corresponding drug on the formulary and remove the related drug it is replacing as soon as possible. For that reason, we continue to encourage that immediate substitutions take place “at the same time,” but propose setting a 30-day limit. To encourage this, Part D sponsors implementing immediate substitutions may provide notice to affected enrollees of the specific changes after they have taken effect.

For the reasons discussed above, for other kinds of maintenance changes that are not immediate, we propose that we would approve only negative formulary changes to the related drug that take effect within 90 days after a corresponding drug is added to the formulary.

We invite comment on these proposed changes, the reasons why Part D sponsors would need a period of time after adding a corresponding drug or biosimilar biological product other than an interchangeable biological product in which to take action, and any other appropriate window of time in which to permit maintenance changes or immediate substitutions to take place, including whether we should maintain a distinction between the two.

(3) Miscellaneous Changes

In re-examining our proposed definition of “maintenance change” in the December 2022 proposed rule at § 423.100, we found a technical error, in that we did not specify in the introductory clause that the changes would apply with respect to “a covered Part D drug.” We hereby propose to make that correction in this proposed rule.

We propose a technical change to our proposed definition of “corresponding drug” included in the December 2022 proposed rule in § 423.100 to specify that the reference to “an unbranded biological product of a biological product” is intended to be a reference to “an unbranded biological product marketed under the same BLA as a brand name biological product.”

3. Summary

In conclusion, we are proposing the changes below to three sections of regulatory text originally proposed in the December 2022 proposed rule. We are currently not proposing updates to

the other proposed regulatory text in the December 2022 proposed rule related to section III.Q., Changes to an Approved Formulary, which, as noted above, remains under consideration.

- In § 423.4, to add a definition of “biosimilar biological product;”
- In § 423.4, to make technical corrections to the proposed definition of an “interchangeable biological product;”
- In § 423.100, to revise the proposed definition of “maintenance change” as follows: to add an introductory clause noting its application to covered Part D drugs; to revise paragraph (1) to require changes “within 90 days of,” rather than “at the same time as,” adding a corresponding drug; to add a new paragraph (2) to include substitution of biosimilar biological products other than interchangeable biological products as a type of maintenance change; and to renumber the remaining maintenance changes listed;
- In § 423.100, to revise the proposed definition of “corresponding drug” to specify that the reference to “an unbranded biological product of a biological product” is intended to be a reference to “an unbranded biological product marketed under the same BLA as a brand name biological product;” and
- In proposed § 423.120(e)(2)(i), to require changes “within 30 days of,” rather than “at the same time as,” adding a corresponding drug.

G. Parallel Marketing and Enrollment Sanctions Following a Contract Termination (§§ 422.510(e) and 423.509(f))

Sections 1857(c)(2) and 1860D–12(b)(3)(B) of the Act provide CMS with the ability to terminate MA (including MA–PD) and PDP contracts if we determine that a contract(s) has met any of the following thresholds:

- Has failed substantially to carry out the contract.
- Is carrying out the contract in a manner that is inconsistent with the efficient and effective administration of, respectively, Part C or Part D of Title XVIII of the Act (that is, the Medicare statute).
- No longer substantially meets the applicable conditions of the applicable part of the statute.

This termination authority is codified at 42 CFR 422.510(a)(1) through (3) and 423.509(a)(1) through (3), respectively. In addition, section 1857(g)(3) of the Act (incorporated for Part D sponsors under section 1860D–12(b)(3)(F)) specifies that intermediate sanctions and civil money penalties (CMPs) can be imposed on the same grounds upon which a contract

could be terminated (63 FR 34968 and 70 FR 4193). CMS codified this authority at §§ 422.752(b) and 423.752(b) with respect to intermediate sanctions, and §§ 422.752(c)(1)(i) and 423.752(c)(1)(i) with respect to CMPs.

If CMS terminates an MA organization or Part D sponsor contract(s) during the plan year but the termination is not effective until January 1 of the following year, the MA organization or Part D sponsor could potentially continue to market and enroll eligible beneficiaries (as described in part 422, subpart B, and part 423, subpart B) into plans under the terminating contract(s) unless CMS imposes separate marketing and enrollment sanctions on the terminating contract(s).⁷⁹ A terminating contract that continues to market to and enroll eligible beneficiaries would cause confusion and disruption for beneficiaries who enroll in the period of time between when the termination action is taken and the January 1 effective date of the termination.

For these reasons, we propose to add paragraph (e) to § 422.510 and paragraph (f) to § 423.509 that, effective contract year 2025, marketing and enrollment sanctions will automatically take effect after a termination is imposed. At paragraph (e)(1) of § 422.510 and paragraph (f)(1) of § 423.509, we propose to state that the marketing and enrollment sanctions will go into effect 15 days after CMS issues a contract termination notice. This timeframe is consistent with the number of days CMS often designates as the effective date for sanctions after CMS issues a sanction notice.

At paragraph (e)(2) of § 422.510 and paragraph (f)(2) of § 423.509, we propose that MA organizations and Part D sponsors would continue to be afforded the same appeals rights and procedures specific to contract terminations under subpart N of 42 CFR parts 422 and 423, however, there would not be a separate appeal for the sanction (in other words the appeal of the termination would include the associated marketing and enrollment sanctions). In addition, at paragraph (e)(3) of § 422.510 and paragraph (f)(3) of § 423.509 we propose that if an MA organization or Part D sponsor appeals the contract termination, the marketing and enrollment sanctions would not be stayed pending the appeal consistent with §§ 422.756(b)(3) and 423.756(b)(3). Finally, at paragraph (e)(4) of § 422.510 and paragraph (f)(4) of § 423.509 we

⁷⁹ Regulations in 42 CFR part 422, subpart B, and part 423, subpart B, permit enrollees to enroll in a plan mid-year during their initial election period or special election periods.

propose that the sanction would remain in effect until the effective date of the termination, or if the termination decision is overturned on appeal, until the final decision to overturn the termination is made by the hearing officer or Administrator.

CMS rarely terminates MA organization and Part D sponsor contracts and, on average, contract terminations affect less than one MA organization or Part D sponsor a year. Therefore, we anticipate that this proposal would not result in additional costs or additional administrative burden for affected MA organizations and Part D sponsors. For example, an MA organization and Part D sponsor would not be required to submit a corrective action plan, and if appealed there would only be one appeal rather than multiple. MA organizations and Part D sponsors would continue to be required to comply with existing regulations that require public and beneficiary notice that their contract is being terminated under this proposal.

H. Update to the Multi-Language Insert Regulation (§§ 422.2267 and 423.2267)

Individuals with limited English proficiency (LEP) experience obstacles to accessing health care in the United States. Language barriers negatively affect the ability of patients with LEP to comprehend their diagnoses and understand medical instructions when they are delivered in English, and impact their comfort with post-discharge care regimens.⁸⁰ For example, Hispanic/Latino individuals with LEP report worse access to care and receipt of fewer preventive services than Hispanic/Latino individuals who speak English proficiently. For Asian Americans who are not proficient in English, language barriers are one of the most significant challenges to accessing health care, including making an appointment, communicating with health care professionals, and gaining knowledge about an illness; this is even more pronounced among older Asian Americans, who are more likely to have limited English proficiency.⁸¹ Studies

show that patients with LEP experience longer hospital stays—leading to a greater risk of line infections, surgical infections, falls, and pressure ulcers—when compared to English-speaking patients; because patients with LEP have greater difficulty understanding medical instructions when those instructions are given in English, they are at higher risk of surgical delays and readmissions.⁸² Although the use of qualified interpreters is effective in improving care for patients with LEP, some clinicians choose not to use them, fail to use them effectively, or rely instead on ad hoc interpreters—such as family members or untrained bilingual staff.⁸³ However, in addition to posing legal and ethical concerns, ad hoc interpreters are more likely to make mistakes than professional interpreters.⁸⁴ Also, clinicians with basic or intermediate non-English spoken language skills often attempt to communicate with the patient on their own without using an interpreter, increasing patient risk.⁸⁵ These barriers contribute to disparities in health outcomes for individuals with LEP, which likely worsened during the COVID-19 pandemic.⁸⁶

The multi-language insert (MLI) required at §§ 422.2267(e)(31) and 423.2267(e)(33) is a standardized communications material that informs

<https://www.tandfonline.com/doi/pdf/10.1080/19371910903240704?needAccess=true>.

⁸² U.S. Department of Health & Human Services, Agency for Healthcare Research & Quality. “Executive Summary: Improving Patient Safety Systems for Patients with Limited English Proficiency”, (September 2020). Retrieved from <https://www.ahrq.gov/health-literacy/professional-training/lepguide/index.html>.

⁸³ Espinoza, J. and Derrington, S. “How Should Clinicians Respond to Language Barriers that Exacerbate Health Inequity?”, *AMA Journal of Ethics* (February 2021) E110. Retrieved from <https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2021-02/cscm3-2102.pdf>.

⁸⁴ Glenn Flores et al., *Errors of Medical Interpretation and Their Potential Clinical Consequences: A Comparison of Professional Versus Ad Hoc Versus No Interpreters*, 5 *Annals of Emerg. Med.* 545 (Nov. 1, 2012), <https://pubmed.ncbi.nlm.nih.gov/22424655/>; Ali Labaf et al., *The Effect of Language Barrier and Non-Professional Interpreters on the Accuracy of Patient-Physician Communication in Emergency Department*, 3 *Adv. J. Emerg. Med.*, June 6, 2019, at p. 4, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6789075/pdf/AJEM-3-e38.pdf>.

⁸⁵ U.S. Department of Health & Human Services, Agency for Healthcare Research & Quality. “Executive Summary: Improving Patient Safety Systems for Patients with Limited English Proficiency”, (September 2020). Retrieved from <https://www.ahrq.gov/health-literacy/professional-training/lepguide/exec-summary.html#what>.

⁸⁶ Lala Tanmoy Das et al., *Addressing Barriers to Care for Patients with Limited English Proficiency During the COVID-19 Pandemic*, *Health Affairs Blog* (July 29, 2020), <https://www.healthaffairs.org/doi/10.1377/hblog20200724.76821/full/>.

enrollees and prospective enrollees that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese. These are the 15 most common non-English languages in the United States. Additionally, §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i) require plans to provide the MLI in any non-English language that is the primary language of at least five percent of the individuals in a plan benefit package (PBP) service area but is not already included on the MLI. These regulations also provide that a plan may opt to include the MLI in any additional languages that do not meet the five percent threshold, where it determines that including the language would be appropriate. The MLI states, “We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service.” The issuance of the MLI is independent of the Medicare written translation requirements for any non-English language that meets the five percent threshold, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2), and the additional written translation requirements for fully integrated D-SNPs (FIDE SNPs) and highly integrated D-SNPs (HIDE SNPs) provided in §§ 422.2267(a)(4) and 423.3367(a)(4).⁸⁷ Additionally, we note that pursuant to CMS’s authority in section 1876(c)(3)(C) to regulate marketing and the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms, we have also established in § 417.428 that most of the marketing and communication regulations in subpart V of part 422, including the MLI requirement in § 422.2267(e)(31), also apply to section 1876 cost plans.

On May 18, 2016, the Office for Civil Rights (OCR) published a final rule (81 FR 31375; hereinafter referenced to as the section 1557 final rule) implementing section 1557 of the Patient Protection and Affordable Care Act (ACA).⁸⁸ Section 1557 of the ACA provides that an individual shall not be excluded from participation in, be denied the benefits of, or be subjected to discrimination on the grounds prohibited under Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d *et*

⁸⁷ This proposal pertains only to the MLI requirements in §§ 422.2267(e)(31) and 423.2267(e)(33), not §§ 422.2267 and 423.2267 broadly.

⁸⁸ Public Law 111–148.

⁸⁰ Espinoza, J. and Derrington, S. “How Should Clinicians Respond to Language Barriers that Exacerbate Health Inequity?”, *AMA Journal of Ethics* (February 2021) E109. Retrieved from <https://journalofethics.ama-assn.org/sites/journalofethics.ama-assn.org/files/2021-02/cscm3-2102.pdf>; Karliner, L., Perez-Stable, and E., Gregorich, S. “Convenient Access to Professional Interpreters in the Hospital Decreases Readmission Rates and Estimated Hospital Expenditures for Patients with Limited English Proficiency”, *Med Care* (March 2017) 199–206. Retrieved from <https://pubmed.ncbi.nlm.nih.gov/27579909/>.

⁸¹ Wooksoo, K. and Keefe, R. “Barriers to Healthcare Among Asian Americans”, *Social Work in Public Health* (2010) 286–295. Retrieved from

seq. (race, color, national origin), Title IX of the Education Amendments of 1972, 20 U.S.C. 1681 *et seq.* (sex), the Age Discrimination Act of 1975, 42 U.S.C. 6101 *et seq.* (age), or section 504 of the Rehabilitation Act of 1973, 29 U.S.C. 794 (disability), under any health program or activity, any part of which is receiving Federal financial assistance; any health program or activity administered by the Department; or any program or activity administered by any entity established under Title I of the Act. The 2016 regulations implementing section 1557 included the requirement that all covered entities include taglines with all “significant communications.” The sample tagline provided by the Department consisted of a sentence stating, in the 15 most common non-English languages in a State or States, “ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-xxx-xxx-xxxx (TTY: 1-xxx-xxx-xxxx).” Because of the inherent duplication with the MLI, CMS issued an HPMS email on August 25, 2016, to revise the Medicare Marketing Guidelines (MMG) at that time to remove the then-applicable MLI requirements.

On June 19, 2020, OCR published a second section 1557 final rule (2020 OCR Rule) (85 FR 37160), which is currently in effect, that repealed the notice and tagline requirements, citing costs, confusion, and waste, but stated that covered entities are still required “to provide taglines whenever such taglines are necessary to ensure meaningful access by LEP individuals to a covered program or activity.” In the February 2020 proposed rule (85 FR 9002), we proposed to require plans to use a disclaimer tagline about the availability of non-English translations in all required materials. However, we did not finalize that proposal in the January 2021 final rule (86 FR 5864). We based this decision on our belief that future rulemaking regarding non-English disclaimers, if appropriate, would be best addressed by OCR, as those requirements would be HHS-wide instead of limited to CMS. We also stated that deferring to OCR’s oversight and management of any requirements related to non-English disclaimers is in the best interest of the Medicare program (86 FR 5995).

It is important to note that none of the actions impacting the various notifications of interpreter services changed the requirement that MA organizations, Part D sponsors, or cost plans must provide these services under applicable law. Plans have long been required to provide interpreters when

necessary to ensure meaningful access to individuals with LEP, consistent with existing civil rights laws. In implementing and carrying out the Part C and D programs under sections 1851(h), 1852(c), 1860–1(b)(1)(B)(vi), 1860D–4(a), and 1860D–4(l) of the Act, CMS considers the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary decision making process; ensuring beneficiaries with LEP are aware of and are able to access interpreter services provides a clear path for this portion of the population to properly understand and access their benefits. For a more detailed discussion of previous rulemaking related to section 1557, the MLI, and non-English translation and interpreter requirements, we direct readers to the August 4, 2022 HHS notice of proposed rulemaking regarding section 1557 of the Affordable Care Act (87 FR 47853 through 47856) (hereinafter referred to as the August 2022 proposed rule) and the January 2022 proposed rule (87 FR 1899 through 1900).⁸⁹

In the Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency final rule (87 FR 27704) (hereafter referred to as the May 2022 final rule), we reinstituted the requirement to use the MLI at §§ 422.2267(e)(31) and 423.2267(e)(33). We noted that we gained additional insight regarding the void created by the lack of any notification requirement associated with the availability of interpreter services for Medicare beneficiaries (87 CFR 27821). We stated that we consider the materials required under §§ 422.2267(e) and 423.2267(e) to be vital to the beneficiary decision-making process. We also noted that we reviewed complaint tracking module (CTM) cases in the Health Plan Management System (HPMS) related to “language” and found a pattern of beneficiary confusion stemming from not fully understanding materials based on a language barrier. We noted that solely relying on the requirements delineated in the 2020 OCR Rule for covered entities to convey the availability of interpreter services is insufficient for the MA, cost plan, and

Part D programs and is not in the best interest of Medicare beneficiaries who are evaluating whether to receive their Medicare benefits through these plans and who are enrolled in these plans. We stated that we believed that informing Medicare beneficiaries that interpreter services are available is essential to realizing the value of our regulatory requirements for interpreter services.

On August 4, 2022, OCR published a proposed rule (87 FR 47824) that proposed to require covered entities to notify the public of the availability of language assistance services and auxiliary aids and services for their health programs and activities using a “Notice of Availability.” Proposed § 92.11(b) would require the Notice of Availability to be provided in English and at least in the 15 most common languages spoken by individuals with LEP in the relevant State or States, and in alternate formats for individuals with disabilities who request auxiliary aids and services to ensure effective communications. If finalized, these proposed provisions would result in misalignment with the MLI requirement under §§ 422.2267(e)(31) and 423.2267(e)(33) which require that notice be provided in the 15 most common non-English languages in the United States. At the time this proposed rule is published, OCR has not issued a final rule on its August 2022 proposed rule, and the 2020 OCR Rule remains in effect.

In addition, per § 438.10(d)(2), States must require managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), prepaid ambulatory health plans (PAHPs), and primary care case management programs to include taglines in written materials that are critical to obtaining services for potential enrollees in the prevalent non-English languages in the State explaining the availability of oral interpretation to understand the information provided, information on how to request auxiliary aids and services, and the toll-free telephone number of the entity providing choice counseling services in the State. Several States that use integrated Medicare and Medicaid materials for D–SNPs and Medicare-Medicaid Plans have contacted CMS and requested that we change the MLI to be based on the 15 most common languages in the State rather than the 15 most common languages nationally because the most common languages in the State are often not the same as the most common 15 languages nationally. For example, while French Creole is included in the current MLI list for the most common languages nationally, it is not a common

⁸⁹ Specifically, we highlight pages 1899–1900 and 1926–1927 of the August 2022 proposed rule and 87 FR 1899 through 1900 of the January 2022 proposed rule.

language in Minnesota. In Minnesota, Hmong and Somali, which are not included in the MLI, are two of the most prevalent languages. In fact, Minnesota informed CMS that only seven of the languages on the national list were included in their list of the 15 most common languages in their State.

As a result of this conflict between the MLI requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) and the Medicaid requirement at § 438.10(d)(2), any applicable integrated plans (AIPs), as defined at § 422.561, that provide integrated Medicare and Medicaid materials for enrollees must currently include the MLI in the 15 most common languages nationally as well as the Medicaid tagline in the prevalent non-English languages in the State if they want to comply with both Medicare and Medicaid regulatory requirements. Specifically, these plans that provide integrated materials must comply with the MLI requirements at §§ 422.2267(e)(31) and 423.2267(e)(33) and the Medicaid requirement at § 438.10(d)(2) to include taglines in written materials that are critical to obtaining services for potential enrollees in the prevalent non-English languages in the State. In the enrollee materials, this can result in a very long multi-page list of statements noting the availability of translations services in many languages. This lengthy list can be a distraction from the main information conveyed in the material. As discussed in greater detail below, we are proposing to update §§ 422.2267(e)(31) and 423.2267(e)(33) to instead require that notice of availability of language assistance services and auxiliary aids and services be provided in the 15 most common languages in a State; we expect that this proposed policy would better align with the Medicaid translation requirements at § 438.10(d)(2).⁹⁰

We believe rulemaking regarding a non-English notice of the availability of language assistance services and auxiliary aids and services is needed to more closely reflect the actual languages spoken in the service area. We also believe it is in the best interest of enrollees for the requirements to align with the Medicaid translation requirements because it will allow D-SNPs that are AIPs to provide a more applicable, concise Notice of

Availability to enrollees that does not distract from the main purpose of the document.

Noting that while OCR has yet to finalize the Notice of Availability policy described in its August 2022 proposed rule, and thus that OCR's proposed policy could be subject to change or not be finalized, alignment of Medicare and OCR rules would help to prevent confusion among MA organizations, Part D sponsors, and cost plans regarding which requirements they must comply with. Should the OCR final rule differ from the original August 2022 proposed rule, we will consider modifying our final rule to align with OCR's final rule.

Therefore, we propose to amend §§ 422.2267(e)(31) and 423.2267(e)(33). First, we propose to replace references to the MLI with references to a Notice of Availability. We propose to modify the language to reflect CMS's proposal that this notice be a model communication material rather than a standardized communication material and thus that CMS would no longer specify the exact text that must be used in the required notice. We propose to change paragraphs (e)(31) and (33) to require MA organizations and Part D sponsors to provide enrollees a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that MA organizations and Part D sponsors provide language assistance services and appropriate auxiliary aids and services free of charge. We are proposing, in new paragraphs (e)(31)(i) and (e)(33)(i), that the Notice of Availability must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication. This proposed State-specific standard would ensure that a significant proportion of each State's particular LEP population receives key information in the appropriate languages. The U.S. Census Bureau's ACS 2009–2013 multi-year data show that the top languages spoken in each State can vary significantly.⁹¹ State-specific language translations provide for flexibility to maximize access to care for individuals with LEP. This updated notice must also include a statement regarding the availability of appropriate auxiliary aids and services to reduce

barriers to access for individuals with disabilities.

We believe this proposal would make it easier for individuals to understand the full scope of available Medicare benefits (as well as Medicaid benefits available through the D-SNPs, where applicable), increasing their ability to make informed health care decisions, and promote a more equitable health care system by increasing the likelihood that MA enrollees have access to information and necessary health care. As an additional benefit, our proposed changes would mitigate the risk that §§ 422.2267(e)(31) and 423.2267(e)(33) could conflict with § 438.10(d)(2) and the forthcoming OCR final rule, if finalized, requiring applicable Medicare plans to comply with two, disparate sets of requirements. Such an outcome adds undue burden on plans. Further, requiring MA organizations and Part D sponsors to provide multiple sets of translated statements accompanying enrollee materials could lead to enrollee confusion and detract from the enrollee material message. Notwithstanding OCR's final rule policy, we believe our proposed changes are appropriate given the benefits of a non-English notice of availability of language assistance services and auxiliary aids and service more closely reflecting the actual languages spoken in the service area and alignment with the Medicaid translation requirements.

Additionally, we propose in §§ 422.2267(e)(31)(ii) and 423.2267(e)(33)(ii) that if there are additional languages in a particular service area that meet the 5-percent service area threshold, described in paragraph §§ 422.2267(a)(2) and 423.2267(a)(2), beyond the languages described in §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i), the Notice of Availability must also be translated into those languages, similar to the current MLI requirements at §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i). While §§ 422.2267(a)(2) and 423.2267(a)(2) apply to the Notice of Availability since it is a required material under §§ 422.2267(e) and 423.2267(e), we wanted to clarify this in the regulation text. MA organizations and Part D sponsors may also opt to translate the Notice of Availability in any additional languages that do not meet the five percent service area threshold at §§ 422.2267(a)(2) and 423.2267(a)(2), where the MA organization or Part D sponsor determines that such inclusion would be appropriate, which is also included in the current MLI requirements at §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i). It is possible that

⁹⁰ We expect the 15 most common languages for a given State to include any language required by the Medicaid program at § 438.10(d)(2). Therefore, our proposed rule would reduce burden on fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans, as defined at § 422.2, and applicable integrated plans, as defined at § 422.561, to comply with regulations at §§ 422.2267(a)(4) and 423.2267(a)(4).

⁹¹ <https://www2.census.gov/library/data/tables/2008/demo/language-use/2009-2013-acs-lang-tables-nation.xls>.

there may be a subpopulation in the plan benefit package service area that uses a language that does not fall within the top 15 languages or meet the five percent service area of a plan benefit package threshold that the plan determines can benefit by receiving the notice. We again note that pursuant to CMS's authority in section 1876(c)(3)(C) to regulate marketing and the authority in section 1876(i)(3)(D) to specify new section 1876 contract terms, and as established in § 417.428, this proposal would also apply to section 1876 cost plans.

To assist plans with fulfilling their requirements under §§ 422.2267(a)(2) and 423.2267(a)(2) to translate required materials into any non-English language that is the primary language of at least 5 percent of the population of a plan service area, since 2009 CMS has provided plans with a list of all languages that are spoken by five percent or more of the population for every county in the U.S. Each fall, we release an HPMS memorandum announcing that MA organizations and Part D sponsors can access this list in the HPMS marketing review module.⁹² However, plans can also use Census Bureau ACS data to determine the top languages spoken in a given State or service area. The September 2023 Medicare Part C & D Language Data Technical Notes⁹³ outlines our methodology for calculating the percentage of the population in a plan's service area speaking a language other than English and provides plans with instructions to make these calculations on their own.

I. Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

Section 1853(a) of the Act requires CMS to risk-adjust payments made to Medicare Advantage (MA) organizations. In order to carry out risk adjustment, section 1853(a)(3)(B) of the Act requires submission of data by MA organizations regarding the services provided to enrollees and other information the Secretary deems necessary. The implementing regulation

at § 422.310(b) requires that MA organizations submit to CMS "the data necessary to characterize the context and purposes of each item and service provided to a Medicare enrollee by a provider, supplier, physician, or other practitioner." Currently, § 422.310(d)(1) provides that MA organizations submit risk adjustment data equivalent to Medicare fee-for-service (FFS) data to CMS as specified by CMS. MA encounter data, which are comprehensive data equivalent to Medicare FFS data, are risk adjustment data.⁹⁴

Section 1106(a)(1) of the Act authorizes the Secretary to adopt regulations governing release of information gathered in the course of administering programs under the Act. In addition, section 1856(b) of the Act authorizes CMS to adopt standards to carry out the MA statute, and section 1857(e)(1) of the Act authorizes CMS to add contract terms that are not inconsistent with the Part C statute and are necessary and appropriate for the program. Currently, § 422.310(f)(1) establishes permissible CMS uses of MA encounter data (referred to as "risk adjustment data" in the regulation), while § 422.310(f)(2) and (3) establish rules for CMS release of data. Prior to 2008, § 422.310(f) provided for CMS to use MA risk adjustment data to risk adjust MA payments and, except for any medical record data also collected under § 422.310, for other purposes. Over time, we subsequently refined the regulatory language describing the scope of permissible uses and releases of the MA risk adjustment data, including MA encounter data, to (i) risk adjusting MA payments, (ii) updating risk adjustment models, (iii) calculating Medicare disproportionate share hospital percentages, (iv) conducting quality review and improvement activities, (v) for Medicare coverage purposes, (vi) conducting evaluations and other analysis to support the Medicare program (including demonstrations) and to support public health initiatives and other health care-related purposes, (vii) for activities to support administration of the Medicare program, (viii) for activities to support program integrity, and (ix) for purposes authorized by other applicable laws (70 FR 4588; 73 FR 48650 through 48654; 79 FR 50325 through 50334).

⁹⁴ See System of Records Notices for the CMS Encounter Data System (EDS), System No. 09–70–0506, published June 17, 2014 (79 FR 34539), as amended at February 14, 2018 (83 FR 6591); and for the CMS Risk Adjustment Suite of Systems (RASS), System No. 09–70–0508, published August 17, 2015 (80 FR 49237), as amended at February 14, 2018 (83 FR 6591).

Section 422.310(f)(2) permits the release of MA encounter data to other HHS agencies, other Federal executive branch agencies, States, and external entities, while § 422.310(f)(3) of our current regulation specifies circumstances under which we may release MA encounter data for the purposes described in § 422.310(f)(1). Currently, we may release the data only after risk adjustment reconciliation for the applicable payment year has been completed or under certain emergency preparedness or extraordinary circumstances. We note that we included a proposal to publicly report aggregated counts of procedures performed by providers, based on MA encounter data, before risk adjustment reconciliation is complete in the Medicare and Medicaid Programs in the CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program proposed rule (hereafter referred to as the August 2023 proposed rule; 88 FR 52262).

Here, we are proposing to allow MA encounter data to be used to support the Medicaid program for certain purposes already specified for use to support the Medicare program in § 422.310(f)(1)(vi) and (vii). Under our proposal, MA risk adjustment data could be used for supporting either program separately or in conjunction. In addition, we are proposing to allow release of MA encounter data to State Medicaid agencies (States) in advance of the completion of risk adjustment reconciliation for the specific purpose of care coordination for individuals who are dually eligible for Medicare and Medicaid, also known as dually eligible individuals. These proposals related to disclosure of MA encounter data are focused on expanding allowable disclosures of these data to support not only the Medicare program or Medicare-Medicaid demonstrations, but also the Medicaid program in the interest of improving care for individuals who are eligible for Medicaid.

We believe disclosure for the purpose of improving States' ability to understand and improve care provided to dually eligible individuals is appropriate and consistent with our intention in prior rulemaking. We clarified that States may access and use MA encounter data while "in the administration of Medicare-Medicaid demonstrations" in the Medicare Program; Hospital Inpatient Prospective

⁹² We released the contract year 2024 version of this HPMS memorandum titled, "Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis" on September 25, 2023. This memorandum can be retrieved at: <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22>.

⁹³ Found in HPMS as described in the September 25, 2023 HPMS memo, "Corrected Contract Year 2024 Translated Model Materials Requirements and Language Data Analysis." This memo can be retrieved at <https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-4-september-18-22>.

Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Hospitals and Certain Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program final rule (hereafter referred to as the August 2014 final rule; 79 FR 50325). Additionally, current regulation text at § 422.310(f)(1)(vi) permits CMS to release MA encounter data to third parties, including States, to “conduct evaluations and other analysis to support the Medicare program (including demonstrations).” This proposal would expand certain allowable use and disclosures of MA encounter data to support the Medicaid program, which would thereby enable State access to comprehensive data for all dually eligible individuals in the State regardless of their enrollment in a demonstration, dual eligible special needs plan (D–SNP), or other MA plan. Our proposal to further expand MA encounter data sharing to include support for the Medicaid program would also be consistent with the goals of the Federal Coordinated Health Care Office, as established in statute. Section 2602 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (Affordable Care Act) established the office within CMS to better integrate benefits and improve coordination for dually eligible individuals, including specific goals and responsibilities such as:

- Providing dually eligible individuals full access to the benefits to which such individuals are entitled under the Medicare and Medicaid programs.
- Improving the quality of health care and long-term services for dually eligible individuals.
- Improving care continuity and ensuring safe and effective care transitions for dually eligible individuals.
- Improving the quality of performance of providers of services and suppliers under the Medicare and Medicaid programs.
- Supporting State efforts to coordinate and align acute care and long-term care services for dually eligible individuals with other items and services furnished under the Medicare program.

MA enrollment has grown to approximately half of all Medicare

beneficiaries; a trend also seen in the enrollment of dually eligible individuals. For example, 51 percent of all dually eligible individuals were enrolled in an MA plan in 2021 (up from 12 percent in December 2006).⁹⁵ ⁹⁶ Such individuals experience the health care system and incur health outcomes as individuals regardless of which health care program pays for the service. But currently, the States’ ability to obtain MA encounter data for program analysis and evaluations or program administration for dually eligible individuals enrolled in an MA plan is limited to support of a Medicare-Medicaid demonstration. Our current regulation text does not specify that we may make MA encounter data available to States for Medicaid program administration, or to conduct evaluations and other analyses for the Medicaid program, with the exception of those evaluations and analyses used to support demonstrations. Therefore, previous rulemaking limits opportunities for States to effectively perform functions such as coordination of care, quality measure design, and program evaluation and analysis by allowing them access to MA encounter data for these activities only for those dually eligible individuals enrolled in Medicare-Medicaid demonstrations.

We are proposing changes to § 422.310(f) to improve access for States to MA encounter data, including making a specific exception to the timing of sharing MA encounter data. We do not intend for our proposals to impact the terms and conditions governing CMS release of MA risk adjustment data as described in § 422.310(f)(2), in accordance with applicable Federal laws and CMS data sharing procedures. As discussed in the August 2014 final rule, CMS data sharing procedures require each recipient of data from CMS to sign and maintain a CMS data sharing agreement, “which addresses privacy and security for the data CMS discloses” and “contains provisions regarding access to and storage of CMS data to ensure that beneficiary identifiable information is stored in a secure system and handled according to CMS’s security policies,” which encompasses the limitations for additional disclosure of CMS data (79 FR 50333). Such provisions would similarly apply to States that receive MA encounter data under the proposed amendments to § 422.310(f) here.

⁹⁵ 2023 Medicare Trustees Report <https://www.cms.gov/oact/tr>.

⁹⁶ <https://www.cms.gov/files/document/managedcareenrollmenttrendsdatabrief2012-2021.pdf>.

As stated in the August 2014 final rule, the data described in paragraphs (a) through (d) would include those elements that constitute an encounter data record, including contract, plan, and provider identifiers, with the exception of disaggregated payment data (79 FR 50325). In accordance with § 422.310(f)(2)(iv), we aggregate payment data to protect commercially sensitive information.

1. Expanding and Clarifying the Programs for Which MA Encounter Data May Be Used for Certain Allowable Purposes

As we stated in the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2015 Rates; Quality Reporting Requirements for Specific Providers; Reasonable Compensation Equivalents for Physician Services in Excluded Teaching Hospitals; Provider Administrative Appeals and Judicial Review; Enforcement Provisions for Organ Transplant Centers; and Electronic Health Record (EHR) Incentive Program proposed rule (hereafter referred to as the May 2014 proposed rule; 79 FR 27978), using MA encounter data enables us, our contractors, and external entities to support Medicare program evaluations, demonstration designs, and effective and efficient operational management of the Medicare program, encourages research into better ways to provide health care, and increases transparency in the administration of the Medicare program (79 FR 28281 through 28282). However, because States lack access to MA encounter data, States’ ability to conduct activities for dually eligible individuals enrolled in MA plans is limited. As Medicare is the primary payer for dually eligible individuals, States generally lack comprehensive data on care provided to dually eligible individuals enrolled in MA. Over the years, various States have requested that CMS share MA encounter data for dually eligible individuals to better coordinate care, conduct quality improvement activities, support program design, conduct evaluations, and improve efficiency in the administration of the Medicaid program.

Our current regulation text at § 422.310(f)(1)(vi) (evaluations and analysis to support the Medicare program) and (vii) (activities to support administration of the program) specifies that for these purposes, the encounter data must be used for the Medicare program. Therefore, though § 422.310(f)(2) permits CMS to release

MA encounter data to States for the purposes listed in paragraph (f)(1), § 422.310(f)(1)(vi) and (vii) do not clearly permit CMS to release MA encounter data to States to support Medicaid program evaluations and analysis or to support administration of the Medicaid program.

We are proposing to add “and Medicaid program” to the current MA encounter data use purposes codified at § 422.310(f)(1)(vi) and (vii). These additions would enable CMS to use the data and release it (in accordance with § 422.310(f)(2) and (3)) for the purposes of evaluation and analysis and program administration for Medicare, Medicaid, or Medicare and Medicaid combined purposes. We believe that our release of MA encounter data for these data use purposes that support the Medicare and Medicaid programs would generally be to the States and would support our responsibility to improve the quality of health care and long-term services for dually eligible individuals; improve care continuity, ensuring safe and effective care transitions for dually eligible individuals; improve the quality of performance of providers of services and suppliers under the Medicare and Medicaid programs for dually eligible individuals; and support State efforts to coordinate and align acute care and long-term care services for dually eligible individuals with other items and services furnished under the Medicare program.

As stated above, CMS data sharing procedures apply to the release of MA encounter data in accordance with § 422.310(f)(2) and contain provisions regarding access to and storage of CMS data to ensure that beneficiary identifiable information is protected. We make other data available to external entities, including States, in accordance with CMS data sharing procedures and Federal laws, including but not limited to the Privacy Act of 1974. We review data requests for appropriate use justifications, including updated or amended use justifications for existing data requests. We employ data sharing agreements, such as a Data Use Agreement and Information Exchange Agreement, that limit external entities to CMS-approved data uses and disclosure of CMS data. For example, States that request data from CMS for care coordination and program integrity initiatives may disclose the data to State contractors, vendors, or other business associates. In accordance with CMS data sharing agreements, these State contractors, vendors, or other business associates must also follow the terms and conditions for use of the CMS data, including limiting use of the CMS-

provided data only for approved purposes. This would mean that, under this proposal, a State receiving MA encounter data for care coordination may disclose MA encounter data to Medicaid managed care plans to coordinate services for enrolled dually eligible individuals. Comments submitted on the August 2014 final rule cited concerns that access to MA encounter data by competitors of the various MA organizations that are required to submit data could permit a competitor to gain an advantage by trending cost and utilization patterns over a number of years. Given that § 422.310(f)(2)(iv) provides for aggregation of dollar amounts reported for the associated encounter to protect commercially sensitive data and that any release of MA encounter data to States would comply with applicable statutes, regulations, and processes including those described above, we believe that concern around potential competitive advantage is mitigated if the risk exists at all. As stated in the August 2014 final rule, we believe that CMS data sharing procedures and review of use justifications “strikes an appropriate balance between the significant benefits of furthering knowledge” and concerns regarding the release of risk adjustment data, including for beneficiary privacy or commercially sensitive information of MA plans (79 FR 50328). Consistent with what we stated in the August 2014 final rule, CMS data sharing agreements have enforcement mechanisms, and data requestors acknowledge these mechanisms. For example, penalties under section 1106(a) of the Social Security Act [42 U.S.C. 1306(a)], including possible fines or imprisonment, and criminal penalties under the Privacy Act [5 U.S.C. 552a(i)(3)] may apply, as well as criminal penalties may be imposed under 18 U.S.C. 641 (79 FR 50333). Requestors of CMS data, such as States, are responsible for abiding by the law, policies, and restrictions of the data sharing agreements—which extends to any downstream disclosures of the data to State contractors, vendors, or other business associates—as condition of receiving the data. We intend to only approve requests for MA encounter data that have clear written data use justifications and identify any downstream disclosure—such as to State contractors, vendors, or other business associates—for each requested purpose. We have not identified any issues regarding competitive harm or disadvantage in our current data sharing programs.

Under this proposal, we would be able to use MA encounter data and disclose it—subject to the other limitations and protections specified in § 422.310(f) and other applicable laws and regulations—to States to perform evaluations and analysis, which would include program planning for dually eligible individuals. For example, access to MA encounter data could support States’ analysis of geographic trends to create targeted community outreach and education, including identification of geographic areas with higher rates of dementia, diabetes, or emergency room visit overutilization; and evaluation of current Medicaid initiatives, including tracking efficacy of opioid overuse and misuse programs by monitoring service utilization for those with opioid dependency, evaluating appropriate and inappropriate use of antibiotic and psychotropic medications, and analyzing deaths among individuals with opioid use disorder. Currently, States generally only receive Medicare FFS data from CMS under current authorities, which results in an incomplete assessment of the dually eligible population. Under this proposal, States could request MA encounter data for all of the dually eligible enrollees they serve and include this growing portion of the dually eligible population in their data analysis and efforts to improve outcomes for low-income older adults and people with disabilities who are enrolled in the Medicaid program.

We are taking this opportunity to make a clarification related to the existing program administration purpose, as specified in § 422.310(f)(1)(vii). In the August 2014 final rule, we stated that, in addition to use of these data for review of bid validity and MLR, we expected there would be additional potential uses for these data as part of the program administration purpose, such as the development of quality measures (79 FR 50326). Consistent with our expectation at that time, we are clarifying here that care coordination would be an allowable use for these data as part of the purpose currently codified at § 422.310(f)(1)(vii)—for activities to support the administration of the Medicare program—which includes activities that are not within the scope of the other permitted uses defined at § 422.310(f)(1). Similar to quality measure development, a use we explicitly named, care coordination is critical to ensuring that individuals receive effective and efficient care, especially when services may be covered under multiple health care

programs, as is the case for dually eligible individuals who are enrolled in Medicaid and an MA plan. We believe use and release of MA encounter data to States to support administering the Medicaid program, including to coordinate care and improve quality of care for Medicaid-covered individuals, is appropriate. For example, in administering the Medicaid program, a State may need MA encounter data to coordinate care for dually eligible individuals, which may include identification of individuals at high risk of institutional placement or other undesirable outcomes based on past service utilization; coordination of services from the MA plan's coverage of an inpatient stay to Medicaid coverage of subsequent home and community-based services; coordination of Medicaid-covered services in a skilled nursing facility for a dually eligible individual after reaching the limits of the individual's coverage through the MA plan; monitoring nursing facility quality of care, including through tracking rates of hospitalization and emergency room visits; and coordination of physical health services with behavioral health services, where Medicaid coverage differs from the MA plan's coverage.

We welcome public comment on this proposal.

2. Adding an Additional Condition Under Which MA Encounter Data May Be Released Prior to Reconciliation

Section 422.310(f)(3) describes the circumstances under which we may release MA encounter data. Specifically, our current regulation provides that MA encounter data will not become available for release unless the risk adjustment reconciliation for the applicable payment year has been completed or under certain emergency preparedness or extraordinary circumstances. Section 422.310(g) specifies the deadlines that we use to determine which risk adjustment data submissions we consider when assigning the risk adjustment factors for payment in a given payment year. This section also establishes a reconciliation process to adjust payments for additional data submitted after the end of the MA risk adjustment data collection year (meaning the year the item or service was furnished to the MA enrollee) but before the established deadline for the payment year, which can be no earlier than January 31 of the year following the payment year. This reconciliation period provides MA organizations an opportunity to update or submit encounter data records and chart review records to be considered

for risk adjustment and payment in the applicable payment year. Section 422.310(b)(1) requires MA organizations to submit data for all items and services provided; therefore, MA organizations must continue to submit encounter data records and data corrections after the final submission deadline if needed. (We note that there are limitations on which submissions after the final reconciliation deadline may be used in risk adjustment. See § 422.310(g).) The timing limitation on release of MA encounter data in our current regulation is tied to the established deadline for the payment year, and it results in a data lag of at least 13 months after the end of the MA risk adjustment data year (that is, the year during which the services were furnished), before CMS may release the MA risk adjustment data for the purposes described in § 422.310(f)(1).⁹⁷ We believe there will be increased utility of MA encounter data for Medicaid programs if the data is released before final reconciliation for coordination of care under the allowable purpose in § 422.310(f)(1)(vii). We believe that the reasons and concerns we identified when adopting the delay in release of MA encounter data can be sufficiently taken into account by CMS as part of evaluating a request to use the data for specific purposes and determining whether to release the data. Further, in many cases, those reasons and concerns likely do not sufficiently apply in the context of care coordination to require a delay in releasing the data as discussed further below.

In order to improve utility of MA encounter data for certain approved purposes, we propose to add a new subsection § 422.310(f)(3)(v) to allow for MA encounter data to be released to States for the purpose of coordinating care for dually eligible individuals when CMS determines that releasing the data to a State Medicaid agency before reconciliation is necessary and appropriate to support activities and uses authorized under paragraph (f)(1)(vii). As discussed above, the proposed amendments to § 422.310(f)(1)(vii) would expand the scope of that provision to include using the data to support administration of the Medicaid program, and in our discussion we clarified that coordination of care activities are within the scope of activities that support administration of these health care

programs. We are specifying care coordination for our proposal for release of MA encounter data prior to reconciliation as we believe providing States access to this more timely data is critical to effectively coordinating care, is directly tied to our responsibility to support States' efforts to coordinate and align care and services for dually eligible individuals, and furthers our goal to improve care continuity and ensure safe and effective care transitions for dually eligible individuals (see 42 U.S.C. 1315B) while accommodating the concerns that led us to adopt the time limits in § 422.310(f)(3). Together, the proposed changes to § 422.310(f)(1)(vii) and (f)(3)(v) would improve timeliness of the MA encounter data we make available to States for coordination of care for dually eligible individuals.

As discussed above, a growing number of dually eligible individuals are enrolled in MA plans. To ensure that these individuals are receiving high quality, efficient care, it is essential that States have access to information on their service utilization in a timely manner. Without timely, comprehensive beneficiary data, which are not currently available to States for all MA enrollees, States cannot conduct care coordination for dually eligible individuals in MA. For example:

- A State looks to coordinate care related to the COVID-19 pandemic for individuals concurrently enrolled in Medicaid and MA plans, such as by identifying people who had COVID-related hospitalizations. In accordance with § 422.310(f)(3), our current release schedule of MA encounter data for research purposes limits available MA encounter data to between 13 and 25 or more months after the service was rendered.⁹⁸ Therefore, with the exception of those dually eligible individuals enrolled in an MA plan under a demonstration or in an MA D-SNP, where the State can use the contract with the plan in accordance with § 422.107 to obtain MA encounter data or other notifications under § 422.107(d)(1) from the D-SNP, States could not access service utilization data for MA enrollees to coordinate care for dually eligible individuals who had a COVID-related hospitalization in a timely manner. Instead, the States would need to wait for the MA encounter data until after risk adjustment reconciliation for the applicable payment year has been completed—which would be months after a dually eligible individual required post-hospitalization follow-up

⁹⁷ "Deadline for Submitting Risk Adjustment Data for Use in Risk Score Calculation Runs for Payment Years 2021, 2022, 2023, and 2024" HPMS memo. <https://www.cms.gov/files/document/py20202021202220232024paymentrunnotice508g.pdf>.

⁹⁸ <https://resdac.org/cms-news/2021-preliminary-medicare-encounter-data-now-available>.

care. However, if States could access timely MA encounter data, then Medicaid care coordinators could follow up after a COVID-related hospitalization to ensure adequate care related to mental health treatment, coordinate approval of durable medical equipment, or ensure physical or rehabilitation therapy while reducing redundant visits or delays in care to the dually eligible individual.

- A State uses a predictive modeling algorithm—using past service utilization, diagnosis, and other data—to identify people at high risk for poor outcomes or institutional placement. The State then targets those high-risk individuals in the Medicaid program for an intensive care management intervention and helps connect such individuals to necessary supports and services. In this case, the timeliness of information on service utilization (for example, an individual discharged from a skilled nursing facility stay could benefit by transition to Medicaid home and community-based services) is more important than the completeness of the available data (that is, whether additional subsequent encounters may later become available) so the State can coordinate care and deliver the intervention when an individual most needs it.

We believe the two examples above represent cases where we would consider sharing MA encounter data with State Medicaid agencies prior to reconciliation as necessary and appropriate to support coordinating care for dually eligible individuals. States cannot rely on MA encounter data after final reconciliation because coordinating services requires access to timely data. For these activities, States rely more on timely data about service utilization than on complete data. Improving access to timely MA encounter data and ensuring Medicaid programs can coordinate care for dually eligible individuals supports our goal to providing dually eligible individuals full access to the benefits to which they are entitled (42 U.S.C. 1315B(d)).

As discussed above, State Medicaid agencies cannot effectively coordinate care for individuals using data that is more than one or two years old. We recognize that the MA encounter data may be subject to edits before final reconciliation given the deadline for submission of risk adjustment data under § 422.310(g), which states that the final submission deadline is a date no earlier than January 31 of the year following the payment year, or that data from some MA organizations or for some enrollees may not be available as quickly as data from or for others.

However, we believe that earlier release of MA encounter data to States for the purpose of care coordination for dually eligible individuals would be appropriate and, as stated above, many of the reasons and concerns to require a delay releasing MA encounter data likely do not sufficiently apply in the context of care coordination. Care coordination activities require State Medicaid agencies, or their contractors, to identify and contact individuals who have received, or are in need of, services from their providers. Since States would use the MA encounter data to identify opportunities for care improvement such as improving transitions of care or to promote the use of underutilized services, we do not foresee any risk to individuals from States using data that may be subject to change in the future. States would be able to use the data to identify more dually eligible individuals who are potentially in need of Medicaid-covered services. States are not required to act on the data and can address potential data concerns arising from using MA encounter data before final reconciliation as States have experience using Medicare data that may not be final for effective care coordination. In fact, many States already obtain timely Medicare FFS claims with a lag between 14 days to three months, depending on the data file, for uses such as care coordination, quality improvement, and program integrity in the Medicaid program. These Medicare FFS claims may also be subject to change subsequent to the States' receipt of the data, yet we are not aware of any problems in these use cases caused by CMS sharing data that is still subject to change. Because the MA encounter data released to States would be for care coordination purposes, we do not anticipate any negative impacts from any potential subsequent changes to the encounters. MA encounter data made available to States prior to reconciliation would not contain disaggregated payment information, in accordance with § 422.310(f)(2)(iv). Unlike MA encounter data used for CMS payment purposes, the pre-reconciliation MA encounter data would have no impact on plan payment. Under this proposal, release of the MA encounter data for care coordination purposes must be necessary and appropriation to support administration of the Medicaid program; we do not believe it would be appropriate or necessary to use the MA data released on this accelerated schedule for payment purposes.

Coordination of care is a clear situation where more timely MA

encounter data is needed for effective intervention without invoking risks that we have cited in the past about sharing MA risk adjustment data before final reconciliation. The timing limits in § 422.310(f)(3) were adopted in the August 2014 final rule in response to comments expressing concern about release of the MA risk adjustment data (79 FR 50331 through 50332). In that prior rulemaking, some commenters cited concerns about release of MA encounter data submitted in the initial years due to concerns regarding systems development and submission challenges. We believe these concerns are mitigated by the subsequent years since the implementation of the August 2014 final rule that have resulted in accumulation of experience submitting, reviewing, and using MA encounter data in accordance with § 422.310(f). In addition, CMS maintains several checks and edits in the encounter data system to minimize duplicate, incomplete, or inappropriate data stored in the encounter data system. We reiterate that this proposal to amend paragraph (f)(3) would only permit the release of MA encounter data to State Medicaid agencies for care coordination for dually eligible individuals.

We also noted in prior rulemaking that our approach to reviewing requests for MA encounter data from external entities would incorporate the Medicare Part A/B and Part D minimum necessary data policy, with additional restrictions to protect beneficiary privacy and commercially sensitive information of MA organizations and incorporated that limitation into paragraph (f)(2) (79 FR 50327). Therefore, this limitation would also apply when reviewing State requests for MA encounter data under the proposed expansion of § 422.310(f)(1)(vi) and (vii), as well as to any State requests for MA encounter data before the reconciliation deadline to support coordination of care. CMS data sharing procedures include a review team that assesses data requests for minimum data necessary and appropriate use justifications for care coordination, and we would only approve release of MA encounter data for any data requests where the requestor has sufficiently demonstrated that the request satisfies all requirements of § 422.310(f). Other commenters on the August 2014 final rule expressed concerns that MA organizations are able to delete, replace, or correct MA encounter data before the reconciliation deadline, which could potentially result in inaccurate or incomplete MA encounter data and that incomplete or inaccurate data should

not be used or released for the purposes outlined in § 422.310(f). As noted in the prior rulemaking, we consider what disclaimers are appropriate to provide to requestors to understand the limitations of the MA encounter data (79 FR 50329 through 50330).⁹⁹ As noted above, States, or their contractors, are not required to act on the data and have experience using Medicare FFS claims that may not be final for effective care coordination. We are not aware of any care coordination issues that have arisen as a result of our sharing more Medicare FFS current data with States under our current data sharing processes. Additionally, CMS makes available technical assistance to States to help with State use and understanding of Medicare data; we intend to extend this technical assistance to States requesting MA encounter data to mitigate issues arising from non-final data. We will evaluate the potential concerns arising from using MA encounter data before final reconciliation when determining whether to release MA encounter data to States for care coordination activities for dually eligible individuals to support administration of the Medicare and Medicaid programs.

Finally, we propose that these amendments to § 422.310(f) would be applicable upon the effective date of the final rule if these proposals are finalized as proposed. As outlined in section I.A., the majority of the proposals in this rule are proposed to be applicable beginning January 1, 2025. We do not believe that delaying the applicability of these proposed amendments beyond the effective date of the final rule is necessary because these proposals address CMS's authority to use and share MA encounter data but do not impose any additional or new obligations on MA organizations.

We welcome public comment on this proposal.

3. Solicitation of Comments on Use of MA Encounter Data To Support Required Medicaid Quality Reporting

In the final rule titled "Medicaid Program and CHIP; Medicaid and Children's Health Insurance Program (CHIP) Core Set Reporting," which appeared in the **Federal Register** on August 31, 2023 (88 FR 60278) ("August 2023 final rule"), we established mandatory Core Set reporting requirements for States, as set forth in the Bipartisan Budget Act of 2018 (Pub. L. 115–123, enacted February 9, 2018)

and the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, enacted October 24, 2018). The new Core Set reporting requirements apply to all States with Medicaid and CHIP programs and include all Medicaid and CHIP participants, including dually eligible individuals enrolled in MA plans.

States can only report certain Child and Adult Core Set measures by using utilization data. For reporting related to dually eligible individuals, this means accessing Medicare data. For dually eligible individuals in Medicare FFS, we make available Medicare FFS claims and events data to States to support, among other purposes, quality reporting for Child and Adult Core Set measures. But we do not currently make available MA encounter data to States in the same way. Although we have not shared MA encounter data broadly for Medicaid quality performance and quality improvement purposes through existing CMS data sharing programs, States may use their contracts with MA D-SNPs, which are required under § 422.107, to obtain Medicare data about the dually eligible individuals enrolled in those plans; this contractual ability to obtain MA encounter data through contracts with plans is specific to D-SNPs and does not include all MA plans. Therefore, we anticipate that reporting on dually eligible individuals enrolled in MA plans will be optional (that is, not mandatory) for States to include in reporting of the Child and Adult Core Sets. As we acknowledged in the August 2023 final rule, "We recognize that States must obtain, link, and analyze Medicare data in order to report the Child and Adult Core Sets of measures for fee-for-service beneficiaries, and that States do not have access to encounter data for Medicare Part C (Medicare Advantage), and we expect to phase in required reporting of Child and Adult Core Set measures for dually eligible beneficiaries" (88 FR 60298 through 60299).

In accordance with current regulation text at § 422.310(f)(2), States may request MA encounter data for the purpose described at § 422.310(f)(1)(iv)—to conduct quality review and improvement activities—which could support Medicaid Child and Adult Core Set reporting. However, the limitations in paragraph (f)(3) on sharing MA encounter data before final reconciliation would frustrate our desire for States to use the data to support timely Child and Adult Core Set reporting. The August 2023 final rule establishes a schedule through which

Core Set reporting to CMS begins in the fall of 2024, applicable to data collected during the 2024 reporting period. However, as stated above, our current release schedule of MA encounter data in accordance with § 422.310(f)(3) limits available MA encounter data to between 13 and 25 or more months after the service was rendered. Therefore, in the fall of 2024, during the 2024 Core Set reporting period, we anticipate only making available MA encounter data for services furnished in the 2022 year. This means that based on the current limitations in paragraph (f)(3), States would be unable to report on 2023 services received by dually eligible individuals enrolled in an MA plan to CMS in the fall of 2024 for the Child and Adult Core Set measures. With over half of dually eligible individuals enrolled in MA plans, we believe it is essential that State Child and Adult Core Set reporting eventually include that population. We are soliciting comments on making MA encounter data available to States to support Child and Adult Core Set reporting as efficiently as possible while complying with § 422.310(f) and balancing considerations related to the timeliness of quality reporting with accuracy and completeness. We intend to take such comments into account in developing future policies and potential additional proposed revisions to § 422.310.

J. Standardize the Medicare Advantage (MA) Risk Adjustment Data Validation (RADV) Appeals Process

In this proposed rule, we are proposing to revise certain timing issues in terms of when RADV medical record review determination and payment error calculation appeals can be requested and adjudicated. Specifically, we are proposing that Medicare Advantage (MA) organizations must exhaust all levels of appeal for medical record review determinations before the payment error calculation appeals process can begin. We believe that this clarification is necessary because RADV payment error calculations are directly based upon the outcomes of medical record review determinations. We also propose several other changes to our regulatory appeals process to conform with these proposed revisions.

Section 1853(a)(1)(C) of the Act requires that CMS risk-adjust payments made to MA organizations. Risk adjustment strengthens the MA program by ensuring that accurate payments are made to MA organizations based on the health status and demographic characteristics of their enrolled beneficiaries, and that MA organizations are paid appropriately for their plan

⁹⁹ For example, see the CCW Medicare Encounter Data User Guide: <https://www2.ccwdata.org/web/guest/user-documentation>.

enrollees (that is, less for healthier enrollees who are expected to incur lower health care costs, and more for less healthy enrollees who are expected to incur higher health care costs). Making accurate payments to MA organizations also ensures we are safeguarding Federal taxpayer dollars.

Contract-level RADV audits are CMS's main corrective action for overpayments made to MA organizations when there is a lack of documentation in the medical record to support the diagnoses reported for risk adjustment. CMS conducts RADV audits of MA organization-submitted diagnosis data from a selection of MA organizations for specific payment years to ensure that the diagnoses they submitted are supported by their enrollees' medical records. CMS can collect the improper payments identified during CMS and Department of Health and Human Services Office of Inspector General (HHS-OIG) audits, including the extrapolated amounts calculated by the OIG. The RADV audit appeals process, as outlined in 42 CFR 422.311, is applicable to both CMS and HHS-OIG audits and is therefore referred to as the "MA RADV audit appeals process." Additional information regarding CMS's contract level RADV audits was outlined in the RADV final rule, CMS-4185-F2, published on February 1, 2023.¹⁰⁰

1. Current MA RADV Appeals Process

CMS previously established a process after notice and comment rulemaking for MA organizations to appeal RADV audit findings as outlined by provisions at 42 CFR 422.311(c)(6) through (8). Once review of the medical records submitted by MA organizations to support audited HCCs is completed and overpayment amounts are calculated, HHS (CMS or HHS-OIG) issues an audit report to each audited MA organization contract. In accordance with § 422.311(b)(1), this audit report includes the following:

- Detailed enrollee-level information relating to confirmed enrollee HCC discrepancies.
- The contract-level RADV-payment error estimate in dollars.
- The contract-level payment adjustment amount to be made in dollars.
- An approximate timeframe for the payment adjustment.
- A description of the MA organization's RADV audit appeal rights.

The MA RADV audit appeals process begins once MA organizations are notified of their audit findings via a RADV audit report. MA organizations have 60 days from the date of issuance of a RADV audit report to file a written request for appeal and must follow the Secretary's RADV audit appeals procedures and requirements under § 422.311. MA organizations may appeal RADV medical record review determinations and/or the MA RADV payment error calculation and must specify which findings the MA organization is appealing when requesting an appeal of a RADV audit finding.

Under CMS's existing RADV audit appeals regulations under 42 CFR 422.311(c)(6) through (8), the MA RADV administrative audit appeals process consists of three levels: reconsideration, hearing, and CMS Administrator review. Below is a summary of the three levels of appeal for background information only. This regulation is not proposing to revise the basic structure of these three levels of appeal.

a. Reconsideration

Reconsideration is the first stage of the RADV audit appeals process. When appealing a medical record review determination, the MA organization's written request must specify the audited HCC(s) that it wishes to appeal and provide a justification of why the audited HCC(s) should not have been identified as an error. When appealing a payment error calculation, the MA organization's written request must include its own RADV payment error calculation that clearly indicates where HHS' payment error calculation was erroneous, as well as additional documentary evidence pertaining to the calculation of the error that the MA organization wishes the reconsideration official to consider. For payment error calculation appeals, a third-party who was not involved in the initial RADV payment error calculation reviews the HHS and MA organization's RADV payment error calculations and recalculates, as appropriate, the payment error using the appropriate payment error calculation method for the relevant audit.

The reconsideration official issues a written reconsideration decision to the MA organization, and this decision is considered final unless the MA organization disagrees with the reconsideration official's decision and submits a valid request for CMS hearing officer review. A new audit report is subsequently issued for either a medical record review determination reconsideration or a payment error

calculation reconsideration only if the reconsideration official's decision is considered final.

b. Hearing Officer Review

An MA organization that disagrees with the reconsideration decision may request a hearing officer review in accordance with procedures and timeframes established by CMS under 42 CFR 422.311(c)(7). If the MA organization appeals the medical record review reconsideration determination, the written request for RADV hearing must include a copy of the written decision of the reconsideration official, specify the audited HCC(s) that the reconsideration official confirmed as being in error, and explain why the MA organization disputes the reconsideration official's determination. If the MA organization appeals a RADV payment error calculation, the written request for RADV hearing must include a copy of the written decision of the reconsideration official and the MA organization's RADV payment error calculation that clearly specifies where the MA organization believes the Secretary's payment error calculation was erroneous.

The hearing officer has the authority to decide whether to uphold or overturn the reconsideration official's decision and, pursuant to this decision, sends a written determination to CMS and the MA organization explaining the basis for the decision. If necessary, a third party who was not involved in the initial RADV payment error calculation recalculates the RADV payment error and issues a new RADV audit report to the MA organization. For MA organizations appealing the RADV payment error calculation only, a third party not involved in the initial RADV payment error calculation recalculates the MA organization's RADV payment error and issues a new RADV audit report to the appellant MA organization and CMS. The hearing officer's decision is final unless the decision is reversed or modified by the CMS Administrator.

c. CMS Administrator Review

Under the existing RADV audit appeals regulation at 42 CFR 422.311(c)(8), a request for CMS Administrator review must be made in writing and filed with the CMS Administrator within 60 days of receipt of the hearing officer's decision. After receiving a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or decline to review the hearing officer's decision. If the CMS Administrator elects to review the hearing decision, the CMS Administrator then will

¹⁰⁰ 88 FR 6643; <https://www.federalregister.gov/documents/2023/02/01/2023-01942/medicare-and-medicaid-programs-policy-and-technical-changes-to-the-medicare-advantage-medicare>.

acknowledge the decision to review the hearing officer's decision in writing and notify CMS and the MA organization of their right to submit comments within 15 days of the date of the notification. The CMS Administrator renders his or her final decision in writing to the parties within 60 days of acknowledging his or her decision to review the hearing officer's decision. The decision of the hearing officer becomes final if the CMS Administrator declines to review the hearing officer's decision or does not render a decision within 60 days.

2. Proposed Policies

In this proposed rule, we are revising the timing of when a medical record review determination and a payment error calculation appeal can be requested and adjudicated. Specifically, we are proposing that MA organizations must exhaust all levels of appeal for medical record review determinations before beginning the payment error calculation appeals process. We believe that this change is necessary because RADV payment error calculations are based upon the outcomes of medical record review determinations and the current regulatory language is somewhat ambiguous regarding this point. Adjudicating medical record review determination appeals prior to payment error calculation appeals alleviates operational concerns for CMS and burden on MA organizations by preventing unnecessary appeals of payment error calculations that will be moot if revisions must be made to payment error calculations based on medical record review determination appeal decisions.

Section 422.311(c)(5)(iii) states that, "for [MA organizations] that appeal both medical record review determination appeal and RADV payment error calculation appeal [,] . . . the Secretary adjudicates the request for the RADV payment error calculation following conclusion of reconsideration of the MA organization's request for medical record review determination appeal." The regulations also state that, for cases in which an MA organization requests both a medical record review determination appeal and payment error calculation appeal, ". . . an [MA organization's] request for appeal of its RADV payment error calculation will not be adjudicated until appeals of RADV medical record review determinations filed by the MA organization have been completed and the decisions are *final for that stage of appeal*" [emphasis added]. This language arguably addresses both those cases in which the final adjudication is reached during the reconsideration

phase, as well as those that proceed to the second and third level of appeal. We propose to delete § 422.311(c)(5)(ii)(C), which requires MA organizations requesting both a medical record review determination appeal and payment error calculation appeal to file their written requests for both appeals within 60 days of the issuance of the RADV audit report before the reconsideration level of administrative appeal. Instead, we propose that MA organizations may request only a medical record review determination appeal or payment error calculation appeal for purposes of reconsideration, and not both at the same time. We propose to amend § 422.311(c)(5)(iii) by providing that MA organizations who request a medical record review determination appeal may only request a payment error calculation appeal after the completion of the medical record review determination administrative RADV appeal process.

An MA organization may also choose to only appeal the payment error calculation, and therefore, no preceding medical record review determination appeal would occur. MA organizations choosing to only file a payment error calculation appeal will not be able to file a medical record review determination appeal after the adjudication of payment error calculation appeal. At § 422.311(c)(5)(ii)(B), we propose to specify that MA organizations will forgo their medical record review determination appeal if they choose to only file a payment error calculation appeal, because medical record review appeals decisions need to be final prior to adjudicating a payment error calculation appeal.

At § 422.311(c)(5)(iii)(A) and (B), we propose to specify that this process is complete when the medical record review determination appeals process has been exhausted through the three levels of appeal, or when the MA organization does not timely request a medical record review determination appeal at the hearing officer or CMS Administrator review stage. At proposed § 422.311(c)(5)(iii)(B), we propose that an MA organization whose medical record review determination appeal has been completed has 60 days from the issuance of a revised RADV audit report to file a written request for payment error calculation appeal, which specifies the issues with which the MA organization disagrees and the reasons for the disagreements. If, as a result of the medical record review determination appeals process, no original determinations are reversed or changed, then the original audit report will be reissued and the MA

organization will have 60 days from the date of issuance to submit a payment error calculation appeal if it so chooses.

We also propose to revise § 422.311(c)(6)(i)(A) to clarify that an MA organization's request for medical record review determination reconsideration must specify any and all audited HCCs from an audit report that the MA organization wishes to dispute. The intent of this revision is to permit an MA organization to submit only one medical record review determination reconsideration request per audited contract, which includes all disputed audited HCCs, given that the results of all audited HCCs for a given audited contract are communicated as part of a single audit report.

We also propose to revise § 422.311(c)(6)(iv)(B) to clarify that the reconsideration official's decision is final unless it is reversed or modified by a final decision of the hearing officer as defined at § 422.311(c)(7)(x).

We also propose to add § 422.311(c)(6)(v) to clarify that the reconsideration official's written decision will not lead to the issuance of a revised audit report until the decision is considered final in accordance with § 422.311(c)(6)(iv)(B). If the reconsideration official's decision is considered final in accordance with § 422.311(c)(6)(iv)(B), the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

We also propose to revise § 422.311(c)(7)(ix) to clarify that if the hearing officer's decision is considered final in accordance with § 422.311(c)(7)(x), the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports for the specific MA contract audit. Once the medical record review determination decision of the adjudicator is final, we believe the same entity that issued the audit report will be able to revise the audit report by applying any medical record review determination findings that may have changed through the medical record review determination appeal process, and issue a revised audit report in the most efficient and streamlined manner. Issuing a revised audit report is a standard process and neutrally applies the final adjudicator's medical record review determination findings. This process is consistent with other long standing CMS appeals program, such as the Provider Reimbursement Review Board (PRRB), where post-adjudication revised determinations are issued by the

same entity (e.g., the Medicare Administrative Contractor for PRRB cases) that issued the original determination.

We also propose the following to provide clarity to the Administrator's level of appeal:

- To revise § 422.311(c)(8)(iii) to add a requirement that if the CMS Administrator does not decline to review or does not elect to review within 90 days of receipt of either the MA organization or CMS's timely request for review (whichever is later), the hearing officer's decision becomes final.
- To revise § 422.311(c)(8)(iv)(A) to clarify that CMS and the MA organization may submit comments within 15 days of the date of the issuance of the notification that the Administrator has elected to review the hearing decision.
- To revise § 422.311(c)(8)(v) to clarify that the requirement of the Administrator to render a final decision in writing within 60 days of the issuance of the notice acknowledging the decision to elect to review the hearing officer's decision and the 60 day time period is determined by the date of the final decision being made by the Administrator, not by the date it is delivered to the parties.
- To revise § 422.311(c)(8)(vi) to clarify the scenarios in which the hearing officer's decision becomes final after a request for Administrator review has been made.
- To add new § 422.311(c)(8)(vii) that states once the Administrator's decision is considered final in accordance with § 422.311(c)(8)(vi), the Secretary will recalculate the MA organization's RADV payment error and issue a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

We also propose to add new § 422.311(c)(9) to specify what actions related to the RADV audit appeals process constitute final agency action. Specifically, in cases when an MA organization appeals a payment error calculation subsequent to an MRRD appeal that has completed the administrative appeals process, the MRRD final decision and the payment error calculation final decision will not be considered a final agency action until the related payment error calculation appeal has completed the administrative appeals process and a final revised audit report has been issued.

We also propose to revise § 422.311(a) to remove the word "annually" for clarity, as the Secretary may conduct RADV audits on differing cadences

between the CMS and HHS–OIG RADV audits.

IV. Benefits for Medicare Advantage and Medicare Prescription Drug Benefit Programs

A. Definition of "Basic Benefits" (§ 422.2)

Section 1852(a)(1)(B)(i) of the Act defines the term "benefits under the original Medicare Fee-for-Service program option" for purposes of the requirement in subparagraph (a)(1)(A) that each MA organization provide enrollees such benefits. Section 17006(c)(1) of the 21st Century Cures Act (Pub. L. 114–255) (hereafter referred to as "the Cures Act") amended section 1852(a)(1)(B)(i) of the Act by inserting "or coverage for organ acquisitions for kidney transplants, including as covered under section 1881(d)" after "hospice care." Per section 17006(c)(3) of the Cures Act, this amendment applies with respect to plan years beginning on or after January 1, 2021. Thus, effective January 1, 2021, MA plans no longer cover organ acquisitions for kidney transplants, including the costs for living donors covered by Medicare pursuant to section 1881(d) of the Act.

In the "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021," final rule (84 FR 15680), hereinafter referred to as the April 2019 final rule and the January 2021 final rule, we amended the definition of "basic benefits" at § 422.100(c)(1) to exclude coverage for organ acquisitions for kidney transplants, effective beginning in 2021, in addition to the existing exclusion for hospice care. In the June 2020 final rule, we also amended several regulations to address coverage of organ acquisition for kidney transplants for MA enrollees, with amendments to §§ 422.258, 422.322, and 422.306. However, we inadvertently omitted making the same type of revision to the "basic benefits" definition at § 422.2. We propose to correct the definition of basic benefits at § 422.2 to add the exclusion of coverage for organ acquisitions for kidney transplants to § 422.2.

Specifically, we propose to revise the "basic benefits" definition at § 422.2 to change the phrase "all Medicare-covered benefits" to "Part A and Part B benefits" and correct the phrase "(except hospice services)" to include, beginning in 2021, organ acquisitions for kidney transplants (which includes

costs covered under section 1881(d) of the Act).

This proposal is a technical change to align the definition of basic benefits with existing law; therefore, neither an economic impact beyond current operating expenses nor an associated paperwork burden are expected.

B. Evidence as to Whether a Special Supplemental Benefit for the Chronically Ill Has a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee (42 CFR 422.102(f)(3)(iii) and (iv) and (f)(4))

The Balanced Budget Act (BBA) of 2018 included new authorities concerning supplemental benefits that may be offered to chronically ill enrollees in Medicare Advantage (MA) plans. We addressed these new supplemental benefits extensively in the Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program (hereafter referred to as "June 2020 final rule") (85 FR 33796, 33800–05), where we referred to them as Special Supplemental Benefits for the Chronically Ill (SSBCI).

As we summarized in the June 2020 final rule, we interpreted the intent of this new category of supplemental benefits as enabling MA plans to better tailor benefit offerings, address gaps in care, and improve health outcomes for chronically ill enrollees who meet the definition established by the statute. Section 1852(a)(3)(D)(ii)(II) of the Act authorizes the Secretary to waive the uniformity requirements generally applicable to the benefits covered by MA plans with respect to SSBCI. Therefore, CMS may allow MA plans to offer SSBCI that are not uniform across the entire population of chronically ill enrollees in the plans but that are tailored and covered for an individual enrollee's specific medical condition and needs (83 FR 16481–82).

In addition to limiting the eligibility of enrollees who can receive SSBCI to chronically ill enrollees, section 1852(a)(3)(D)(ii)(I) of the Act requires that an item or service offered as an SSBCI have a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollee. We codified this statutory requirement as part of the definition of SSBCI at § 422.102(f)(1)(ii).

As we provided in a Health Plan Management System (HPMS) memorandum dated April 24, 2019 ("2019 HPMS memo" hereafter), SSBCI can be in the form of:

- Reduced cost sharing for Medicare-covered benefits;

- Reduced cost sharing for primarily health-related supplemental benefits;
- Additional primarily health-related supplemental benefits; and/or
- Non-primarily health-related supplemental benefits.

To offer an item or service as an SSBCI to an enrollee, an MA plan must make at least two separate determinations with respect to that enrollee in order to satisfy the statutory and regulatory requirements for these benefits. First, the MA plan must determine that an enrollee meets the definition of “chronically ill enrollee.” Section 1852(a)(3)(D)(iii) of the Act defines “chronically ill enrollee” as an individual enrolled in the MA plan who meets all of the following: (I) has one or more comorbid and medically complex chronic conditions that is life-threatening or significantly limits the overall health or function of the enrollee; (II) has a high risk of hospitalization or other adverse health outcomes; and (III) requires intensive care coordination. Per § 422.102(f)(1)(i)(B), CMS may publish a non-exhaustive list of conditions that are medically complex chronic conditions that are life-threatening or significantly limit the overall health or function of an individual. This list is currently the same as the list of chronic conditions for which MA organizations may offer chronic condition special needs plans, which can be found in section 20.1.2 of chapter 16–B of the Medicare Managed Care Manual. We require, at § 422.102(f)(3)(i), the MA plan to have written policies for making this determination and to document each determination that an enrollee is a chronically ill enrollee. Documentation of this determination must be available to CMS upon request according to § 422.102(f)(3)(ii).

Second, the MA plan must determine that the SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the enrollee. Per § 422.102(f)(3)(iii), the MA plan “must have written policies based on objective criteria for determining a chronically ill enrollee’s eligibility to receive a particular SSBCI and must document these criteria.” We also require the MA plan to document “each determination that an enrollee is eligible to receive an SSBCI and make this information available to CMS upon request” at § 422.102(f)(3)(iv).

We do not define or definitively interpret the phrase “has a reasonable expectation of improving or maintaining the health or overall function of the enrollee” in regulation or policy guidance. Rather, in a Health Plan Management System (HPMS)

memorandum dated April 24, 2019 (“2019 HPMS memo” hereafter), we provided MA plans with “broad discretion in determining what may be considered ‘a reasonable expectation’ when choosing to offer specific items and services as SSBCI.” We granted MA plans this discretion so that they might effectively tailor their SSBCI offerings and the eligibility standards for those offerings to the specific chronically ill population upon which the plan is focusing.

We further indicated that “CMS will provide supporting evidence or data to an MA organization if CMS determines that an MA plan may not offer a specific item or service as an SSBCI because it does not have a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee.” In other words, we placed the burden on CMS, and not the MA plan, to generate evidence demonstrating whether the “reasonable expectation” standard—a standard that we granted broad discretion for an MA plan to determine—has been met when offering items or services as SSBCI.

Supplemental benefits, including SSBCI, are generally funded using MA plan rebate dollars.¹⁰¹ When submitting an annual bid to participate in the MA program, an MA organization includes in its bid a Plan Benefit Package (PBP) and Bid Pricing Tool for each of its plans, where the MA organization provides information to CMS on the premiums, cost sharing, and supplemental benefits (including SSBCI) it proposes to offer. Since issuing the 2019 HPMS memo, the number of MA plans that offer SSBCI—and the number and scope of SSBCI offered by an individual plan—has significantly increased. We have observed these trends in reviewing PBPs from MA plans submitted in the past few years.

Based on our internal data, 101 MA plans offered a food and produce benefit in contract year 2020, while 929 MA plans are offering this as an SSBCI in contract year 2023.¹⁰² Similarly, 88 MA plans offered transportation for non-medical needs as an SSBCI in contract year 2020. In contract year 2023, 478 MA plans are offering this as an SSBCI.¹⁰³ MA plans are also continuing

to identify items or services as SSBCI that were not included as examples in the 2019 HPMS memo. When an MA plan is offering such a benefit, it indicates this in the PBP¹⁰⁴ that it submits with its bid. The MA plan categorizes the benefit within our PBP submission system as an “other” SSBCI (a benefit designation within the PBP submission system) and describes the proposed new benefit in a “free text” field. While 51 MA plans offered an “other” non-primarily health-related supplemental benefit in contract year 2020, 440 plans are offering at least one “other” non-primarily health-related SSBCI in contract year 2023—and 226 plans are offering at least two.¹⁰⁵

Through SSBCI, MA organizations can design and implement benefits, including non-primarily health-related benefits, that may be able to holistically address various needs of chronically ill enrollees. As these benefits become a more significant part of the MA program, we believe it is important to update our processes for reviewing and approving SSBCI to manage the growth and development of new SSBCI offerings, as well as to ensure compliance with the statutory requirements at section 1852(a)(3)(D). Additionally, section 1854(b)(1)(C) of the Act requires that MA plans offer the value of MA rebates back to enrollees in the form of payment for supplemental benefits, cost sharing reductions, or payment of Part B or D premiums. As an increasing share of Medicare dollars is going toward MA rebates that plans are using to offer SSBCI, we believe that revising the regulation to adopt greater review and scrutiny of these benefits is important for CMS to maintain good stewardship of Medicare dollars, including the MA rebates used to pay for these benefits, and for ensuring that the SSBCI offered are consistent with applicable law and those most likely to improve or maintain the health or overall function of chronically ill enrollees. Therefore, we propose to update our processes to simultaneously ensure effective program administration and oversight, while enabling MA organizations to offer SSBCI and improve health outcomes for chronically ill enrollees.

Currently, the burden is on CMS to review SSBCI included in an MA organization’s bid and determine whether sufficient evidence or data exists to demonstrate that it has a

¹⁰¹ MA plan rebates are a portion of the amount by which the bidding benchmark or maximum MA capitation rate for a service area exceeds the plan’s bid; MA plans are obligated to use the MA rebates for the purposes specified in 42 CFR 422.266: payment of supplemental benefits (including reductions in cost sharing) or reductions in Part B or Part D premiums.

¹⁰² Taken from internal data.

¹⁰³ Taken from internal data.

¹⁰⁴ A PBP is a set of benefits for a defined MA (or Prescription Drug Plan) service area. The PBP is submitted by MA organizations and PDP sponsors to CMS for benefit analysis, marketing, and beneficiary communication purposes.

¹⁰⁵ Taken from internal data.

reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. Given the growth in the quantity and type of SSBCI offerings and given the associated burden increase on CMS in reviewing and approving bids that include SSBCI, we believe that it would be more efficient for the MA organization, rather than CMS, to demonstrate that the reasonable expectation standard has been met.

When CMS provides MA organizations with broad latitude in offering items or services as SSBCI and in establishing what a “reasonable expectation” means for a given SSBCI, we believe that it is appropriate for the MA organization, rather than CMS, to identify supporting evidence or data to support an SSBCI and to establish compliance with the applicable law.

We are proposing that an MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate through relevant acceptable evidence that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. As part of shifting responsibility this way, we are proposing, as relevant to an MA organization that includes SSBCI in its bid, to: (1) require the MA organization to establish, by the date on which it submits its bid, a bibliography of “relevant acceptable evidence” related to the item or service the MA organization would offer as an SSBCI during the applicable coverage year; (2) require that an MA plan follow its written policies (that must be based on objective criteria) for determining eligibility for an SSBCI when making such determinations; (3) require the MA plan to document denials of SSBCI eligibility rather than approvals; and (4) codify CMS’s authority to decline to accept a bid due to the SSBCI the MA organization includes in its bid and to review SSBCI offerings annually for compliance, taking into account the evidence available at the time. In addition, we propose to make a technical edit to § 422.102(f)(1)(i)(A)(2) to correct a typographical error. We describe each proposal in greater detail below.

First, we propose to redesignate what is currently § 422.102(f)(3) to § 422.102(f)(4), and to address, at new § 422.102(f)(3), new requirements for each MA plan that includes an item or service as SSBCI in its bid. The MA organization must be able to demonstrate through relevant acceptable evidence that the item or service to be offered as SSBCI has a reasonable

expectation of improving or maintaining the health or overall function of a chronically ill enrollee and must, by the date on which it submits its bid to CMS, establish a bibliography of all “relevant acceptable evidence” concerning the impact that the item or service has on the health or overall function of its recipient. The bibliography must be made available to CMS upon request. As part of this proposal, an MA organization would be required to include, for each citation in its written bibliography, a working hyperlink to or a document containing the entire source cited. This proposal would apply only to SSBCI offered in the form of additional primarily health-related supplemental benefits or SSBCI offered in the form of non-primarily health-related supplemental benefits. It would not apply to an SSBCI offered in the form of reduced cost sharing, regardless of the benefit for which it is offered. We also intend, at this time, that the proposal not apply to supplemental benefits offered under the Value-Based Insurance Design (VBID) Model administered by the Center for Medicare and Medicaid Innovation (CMMI), unless CMMI incorporates this policy within the VBID Model.

We also propose, in new paragraph (f)(3)(iv), that the MA organization must make its bibliography of relevant acceptable evidence available to CMS upon request. CMS may request and use this bibliography, without limitation, during bid review to assess whether SSBCI offerings comply with regulatory requirements, or during the coverage year as part of CMS’s oversight activities. CMS does not intend, at this time, to require MA organizations to submit these bibliographies as a matter of course in submitting bids.

We propose that the term “relevant acceptable evidence” would include large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to investigate whether the item or service (that is proposed to be covered as an SSBCI) impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same. We further propose that the MA plan must include in its bibliography all relevant acceptable evidence published within the 10 years preceding the month in which the MA plan submits its bid. Ideally, relevant acceptable evidence should include studies and other investigations specific to the chronic conditions for which the MA organization intends to target the SSBCI, but we are not proposing to make this

a requirement at this time. We are concerned that relevant acceptable evidence applicable to many SSBCI will already be limited, and that requiring a bibliography be limited to only studies concerning certain chronic conditions would discourage the development of new SSBCI. Similarly, to the extent there exists sufficient relevant acceptable evidence that the item or service meets the reasonable expectation standard for a sample of a population, an MA organization may still offer an SSBCI to enrollees with a specific chronic condition even in the absence of any studies addressing the connection between an item or service and its effect on the health or overall function of individuals with that condition.

We propose that, in the absence of publications that meet these standards, “relevant acceptable evidence” for purposes of the MA plan’s bibliography could include case studies, Federal policies or reports, and internal analyses or any other investigation of the impact that the item or service has on the health or overall function of its recipient. By “bibliography,” we mean a list, and not a description, of scholarly publications or other works, as we describe below.

In our April 2023 final rule, we discussed what constituted sufficiently high-quality clinical literature in the context of an MA organization establishing internal clinical criteria for certain Medicare basic benefits (88 FR 22189, 22197). We believe that those standards are also applicable for identifying “relevant acceptable evidence” in the context of supporting whether an item or service offered as SSBCI has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. Therefore, our proposal for § 422.102(f)(3)(ii) largely tracks the language in § 422.101(b)(6) describing acceptable clinical literature for purposes of establishing internal coverage criteria, but with revisions to be specific to the context of SSBCI and the reasonable expectation standard.

Literature that CMS considers to be “relevant acceptable evidence” for supporting an SSBCI offering include large, randomized controlled trials or cohort studies or all-or-none studies with clear results, published in a peer-reviewed journal, and specifically designed to answer a question relevant to the requirements for offering and covering SSBCI and how the MA plan will implement the coverage—such as the impact of structural home modifications on health or overall function. Literature might also include that which involves large systematic

reviews or meta-analyses summarizing the literature specifically related to the subject of the SSBCI—such as meal delivery, availability of certain food or produce, or access to pest control—published in a peer-reviewed journal with clear and consistent results. Under this proposal, an MA organization would be required to cite all such available evidence in its bibliography, and not just studies that present findings favorable to its SSBCI offering.

We also propose that, in the absence of literature that conforms to these standards for relevant acceptable evidence, an MA organization would be required to include in its bibliography evidence that is unpublished, is a case series or report, or derived solely from internal analyses within the MA organization. In this way, our proposed policy would deviate from the standard we established for the type of evidence necessary to support an MA organization's internal coverage criteria for Medicare basic benefits. We believe this deviation is appropriate as there is relatively less research into the impact of the provision on items or services commonly offered as SSBCI on health or overall function of chronically ill individuals.

We are not proposing that relevant acceptable evidence must directly address whether there is a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee with a specific chronic illness or condition (conditions that the MA plan would have identified in its PBP submission), but such materials may be more persuasive than materials that only describe the impact of certain items and services—particularly non-primarily health-related items and services—on healthier individuals or populations. Further, our proposal is limited to SSBCI offered as additional primarily health-related supplemental benefits and non-primarily health-related supplemental benefits. We are not proposing to require a bibliography for SSBCI that are exclusively cost sharing reductions for Medicare-covered benefits or primarily health-related supplemental benefits, so the regulation text is limited to SSBCI that are items or services. Although we are not proposing to apply this new documentation requirement to cost sharing reductions offered as SSBCI, that type of SSBCI must also meet the reasonable expectation standard to be offered as SSBCI.

We believe that this proposal would serve our goal of ensuring that SSBCI regulatory standards are met—specifically, that an item or service covered as an SSBCI has a reasonable

expectation of improving or maintaining the health or overall function of a chronically ill enrollee. We expect that rigorous research like that we describe above might be limited, and that some studies may not produce results favorable to the offering of an SSBCI. However, when there are also favorable studies, the existence of such unfavorable studies does not necessarily mean that there could not be a “reasonable expectation” that the SSBCI would improve or maintain the health or overall function of a chronically ill enrollee. And it is not our goal that mixed results in current literature—or the lack of rigorous research at all—would reduce innovation in SSBCI offerings. We wish to continue to see MA organizations identify new ways to deliver helpful benefits to chronically ill enrollees that can address their social needs while also improving or maintain the health or overall function of these chronically ill enrollees. Our goal is to ensure that SSBCI innovation occurs in a manner that is grounded to the extent possible in research, and that MA organizations and CMS alike are tracking to the most current research relevant to SSBCI offerings. We believe this proposal would continue to promote SSBCI innovation while helping to ensure that when Medicare funds are used to offer SSBCI, such offerings meet statutory requirements.

We solicit comments on our proposed requirement that an MA organization that includes an item or service as SSBCI in its bid must, by the date on which it submits its bid to CMS, establish in writing a bibliography of all relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient. We also solicit comments on our definition of “relevant acceptable evidence,” including the specific parameters or features of studies or other resources that would be most appropriate to include in our definition. We also solicit comments on our proposal that, for each citation in the written bibliography, the MA organization would be required to include a working hyperlink to or a document containing the entire source cited. Additionally, we solicit comments on whether we should apply this requirement to all items or services offered as SSBCI, or whether there are certain types or categories of SSBCI for which this requirement should not apply.

Second, for clarity, we propose to explicitly require at redesignated § 422.102(f)(4)(iii) that an MA plan apply its written policies, which must be based on objective criteria, that it

establishes for determining whether an enrollee is eligible to receive an SSBCI. The regulation currently requires MA organizations to have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI and must document these criteria. While we anticipate that MA plans are already applying their written policies that identify the eligibility criteria when making these determinations, we propose to make clear that an MA plan must apply its written policies when making SSBCI eligibility determinations.

We are considering whether to exclude the policies required by current § 422.102(f)(3) (that is, the requirements we are proposing to redesignate to new paragraph (f)(4)) from the general rule reflected in § 422.111(d) that MA plans may change plan rules during the year so long as notice is provided to enrollees. We solicit comments on whether CMS should permit changes in SSBCI eligibility policies during the coverage year, and, if so, the limitations or flexibilities that CMS should implement that would still allow CMS to provide effective oversight over SSBCI offerings. The ability to change plan rules during the year does not permit changes in benefit coverage but would include policies like utilization management requirements, evidentiary standards for a specific enrollee to be determined eligible for a particular SSBCI, or the specific objective criteria used by a plan as part of SSBCI eligibility determinations.

Third, we are proposing to amend redesignated paragraph (f)(4)(iv) to require that an MA plan document each instance wherein the plan determines that an enrollee is ineligible to receive an SSBCI. Denials of coverage when an enrollee requests an SSBCI are organization determinations subject to the rules in subpart M, including the requirements related to the timing and content of denial notices in § 422.568. By fully documenting denials as required by this proposal, MA organizations should be better placed to address any appeals, including when an adverse reconsideration must be sent to the independent review entity for review. Similarly, requiring robust documentation of denials of SSBCI by MA organizations will make oversight and monitoring by CMS easier and more productive, should CMS request documentation.

We solicit comments on our proposal to require an MA plan to document its findings that a chronically ill enrollee is ineligible, rather than eligible, for an SSBCI.

Fourth, we are proposing to add § 422.102(f)(5) to codify CMS's authority to decline to approve an MA organization's bid, if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting. We clarify that while this proposal would establish a specific basis on which CMS may decline to approve an MA organization's bid, our authority to enforce compliance with other regulations and to negotiate bids (see section 1854(a) of the Act and subpart F) would not be limited by this provision. As described in section 1854(a)(5)(C) of the Act, CMS is not obligated to accept any or every bid submitted by an MA organization, and CMS may reject bids that propose significant increases in cost sharing or decreases in benefits offered under the plan. Similarly, CMS's authority to review benefits to ensure non-discrimination is not limited or affected under this proposal. This proposal is intended to clarify and establish that CMS's review of bids that include SSBCI could include specific evaluation of SSBCI and that CMS may decline to approve bids based on a lack of relevant acceptable evidence in support of the SSBCI offering the MA organization includes in its bid.

We also propose to codify that, regardless of whether an SSBCI offering was approved in the past, CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, considering the relevant acceptable evidence applicable to each item or service at the time the bid is submitted. Under this proposal, CMS would have clear authority to evaluate an SSBCI included in a bid each year based on the evidence available at that time. CMS would not be bound to approve a bid that contains a certain SSBCI only because CMS approved a bid with the same SSBCI in the past. We believe this provision, if finalized, would help ensure sound use of Medicare dollars by establishing a clear connection between an SSBCI and the most current evidence addressing whether there is a reasonable expectation that the SSBCI will improve or maintain the health or overall function of a chronically ill enrollee.

We believe that codifying that CMS may decline to approve a bid for an MA organization to offer certain SSBCI is appropriate to support CMS's programmatic oversight function. CMS

already possesses the authority to negotiate and reject bids under section 1854 of the Act, and to establish certain minimum requirements related to SSBCI under section 1852 of the Act. We can rely on these bases to decline to approve bids that include SSBCI that lack evidence to support the MA organization's expectations related to the SSBCI, but we believe it prudent to establish clearly how our evaluation of individual SSBCI offerings and the evidence supporting these offerings fit within our bid negotiation and approval authority. We believe that SSBCI provide a critical source of innovation, and we wish to see MA organizations continue to develop impactful benefits tailored to their chronically ill enrollees. However, we must also ensure that benefits offered within the MA program comply with all applicable statutory and regulatory standards. We believe it is critical for effective program administration that CMS be able to obtain, upon request, relevant acceptable evidence from an MA organization to support CMS's review of SSBCI each year in light of the information and evidence available at that point in time.

We solicit comment on this proposal to codify CMS's authority to decline to approve an MA organization's bid if the MA organization fails to demonstrate, through relevant acceptable evidence, that an SSBCI included in the bid has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.

The policies proposed in this section work together to place the burden of showing whether an item or service offered as SSBCI has a reasonable expectation of improving the health or overall function of a chronically ill enrollee onto the MA organization. Implementing these proposals would change the policy set forth in the 2019 HPMS memo requiring CMS to provide supporting evidence or data to an MA organization if CMS determines that an MA plan may not offer a specific item or service as an SSBCI because it has not met the reasonable expectation standard. Under these proposals, the MA organization must, in advance of including an SSBCI in its bid, have already conducted research on the evidence establishing a reasonable expectation that the item or service would improve or maintain the health or overall function of the recipient of the item or service. By the time the MA organization submits its bid, it must be able to show CMS, upon request, the relevant applicable evidence that supports the reasonable expectation that

the item or service would improve or maintain the health or overall function of the chronically ill enrollees it is targeting. We expect that MA plans are already proactively conducting similar research and establishing written policies for implementing SSBCI based on this research when designing them. Additionally, MA plans may seek guidance from CMS regarding SSBCI items or services not defined in the PBP or in previous CMS guidance prior to bid submission. As such, we believe this proposal, if implemented, would create efficiency while imposing relatively little burden on MA plans.

In addition, under this proposal, MA plans would be required to document and submit to CMS upon request each determination that an enrollee is not eligible to receive an SSBCI. We believe that requiring an MA organization to support its SSBCI offerings with a written bibliography of relevant acceptable evidence and an MA plan to document denials of SSBCI work together to ensure that SSBCI are being implemented in an evidence-based, non-discriminatory, and fair manner. The evidence base established by an MA organization could serve to inform an MA plan's objective criteria for determining eligibility. By requiring an MA plan to document instances of SSBCI denials, we believe this proposal would improve the experience of MA plans, enrollees, and CMS in managing and oversight of appeals of such denials. Further, it would help ensure that MA plans are not denying access to SSBCI based on factors that are biased or discriminatory or unrelated to the basis on which the SSBCI are reasonably expected to improve or maintain the health or overall function of the chronically ill enrollees. For example, researchers have identified that certain algorithms that have been used to decide who gets access to additional services can have clear racial bias, when factors such as expected future cost or expected future utilization are incorporated into the algorithm.¹⁰⁶ By codifying CMS' authority to decline to approve a bid that includes an SSBCI not supported by evidence, this proposal also serves to ensure appropriate program administration and oversight.

Finally, we propose to make a technical edit to § 422.102(f)(1)(i)(A)(2) to correct a typographical error. In our June 2020 final rule, we noted that section 1852(a)(3)(D)(ii) of the Act, as

¹⁰⁶ See, e.g., Ziad Obermeyer et al., Dissecting racial bias in an algorithm used to manage the health of populations. *Science* 366, 447–453 (2019). DOI:10.1126/science.aax2342.

amended, defines a chronically ill enrollee as an individual who, among other requirements, “[h]as a high risk of hospitalization or other adverse health outcomes[.]” We then indicated that “we proposed to codify this definition of a chronically ill enrollee” at § 422.102(f)(1)(i). However, our regulation at § 422.102(f)(1)(i)(A)(2) currently reads: “Has a high risk of hospitalization of other adverse outcomes[.]” We propose to substitute “or” for the second “of” in this provision, such that it aligns with the statutory language that we intended to codify in our regulation.

C. Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111(l) and 422.2267(e)(42))

Per CMS regulations at § 422.101, MA organizations are permitted to offer mandatory supplemental benefits, optional supplemental benefits, and special supplemental benefits for the chronically ill (SSBCI). When submitting an annual bid to participate in the MA program, an MA organization includes a Plan Benefit Package (PBP) and Bid Pricing Tool (BPT) for each of its plans where the MA organization provides information to CMS on the premiums, cost sharing, and supplemental benefits (including SSBCI) it proposes to offer. The number of supplemental benefit offerings has risen significantly in recent years, as observed through trends identified in CMS’s annual PBP reviews. In 2023, roughly \$61 billion was directed towards supplemental benefits in MA. At the same time, CMS has received reports that MA organizations have observed low utilization of these benefits by their enrollees, and it is unclear whether plans are actively encouraging utilization of these benefits by their enrollees, which could be an important part of a plan’s overall care coordination efforts.

CMS remains concerned that utilization of these benefits is low and has taken multiple steps to obtain more complete data in this area. For example, in the May 2022 final rule, we finalized expanded Medical Loss Ratio (MLR) reporting requirements, requiring MA organizations to report expenditures on popular supplemental benefit categories such as dental, vision, hearing, transportation, and the fitness benefit (87 FR 27704, 27826–28).¹⁰⁷ In addition, in March 2023, as a part of our Part C reporting requirements, we announced

our intent to collect data to better understand the utilization of supplemental benefits, which if finalized, would include requiring MA plans to report utilization and cost data for all supplemental benefit offerings (88 FR 15726). Currently, there is no specific requirement for MA organizations, beyond more general care coordination requirements, to conduct outreach to enrollees to encourage utilization of supplemental benefits.

CMS understands that projected supplemental benefit utilization, that is, the extent to which an MA organization expects a particular supplemental benefit to be accessed during a plan year, is estimated by an MA organization in part by the type and extent of outreach conducted for the benefit.¹⁰⁸ We are concerned that beneficiaries may make enrollment decisions based on the allure of supplemental benefits that are extensively marketed by a given MA plan during the annual election period (AEP) only to not fully utilize, or utilize at all, those supplemental benefits during the plan year. This underutilization may be due to a lack of effort by the plan to help the beneficiary access the benefits or a lack of easy ability to know what benefits have not been accessed and are still available to the enrollee throughout the year. Such underutilization of supplemental benefits may nullify any potential health value offered by these extra benefits.

Additionally, section 1854(b)(1)(C) requires that MA plans offer the value of MA rebates back to enrollees in the form of payment for supplemental benefits, cost sharing reductions, or payment of Part B or D premiums. Therefore, CMS has an interest in ensuring that MA rebates are provided to enrollees in a way that they can benefit from the value of these rebate dollars. For example, analysis indicates that while supplemental dental benefits are one of the most widely offered supplemental benefits in MA plans, enrollees in these plans are no more likely to access these services than Traditional Medicare enrollees.¹⁰⁹

As discussed, MA organizations are given the choice of how to provide MA rebates to their enrollees. Organizations

may, instead of offering supplemental benefits in the form of covering additional items and services, use rebate dollars to further reduce Part B and Part D premiums, reduce cost sharing for basic benefits compared to cost sharing in Traditional Medicare, and reduce cost sharing in other ways, such as reducing maximum out-of-pocket (MOOP) amounts.

Over the last several years, CMS has observed upticks in (1) the number and variety of supplemental benefits offered by MA plans, (2) plan marketing activities by MA organizations, and (3) overall MA enrollment; we presume that an enrollee’s plan choice is influenced, at least in part, by the supplemental benefits an MA plan offers because the absence or presence of a particular supplemental benefit represents a distinguishable and easily understood difference between one plan and another. We are also concerned that some MA plans may be using these supplemental benefits primarily as marketing tools to steer enrollment towards their plan and are not taking steps to ensure that their enrollees are using the benefits being offered or tracking if these benefits are improving health or quality of care outcomes or addressing social determinants of health. We believe targeted communications specific to the utilization of supplemental benefits may further ensure that covered benefits (including those that are heavily marketed) are accessed and used by plan enrollees during the plan year. This outreach, in conjunction with the improved collection of utilization data for these supplemental benefits through MLR and our proposed collection through Part C reporting, should help inform whether future rulemaking is warranted.

Finally, CMS is also working to achieve policy goals that advance health equity across its programs and pursue a comprehensive approach to advancing health equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Several studies have pointed to disparities in health care utilization. For example, a Kaiser Family Foundation (KFF) study¹¹⁰ found that there are significant racial and ethnic disparities in utilization of care among individuals with health insurance. Additionally, underserved populations tend to have a disproportionate prevalence of unmet social determinants of health needs,

¹⁰⁷ Available at <https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and>.

¹⁰⁸ U.S. Government Accountability Office (GAO). “MEDICARE ADVANTAGE Plans Generally Offered Some Supplemental Benefits, but CMS Has Limited Data on Utilization.” Report to Congressional Committee, 31 Jan. 2023, p. 20, www.gao.gov/products/gao-23-105527.

¹⁰⁹ <https://www.cms.gov/research-statistics-data-and-systems/research/mcbs/data-briefs/dental-coverage-status-and-utilization-preventive-dental-services-medicare-beneficiaries-poster>.

¹¹⁰ <https://www.kff.org/report-section/racial-and-ethnic-disparities-in-access-to-and-utilization-of-care-among-insured-adults-issue-brief/>.

which can adversely affect health. We believe that the ability to offer supplemental benefits provides MA plans the unique opportunity to use Trust Fund dollars (in the form of MA rebates) to fill in coverage gaps in Traditional Medicare, by offering additional health care benefits or SSBCI that address unmet social determinants of health needs, and as such, all eligible MA enrollees should benefit from these offerings. Targeted outreach specific to the utilization of supplemental benefits may also serve to further ensure more equitable utilization of these benefits.

The establishment of a minimum requirement for targeted outreach with respect to supplemental benefits that have not been accessed by enrollees would standardize a process to ensure all enrollees served under MA are aware of and utilizing, as appropriate, the supplemental benefits available to them. Section 1852(c)(1) of the Act requires, in part, that MA organizations disclose detailed descriptions of plan provisions, including supplemental benefits, in a clear, accurate, and standardized form to each enrollee of a plan at the time of enrollment and at least annually thereafter. We propose to use our authority to establish standards under Part C in section 1856(b)(1) of the Act to ensure adequate notice is provided to enrollees regarding supplemental benefits coverage. This proposal will further implement the disclosure requirement in section 1852(c)(1)(F) of the Act. Specifically, we propose that MA organizations must provide a model notification to enrollees of supplemental benefits they have not yet accessed. We propose to meet this goal by adding new provisions at §§ 422.111(l) and 422.2267(e)(42) to establish this new disclosure requirement and the details of the required notice, respectively.

This proposed requirement would ensure that a minimum outreach effort is conducted by MA organizations to inform enrollees of supplemental benefits available under their plan that the enrollee has not yet accessed. We propose that, beginning January 1, 2026, MA organizations must mail a mid-year notice annually, but not sooner than June 30 and not later than July 31 of the plan year, to each enrollee with information pertaining to each supplemental benefit available during that plan year that the enrollee has not begun to use. We understand that there may be a lag between the time when a benefit is accessed and when a claim is processed, so we would require that the information used to identify recipients of this notice be as up to date as possible at the time of mailing. MA organizations are not required to include

supplemental benefits that have been accessed, but are not yet exhausted, in this proposed mid-year notice.

Understanding that not all Medicare beneficiaries enroll in an MA plan during the AEP, we are specifically seeking comment on how CMS should address the timing of the notice for beneficiaries that have an enrollment effective date after January 1. One possible approach we are considering is to require the notice to be sent six months after the effective date of the enrollment for the first year of enrollment, and then for subsequent years, revert to mailing the notice between the proposed delivery dates of June 30 and July 31. Another option CMS is considering is to not require the notice to be mailed for the first year of enrollment for those beneficiaries with an effective date of May 1 or later, as they would be receiving their Evidence of Coverage (EOC) at around this same time but will not have had significant time in which to access these benefits. Those enrollees who would be exempt from the mailing, based on their enrollment effective date, would then receive the notice (if applicable because one or more supplemental benefits have not been accessed by the enrollee) between June 30 and July 31 in subsequent enrollment years.

For each covered mandatory supplemental benefit and optional supplemental benefit (if the enrollee has elected) the enrollee is eligible for, but has not accessed, the MA organization must list in the notice the information about each such benefit that appears in EOC. For SSBCI, MA organizations must include an explanation of the SSBCI covered under the plan (including eligibility criteria and limitations and scope of the covered items and services) and must also provide point-of-contact information (which can be the customer service line or a separate dedicated line), with trained staff that enrollees can contact to inquire about or begin the SSBCI eligibility determination process and to address any other questions the enrollee may have about the availability of SSBCI under their plan. When an enrollee has been determined by the plan to be eligible for one or more specific SSBCI but has not accessed the SSBCI benefit by June 30 of the plan year, the notice must also include a description of the SSBCI to which the enrollee is entitled and must describe any limitations on the benefit. Note the proposals at section VI.A of this proposed rule that, if finalized, would require specific SSBCI disclaimers for marketing and communications materials that discuss the limitations of the SSBCI benefit being offered; we also

propose that this mid-year notice must include the SSBCI disclaimer to ensure that the necessary information provided in the disclaimer is also provided to the enrollee in the notice.

Furthermore, we are proposing that each notice must include the scope of the supplemental benefit(s), applicable cost sharing, instructions on how to access the benefit(s), applicable information on the use of network providers for each available benefit, list the benefits consistent with the format of the EOC, and a toll-free customer service number and, as required, a corresponding TTY number to call if additional help is needed. We solicit comments on the required content of the mid-year notice.

We request comment on our proposal to require MA plans to provide enrollees with mid-year notification of covered mandatory and optional supplemental benefits (if elected) that have not been at least partially accessed by that enrollee, particularly the appropriate timing (if any) of the notice for MA enrollees who enroll in the plan mid-year.

D. Annual Health Equity Analysis of Utilization Management Policies and Procedures

In recent years, CMS has received feedback from interested parties, including people with Medicare, patient groups, consumer advocates, and providers that utilization management (UM) practices in Medicare Advantage (MA), especially the use of prior authorization, can sometimes create a barrier for patients in accessing medically necessary care. Further, some research has indicated that the use of prior authorization may disproportionately impact individuals who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality,¹¹¹ due to several factors, including; the administrative burden associated with processing prior authorization requests (for example, providers and administrative staff serving historically underserved populations, in particular, may not have the time or resources to complete the prior authorization process, including navigating the appeals process¹¹²), a reduction in medication adherence, and overall worse medical outcomes due to delayed or denied care. Research has also shown

¹¹¹ <https://www.hmpglobelearningnetwork.com/site/frmc/commentary/addressing-health-inequities-prior-authorization>; and <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10024078/>.

¹¹² <http://abcadio.org/wp-content/uploads/2019/03/AB-20190227-PA-White-Paper-Survey-Results-final.pdf>.

that dual eligibility for Medicare and Medicaid is one of the most influential predictors of poor health outcomes, and that disability is also an important risk factor linked to health outcomes.¹¹³

On January 20, 2021, President Biden issued Executive Order 13985: “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” (E.O. 13985).¹¹⁴ E.O. 13985 describes the Administration’s policy goals to advance equity across Federal programs and directs Federal agencies to pursue a comprehensive approach to advancing equity for all, including those who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality. Consistent with this Executive order, CMS announced “Advance Equity” as the first pillar of its 2022 Strategic Plan.¹¹⁵ This pillar emphasizes the importance of advancing health equity by addressing the health disparities that impact our health care system. 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.”¹¹⁶

The April 2023 final rule¹¹⁷ included several policy changes to advance health equity, as well as changes to address concerns from interested parties about the use of utilization management policies and procedures, including prior authorization, by MA plans. CMS understands that utilization management is an important means to coordinate care, reduce inappropriate utilization, and promote cost-efficient care. The April 2023 final rule adopted several important guardrails to ensure that utilization management policies and procedures are used, and associated

coverage decisions are made, in ways that ensure timely and appropriate access to covered items and services for people enrolled in MA plans. CMS also continues to work to identify regulatory actions that can help support CMS’s goal to advance health equity and improve access to covered benefits for enrollees.

Authority for MA organizations to use utilization management policies and procedures regarding basic benefits is subject to the mandate in section 1852(a)(1) of the Act that MA plans cover Medicare Part A and Part B benefits (subject to specific, limited statutory exclusions) and, thus, to CMS’s authority under section 1856(b) of the Act to adopt standards to carry out the MA statutory provisions. In addition, the MA statute and MA contracts cover both the basic and supplemental benefits covered under MA plans, so additional contract terms added by CMS pursuant to section 1857(e)(1) of the Act may also address supplemental benefits. Additionally, per section 1852(b) of the Act and § 422.100(f)(2), plan designs and benefits may not discriminate against beneficiaries, promote discrimination, discourage enrollment, encourage disenrollment, steer subsets of Medicare beneficiaries to particular MA plans, or inhibit access to services. These requirements apply to both basic and supplemental benefits. We consider utilization management policies and procedures to be part of the plan benefit design, and therefore they cannot be used to discriminate or direct enrollees away from certain types of services.

In the April 2023 final rule, CMS finalized a new regulation at § 422.137, which requires all MA organizations that use UM policies and procedures to establish a Utilization Management Committee to review and approve all UM policies and procedures at least annually and ensure consistency with Traditional Medicare’s national and local coverage decisions and relevant Medicare statutes and regulations. Per § 422.137, an MA plan may not use any UM policies and procedures for basic or supplemental benefits on or after January 1, 2024, unless those policies and procedures have been reviewed and approved by the UM committee. While this requirement will ensure that all UM policies and procedures are kept up to date, we believe that reviewing and analyzing these policies from a health equity perspective is an important beneficiary protection. In addition, such an analysis may assist in ensuring that MA plan designs do not deny, limit, or condition the coverage or provision of benefits on a prohibited basis (such as

a disability) and are not likely to substantially discourage enrollment by certain MA eligible individuals with the organization. For these reasons, we propose to add health equity-related requirements to § 422.137. First, we propose at § 422.137(c)(5) to require that beginning January 1, 2025, the UM committee must include at least one member with expertise in health equity. We are proposing that health equity expertise includes educational degrees or credentials with an emphasis on health equity, experience conducting studies identifying disparities amongst different population groups, experience leading organization-wide policies, programs, or services to achieve health equity, or experience leading advocacy efforts to achieve health equity. Since there is no universally accepted definition of expertise in health equity, we referred to materials from the Council on Linkages Between Academia and Public Health Practice¹¹⁸ and the National Board of Public Health Examiners,¹¹⁹ to describe “expertise in health equity” in the context of MA and prior authorization.

We also propose to add a requirement at § 422.137(d)(6) that the UM committee must conduct an annual health equity analysis of the use of prior authorization. We propose that the member of the UM committee, who has health equity expertise, as required at the proposed § 422.137(c)(5), must approve the final report of the analysis before it is posted on the plan’s publicly available website. The proposed analysis would examine the impact of prior authorization at the plan level, on enrollees with one or more of the following social risk factors (SRF): (1) receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid (LIS/DE); or (2) having a disability. Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems. CMS chose these SRFs because they mirror the SRFs that will be used to measure the Health Equity Index reward for the 2027 Star Ratings (see § 422.166(f)(3)), and we believe it is important to align expectations and metrics across the program. Moreover, CMS is requiring this analysis to take place at the MA plan level because the relevant information regarding enrollees with the specified SRFs is available at

¹¹³ https://www.aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf?ga=2.49530854.1703779054.1662938643-470268562.1638986031.

¹¹⁴ 86 FR 7009 (January 25, 2021); <https://www.federalregister.gov/d/2022-26956/p-227>.

¹¹⁵ 87 FR 79479 fn. 7 (December 27, 2022); <https://www.federalregister.gov/d/2022-26956/p-228>.

¹¹⁶ 87 FR 79479 fn. 8 (December 27, 2022); <https://www.federalregister.gov/d/2022-26956/p-229>.

¹¹⁷ “Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” final rule, which appeared in the **Federal Register** on April 12, 2023 (88 FR 22120).

¹¹⁸ https://www.phf.org/resourcestools/Documents/Core_Competencies_for_Public_Health_Professionals_2021October.pdf.

¹¹⁹ <https://www.nbphe.org/cph-content-outline/>.

the plan level, and we believe this level of analysis is important to discern the actual impact of the use of utilization management on enrollees that may be particularly subject to health disparities.

To gain a deeper understanding of the impact of prior authorization practices on enrollees with the specified SRFs, the proposed analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. This will allow the MA plan and CMS to begin to identify whether the use of prior authorization causes any persistent disparities among enrollees with the specified SRFs. The proposed analysis must use the following metrics, calculated for enrollees with the specified SRFs, and for enrollees without the specified SRFs, from the prior contract year, to conduct the analysis:

- The percentage of standard prior authorization requests that were approved, aggregated for all items and services.
- The percentage of standard prior authorization requests that were denied, aggregated for all items and services.
- The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.
- The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

We propose to add at § 422.137(d)(7) that by July 1, 2025, and annually thereafter, the health equity analysis be posted on the plan's publicly available website in a prominent manner and clearly identified in the footer of the website. We propose that the health equity analysis must be easily accessible to the general public, without barriers, including but not limited to ensuring the information is available: free of charge; without having to establish a user account or password; without

having to submit personal identifying information (PII); in a machine-readable format with the data contained within that file being digitally searchable and downloadable from a link in the footer of the plan's publicly available website, and include a .txt file in the root directory of the website domain that includes a direct link to the machine-readable file, in a format described by CMS (which CMS will provide in guidance), to establish and maintain automated access. We believe that by making this information more easily accessible to automated searches and data pulls, it will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information and capturing it in a meaningful way across MA plans.

Finally, we welcome comment on this proposal and seek comment on the following:

- Additional populations CMS should consider including in the health equity analysis, including but not limited to: Members of racial and ethnic communities, members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; members of rural communities; and persons otherwise adversely affected by persistent poverty or inequality.
- If there should be further definition for what constitutes "expertise in health equity," and if so, what other qualifications to include in a definition of "expertise in health equity."
- The proposed requirements for publicly posting the results on the plan's website under § 422.137(d)(7) to ensure the data will be easily accessible to both the public and researchers.
- Alternatives to the July 1, 2025, deadline for the initial analysis to be posted to the plan's publicly available website.
- CMS is considering adding an additional requirement that the UM Committee submit to CMS the link to the analysis report. This would allow CMS to post every link in one centralized location. We believe this would increase accessibility and transparency.

In addition, we request comment on any specific items or services, or groups of items or services, subject to prior authorization that CMS should consider also disaggregating in the analysis to consider for future rulemaking. If further disaggregation of a group of items or services is requested, CMS is soliciting comment on what specific items or services would be included within the group. For example, if CMS should consider disaggregating a group

of items or services related to behavioral health treatment in the health equity analysis, what items or services should CMS consider a part of behavioral health treatment.

V. Enrollment and Appeals

A. Revise Initial Coverage Election Period Timeframe To Coordinate With A/B Enrollment (§ 422.62)

Section 4001 of the Balanced Budget Act of 1997 (Pub. L. 105–33) added sections 1851 through 1859 to the Social Security Act (the Act) establishing Part C of the Medicare program known originally as "Medicare+Choice" (M+C) and later as Medicare Advantage (MA). As enacted, section 1851(e) of the Act establishes specific parameters in which elections can be made and/or changed during enrollment and disenrollment periods under the MA program. Specifically, section 1851(e)(1) of the Act requires that the Secretary specify an initial coverage election period (ICEP) during which an individual who first becomes entitled to Part A benefits and enrolled in Part B may elect an MA plan. The statute further stipulates that if an individual elects an MA plan during that period, coverage under the plan will become effective as of the first day on which the individual may receive that coverage. Consistent with this section of the Act, in the Medicare Program; Establishment of the Medicare+Choice Program interim final rule with comment period which appeared in the **Federal Register** on June 26, 1998, (herein referred to as the June 1998 interim final rule), CMS codified this policy at § 422.62(a)(1) (63 FR 35072).

In order for an individual to have coverage under an MA plan, effective as of the first day on which the individual may receive such coverage, the individual must elect an MA plan before he or she is actually entitled to Part A and enrolled in Part B coverage. Therefore, in the June 1998 interim final rule CMS codified the ICEP to begin 3 months prior to the month the individual is first entitled to both Part A and enrolled in Part B and ends the last day of the month preceding the month of entitlement (63 FR 35072).

Section 102 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) revised section 1851(e)(1) of the Act to provide for an ICEP for MA that ends on the later of, the day it would end under pre-MMA rules as described above, or the last day of an individual's Medicare Part B initial enrollment period (IEP). This approach extended an individual's ICEP which

helped to ensure that an individual who uses their IEP to enroll in Medicare Part A and B has the opportunity to elect an MA or MA prescription drug (MA-PD) plan following their first entitlement to Part A and enrollment in Part B. Consistent with the revised provisions of section 1851(e)(1) of the Act, CMS codified this policy at § 422.62(a)(1) in the Medicare Program; Establishment of the Medicare Advantage Program final rule which appeared in the **Federal Register** on January 28, 2005 (70 FR 4717).

As described in § 422.50(a)(1), eligibility for MA or MA-PD enrollment generally requires that an individual first have Medicare Parts A and B and meet all other eligibility requirements to do so. The ICEP is the period during which an individual newly eligible for MA may make an initial enrollment request to enroll in an MA or MA-PD plan. Currently, once an individual first has both Parts A and B, their ICEP begins 3 months immediately before the individual's first entitlement to Medicare Part A and enrollment in Part B and ends on the later of:

- The last day of the month preceding entitlement to Part A and enrollment in Part B, or;
- The last day of the individual's Part B IEP.

Individuals who want to enroll in premium-Part A, Part B, or both, must submit a timely enrollment request during their IEP, the General Enrollment Period (GEP), or an existing special enrollment period (SEP) for which they are eligible. Eligible individuals may choose to enroll in both Part A and B during their first opportunity, that is, during their IEP. These individuals have an ICEP as described in § 422.62(a)(1)(ii), that is, they can choose to enroll in an MA plan (with or without drug coverage) at the time of, or after, they have both Part A and B, up until the last day of their IEP. However, not all individuals enroll in both Part A and B during their IEP. Other individuals, such as those who are working past age 65, may not have both Part A and B for the first time until after their IEP. These individuals may only have Part A and/or B for the first time when they use an SEP or a future GEP to enroll. To note, prior to January 1, 2023, individuals who enrolled in Part A and/or Part B during the GEP had a universal effective date of July 1st. These individuals had an ICEP as described in § 462.22(a)(1)(i), that is, the ICEP started April 1st and ended June 30th. Although these individuals had to decide whether to enroll in an MA or MA-PD plan prior to their July 1st effective date, they did have time to

consider their options, as the GEP is January 1st–March 31st annually, and their enrollment in Part B, (and Part A if applicable), was not effective until July 1st. However, the Consolidated Appropriations Act, 2021, (CAA) (Pub. L. 116–260), revised sections 1838(a)(2)(D)(ii) and 1838(a)(3)(B)(ii) of the Act to provide that for individuals who enroll during the GEP in a month beginning on or after January 1, 2023, their entitlement would begin with the first day of the month following the month in which they enroll. For example, if an individual has Part A, but enrolls in Part B in March, during the GEP, they would first have both Part A and Part B effective April 1st. Although this provides for an earlier Medicare effective date, the individual's ICEP would occur prior to that Medicare effective date, that is, as described in § 422.62(a)(1)(i) above, and they no longer have that additional time to consider their options.

Currently, the individuals described above have an ICEP as described in § 422.62(a)(1)(i) and can only enroll in an MA plan (with or without drug coverage) *prior* to the effective date of their Part A and B coverage. For example, an individual's 65th birthday is April 20, 2022, and they are eligible for Medicare Part A and Part B beginning April 1, 2022. They have premium-free Part A; however, the individual is still working, and has employer health insurance, so they decide not to enroll in Part B during their IEP. The individual retires in April 2023, and enrolls in Part B effective May 1, 2023 (using a Part B SEP). The individual's ICEP would be February 1st through April 30, 2023. These individuals need to decide if they want to receive their Medicare coverage through an MA plan prior to the effective date of their enrollment in both Part A and B. In this example, the individual would have to enroll in an MA plan using the ICEP by April 30, 2023.

Section 422.62(a)(1) was intended to provide beneficiaries who enroll in both Part A and Part B for the first time with the opportunity to elect an MA plan *at the time* that both their Part A and B coverage were effective. However, in practice, individuals described above, who do not enroll in Part B during their IEP, do not have an opportunity to elect to receive their coverage through an MA plan *after* their Part A and B coverage goes into effect. When an individual enrolls in both Part A and B for the first time using an SEP or the GEP, they have to determine, prior to the start of their coverage, if they want to receive their coverage through Original Medicare or

an MA plan prior to the effective date of their Part A and B coverage. If they do not use their ICEP to enroll in an MA plan prior to when their Part A and B coverage becomes effective, they lose the opportunity to enroll in an MA plan to receive their Medicare coverage and will generally have to wait until the next enrollment period that is available to them to choose an MA plan.

To provide more flexibility, we are proposing to revise the end date for the ICEP for those who cannot use their ICEP during their IEP. That is, we are proposing in § 422.62(a)(1)(i) that an individual would have 2 months after the month in which they are first entitled to Part A and enrolled in Part B to use their ICEP. Under proposed § 422.62(a)(1)(i), the individual's ICEP would begin 3 months prior to the month the individual is first entitled to Part A and enrolled in Part B and would end on the last day of the second month after the month in which the individual is first entitled to Part A and enrolled in Part B. Using the example above, we are proposing that the individual's ICEP would be February 1st through June 30, 2023, instead of February 1st to April 30th. As described in § 422.68(a)(1), if an election is made prior to the month of entitlement in both Part A and Part B, the MA election would be effective as of the first date of the month that the individual is entitled to both Part A and Part B.

We believe that extending the timeframe for the ICEP under § 422.62(a)(1)(i) would provide beneficiaries that are new to Medicare additional time to decide if they want to receive their coverage through an MA plan. We believe that extending this timeframe would help those new to Medicare to explore their options and select coverage that best suits their needs and reduce the number of instances where an individual inadvertently missed their ICEP and has to wait until the next open enrollment period to enroll in MA or MA-PD plan. This proposal also supports President Biden's April 5, 2022 *Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage*,¹²⁰ which, among other things, requires agencies to examine policies or practices that make it easier for all consumers to enroll in and retain coverage, understand their coverage options and select appropriate coverage, and also examine policies or practices

¹²⁰ 87 FR 20689 (April 8, 2022); <https://www.whitehouse.gov/briefing-room/presidential-actions/2022/04/05/executive-order-on-continuing-to-strengthen-americans-access-to-affordable-quality-health-coverage/>.

that strengthen benefits and improve access to health care providers.

This proposed change in the ICEP timeframe aligns with the SEP timeframe that we have established in § 422.62(b)(10), for individuals to enroll in an MA or MA–PD plan when their Medicare entitlement determination is made for a retroactive effective date, and the individual has not been provided the opportunity to elect an MA or MA–PD plan during their ICEP. It also aligns with the timeframe we have established in § 422.62(b)(26), effective January 1, 2024, for an individual to enroll in an MA plan when they enroll in Part A and/or Part B using an exceptional condition SEP, as described in §§ 406.27 and 407.23.

This proposal would extend the timeframe of an existing enrollment period and would not result in a new or additional paperwork burden since MA organizations are currently assessing applicants' eligibility for election periods as part of existing enrollment processes. All burden impacts of these provisions have already been accounted for under OMB control number 0938–1378 (CMS–10718). Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Fund.

B. Enhance Enrollees' Right To Appeal an MA Plan's Decision To Terminate Coverage for Non-Hospital Provider Services (§ 422.626)

Medicare Advantage (MA) enrollees have the right to a fast-track appeal by an Independent Review Entity (IRE) when their covered skilled nursing facility (SNF), home health, or comprehensive outpatient rehabilitation facility (CORF) services are being terminated. The regulations for these reviews at the request of an MA enrollee are located at 42 CFR 422.624 and 422.626. Section 422.624 requires these providers of services to deliver a standardized written notice to the enrollee of the MA organization's decision to terminate the provider's services for the enrollee. This notice, called the Notice of Medicare Non-Coverage (NOMNC), must be furnished to the enrollee before services from the providers are terminated. The NOMNC informs enrollees of their right to a fast-track appeal of the termination of these provider services and how to appeal to the IRE. CMS currently contracts with certain Quality Improvement Organizations (QIOs) that have contracts under Title XI, Part B and section 1862(g) of the Act to perform as the IRE for these specific reviews. The NOMNC is subject to the Paperwork Reduction Act (PRA) process and approval by the

Office of Management and Budget (OMB). There is a parallel appeal process in effect for Medicare beneficiaries in Original Medicare (42 CFR 405.1200 and 405.1202).

Presently, if an MA enrollee misses the deadline to appeal as stated on the NOMNC, the appeal is considered untimely, and the enrollee loses their right to a fast-track appeal to the QIO. Enrollees may, instead, request an expedited reconsideration by their MA plan, as described in § 422.584. The QIO is unable to accept untimely requests from MA enrollees but does perform appeals for untimely requests from Medicare beneficiaries in Original Medicare as described at § 405.1202(b)(4).

Further, MA enrollees forfeit their right to appeal to the QIO if they leave a facility or otherwise end services from one of these providers before the termination date listed on the NOMNC, even if their appeal requests to the QIO are timely. (The MA enrollee retains the right to appeal to their MA plan in such cases because the decision to terminate the services is an appealable organization determination per § 422.566(b)(3).) Beneficiaries in Original Medicare retain their right to appeal to the QIO, regardless of whether they end services before the termination date on the NOMNC.

This proposed rule would modify the existing regulations regarding fast-track appeals for enrollees when they untimely request an appeal to the QIO, or still wish to appeal after they end services on or before the planned termination date. The proposed changes would bring the MA program further into alignment with Original Medicare regulations and procedures for the parallel appeals process. Finally, these changes were recommended by interested parties in comments to a previous rulemaking (CMS–4201–P, February 27, 2022).

Specifically, the proposed changes would (1) require the QIO, instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) allow enrollees the right to appeal the decision to terminate services after leaving an SNF or otherwise ending covered care before the planned termination date. The proposed changes are modeled after the parallel process in effect for Original Medicare at 42 CFR 405.1200 through 405.1202.

To implement these changes, we are proposing to revise § 422.626(a)(2) to specify that if an enrollee makes an untimely request for a fast-track appeal, the QIO will accept the request and

perform the appeal. We would also specify that the IRE decision timeframe in § 422.626(d)(5) and the financial liability provision in § 422.626(b) would not apply. The provision for untimely appeal requests by enrollees in proposed § 422.626(a)(2) closely parallel 422 CFR 405.1202(b)(4) which establishes that the QIO will review untimely appeals of terminations of certain provider services from beneficiaries in Original Medicare.

Secondly, we propose removing the provision at § 422.626(a)(3) that prevents enrollees from appealing to the QIO if they end their covered services on or before the date on their termination notice, even in instances of timely requests for fast-track appeals. Removal of this provision preserves the appeal rights of MA enrollees who receive a termination notice, regardless of whether they decide to leave a provider or stop receiving their services.

This proposed expedited coverage appeals process would afford enrollees in MA plans access to similar procedures for fast-track appeals as for beneficiaries in Original Medicare in the parallel process. Untimely enrollee fast-track appeals would be absorbed into the existing process for timely appeals at § 422.626, and thus, would not necessitate additional changes to the existing fast-track process. The burden on MA plans would be minimal and would only require that MA plans provide notices as required at § 422.626(d)(1) for these appeals. Further MA plans would no longer have to perform the untimely appeals as currently required at § 422.626(a)(2). Beneficiary advocacy organizations, in comments to previous rulemakings on this topic, supported changes that would afford enrollees more time to appeal and afford access to IRE appeals even for untimely requests.

The burden of conducting these reviews is currently approved under OMB collection 0938–0953. The proposed changes would require that untimely fast-track appeals would be performed by the QIO, rather than the enrollee's health plan; thus, any burden related to this proposal would result in a shift in fast-track appeals from health plans to QIOs.

C. Amendments to Part C and Part D Reporting Requirements (§§ 422.516 and 423.514)

CMS has authority under sections 1857(e)(1) and 1860D–12(b)(3)(D) of the Act to require MA organizations and Part D plan sponsors to provide CMS “with such information . . . as the Secretary may find necessary and appropriate.” CMS also has authority, in

section 1856(b) of the Act, to establish standards to carry out the MA program.

Likewise, existing CMS regulations cover a broad range of topics and data to be submitted to CMS. Under these authorities, CMS established reporting requirements at §§ 422.516(a) (Validation of Part C reporting requirements) and 423.514(a) (Validation of Part D reporting requirements), respectively. Pursuant to §§ 422.516(a) and 423.514(a), each MA organization and Part D sponsor must have an effective procedure to develop, compile, evaluate, and report information to CMS at the times and in the manner that CMS requires. In addition, §§ 422.504(f)(2) and 423.505(f)(2) require MA organizations and Part D plan sponsors, respectively, to submit to CMS all information that is necessary for CMS “to administer and evaluate” the MA and Part D programs and to facilitate informed enrollment decisions by beneficiaries. Part D sponsors are also required to report all data elements included in all its drug claims by § 422.505(f)(3). Sections 422.504(f)(2), 422.516(a), 423.505(f)(2), and 423.514(a) each list general topics of information and data to be provided to CMS, including benefits, enrollee costs, quality and performance, cost of operations, information demonstrating that the plan is fiscally sound, patterns of utilization, information about beneficiary appeals and grievances, and information regarding actions, reviews, findings, or other similar actions by States, other regulatory bodies, or any other certifying or accrediting organization.

For many years, CMS has used this authority to collect retrospective information from MA organizations and Part D sponsors according to the Parts C and D Reporting Requirements that we issue each year, which can be accessed on CMS’s website.¹²¹ In addition to the data elements, reporting frequency and timelines, and levels of reporting found in the Reporting Requirements information collection documents, CMS also issues Technical Specifications, which supplement the Reporting Requirements and serve to further clarify data elements and outline CMS’s planned data analyses. The reporting timelines and required levels of reporting may vary by reporting section. While many of the current data elements are collected in aggregate at

the contract level, such as grievances, enrollment/disenrollment, rewards and incentives, and payments to providers, the collection of more granular data is also supported by the regulations. CMS has the ability to collect more granular data, per the Part C and D Reporting Requirements as set forth in §§ 422.516(a) and 423.514(a), or to collect more timely data with greater frequency or closer in real-time than we have historically done. We propose revisions to update §§ 422.516(a) and 423.514(a). Section 422.516 currently reads, “Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, statistics and other information.” We propose to strike the term “statistics,” as well as the words “and other,” with the understanding that the broader term “information” which is already at § 422.516(a), includes statistics, Part C data, and information on plan administration. In a conforming proposal to amend § 423.514(a), we propose to strike the term “statistics” and add “information.” CMS does not interpret these regulations to limit data collection to statistical or aggregated data and we are using this rulemaking as an opportunity to ensure that we are clear and consistent with our interpretation of these rules.

Additionally, we propose to amend §§ 422.516(a)(2) and 423.514(a)(2) to make an affirmative change regarding CMS’s collection of information related to what occurs from beginning to end when beneficiaries seek to get coverage from their health and drug plans for specific services. In other words, under the existing requirements CMS has the ability to collect information related to all plan activities regarding adjudicating requests for coverage and plan procedures related to making service utilization decisions, and we aim to make this more transparent through this proposal. This could include, for example, information on pharmacy rejections, initial determinations, decision rationales, and plan level appeals. Both §§ 422.516(a)(2) and 423.514(a)(2) currently require plans to report “The patterns of utilization of services.” We propose to amend both sections to read, “The procedures related to and utilization of its services and items” to be clear that these regulations authorize reporting and data collection about MA and Part D plan procedures related to coverage,

utilization in the aggregate, and beneficiary-level utilization, including the steps beneficiaries may need to take to access covered benefits. Such information will ensure that CMS may better understand under what circumstances plans choose whether to provide or pay for a service or item.

CMS is not proposing to change specific current data collection efforts through this rulemaking. Any future information collection would be addressed through the Office of Management and Budget (OMB) Paperwork Reduction Act (PRA) process, which would provide advance notice to interested parties and provides both a 60- and 30-day public comment period on drafts of the proposed collection.

We do not believe the proposed changes to §§ 422.516(a) and 423.514(a) have either paperwork burden or impact on the Medicare Trust Fund at this time. These proposed changes allow CMS, in the future, to add new burden to plans in collection efforts; however, any such new burden associated with a new data collection would be estimated through the PRA process.

D. Amendments To Establish Consistency in Part C and Part D Timeframes for Filing an Appeal Based on Receipt of the Written Decision (§§ 422.582, 422.584, 422.633, 423.582, 423.584, and 423.600)

Based on general feedback CMS has received from interested parties regarding a variance in the regulatory timeframe for beneficiaries to file an appeal with an MA organization or Part D plan sponsor, we are proposing to amend the Parts C and D regulations at §§ 422.582(b), 422.584(b), 422.633(d)(1), 423.582(b), 423.584(b), and 423.600(a) with respect to how long an enrollee has to file an appeal with a plan or the Part D Independent Review Entity (IRE). These proposed amendments aim to ensure consistency with the regulations at §§ 422.602(b)(2), 423.2002(d), 422.608, and 423.2102(a)(3), applicable to Administrative Law Judge (ALJ) and Medicare Appeals Council (Council) reviews, that either state or cross-reference the Medicare FFS regulations at 42 CFR part 405 that prescribe that the date of receipt of the notice of decision or dismissal is presumed to be 5 calendar days after the date of the notice, unless there is evidence to the contrary. These proposals would also apply to integrated organization determinations and reconsiderations. In addition, because cost plans are required, by §§ 417.600 and 417.840, to comply with the MA appeal regulations,

¹²¹ Part C Reporting Requirements are at <https://www.cms.gov/medicare/health-plans/healthplansgeninfo/reportingrequirements> and Part D Reporting Requirements are at <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/rxcontracting-reportingoversight>.

these proposed changes will also apply to cost plan appeals.

Pursuant to our authority under section 1856(b) and 1860D–12 of the Act to adopt standards to carry out the Part C and Part D programs and in order to implement sections 1852(g)(2) and 1860D–4(g) and (h) of the Act regarding coverage decisions and appeals, CMS established procedures and minimum standards for an enrollee to file an appeal regarding benefits with an MA organization, Part D plan sponsor, and IREs. These requirements are codified in regulation at 42 CFR parts 422 and 423, subpart M. See also section 1876(c)(5) of the Act regarding cost plans' obligations to have appeal processes.

Specifically, section 1852(g)(2)(A) of the Act requires that an MA organization shall provide for reconsideration of a determination upon request by the enrollee involved. The reconsideration shall be made no later than 60 days after the date of the receipt of the request for reconsideration. Section 1860D–4(g)(1) of the Act requires that a Part D plan sponsor shall meet the requirements of paragraph (2)(A) of section 1852(g) with respect to providing for reconsideration of a determination upon request by the enrollee involved.

While section 1852 of the Act does not specify the timeframe in which an enrollee must request an appeal of an unfavorable organization determination, integrated organization determination or coverage determination, the timeframe for filing an appeal in the Part C and Part D programs is established in regulations. Sections 422.582(b), 422.633(d)(1), and 423.582(b) state that an appeal must be filed within 60 calendar days from the date of the notice issued as a result of the organization determination, integrated organization determination, coverage determination, or at-risk determination. Plans are permitted to extend this filing deadline for good cause.

We continue to believe that a 60 calendar day filing timeframe strikes an appropriate balance between due process rights and the goal of administrative finality in the administrative appeals process. However, to establish consistency with the regulations applicable to ALJ and Council reviews with respect to receipt of the notice of decision or dismissal and how that relates to the timeframe for requesting an appeal, we are proposing to account for a presumption that it will generally take 5 calendar days for a notice to be received by an enrollee or other appropriate party. Therefore, we are proposing to revise §§ 422.582(b), 422.633(d)(1)(i),

423.582(b), and 423.600(a) to state that a request for a Part C reconsideration, Part D redetermination, Part D at-risk redeterminations and Part D IRE reconsiderations must be filed within 60 calendar days after receipt of the written determination notice. The proposal also includes adding new §§ 422.582(b)(1), 422.633(d)(1)(i), and 423.582(b)(1), which would provide that the date of receipt of the organization determination, integrated organization determination, coverage determination, or at-risk determination is presumed to be 5 calendar days after the date of the written organization determination, integrated organization determination, coverage determination or at-risk determination, unless there is evidence to the contrary. Based on CMS's experience with audits and other similar review of plan documents, we realize that it is standard practice that the date of the written decision notice is the date the plan sends the notice. The presumption that the notice is received 5 calendar days after the date of the decision is a long-standing policy with respect to IRE appeals and has been codified in regulation at §§ 422.602(b)(2), 423.2002(d), and 423.2102(a)(3) regarding hearings before an ALJ and Council; further, § 422.608 regarding MA appeals to the Medicare Appeals Council provides that the regulations under part 405 regarding Council review apply to such MA appeals, which would include the provision at § 405.1102(a)(2) that applies the same 5 day rule. To ensure consistency throughout the administrative appeals process, we believe it is appropriate and practical to adopt this approach for plan and Part D IRE appeals in §§ 422.582(b), 422.633(d)(1), 423.582(b), 423.584, and 423.600(a).

In addition to the aforementioned proposals related to when an organization determination, integrated organization determination, coverage determination, or at-risk determination is presumed to be received by an enrollee or other appropriate party, we are also proposing to add language to §§ 422.582, 422.633, 423.582, and 423.600(a) that specifies when an appeal is considered filed with a plan and the Part D IRE. Specifically, we are proposing to add new §§ 422.582(b)(2), 422.633(d)(1)(ii), 423.582(b)(2), and 423.600(a) to provide that for purposes of meeting the 60 calendar day filing deadline, the appeal request is considered filed on the date it is received by the plan, plan-delegated entity or Part D IRE specified in the written organization determination,

integrated organization determination, coverage determination, at-risk determination, or redetermination. The inclusion of when a request is considered filed would codify what currently exists in CMS's sub-regulatory guidance and the Part D IRE procedures manual. CMS's sub-regulatory guidance indicates that a standard request is considered filed when any unit in the plan or delegated entity receives the request. An expedited request is considered filed when it is received by the department responsible for processing it. Pursuant to existing manual guidance, plan material should clearly state where requests should be sent, and plan policy and procedures should clearly indicate how to route requests that are received in an incorrect location to the correct location as expeditiously as possible.

These proposed revisions related to when a notice is presumed to have been received would ensure that the time to request an appeal is not truncated by the time it takes for a coverage decision notice to reach an enrollee by mail or other delivery method. If these proposals are finalized, corresponding changes would be made to the Part C and Part D standardized denial notices so that enrollees are accurately informed of the timeframe for requesting an appeal.

We are also proposing clarifications to §§ 422.584(b) and 423.584(b) to explicitly state the timeframe in which an enrollee must file an expedited plan appeal for it to be timely. The current text of §§ 422.584 and 423.584 does not include the 60-calendar day timeframe for filing an expedited appeal request, but CMS manual guidance for Part C and Part D appeals has long reflected this 60-calendar day timeframe. We also note that this timeframe for filing an appeal is consistent with the current regulations at §§ 422.582(b) and 423.582(b) for filing a request for a standard appeal. Neither sections 1852 and 1860D–4 of the Act, nor §§ 422.584 and 423.584 specify the timeframe in which an enrollee must request an expedited appeal of an unfavorable organization determination, coverage determination or at-risk determination in the Part C and Part D programs. This provision would codify existing guidance. We are certain that plans already comply as this long-standing policy is reflected in CMS's sub-regulatory guidance¹²² and

¹²² <https://www.cms.gov/medicare/appeals-and-grievances/mmcaag/downloads/parts-c-and-d-enrollee-grievances-organization-coverage-determinations-and-appeals-guidance.pdf>.

standardized denial notices¹²³ that explain an enrollee's right to appeal. Additionally, we have not received any complaints on this matter. In proposing new §§ 422.584(b)(3) and (4) and 423.584(b)(3) and (4), we also propose to add the procedure and timeframe for filing expedited organization determinations and coverage determinations consistent with proposed requirements at §§ 422.582(b)(1) and (2) and 423.582(b)(1) and (2).

If finalized, we believe these proposals would enhance consistency in the administrative appeals process and provide greater clarity on the timeframe for requesting an appeal and when an appeal request is considered received by the plan. Theoretically, the proposed amendments may result in a small increase in the number of appeals from allowing 65 versus 60 days to appeal an organization determination, integrated organization determination, coverage determination or at-risk determination. However, we believe, based on the low level of dismissals at the plan level due to untimely filing, that most enrollees who wish to appeal a denial do so immediately, thereby mitigating the impact of 5 additional days for a plan to accept an appeal request if this proposal is finalized. Consequently, we are not associating impact to the Medicare Trust Fund. We solicit interested party input on the accuracy of this assumption.

E. Authorized Representatives for Parts C/D Elections (§§ 422.60 and 423.32)

Section 1851(c)(1) of the Act gives the Secretary the authority to establish a process through which MA elections, that is, enrollments and disenrollments, are made and changed. This authority includes establishing the form and manner in which elections are made. Section 1860D–1(b)(1)(A) of the Act gives the Secretary the authority to establish a process for enrollment, disenrollment, termination, and change of enrollments in Part D prescription drug plans. Likewise, section 1860D–1(b)(1)(B)(ii) of the Act directs CMS to use rules similar to those established in the MA context pursuant to 1851(c) for purposes of establishing rules for enrollment, disenrollment, termination, and change of enrollment with an MA–PD plan.

Consistent with these sections of the Act, Parts C and D regulations set forth our election processes under §§ 422.60 and 423.32. These enrollment processes require that Part C/D eligible

individuals wishing to make an election must file an appropriate enrollment form, or other approved mechanism, with the plan. The regulations also provide information for plans on the process for accepting election requests, notice that must be provided, and other ways in which the plan may receive an election on behalf of the beneficiary.

Though the term “authorized representative” is not used in the context of the statutory provisions within the Act governing MA and Part D enrollment and eligibility (for example, sections 1851 and 1860D–1), “authorized representative”—and other similar terms—are used in other contexts throughout the Act. Section 1866(f)(3) of the Act defines the term “advance directive,” deferring to applicable State law to recognize written instructions such as a living will or durable power of attorney for health care. Section 1862(b)(2)(B)(vii)(IV) of the Act recognizes that an individual may be represented by an “authorized representative” in secondary payer disputes. Section 1864(a) of the Act allows a patient’s “legal representative” to stand in the place of the patient and give consent regarding use of the patient’s medical records.

In the June 1998 interim final rule that first established the M+C program, now the MA program (63 FR 34985), we acknowledged in Part C enrollment regulations at § 422.60(c) that there are situations where an individual may assist a beneficiary in completing an enrollment request and required the individual to indicate their relationship to the beneficiary. In the “Medicare Program; Medicare Prescription Drug Benefit” final rule which appeared in the **Federal Register** on January 28, 2005 (70 FR 4194), we first recognized in § 423.32(b) that an authorized representative may assist a beneficiary in completing an enrollment request, and required authorized representatives to indicate that they provided assistance. In response to public comments about the term “authorized representative” in that rule, we indicated that CMS would recognize and rely on State laws that authorize a person to effect an enrollment on behalf of a Medicare beneficiary for purposes of this provision. We also stated that the authorized representative would constitute the “individual” for purposes of making the enrollment or disenrollment request.

Historically, we have provided the definition and policies related to authorized representatives in our sub-

regulatory manuals.¹²⁴ We are now proposing to add new paragraphs §§ 422.60(h) and 423.32(h) to codify our longstanding guidance on authorized representatives making Parts C and D elections on behalf of beneficiaries.

Current regulation in § 423.32(b)(i) acknowledges that an “authorized representative” may assist a beneficiary in completing an enrollment form, but it does not define who an “authorized representative” is. A similar term, “representative,” is currently defined under §§ 422.561 and 423.560; however, that definition is used only in the appeals context and applies only to subpart M of the MA and Part D regulations. Therefore, we are defining the term “authorized representative” for subpart B (eligibility, election, and enrollment).

Our proposal defers to the law of the State in which the beneficiary resides to determine who is a legal representative. Deference to State law on these matters is consistent with other similar practices within CMS, including in the MA appeals definition of “representative” (§ 422.561) and Medicaid’s definition of “authorized representative” (§§ 435.923; 438.402), as well as in the HIPAA privacy regulations’ description of “personal representative” (45 CFR 164.502(g)).

For those with State legal authority to act and make health care decisions on behalf of a beneficiary, our proposal would codify at paragraph (h)(1) of §§ 422.60 and 423.32 that authorized representatives will constitute the “beneficiary” or the “enrollee” for the purposes of making an election, meaning that CMS, MA organizations, and Part D sponsors will consider the authorized representative to be the beneficiary/enrollee during the election process. Any mention of beneficiary/enrollee in our enrollment and eligibility regulations would be considered to also include “authorized representative,” where applicable. Our proposal at paragraph (h)(2) of §§ 422.60 and 423.32 would clarify that authorized representatives under State law may include court-appointed legal guardians, durable powers of attorney for health care decisions and State surrogate consent laws as examples of those State law concepts that allow the authorized representative to make health care decisions on behalf of the individual. This is not a complete list; we would defer to applicable State law granting authority to act and make

¹²³ <https://www.cms.gov/medicare/medicare-general-information/bni/madenialnotices>.

¹²⁴ This guidance can be found in chapter 2, sections 10 and 40.2.1 of the Medicare Managed Care Manual and chapter 3, sections 10 and 40.2.1 of the Prescription Drug Benefit Manual.

health care decisions on behalf of the beneficiary.

Codifying this longstanding guidance provides plans, beneficiaries and their caregivers, and other interested parties clarity and transparency on the requirements when those purporting to be the representatives of the beneficiary attempt to make election decisions on their behalf. We have not received negative public feedback on this longstanding policy. However, we have recently answered questions on plan procedures when dealing with authorized representatives. We are proposing to codify this longstanding guidance in order to clarify our policy regarding the role of authorized representatives in the MA and Part D enrollment process, including the applicability of State law in this context.

This proposal represents the codification of longstanding MA and Part D sub-regulatory guidance. Based on questions from plans and beneficiaries related to current guidance, we conclude that the guidance has been previously implemented and is currently being followed by plans. Therefore, there is no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there is also no impact to the Medicare Trust Fund. All information impacts related to the current process for determining a beneficiary's eligibility for an election period and processing election requests have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267), 0938–1378 (CMS–10718), and 0938–0964 (CMS–10141).

F. Open Enrollment Period for Institutionalized Individuals (OEPI) End Date (§ 422.62(a)(4))

Section 1851(e) of the Act establishes the coverage election periods for making or changing elections in the Medicare+Choice (M+C), later known as Medicare Advantage (MA), program. Section 501(b) of the Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) amended section 1851(e)(2) of the Act by adding a new subparagraph (D), which provides for continuous open enrollment for institutionalized individuals after 2001. CMS published a final rule with comment period (65 FR 40317) in June 2000 implementing section 1851(e)(2)(D) by establishing a new continuous open enrollment period for institutionalized individuals (OEPI) at then § 422.62(a)(6). In subsequent rulemaking (83 FR 16722), the OEPI regulations were further updated to reflect conforming changes related to implementation of Title II of The Medicare Prescription Drug,

Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173) (70 FR 4717) and to redesignate this provision from § 422.62(a)(6) through (4).

As noted above, the OEPI is continuous. Individuals may use the OEPI to enroll in, change, or disenroll from a plan. Individuals are eligible for the OEPI if they move into, reside in, or move out of an institution. Longstanding sub-regulatory guidance has stated that the OEPI ends 2 months after an individual moves out of an institution, but this has not been articulated in regulations.¹²⁵

To provide transparency and stability for plans, beneficiaries and their caregivers, and other interested parties about this aspect of MA enrollment, we propose to codify current sub-regulatory guidance that defines when the OEPI ends. Specifically, we propose to codify at new § 422.62(a)(4)(ii) that the OEPI ends on the last day of the second month after the month the individual ceases to reside in one of the long-term care facility settings described in the definition of “institutionalized” at § 422.2.

This proposal would define when the OEPI ends and would not result in a new or additional paperwork burden since MA organizations are currently implementing the policy related to the OEPI end date as part of existing enrollment processes. All burden impacts related to an applicant's eligibility for an election period have already been accounted for under OMB control number 0938–0753 (CMS–R–267). Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Fund.

G. Beneficiary Choice of C/D Effective Date if Eligible for More Than One Election Period (§§ 422.68 and 423.40)

Section 1851(f) of the Act establishes the effective dates of elections and changes of elections for MA plans. In the June 1998 interim final rule, we specified the effective dates for elections and changes of elections of M+C (now MA) plan coverage made during various specified enrollment periods (63 FR 34968). The effective date requirements for the initial coverage election period (ICEP), annual election period (AEP), MA open enrollment period (MA–OEP), open enrollment period for institutionalized individuals (OEPI), and special election periods (SEP) are codified in regulation at § 422.68. For Part D plans, section 1860D–1(b)(1)(B)(iv) of the Act directs us to establish similar rules for effective dates

of elections and changes of elections to those provided under the MA program statute at section 1851(f). In the January 2005 Part D final rule, we specified the effective dates for elections and changes of elections of Part D coverage made during various specified enrollment periods (70 FR 4193). The effective date requirements for the initial enrollment period (IEP) for Part D, AEP, and SEPs are codified in regulation at § 423.40.

Existing regulations at §§ 422.68 and 423.40 do not address what the MA organization or Part D plan sponsor should do when a beneficiary is eligible for more than one election period, thus resulting in more than one possible effective date for their election choice. For example, the beneficiary is eligible to make a change in their election choice during the MA–OEP, but they are also eligible for an SEP due to changes in the individual's circumstances. Current sub-regulatory guidance provides that the MA organization or Part D plan sponsor determine the proper effective date based on the election period for which the beneficiary is eligible before the enrollment or disenrollment may be transmitted to CMS.¹²⁶ Because the election period determines the effective date of the election in most instances, with the exception of some SEPs or when election periods overlap, beneficiaries may not request their election effective date. The MA organization or Part D plan sponsor determines the effective date once the election period is identified. If a beneficiary is eligible for more than one election period, which results in more than one possible effective date, CMS's sub-regulatory guidance¹²⁷ directs the MA organization or Part D plan sponsor to allow the beneficiary to choose the election period that results in the desired effective date. To determine the beneficiary's choice of election period, MA organizations and Part D plan sponsors are instructed to attempt to contact the beneficiary, and to document their attempt(s). However, sub-regulatory guidance¹²⁸ states that this does not apply to beneficiary requests for enrollment into an employer or union group health plan (EGHP) using the group enrollment

¹²⁶ This guidance can be found in chapter 2, section 30.6 and 30.7 of the Medicare Managed Care Manual and chapter 3, section 30.4 and 30.5 of the Prescription Drug Benefit Manual.

¹²⁷ This guidance can be found in chapter 2, section 30.6 of the Medicare Managed Care Manual and chapter 3, section 30.4 of the Prescription Drug Benefit Manual.

¹²⁸ This guidance can be found in chapter 2, section 30.6 of the Medicare Managed Care Manual and chapter 3, section 30.4 of the Prescription Drug Benefit Manual.

¹²⁵ This guidance can be found in chapter 2, section 30.3 of the Medicare Managed Care Manual.

mechanism. Beneficiaries who make an election via the employer or union election process will be assigned an effective date according to the SEP EGHP, unless the beneficiary requests a different effective date that is allowed by one of the other election periods for which they are eligible.

Because a beneficiary must be entitled to Medicare Part A and enrolled in Medicare Part B in order to be eligible to receive coverage under a MA or MA-PD plan, CMS's sub-regulatory guidance¹²⁹ explains that if one of the election periods for which the beneficiary is eligible is the ICEP, the beneficiary may not choose an effective date any earlier than the month of entitlement to Part A and enrollment in Part B. Likewise, because a beneficiary must be entitled to Part A or enrolled in Part B in order to be eligible for coverage under a Part D plan, sub-regulatory guidance explains that if one of the election periods for which the beneficiary is eligible is the Part D IEP, the beneficiary may not choose an effective date any earlier than the month of entitlement to Part A and/or enrollment in Part B.¹³⁰

Furthermore, sub-regulatory guidance¹³¹ provides that if a beneficiary is eligible for more than one election period and does not choose which election period to use, and the MA organization or Part D plan sponsor is unable to contact the beneficiary, the MA organization or Part D plan sponsor assigns an election period for the beneficiary using the following ranking of election periods (1 = Highest, 5 = Lowest): (1) ICEP/Part D IEP, (2) MA-OEP, (3) SEP, (4) AEP, and (5) OEPI. The election period with the highest rank generally determines the effective date of enrollment. In addition, if an MA organization or Part D sponsor receives a disenrollment request when more than one election period applies, the plan is instructed to allow the beneficiary to choose which election period to use. If the beneficiary does not make a choice, then the plan is directed to assign the election period that results in the earliest disenrollment.

To provide transparency and stability about the MA and Part D program for plans, beneficiaries, and other interested parties, we are proposing at new

§§ 422.68(g) and 423.40(f) that if the MA organization or Part D plan sponsor receives an enrollment or disenrollment request, determines the beneficiary is eligible for more than one election period and the election periods allow for more than one effective date, the MA organization or Part D plan sponsor must allow the beneficiary to choose the election period that results in the desired effective date. We also propose at §§ 422.68(g)(1) and 423.40(f)(1) that the MA organization or Part D plan sponsor must attempt to contact the beneficiary, and must document its attempt(s), to determine the beneficiary's choice. The plan may contact the beneficiary by phone, in writing, or any other communication mechanism. Plans would annotate the outcome of the contact(s) and retain the record as part of the individual's enrollment or disenrollment request. In addition, we propose at §§ 422.68(g)(2) and 423.40(f)(2) to require that the MA organization or Part D plan sponsor must use the proposed ranking of election periods to assign an election period if the beneficiary does not make a choice. With the exception of the SEP EGHP noted earlier, if a beneficiary is simultaneously eligible for more than one SEP and they do not make a choice, and the MA organization or PDP sponsor is unable to obtain the beneficiary's desired enrollment effective date, the MA organization or PDP sponsor should assign the SEP that results in an effective date of the first of the month after the enrollment request is received by the plan. Finally, we propose at §§ 422.68(g)(3) and 423.40(f)(3) to require that if the MA organization or Part D plan sponsor is unable to obtain the beneficiary's desired disenrollment effective date, they must assign an election period that results in the earliest disenrollment.

This proposal represents the codification of longstanding MA and Part D sub-regulatory guidance. Based on infrequent complaints and questions from plans and beneficiaries related to current guidance, we conclude that the guidance has been previously implemented and is currently being followed by plans. There is no additional paperwork burden associated with codifying this longstanding sub-regulatory policy, and there is also no impact to the Medicare Trust Fund. All information impacts related to the current process for determining a beneficiary's eligibility for an election period and processing election requests have already been accounted for under OMB control number 0938–0753 (CMS–

R–267) for Part C and 0938–0964 (CMS–10141) for Part D.

VI. Medicare Advantage/Part C and Part D Prescription Drug Plan Marketing and Communications

A. Marketing and Communications Requirements for Special Supplemental Benefits for the Chronically Ill (SSBCI) (§ 422.2267)

Section 1851(h) and (j) of the Act provide a structural framework for how MA organizations may market to beneficiaries and direct CMS to set standards related to the review of marketing materials and establish limitations on marketing activities, as part of the standards for carrying out the MA program under section 1856(b) of the Act. In the Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (hereinafter referred to as the January 2021 final rule), CMS used this statutory authority to codify guidance from the Medicare Communications & Marketing Guidelines (MCMG) into subpart V of part 422. Several commenters in that prior rulemaking urged CMS to add specific provisions in the marketing and communications regulations regarding how MA organizations may market SSBCI described in § 422.102(f). In response, CMS established a new requirement for a disclaimer to be used when SSBCI are mentioned. The SSBCI disclaimer was originally codified at § 422.2267(e)(32), and it currently appears at paragraph (e)(34). Currently, that regulation requires MA organizations to: (i) convey that the benefits mentioned are a part of special supplemental benefits, (ii) convey that not all members will qualify for these benefits; and (iii) include the model content in the material copy which mentions SSBCI benefits. Section 422.2267(e)(34) does not explicitly state that it applies to both marketing and communications materials, but our sub-regulatory guidance is clear that it applies whenever SSBCI are mentioned; the disclaimer is required regardless of whether the material that mentions the benefits is a marketing or communications material. The purpose of the SSBCI disclaimer is to ensure that beneficiaries are aware that SSBCI are not available to all plan enrollees and that the eligibility for these benefits is limited by section 1852(a)(3)(D) of the Act and § 422.102(f). Ensuring a clear statement of these limitations in a

¹²⁹ This guidance on effective dates of elections is currently outlined in section 30.6 of chapter 2 of the Medicare Managed Care Manual.

¹³⁰ This guidance on effective dates of elections is currently outlined in section 30.4 of chapter 3 of the Medicare Prescription Drug Benefit Manual.

¹³¹ This guidance can be found in sections 30.6 and 30.7 of chapter 2 of the Medicare Managed Care Manual and sections 30.4 and 30.5 of chapter 3 of the Medicare Prescription Drug Benefit Manual.

disclaimer guards against beneficiary confusion or misunderstanding of the scope of SSBCI, and thus lessens the chance that a beneficiary will enroll in a certain plan believing they can access that plan's SSBCI for which they may not ultimately be eligible.

Per the January 2021 final rule, MA organizations were required to comply with the new SSBCI disclaimer requirement beginning January 1, 2022. Since MA organizations have had over a year to implement their use of the SSBCI disclaimer, we are taking an opportunity to reevaluate the requirement at § 422.2267(e)(34), considering our observation of its actual implementation.

MA organizations market SSBCI by advertising various benefits, including coverage of groceries, pest control, prepared meals, household items, gasoline, utility bills, auto repair, pet supplies or grooming, and more. Although some of these benefits may be available under a given plan, the enrollee must meet the criteria established to receive a particular SSBCI. In many instances, MA organizations have been found to use marketing to potentially misrepresent the benefit offered, oftentimes not presenting a clear picture of the benefit and limits on eligibility. In a May 2022 letter sent to Congress, the National Association of Insurance Commissioners (NAIC) detailed its findings from surveys with State departments of insurance, showing "an increase in complaints from seniors about confusing, misleading and potentially deceptive advertising and marketing of these plans."¹³² Additionally, as discussed in prior rulemaking, CMS has seen an increase in complaints related to marketing, with more than twice as many complaints related to marketing in 2021 compared to 2020.¹³³ As evidenced by complaints CMS has received, some of the current marketing of SSBCI has the potential to give beneficiaries the wrong impression by leading them to believe they can automatically receive all SSBCI available by enrolling in the plan.

CMS has seen multiple examples of such misleading SSBCI advertisements among MA organizations. We have seen

ads (for example, online, billboards, television) in which the MA organization presents an extensive list of benefits that are available, with this list being displayed prominently in large font and the SSBCI disclaimer appearing in very small font at the end of the ad. Often the disclaimer is brief, merely stating that the enrollee must have one of the identified chronic conditions in order to receive the benefit and that eligibility will be determined after enrollment, with no other information provided. A beneficiary reading such an ad could easily miss the small-size disclaimer at the end because their attention is immediately drawn to the long, attractive list of appealing benefits prominently displayed in large, bold font. This type of SSBCI marketing is potentially misleading because, at face value, it might appear to a beneficiary that if they enroll in the advertised plan, they can receive all the highlighted benefits, without any question as to the beneficiary's eligibility, what an eligibility determination entails, or when eligibility is assessed.

Based on our findings, we propose to expand the current required SSBCI disclaimer to include more specific requirements, with the intention of increasing transparency for beneficiaries and decreasing misleading advertising by MA organizations. Our proposed expansion of the SSBCI disclaimer would clarify what must occur for an enrollee to be eligible for the SSBCI. That is, per § 422.102(f), the enrollee must first have the required chronic condition(s), then they must meet the definition of a "chronically ill enrollee" at § 422.102(f)(1)(i)(A), and finally the MA organization must determine that the enrollee is eligible to receive a particular SSBCI under the plan's coverage criteria. An MA organization designs and limits its SSBCI to target specific chronic conditions. An enrollee might meet the definition of "chronically ill enrollee" but nonetheless be ineligible for the MA organization's advertised SSBCI because they do not have the specific chronic condition(s) required for the particular SSBCI being advertised. Taking these important SSBCI eligibility requirements into account, our proposal amends the required SSBCI disclaimer content to clearly communicate the eligibility parameters to beneficiaries without misleading them. Specifically, at § 422.2267(e)(34), we are proposing three key changes to the regulation and two clarifications.

First, we are proposing to redesignate current paragraph (e)(34)(ii) as paragraph (e)(34)(iii) and add a new

paragraph (e)(34)(ii), in which we propose to require MA organizations offering SSBCI to list, in their SSBCI disclaimer, the chronic condition or conditions the enrollee must have to be eligible for the SSBCI offered by the MA organization. Per § 422.102(f)(1)(i)(A), a "chronically ill enrollee" must have one or more comorbid and medically complex chronic conditions to be eligible for SSBCI. (See section IV.B. of this proposed rule for a more detailed discussion of the definition of "chronically ill enrollee" and eligibility for SSBCI as part of our proposal to strengthen the requirements for how determinations are made that a particular item or service may be offered as SSBCI and eligibility determinations for SSBCI.) We are proposing that if the number of condition(s) is five or fewer, then the SSBCI disclaimer must list all condition(s), and if the number of conditions is more than five, then the SSBCI disclaimer must list the top five conditions, as determined by the MA organization. For this top five list, we are proposing it is the MA organization's discretion as to which five conditions to include. In making this determination, an MA organization might consider factors such as which conditions are more common or less obscure among the enrollee population the MA organization intends to serve. We believe that five is a reasonable number of conditions for the MA organization to list, so that a beneficiary may have an idea of the types of conditions that may be considered for eligibility for the SSBCI, without listing so many conditions that a beneficiary ignores the information.

Second, we propose to revise newly redesignated paragraph (e)(34)(iii). Section 422.2267(e)(34)(ii) currently requires that MA organizations that offer SSBCI convey that not all members will qualify. We are proposing to expand this provision to require that the MA organization must convey in its SSBCI disclaimer that even if the enrollee has a listed chronic condition, the enrollee may not receive the benefit because coverage of the item or service depends on the enrollee being a "chronically ill enrollee" as defined in § 422.102(f)(1)(i)(A) and on the MA organization's coverage criteria for a specific SSBCI item or service required by § 422.102(f)(4). Section 1852(a)(3)(D) of the Act and § 422.102(f) provide that SSBCI are a permissible category of MA supplemental benefits only for a "chronically ill enrollee," as that term is specifically defined, and the item or service must have a reasonable expectation of improving or maintaining

¹³² <https://content.naic.org/sites/default/files/State%20MA%20Marketing%20Authority%20Senate%20Letter%20.pdf>.

¹³³ See Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency final rule (87 FR 27704, May 9, 2022).

the health or overall function of the chronically ill enrollee. In other words, just because an enrollee has one of the conditions listed in the SSBCI disclaimer, it does not automatically mean that they are eligible to receive the relevant SSBCI, as other criteria will also need to be met. In addition, a particular item or service must meet the requirements in § 422.102(f)(1)(ii) to be offered as an SSBCI. Likewise, if the requirements we are proposing to add to § 422.102(f) for the item or service to be covered as an SSBCI are finalized, an MA organization would also need to meet those requirements to offer SSBCI (see section IV.B. of this proposed rule). Determinations on whether an MA organization may offer coverage of a particular item or service as an SSBCI will generally be made before an MA organization begins marketing or communicating the benefits, therefore, we are not including those requirements from the proposal in section IV.B. of this proposed rule in the proposed expansion of the SSBCI disclaimer. Our proposed newly redesignated § 422.2267(e)(34)(iii) refers to the eligibility requirements and MA organization responsibilities in § 422.102(f) because we expect the MA organization to use this information in developing their SSBCI disclaimer to clearly convey that not all enrollees with the required condition(s) will be eligible to receive the SSBCI. Per § 422.102(f) currently and with the revisions proposed in section IV.B. of this proposed rule, MA organizations offering SSBCI must have written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI.

The SSBCI disclaimer is model content, so each MA organization may tailor their disclaimer's language to convey that, in addition to having an eligible chronic condition, the enrollee must also meet other eligibility requirements (that is, the definition of a "chronically ill enrollee" and the coverage criteria of the MA organization for a specific SSBCI item or service) in order to receive the SSBCI. MA organizations would not need to specifically detail the additional eligibility requirements (such as the coverage criteria) in the disclaimer, but rather convey that coverage is dependent on additional factors, not only on the fact that the enrollee has an eligible chronic condition. For example, an MA organization might use the following language in its SSBCI disclaimer: "Eligibility for this benefit cannot be guaranteed based solely on your condition. All applicable eligibility

requirements must be met before the benefit is provided. For details, please contact us." We are providing this language as an example, as the SSBCI disclaimer is model content. Therefore, in developing their SSBCI disclaimer, MA organizations may deviate from the model so long as they accurately convey the required information and follow CMS's specified order of content, if specified (§ 422.2267(c)). Currently, § 422.2267(e)(34) does not specify the order of content for the SSBCI disclaimer, and we are not proposing to add such a requirement; however, MA organizations must accurately convey the required information listed in the proposed regulatory text at § 422.2267(e)(34)(i) through (iii) in their SSBCI disclaimer. In addition, the disclaimer as drafted by the MA organization must be clear, accurate, and comply with all applicable rules on marketing, communications, and the standards for required materials and content at § 422.2267(a).

Third, at new proposed paragraph (e)(34)(iv), we are proposing specific formatting requirements for MA organizations' SSBCI disclaimers in ads, related to font and reading pace. These proposed formatting requirements would apply to SSBCI disclaimers in any type of ad, whether marketing or communications. For print ads, we reiterate our existing requirement under paragraph (a)(1) that MA organizations must display the disclaimer in 12-point font, Times New Roman or equivalent. For television, online, social media, radio, or other-voice-based ads, we propose that MA organizations must either: (1) read the disclaimer at the same pace as the organization does for the phone number or other contact information mentioned in the ad, or (2) display the disclaimer in the same font size as the phone number or other contact information mentioned in the ad. For outdoor advertising (ODA)—which is defined in § 422.2260 and includes billboards—we propose that MA organizations must display the disclaimer in the same font size as the phone number or other contact information appearing on the billboard or other ODA. The specific font and reading pace requirements for the SSBCI disclaimer in ads would appear at new proposed paragraphs (e)(34)(iv)(A) and (B).

Finally, in revisiting the requirement at § 422.2267(e)(34), we believe additional clarification of current requirements is appropriate. In the introductory language at paragraph (e)(34), we propose a minor addition to clarify that the SSBCI disclaimer must be used by MA organizations who offer

CMS-approved SSBCI (as specified in § 422.102(f)). Also, current paragraph (e)(34)(iii) (requiring the MA organization to include the SSBCI disclaimer in the material copy which mentions SSBCI benefits) would be revised and moved to new proposed paragraph (e)(34)(v). In this newly redesignated paragraph (e)(34)(v), we propose to clarify that MA organizations must include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI. We also propose a slight adjustment in this paragraph to delete the redundant word "benefits" after "SSBCI."

In summary, this proposal would expand upon the current SSBCI disclaimer requirements at § 422.2267(e)(34) in several important ways. Requiring a more robust disclaimer with specific conditions listed would provide beneficiaries with more information to determine whether a particular plan with SSBCI is appropriate for their needs. We believe the revised disclaimer would diminish the ambiguity of when SSBCI are covered, thus reducing the potential for misleading information or misleading advertising. Our goal is to ensure that beneficiaries enrolling in MA choose a plan that best meets their health care needs. Transparency and precision in marketing and communications to current and potential enrollees is of utmost importance in this proposal.

We are not scoring this provision in the COI section since we believe all burden impacts of this provision have already been accounted for under OMB control number 0938–1051 (CMS–10260). In addition, this provision is not expected to have any economic impact on the Medicare Trust Fund. We welcome comment on our proposed amendments to § 422.2267(e)(34), and we thank commenters in advance for their feedback.

B. Agent Broker Compensation

Pursuant to section 1851(j)(2)(D) of the Act, the Secretary has a statutory obligation to establish guidelines to ensure that the use of agent and broker compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage (MA) plan that is intended to best meet beneficiaries' health care needs. In September 2008, CMS published the "Medicare Program; Revisions to the Medicare Advantage and Prescription Drug Benefit Programs" interim final rule (73 FR 54226, 54237), our first regulation to establish requirements for agent and broker compensation, which included certain limitations on agent and broker compensation and other

safeguards. In that rulemaking, we noted that these reforms addressed concerns that the previously permitted compensation structure resulted in financial incentives for agents to only market and enroll beneficiaries in some plan products and not others due to larger commissions. These incentives potentially resulted in beneficiaries being directed towards plans that were not best suited to their needs.

In that interim final rule, we noted that depending on the circumstances, agent and broker relationships can be problematic under the Federal anti-kickback statute if they involve, by way of example only, compensation in excess of fair market value, compensation structures tied to the health status of the beneficiary (for example, cherry-picking), or compensation that varies based on the attainment of certain enrollment targets. These and other fraud and abuse risks exist among the current agent and broker relationships. We note that the HHS Office of the Inspector General (OIG) advisory opinion process is available to parties seeking OIG's opinion as to the legality of a particular arrangement. Information about this process remains available on the OIG's website at <http://oig.hhs.gov/compliance/advisory-opinions/process/>.

In subsequent years, agents and brokers have become an integral part of the industry, helping millions of Medicare beneficiaries to learn about and enroll in Medicare, MA plans, and PDPs by providing expert guidance on plan options in their local area, while assisting with everything from comparing costs and coverage to applying for financial assistance. CMS has also adopted updates to the agent and broker compensation requirements. It has become apparent that shifts in the MA industry and resulting changes in contract terms offered to agents and brokers for enrollment-related services and expenses, warrant further action to ensure CMS is complying with its statutory requirement to ensure compensation paid to agents and brokers incentivizes them to enroll individuals in the MA plan that is intended to best meet their health care needs.

CMS has observed that the MA marketplace, nationwide, has become increasingly consolidated among a few large national parent organizations, which presumably have greater capital to expend on sales, marketing, and other incentives and bonus payments to agents and brokers than smaller market MA plans. This provides a greater opportunity for these larger organizations, either directly or through

third parties, to use financial incentives outside and potentially in violation of the compensation cap set by CMS to encourage agents and brokers to enroll individuals in their plan over a competitor's plans. For example, CMS has seen web-based advertisements for agents and brokers to work with or sell particular plans where the agents and brokers are offered bonuses and perks (such as golf parties, trips, and extra cash) in exchange for enrollments. These payments, while being presented to the agents and brokers as innocuous bonuses or incentives, are implemented in such a way that allows the plan sponsor, in most cases, to credibly account for these anti-competitive payments as "administrative" rather than "compensation," and these payments are therefore not limited by the regulatory limits on compensation.

CMS has also received complaints from a host of different organizations, including State partners, beneficiary advocacy organizations, and MA plans. A common thread to the complaints is that agents and brokers are being paid, typically through various purported administrative and other add-on payments, amounts that cumulatively exceed the maximum compensation allowed under the current regulations. Moreover, CMS has observed that such payments have created an environment, not dissimilar to what prompted CMS to engage in the original agent and broker compensation requirements in 2008, where the amounts being paid for activities that do not fall under the umbrella of "compensation," are rapidly increasing. The result is that agents and brokers are presented with a new suite of questionable financial incentives that are likely to influence which MA plan an agent encourages a beneficiary to select during enrollment.

We believe these financial incentives are contributing to behaviors that are driving an increase in MA marketing complaints received by CMS in recent years. As was discussed in our most recent Medicare Program Contract Year 2023 Rule, based on the most recent data available at that time, in 2021, CMS received more than twice the number of beneficiary complaints related to marketing of MA plans compared to 2020, and for some states those numbers were much higher (87 FR 27704, 27704–27902). These complaints are typically filed by enrollees or their caregivers with CMS through 1–800–Medicare or CMS regional offices, and generally allege that a beneficiary was encouraged or pressured to join an MA plan, and that once enrolled, the plan was not what the enrollee expected or what was

explained to them when they spoke to an agent or broker.

In the Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly final rule (88 FR 22234–22256), which appeared in the **Federal Register** on April 12, 2023, we discussed at length the rapidly increasing use of various marketing activities that typically result in beneficiaries being connected with agents and brokers to be enrolled in MA plans. Based on a number of complaints CMS reviewed, as well as audio recordings of sale calls, it appears that the increased marketing of 1–800 numbers to facilitate enrollment in Medicare Advantage plans through national television advertisements combined with the subsequent actions of agents and brokers when beneficiaries responded to those ads resulted in beneficiary confusion. In some instances, through listening to the call recording, CMS observed that when beneficiaries reached an agent or broker in response to these television ads, the beneficiary was often pressured by the agent or broker to continue with a plan enrollment even though the beneficiary was clearly confused.

At the same time, these types of complaints have escalated at a pace that mirrors the growth of administrative or add-on payments, which we contend are being misused as a means to compensate over and above the CMS-set compensation limits on payment to agents and brokers. We also note that such payments appear to have no regional correlation, that is, they are generated across the country.¹³⁴ CMS is concerned that when the value of administrative payments offered to agents and brokers reaches the levels that CMS has observed in recent years, these payments may distort the process that agents and brokers are expected to engage in when they assist beneficiaries in weighing the merits of different available plans. This distortion disadvantages beneficiaries who enroll in a plan based on the recommendation or encouragement of an agent or broker who may be influenced by how much or what kind of administrative payment the agent or broker expects to receive, rather than enrolling the beneficiary in a plan that is intended to best meet the beneficiary's health care needs.

Consequently, the rise in MA marketing complaints noted above

¹³⁴ <https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment/agent-broker-compensation>.

suggests that agents and brokers are being influenced to engage in high pressure tactics, which may in turn cause beneficiary confusion about their enrollment choices, to meet enrollment targets or earn “administrative payments” in excess of their compensation payment. Although CMS’s existing regulations already prohibit plans, and by extension their agents and brokers, from engaging in misleading or confusing communications with current or potential enrollees, additional limitations on payments to agents and brokers may be necessary to adequately address the rise in MA marketing complaints described here.

Additionally, while the proposals described in this proposed rule are focused on payments and compensation made to agents and brokers, CMS is also concerned about how payments from MA plans to third party marketing organizations (TPMOs) may further influence or obscure the activities of agent and brokers. In particular, CMS is interested in the effect of payments made to Field Marketing Organizations (FMOs), which is a type of TPMO that employs agents and brokers to complete MA enrollment activities and may also conduct additional marketing activities on behalf of MA plans, such as lead generating and advertising. In fact, at the time of our first agent and broker compensation regulation, CMS expressed concern about amounts paid to FMOs for services that do not necessarily relate directly to enrollments completed by the agent or broker who deals directly with the beneficiary (73 FR 54239). Some examples of such services are training, material development, customer service, direct mail, and agent recruitment.

As we noted in the preamble to the two interim final rules published in 2008 (73 FR 67406 and 73 FR 54226), all parties should be mindful that their compensation arrangements, including arrangements with FMOs and other similar type entities, must comply with the fraud and abuse laws, including the Federal anti-kickback statute. Beginning as early as 2010, an OIG report indicated that “plan sponsors may have created financial incentives that could lead FMOs to encourage sales agents to enroll Medicare beneficiaries in plans that do not meet their health care needs. Because FMOs, like sales agents, may influence Medicare beneficiaries’ enrollment in MA plans, CMS should issue additional regulations more clearly defining how and how much FMOs should be paid for their

services.”¹³⁵ In the time since CMS first began to regulate agent and broker compensation, we have seen the FMO landscape change from mostly small regionally-based companies to a largely consolidated group of large national private equity-backed or publicly-traded companies.

We have also observed that, similar to the additional payments made to agents and brokers, there has been a steep increase in administrative payments made to FMOs by MA organizations. Likewise, CMS is concerned that these quick increases in fees have resulted in a “bidding war” among plans to secure anti-competitive contract terms with FMOs and their affiliated agents and brokers. If left unaddressed, such bidding wars will continue to escalate with anti-competitive results, as smaller, local or regional plans that are unable to pay exorbitant fees to FMOs risk losing enrollees to larger, national plans who can. In addition to comments on our proposals here to help us develop additional regulatory action, we specifically request comments regarding how CMS can further ensure that payments made by MA plans to FMOs do not undercut the intended outcome of the agent and broker compensation proposals included in this proposed rule.

Finally, in addition to the undue influence that perks, add-on payments, volume bonuses and other financial incentives paid by MA organizations to FMOs may have on agents and brokers, they also create a situation where there is an unlevel playing field among plans. Larger, national plans are more able to shoulder the added costs being paid as compared to smaller, more locally based MA plans. Furthermore, we have received reports that some larger FMOs are more likely to contract with national plans, negatively impacting competition. On July 9, 2021, President Biden issued Executive Order (E.O.) 14036: “Promoting Competition in the American Economy” (hereinafter referred to as E.O. 14036). E.O. 14036 describes the Administration’s policy goals to promote a fair, open, competitive marketplace, and directs the U.S. Department of Health and Human Services to consider policies that ensure Americans can choose health insurance plans that meet their needs and compare plan offerings, furthering competition and consumer choice. The proposed regulatory changes included here also aim to deter

anti-competitive practices engaged in by MA organizations, agents, brokers, and TPMOs that prevent beneficiaries from exercising fully informed choice and limit competition in the Medicare plan marketplace among Traditional Medicare, MA plans, and Medigap plans.

In this proposed rule we are focusing on current payment structures among MA organizations, agents, brokers, and TPMOs, specifically FMOs, that may incentivize agents or brokers to emphasize or prioritize one plan over another, irrespective of the beneficiary’s needs, leading to enrollment in a plan that does not best fit the beneficiary’s needs and a distortion of the competitive process.

As noted above, section 1851(j)(2)(D) and 1851(h)(4)(D) of the Social Security Act directs the Secretary to set limits on compensation rates to “ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs,” and that the Secretary “shall only permit a Medicare Advantage organization (and the agents, brokers, and other third parties representing such organization) to conduct the activities described in subsection (j)(2) in accordance with the limitations established under such subsection.”

Our regulations at § 422.2274 set out limitations regarding various types of payments and compensation that may be paid to agents, brokers, and third parties who represent MA organizations. Each of these limitations is intended to better align the professional incentives of the agents and brokers with the interests of the Medicare beneficiaries they serve. Our regulations specify maximum compensation amounts that may be paid to agents and brokers for initial enrollment and renewals. The regulations also allow for payment to agents and brokers for administrative costs such as training and operational overhead, as long as the payments are at or below the value of those services in the marketplace. The maximum compensation for initial and renewal enrollments and the requirement that administrative payments reflect fair market value for actual administrative services are intended to ensure incentives for agents and brokers to help enroll beneficiaries into MA plans that best meet their health care needs.

However, while CMS has affirmatively stated the types of allowable payment arrangements and the parameters for those payments in regulations at § 422.2274, some recent studies suggest that MA plans offer

¹³⁵ Levinson, Daniel R, BENEFICIARIES REMAIN VULNERABLE TO SALES AGENTS’ MARKETING OF MEDICARE ADVANTAGE PLANS (March 2010); <https://oig.hhs.gov/oei/reports/oei-05-09-00070.pdf>.

additional or alternative incentives to agents and brokers, often through third parties such as FMOs, to prioritize enrollment into some plans over others. These incentives are both explicit (in the form of higher payments purportedly for administrative services) and implicit (such as in the case of passing on leads, as discussed below).¹³⁶

As previously mentioned, we believe payments categorized by MA organizations as “administrative expenses,” paid by MA organizations to agents and brokers, have significantly outpaced the market rates for similar services provided in non-MA markets, such as Traditional Medicare with Medigap. This is based on information shared by insurance associations and focus groups and published in research articles by groups such as the Commonwealth Fund, which found that “most brokers and agents in the focus groups recalled receiving higher commissions [total payments, including commission and administrative payments]—sometimes much higher—for enrolling people in Medicare Advantage plans compared to Medigap.”¹³⁷

Similarly, some MA organizations are paying for things such as travel or operational overhead on a “per enrollment” basis, resulting in instances where an agent or broker may be paid multiple times for the same, one-time expense, if the agent incurring the expense happened to enroll more than one beneficiary into the plan making the payment. For example, an agent could be reimbursed for the cost of traveling to an event where that agent enrolls a beneficiary into an MA plan; if the cost of travel is paid on a “per enrollment” basis, the agent would be reimbursed the price of the trip multiplied by the number of enrollments the agent facilitated while at that event. In this scenario, whichever MA organization reimburses for travel at the highest rates would effectively be offering a higher commission per enrollee. This would inherently create a conflict of interest for the agent. As the Secretary must “ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare

Advantage plan that is intended to best meet their health care needs,” we believe this type of conflict must be addressed.

We are also concerned that other activities undertaken by a TPMO, as a part of their business relationships with MA organizations, may influence the plan choices offered or how plan choices are presented by the agent or broker to a prospective enrollee. For example, we have learned of arrangements where an entity, such as an FMO, provides an MA organization with both marketing and brokering services. As part of the arrangement, the MA organization pays the FMO for leads generated by the FMO and then the leads are given directly to the FMO’s agents instead of to the MA organization itself (or the MA organization’s other contracted agents and brokers). When the FMO’s agents then contact the individual and enroll the individual into an MA plan, the MA organization pays the agent or the FMO the enrollment compensation described in § 422.2267(d), separate and apart from any referral fee paid to the FMO.

While MA organizations that are engaged in these types of arrangements (such as paying FMOs for lead generating activities and marketing, then giving the leads to the FMO’s agents and then paying compensation for that same enrollment) might argue that they are not intended to influence an agent or broker in determining which plan “best meets the health care needs of a beneficiary,” we believe it is likely that these arrangements are having this effect. We believe that current contracts in place between FMOs and MA plans can trickle down to influence agents and brokers in enrolling more beneficiaries into those plans that also provide the agents and brokers with leads, regardless of the appropriateness of the plan is for the individual enrollees. In fact, FMOs could leverage these leads as a form of additional compensation by “rewarding” agents who enroll beneficiaries into a specific plan with additional leads. Therefore, CMS is required under section 1851(j)(2)(D) of the Social Security Act to establish guidelines that will bring the incentives for agents and brokers to enroll individuals in an MA plan that is intended to best meet their health care needs, in accordance with the statute.

In this rule we are proposing to: (1) generally prohibit contract terms between MA organizations and agents, brokers, or other TPMOs that may interfere with the agent’s or broker’s ability to objectively assess and recommend the plan which best fits a beneficiary’s health care needs; (2) set a

single agent and broker compensation rate for all plans, while revising the scope of what is considered “compensation;” and (3) eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. We are also proposing to make conforming edits to the agent broker compensation rules at § 423.2274.

1. Limitation on Contract Terms

We propose to add at § 422.2274(c)(13) that, beginning in contract year 2025, MA organizations must ensure that no provision of a contract with an agent, broker, or TPMO has the direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent’s or broker’s ability to objectively assess and recommend which plan best meets the health care needs of a beneficiary.

Examples of the anti-competitive contract terms we intend to prohibit would include, for instance, those that specify renewal or other terms of a plan’s contract with an agent broker or FMO contingent upon preferentially higher rates of enrollment; that make an MA organizations contract with an FMO or reimbursement rates for marketing activities contingent upon agents and brokers employed by the FMO meeting specified enrollment quotas; terms that provide for bonuses or additional payments from an MA organizations to an FMO with the explicit or implicit understanding that the money be passed on to agents or brokers based on enrollment volume in plans sponsored by that MA organizations; for an FMO to provide an agent or broker leads or other incentives based on previously enrolling beneficiaries into specific plans for a reason other than what best meets their health care needs.

We believe this proposal gives plans further direction as to the types of incentives and outcomes that must be avoided without being overly prescriptive as to how the plans should structure these arrangements.

We seek comment on this proposal.

2. Compensation Rates

Under current regulations, compensation for agents and brokers (described at § 422.2274(d)(2) and excluding administrative payments as described in § 422.2274(e)) may be paid at a rate determined by the MA organization but may not exceed caps that CMS calculates each year, based on Fair Market Value (FMV) as specified at § 422.2274(a). For example, the CY2023 national agent/broker FMV compensation caps are \$601 for each

¹³⁶ The Commonwealth Fund, *The Challenges of Choosing Medicare Coverage: Views from Insurance Brokers and Agents* (Feb. 28, 2023); <https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents>.

¹³⁷ The Commonwealth Fund, *The Challenges of Choosing Medicare Coverage: Views from Insurance Brokers and Agents* (Feb. 28, 2023); <https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents>.

MA initial enrollment, \$301 for a MA renewal enrollment, \$92 for each Part D initial enrollment, and \$46 for a Part D renewal enrollment.

We have learned that overall payments to agents and brokers can vary significantly depending on which plan an individual enrolls in. We are concerned that the lack of a uniform compensation standard across plans can encourage the types of arrangements that provide strong financial incentives for agents and brokers to favor some plans over others and that these incentives could result in beneficiaries enrolling in plans that do not best fit their needs. To eliminate this potential for bias and ensure that CMS's regulations governing agent and broker compensation ensure that agents and brokers are incented to enroll individuals in the MA plan that is intended to best meet their health care needs, we are proposing to amend our regulations to require that all payments to agents or brokers that are tied to enrollment, related to an enrollment in an MA plan or product, or are for services conducted as part of the relationship associated with the enrollment into an MA plan or product must be included under compensation, as defined at § 422.2274(a), including payments for activities previously excluded under paragraph (ii) of the definition of compensation at § 422.2274(a), and are regulated by the compensation requirements of § 422.2274(d)(1) through (3). We are also proposing to make conforming amendments to the regulations at § 422.2274(e)(2) to clarify that all administrative payments are included in the calculation of enrollment-based compensation; this proposal is further discussed at section VI.B.3. of this proposed rule.

Further, we are proposing to change the caps on compensation payments that are currently provided in § 422.2274 to set rates that would be paid by all plans across the board. Under this proposal, agents and brokers would be paid the same amount either from the MA plan directly or by an FMO. We note that the proposal does not extend to payments for referrals as described at § 422.2274(f); we believe the cap set on referral payments is sufficient to avoid the harms described above, and that a referral payment is often made in lieu of a compensation payment, and so it does not provide the same incentives as compensation payments.

We believe that this approach would level the playing field for all plans represented by an agent or broker and promote competition. In addition, by

explicitly saying that compensation extends to additional activities as a part of the relationship between the agent and the beneficiary, we reinforce CMS's longstanding understanding that the initial and renewal compensation amounts are based on the fact that additional work may be done by an agent or broker throughout the plan year, including fielding follow-up questions from the beneficiary or collecting additional information from them would enhance a beneficiary's ability to get the most out of their plan.

MA organizations are currently required, under § 422.2274(c)(5), to report to CMS on an annual basis the specific rates and range of rates they will be paying independent agents and brokers. We propose to remove the reporting requirement at § 422.2274(c)(5), as all agents and brokers would be paid the same compensation rate in a given year under our proposal.

We seek comment on this proposal.

3. Administrative Payments

As discussed above, CMS is proposing that all payments to an agent or broker relating to the initial enrollment, renewal, or services related to a plan product would be included in the definition of compensation. For consistency with that proposed policy, we are also proposing to remove the separate regulatory authority regarding "administrative payments" currently at § 422.2274(e)(1), and to amend § 422.2274(e)(2) to clarify that the portion of an agent's compensation for an enrollment may be calculated and updated independently. We believe this step is necessary to ensure that MA organizations cannot utilize the existing regulatory framework allowing for separate payment for administrative services to effectively circumvent the FMV caps on agent and broker compensation.

For instance, we understand that many plans are paying agents and brokers for conducting health risk assessments (HRAs) and categorize these HRAs as an "administrative service." We understand the fair market value of these services, when provided by non-medical staff, to be approximately \$12.50 per hour and the time required to complete an HRA is intended to be no more than twenty minutes.¹³⁸ However, we have been made aware of instances of an agent or broker enrolling a beneficiary into a

plan, asking the enrollee to complete one of these short assessments, and then being compensated at rates of up to \$125 per HRA.¹³⁹ Compensation at these levels is not consistent with market value. Moreover, a study funded by the CDC to provide guidance for best practices "recommend that HRAs be tied closely with clinician practice and be collected electronically and incorporated into electronic/patient health records [. . .] agents/brokers lack the necessary health care knowledge, information technology capabilities, and provider relationships to link HRAs in the recommended way."¹⁴⁰ For this reason, we believe that the HRAs completed by agents and brokers do not have the same value as those performed and interpreted by health care providers or in a health care setting.

Similarly, according to recent market surveys and information gleaned from oversight activities, payments purportedly for training and testing and other administrative tasks for agents and brokers selling some MA plans seem to significantly outpace payments for similar activities made by other MA plans, as well as payments for similar activities undertaken by insurance agents and brokers in other industries. The higher overall cost as compared to other industries, combined with the otherwise inexplicable difference in payments for administrative activities for some MA organizations compared to others, further points to the payment for these administrative activities being used as a mechanism to effectively pay agents and brokers enrollment compensation amounts in excess of the limits specified at § 422.2274(a) and (d).

By eliminating separate payment for administrative services, CMS expects that this proposal would eliminate a significant method which some plans may have used to circumvent the regulatory limits on enrollment compensation. Furthermore, we believe ensuring a fixed payment rate for agents will result in compensation greater than what is currently provided through typical contractual arrangements with FMOs, as there would no longer be a

¹³⁹ <https://4239296.fs1.hubspotusercontent-na1.net/hubsfs/4239296/2023%20Plan%20Year%20Docs/2023%20HRA%20Instructions/Cigna%202023%20HRA%20Details.pdf>.

¹⁴⁰ The Commonwealth Fund, The Challenges of Choosing Medicare Coverage: Views from Insurance Brokers and Agents (Feb. 28, 2023); <https://www.commonwealthfund.org/publications/2023/feb/challenges-choosing-medicare-coverage-views-insurance-brokers-agents>; cf. Guidance on Development of Health Risk Assessment as Part of the Annual Wellness Visit for Medicare Beneficiaries—(section 4103 of the Patient Protection and Affordable Care Act) <https://www.cdc.gov/policy/paao/hra/hraawvguidance-reportfinal.pdf>.

¹³⁸ CDC, Interim Guidance for Health Risk Assessments and their Modes of Provision for Medicare Beneficiaries; <https://www.cms.gov/files/document/healthriskassessmentscdcfinalpdf>.

range of compensation rates at which the MA organizations could pay for agents and brokers' services. While our proposal would prohibit separate administrative payments, as described below, we propose to adjust the FMV for compensation to take into account costs for certain appropriate administrative activities.

We recognize that this approach could have some drawbacks, particularly as this policy would, in effect, leave agents and brokers unable to directly recoup administrative costs such as overhead or lead purchasing from its compensation from Medicare health and drug plans, unless the agent has a certain volume of business. For instance, the cost of a customer relationship management (CRM) system (the software used to connect and log calls to potential enrollees) is about \$50 per month. This expense would require at least one enrollment commission per year to cover these costs, whereas it is currently permissible for an MA organization to pay for these costs directly, leaving the entire commission as income for the agent or broker. However, given the high volume of enrollees that use an agent or broker for enrollment services, we do not believe there to be a large risk of agents or brokers failing to cross that initial threshold to recoup their administrative costs.

We considered an alternate policy proposal wherein we would maintain our current definitions of compensation and administrative payments but would remove the option for a plan to make administrative payments based on enrollment, as currently codified at § 422.2274(e)(2). We considered instead requiring that administrative payments be made a maximum of one time per administrative cost, per agent or broker. We considered the argument that these expenses, such as payments for training and testing, or nonmonetary compensation such as leads, should be paid at their FMV and not as a factor of overall enrollment because the value of such administrative tasks is usually a fixed rate, regardless of how many enrollments are ultimately generated by the agent or broker engaged in these administrative tasks.

We also considered whether, under this alternative policy approach, it would be best to require that each administrative expense be reimbursed at the same rate by each contracting MA organization as a means of encouraging agents and brokers to represent multiple plans at any given time. However, this alternative policy would, of necessity, be comparatively prescriptive and could present challenges for all parties as it relates to the tracking these expenses.

We believe our proposal to include all payments to an agent or broker under the definition of compensation is likely to reduce the ability of plans and/or TPMOs to circumvent the maximum compensation rates defined by CMS via the annual FMV determination.

We seek comment on this proposal. We are also proposing to increase the compensation rate described at § 422.2274(a) to add certain appropriate administrative costs. In particular, we believe that the administrative cost of the licensing and training and testing requirements at § 422.2274(b), and the recording requirements at § 422.2274(g)(2)(ii), may warrant an increase in the rate of compensation given the significant and predictable cost of these mandatory activities.¹⁴¹ Based on our fair market value analysis, we believe these activities would warrant increasing the base compensation rate by \$31,¹⁴² and be updated annually as part of the scheduled compensation rate update described at § 422.2274(a). Therefore, we propose to add, beginning in 2025, that FMV will be increased by \$31 to account for administrative payments included under the compensation rate, and to be updated annually in compliance with the requirements for FMV updates.

We believe it is necessary to increase the rate for compensation by \$31, based on the estimated costs for training, testing, and call recording that would need to be covered by this single enrollment-based payment. We are proposing to begin with a one-time \$31 increase, including various locality-specific adjustments, with annual FMV updates to this amount as described by the regulation, including "adding the current year FMV and the product of the current year FMV and MA Growth Percentage for aged and disabled beneficiaries." We note that we are not proposing a proportionate increase to compensation for renewals and we considered this in determining the amount by which we are proposing to increase the rate for compensation for enrollments.

We seek comment on our proposal to increase the rate for compensation to account for necessary administrative costs that would be incorporated into this rate under our previous proposal. Specifically, CMS is requesting comment on the administrative costs

that should be considered, and how else we might determine their value, as we consider the future of the compensation structure.

4. Agent Broker Compensation for Part D Plans

Finally, we also are proposing to apply each of the proposals described above to the sale of PDP plans by agents and brokers, as codified at § 423.2274.

Pursuant to sections 1851(j)(2)(D) and 1860D-4(l) of the Act, the Secretary has a statutory obligation to establish guidelines to ensure that the use of agent and broker compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage (MA) and Part D prescription drug plans that are intended to best meet beneficiaries' health care needs.

Because the same agents and brokers are often licensed to sell both MA plans and PDPs, we believe it is necessary under our statutory authority to apply the same compensation rules to the sale of both MA plans and PDPs in order to ensure that both plan types are being held to the same standards and are on a 'level playing field' when it comes to incentives faced by agents and brokers. This includes increasing the FMV rate compensation rate by \$31.

We also believe it is necessary to extend these regulations to the sale of PDPs to avoid shifting the incentives discussed at length above, such as the incentive for agents to favor one plan over another based upon bonuses or other payments that are not currently accounted for under the definition of "compensation." If conforming changes are not made to the sale of PDP plans, the PDP plans may have an unfair advantage in that they have the opportunity to offer additional payments and perks to FMOs and agents, while MA plan sponsors are limited by the policies proposed above. Therefore, for the same reasons discussed above regarding proposed changes to § 422.2274, we propose to make conforming amendments to § 423.2274.

We seek comment on this proposal, and specifically whether and to what extent modifications to these proposals should be made to account for differences between MA and Part D plan types.

VII. Medicare Advantage/Part C and Part D Prescription Drug Plan Quality Rating System

A. Introduction

CMS develops and publicly posts a 5-star rating system for Medicare Advantage (MA)/Part C and Part D plans

¹⁴¹ <https://www.cms.gov/medicare/enrollment-renewal/managed-care-eligibility-enrollment/agent-broker-compensation>.

¹⁴² Our calculations arriving at this number are further discussed in the COI in section X.B.10 titled ICRs Regarding Agent Broker Compensation (§ 422.2274).

as part of its responsibility to disseminate comparative information, including information about quality, to beneficiaries under sections 1851(d) and 1860D–1(c) of the Act and based on the collection of different types of quality data under section 1852(e) of the Act. The Part C and Part D Star Ratings system is used to determine quality bonus payment (QBP) ratings for MA plans under section 1853(o) of the Act and the amount of MA beneficiary rebates under section 1854(b) of the Act. Cost plans under section 1876 of the Act are also included in the MA and Part D Star Ratings system, as codified at § 417.472(k). We use multiple data sources to measure quality and performance of contracts, such as CMS administrative data, surveys of enrollees, information provided directly from health and drug plans, and data collected by CMS contractors. Various regulations, including §§ 417.472(j) and (k), 422.152(b), 423.153(c), and 423.156, require plans to report on quality improvement and quality assurance and to provide data which help beneficiaries compare plans. The methodology for the Star Ratings system for the MA and Part D programs is codified at §§ 422.160 through 422.166 and 423.180 through 423.186, respectively, and we have specified the measures used in setting Star Ratings through rulemaking. In addition, the cost plan regulation at § 417.472(k) requires cost contracts to be subject to the parts 422 and 423 Medicare Advantage and Part D Prescription Drug Program Quality Rating System. (83 FR 16526–27) As a result, the proposals here would apply to the quality ratings for MA plans, cost plans, and Part D plans. We generally use “Part C” to refer to the quality measures and ratings system that applies to MA plans and cost plans.

We have continued to identify enhancements to the Star Ratings program to ensure it is aligned with the CMS Quality Strategy as that Strategy evolves over time. To support the CMS National Quality Strategy, CMS is moving towards a building-block approach to streamline quality measures across CMS quality and value-based care programs. Across our programs, where applicable, we are considering including the Universal Foundation¹⁴³ of quality measures, which is a set of measures that are aligned across CMS programs. CMS is committed to aligning a set of measures across all our quality and value-based care programs and ensuring we measure quality across the entire care continuum in a way that

promotes the best, safest, and most equitable care for all individuals. Improving alignment of measures across Federal programs and with private payers will reduce provider burden while also improving the effectiveness and comparability of measures. The Universal Foundation of quality measures will focus provider attention, reduce burden, identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. The Universal Foundation is a building block to which programs will add additional aligned or program-specific measures. The set of measures will evolve over time to meet the needs of individuals served across CMS programs. We have submitted the Initiation and Engagement of Substance Use Disorder Treatment (IET) measure (Part C) (a Universal Foundation measure) to the 2023 Measures under Consideration process for review by the Measures Application Partnership prior to proposing use of that measure in the Star Ratings system through future rulemaking to align with the Universal Foundation. We also note that, beginning with measurement year 2023, Part C contracts are beginning to report to CMS additional measures that are part of the Universal Foundation, such as Adult Immunization Status, Depression Screening and Follow-Up for Adolescents and Adults, and Social Need Screening and Intervention, for the display page. We have previously solicited feedback regarding potentially proposing these measures as Star Ratings in the future through both the Advance Notice of Methodological Changes for Calendar Year (CY) 2023 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies and the Advance Notice of Methodological Changes for Calendar Year (CY) 2024 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. We intend to submit these measures to the Measures Under Consideration process for review by the Measures Application Partnership in the future and propose them through future rulemaking as additional Star Ratings measures. The remaining measures that are part of the Universal Foundation are already part of the current Part C and D Star Ratings program.

In this proposed rule, we are also proposing to update the Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) measure (Part D).

We are also proposing the following methodological enhancements, clarifications, and operational updates:

- Revise the process for identifying data completeness issues and calculating scaled reductions for the Part C appeals measures.
- Update how the CAI and HEI reward are calculated in the case of contract consolidations.
- Revise an aspect of the QBP appeals process.
- Add that a sponsor may request CMS review of its contract's administrative claims data used for the Part D Patient Safety measures no later than the annual deadline set by CMS for the applicable Star Ratings year.

Unless otherwise stated, proposed changes would apply (that is, data would be collected and performance measured) for the 2025 measurement period and the 2027 Star Ratings.

B. Adding, Updating, and Removing Measures (§§ 422.164 and 423.184)

The regulations at §§ 422.164 and 423.184 specify the criteria and procedures for adding, updating, and removing measures for the Star Ratings program. In the “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” final rule which appeared in the **Federal Register** on April 16, 2018 (83 FR 16532) (hereinafter referred to as the April 2018 final rule), we stated we are committed to continuing to improve the Part C and Part D Star Ratings system and anticipated that over time measures would be added, updated, and removed. We also specified at §§ 422.164(d) and 423.184(d) rules for measure updates based on whether they are substantive or non-substantive. The regulations, at paragraph (d)(1), list examples of non-substantive updates. See also 83 FR 16534–37. Due to the regular updates and revisions made to measures, CMS does not codify a list in regulation text of the measures (and their specifications) adopted for the Part C and Part D Star Ratings program. CMS lists the measures used for the Star Ratings each year in the Medicare Part C & D Star Ratings Technical Notes or similar guidance issued with publication of the Star Ratings. In this rule, CMS is proposing a measure change to the Star Ratings program and an updated methodology for calculating scaled reductions of the Part C appeals measures for performance periods beginning on or after January 1, 2025, unless noted otherwise.

¹⁴³ <https://www.nejm.org/doi/full/10.1056/NEJMp2215539>.

We are committed to continuing to improve the Part C and Part D Star Ratings system by focusing on improving clinical and other health outcomes. Consistent with §§ 422.164(c)(1) and 423.184(c)(1), we continue to review measures that are nationally endorsed and in alignment with the private sector. For example, we regularly review measures developed by NCQA and PQA.

1. Proposed Measure Update

a. Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR) (Part D)

Section 1860D–4(c)(2) of the Act requires all Part D sponsors to have an MTM program designed to assure, with respect to targeted beneficiaries, that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use, and to reduce the risk of adverse events, including adverse drug interactions. Section 1860D–4(c)(2)(A)(ii) of the Act requires Part D sponsors to target those Part D enrollees who have multiple chronic diseases, are taking multiple Part D drugs, and are likely to meet a cost threshold for covered Part D drugs established by the Secretary. CMS codified the MTM targeting criteria at § 423.153(d)(2).

CMS also uses the MTM Program Completion Rate for CMR Star Rating measure, which is defined as the percent of MTM program enrollees who received a CMR during the reporting period. The Part D MTM Program Completion Rate for CMR measure shows how many members in a plan's MTM program had an assessment from their plan by a pharmacist or other health professional to help them manage their medications. As part of the completion of a CMR, a Part D enrollee receives a written summary of the discussion in CMS's Standardized Format, including an action plan that recommends what the member can do to better understand and use their medications.¹⁴⁴

In the December 27, 2022 proposed rule, “Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of

All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications” (87 FR 79452), hereafter referred to as the December 2022 proposed rule, CMS proposed changes to the MTM program targeting criteria, including: (1) requiring plan sponsors to target all core chronic diseases identified by CMS, codifying the current 9 core chronic diseases¹⁴⁵ in regulation, and adding HIV/AIDS for a total of 10 core chronic diseases; (2) lowering the maximum number of covered Part D drugs a sponsor may require from 8 to 5 drugs and requiring sponsors to include all Part D maintenance drugs in their targeting criteria; and (3) revising the methodology for calculating the cost threshold (\$4,935 in 2023) to be commensurate with the average annual cost of 5 generic drugs (\$1,004 in 2020). We estimated that the proposed changes would increase the number and percentage of Part D enrollees eligible for MTM from 4.5 million (9 percent) to 11.4 million (23 percent).

As noted in the April 12, 2023 final rule, “Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly” (88 FR 22120), hereafter referred to as the April 2023 final rule, we did not address comments received on the provisions of the proposed rule that were not finalized in that rule, such as the proposed MTM program targeting criteria changes, and stated that they would be addressed at a later time, in a subsequent rulemaking document, as appropriate. If those proposed changes were to be finalized, the number of Part D enrollees eligible for MTM programs would increase, and the denominator of the MTM Program Completion Rate for CMR Measure would expand accordingly; therefore such changes in the targeting criteria would be substantive updates to the Star Rating measure per § 423.184(d)(2). Specifically, these proposed changes to the targeting criteria would not update the actual measure specifications but would meaningfully impact the number of Part D enrollees eligible for MTM services from 9 percent to an estimated

23 percent and, thus, substantially increase the number of enrollees included in the denominator of the MTM Program Completion Rate for CMR Measure, if finalized.

Accordingly, if the changes to eligibility for the MTM program in the December 2022 proposed rule (described above) are finalized in a future rule, in this proposed rule CMS proposes to move the MTM Program Completion Rate for CMR Star Rating measure to a display measure for at least 2 years due to substantive measure updates. For example, if such MTM program eligibility changes are finalized for CY 2025, our proposal in this rule would move the measure to the display page for at least 2 years prior to using the updated measure to calculate and assign Star Ratings. There would be no legacy measure to calculate while the updated measure using the same measure specifications is on the display page because the MTM-eligible denominator population would have meaningfully increased due to changes in the program requirements. Therefore, the measure would be removed from the Star Ratings entirely for the 2025 and 2026 measurement years and would return to the Star Ratings program no earlier than the 2027 measurement year for the 2029 Star Ratings. CMS does not anticipate any additional burden associated with the measure update, as burden tied to the changes in the MTM eligibility criteria is already considered in estimates for the December 2022 proposed rule.

If the changes to eligibility for MTM programs described above and in the December 2022 proposed rule are not finalized, CMS would not make any substantive changes to the MTM Program Completion Rate for CMR measure—that is, we would also not finalize the proposal in this rule to update the Star Rating measure.

Table GB1 summarizes the updated MTM Program Completion Rate for CMR measure addressed in this proposed rule. The measure description listed in this table is a high-level description. The annual Star Ratings measure specifications supporting document, Medicare Part C & D Star Ratings Technical Notes, provides detailed specifications for each measure. Detailed specifications include, where appropriate, more specific identification of a measure's: (1) numerator, (2) denominator, (3) calculation, (4) timeframe, (5) case-mix adjustment, and (6) exclusions. The Technical Notes document is updated annually. The annual Star Ratings are produced in the fall of the prior year. For example, the 2027 Stars Ratings are produced in the

¹⁴⁴ The Medicare Part C & D Star Ratings Technical Notes provide details on existing measures and are available at: <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovgenin/performance/data>.

¹⁴⁵ The current core chronic diseases are diabetes*, hypertension*, dyslipidemia*, chronic congestive heart failure*, Alzheimer's disease, end stage renal disease (ESRD), respiratory disease (including asthma*, chronic obstructive pulmonary disease (COPD), and other chronic lung disorders), bone disease-arthritis (osteoporosis, osteoarthritis, and rheumatoid arthritis), and mental health (including depression, schizophrenia, bipolar disorder, and other chronic/disabling mental health conditions). Enumerated in statute (*).

fall of 2026. If a measurement period is listed as “the calendar year 2 years prior

to the Star Ratings year” and the Star Ratings year is 2027, the measurement

period is referencing the January 1, 2025, to December 31, 2025, period.

TABLE GB1. SUMMARY OF PROPOSED REVISED INDIVIDUAL STAR RATING MEASURE FOR PERFORMANCE PERIODS BEGINNING ON OR AFTER JANUARY 1, 2025

Measure	Measure Description	Domain	Measure Category and Weight	Data Source	Measurement Period	CMIT ID	Statistical Method for Assigning Star Rating	Reporting Requirements (Contract Type)
Part D Measure								
Medication Therapy Management (MTM) Program Completion Rate for Comprehensive Medication Review (CMR)*	The percent of MTM program enrollees, 18 years or older, who received a CMR during the reporting period.	Drug Safety and Accuracy of Drug Pricing	Process Measure Weight of 1	Part D Plan Reporting Requirements	The calendar year 2 years prior to the Star Ratings year	00454-01-C-PARTD	Clustering	MA-PD and PDP

* Effective as soon as the 2027 measurement year.

C. Data Integrity (§§ 422.164(g) and 423.184(g))

We currently have rules specified at §§ 422.164(g) and 423.184(g) to reduce a measure rating when CMS determines that a contract’s measure data are incomplete, inaccurate, or biased. For the Part C appeals measures, we have statistical criteria to reduce a contract’s appeals measures for missing Independent Review Entity (IRE) data. Specifically, these criteria allow us to use scaled reductions for the appeals measures to account for the degree to which the data are missing. See 83 FR 16562–16564. The data underlying a measure score and Star Rating must be complete, accurate, and unbiased for them to be useful for the purposes we have codified at §§ 422.160(b) and 423.180(b). In the April 2018 final rule (83 FR 16562), CMS codified at §§ 422.164(g)(1)(iii) and 423.184(g)(1)(ii) a policy to make scaled reductions to the Part C and D appeals measures’ Star Ratings when the relevant IRE data are not complete based on the Timeliness Monitoring Project (TMP) or audit information. As provided under § 423.184(e)(1)(ii), we removed the two Part D appeals measures (Appeals Auto-Forward and Appeals Upheld) beginning with the 2020 measurement year and 2022 Star Ratings in the 2020 Rate Announcement¹⁴⁶ due to low statistical reliability; thus, the scaled reductions are no longer applicable to the Part D appeals measures. However, we made no changes to the scaled reductions used with the Part C appeals measures, Plan Makes Timely Decisions

about Appeals and Reviewing Appeals Decisions, because there were no similar statistical reliability issues with those measures. Therefore, these two Part C measures continue to be subject to the scaled reductions authorized at § 422.164(g)(1)(iii) based on TMP or audit information.

Because the Part D appeals measures are no longer part of the Star Ratings, we are proposing to remove and reserve the paragraphs at §§ 422.164(g)(1)(iii)(B), (F), and (I) and 423.184(g)(1)(ii). Paragraphs (g)(1)(iii)(B), (F), and (I) of § 422.164 all address how the error rate on the TMP for the Part D appeals measures had been used in calculating scaled reductions for MA–PDs that are measured on both Part C and Part D appeals. Currently, § 423.184(g)(1)(ii) addresses the scaled reductions for Part D appeals measures based on the TMP. Given the removal of the Part D appeals measures from the Star Ratings, these provisions are moot. We propose to reserve the relevant paragraphs to avoid the risk that redesignating the remaining paragraphs would cause unintended consequences with any existing references to these provisions.

The completeness of the IRE data is critical to support fair and accurate measurement of the two Part C appeals measures. Since the 2019 Star Ratings we have used data from the TMP, which uses the Part C audit protocols for collecting Organization Determinations, Appeals and Grievances (ODAG) universes, to determine whether the IRE data used to calculate the Part C appeals measures are complete. As described at § 422.164(g)(1)(iii), we use scaled reductions to account for the degree to which the IRE data are missing. The current regulations describe how scaled reductions are based on the TMP.

However, due to a change in the Part C audit protocols for collecting universes of ODAG data, we are proposing to modify, and in one case reserve, paragraphs (g)(1)(iii) introductory text, (g)(1)(iii)(A)(1) and (2), (g)(1)(iii)(H) and (J), (g)(1)(iii)(K)(2), and (g)(1)(iii)(O) to change how we address reductions in the Star Ratings for Part C appeals measures using different data. We are proposing to revise the introductory language in § 422.164(g)(1)(iii) to remove references to the timeliness monitoring study and audits and replace them with references to data from MA organizations, the IRE or CMS administrative sources. In addition, our proposed revisions to this paragraph include minor grammatical changes to the verb tense. We are also proposing to modify § 422.164(g)(1)(iii)(A) to use data from MA organizations, the IRE, or CMS administrative sources to determine the completeness of the data at the IRE for the Part C appeals measures starting with the 2025 measurement year and the 2027 Star Ratings. Currently, data collected through § 422.516(a) could be used to confirm the completeness of the IRE data; however, data collected from MA organizations through other mechanisms in addition to data from the IRE or CMS administrative sources could be used in the future. The proposed amendment to § 422.164(g)(1)(iii)(A) is not intended to limit the data CMS uses to conduct analyses of the completeness of the IRE data in order to adapt to changing information submissions that could be reliably used for the same purpose in the future. The revisions proposed for the other paragraphs provide for a new calculation to implement scaled reductions for the Part C appeals

¹⁴⁶ Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter (*cms.gov*).

measures for specific data integrity issues.

Part C contracts are required to send partially favorable (partially adverse) and unfavorable (adverse) decisions to the IRE within applicable timeframes as specified at § 422.590(a) through (e). In order for the existing Part C appeals measures (Plan Makes Timely Decisions about Appeals and Reviewing Appeals Decisions) to accurately reflect plan performances in those areas, the appeals must be sent to the IRE because the data source for these measures is based on the data that have been submitted to the IRE. Currently, through the Part C Reporting Requirements as set forth at § 422.516(a), CMS collects information at the contract level from MA organizations about the number of partially favorable reconsiderations (that is, the number of partially favorable claims and the number of partially favorable service requests by enrollees/representatives and non-contract providers) and unfavorable reconsiderations (that is, the number of partially favorable claims and the number of partially favorable service requests by enrollees/representatives

and non-contract providers) over a calendar year.¹⁴⁷ These data are subject to data validation requirements, in accordance with specifications developed by CMS, under § 422.516(g), to confirm that they are reliable, valid, complete, and comparable. CMS would use this information to determine the total number of cases that should have been sent to the IRE over the measurement year (that is, number of partially favorable reconsiderations + number of unfavorable reconsiderations) to compare to information from the IRE about submissions received from each MA organization. In the future, CMS may use detailed beneficiary-level data collected on the number of partially favorable reconsiderations and the number of unfavorable reconsiderations if such more detailed information is collected under CMS's statutory and regulatory authority to require reporting and data submission from MA organizations (such as the reporting requirements in §§ 422.504(f)(2) and/or 422.516(a)).

To determine if a contract may be subject to a potential reduction for the Part C appeals measures' Star Ratings,

CMS is proposing to compare the total number of appeals received by the IRE, including all appeals regardless of their disposition (for example, including appeals that are dismissed for reasons other than the plan's agreement to cover the disputed services and withdrawn appeals), to the total number of appeals that were supposed to go to the IRE. The total number of appeals that were supposed to be sent to the IRE would be based on the sum of the number of partially favorable reconsiderations and the number of unfavorable reconsiderations from the Part C Reporting Requirements during the measurement year (January 1 to December 31st). We propose to modify the calculation of the error rate at § 422.164(g)(1)(iii)(H) by taking 1 minus the quotient of the total number of cases received by the IRE and the total number of cases that were supposed to be sent to the IRE (Equation 1). The total number of appeals that were supposed to be sent to the IRE in Equation 2 would be calculated from the data described in the proposed revisions to § 422.164(g)(1)(iii)(A):

Equation (1)

$$\text{Part C Calculated Error Rate} = 1 - \frac{\text{Total number of cases received by the IRE}}{\text{Total number of cases that should have been forwarded to the IRE}}$$

Equation (2)

$$\begin{aligned} \text{Total Number of Cases that should have been forwarded to the IRE} \\ = \text{Number of partially favorable reconsiderations} \\ + \text{Number of unfavorable reconsiderations} \end{aligned}$$

We propose to remove and reserve § 422.164(g)(1)(iii)(J) because we intend to calculate the Part C error rate based on 12 months rather than a projected number of cases not forwarded to the IRE in a 3-month period as has historically been done with the TMP data. Currently, a contract is subject to a possible reduction due to lack of IRE data completeness if the calculated error rate is 20 percent or more and the projected number of cases not forwarded to the IRE is at least 10 in a 3-month period as described at § 422.164(g)(1)(iii)(K). We are proposing to modify § 422.164(g)(1)(iii)(K)(2) so that the number of cases not forwarded to the IRE is at least 10 for the measurement year (that is, total number of cases that should have been forwarded to the IRE minus the total

number of cases received by the IRE is at least 10 for the measurement year). The requirement for a minimum number of cases is needed to address statistical concerns with precision and small numbers. If a contract meets only one of the conditions specified in paragraph (K), the contract would not be subject to reductions for IRE data completeness issues.

We are proposing at § 422.164(g)(1)(iii)(O) that the two Part C appeals measure Star Ratings be reduced to 1 star if CMS does not have accurate, complete, and unbiased data to validate the completeness of the Part C appeals measures. For example, the data collected in the Part C Reporting Requirements go through a data validation process (§ 422.516(a)). CMS has developed and implemented data

validation standards to ensure that data reported by sponsoring organizations pursuant to § 422.516 satisfy the regulatory obligation. If these data are used to validate the completeness of the IRE data used to calculate the Part C appeals measures, we would reduce the two Part C appeals measure Star Ratings to 1 star if a contract fails data validation of the applicable Part C Reporting Requirements sections for reconsiderations by not scoring at least 95 percent or is not compliant with data validation standards (which includes sub-standards as applicable), since we cannot confirm the data used for the Part C appeals measures.

We also propose to update § 422.164(g)(1)(iii)(A)(2) to change the data source in the case of contract consolidations so that the data

¹⁴⁷ Elements E through L in Subsection #4 on page 15 at [https://www.cms.gov/files/document/](https://www.cms.gov/files/document/cy2023-part--technical-specifications-222023.pdf)

[cy2023-part--technical-specifications-222023.pdf](https://www.cms.gov/files/document/cy2023-part--technical-specifications-222023.pdf)

are currently used to identify favorable and partially favorable reconsiderations.

described in paragraph (g)(1)(iii)(A)(1) are combined for consumed and surviving contracts for the first year after consolidation. In addition, we propose to delete the phrase “For contract consolidations approved on or after January 1, 2022” as unnecessary.

We are not proposing to update the steps currently described at § 422.164(g)(1)(iii)(C) through (E) and (G), (g)(1)(iii)(K)(1), and (g)(1)(iii)(L) through (N) to determine whether a scaled reduction should be applied to the two Part C appeals measures. We welcome feedback on this updated approach for making scaled reductions proposed at § 422.164(g)(1)(iii) introductory text, (g)(1)(iii)(A)(1) and (2), (g)(1)(iii)(H), (g)(1)(iii)(K)(2), and (g)(1)(iii)(O), the removal of the Part D related provisions at §§ 422.164(g)(1)(iii)(B), (F), and (I) and 423.184(g)(1)(ii), and removal of the provision at § 422.164(g)(1)(iii)(J).

D. Review of Sponsor's Data (§§ 422.164(h) and 423.184(h))

Currently, §§ 422.164(h) and 423.184(h) provide that an MA organization (and a cost plan organization as the regulations are applied under § 417.472(k)) and a Part D plan sponsor may request a review of certain administrative data (that is, the contracts' appeals data and Complaints Tracking Module data) before Star Ratings are calculated. The regulations provide that CMS will establish an annual deadline by which such requests must be submitted. At §§ 422.164(h)(3) and 423.184(h)(3), CMS proposes to expand the policy for requests that CMS review certain data used for Star Ratings to include administrative data used for their contract's Part D Star Rating Patient Safety measures. These requests would also have to be received by the annual deadline set by CMS. We intend that the requests could include CMS's review of Prescription Drug Event (PDE), diagnosis code, and enrollment data but the requests are not necessarily limited to these specific data.

CMS reports and updates the rates for the current Part D Star Ratings Patient Safety measures (that is, Medication Adherence for Cholesterol (Statins) (ADH-Statins), Medication Adherence for Hypertension (RAS Antagonists) (ADH-RAS), Medication Adherence for Diabetes Medications (ADH-Diabetes), and Statin Use in Persons with Diabetes (SUPD) measures) via the Patient Safety Analysis Web Portal for sponsors to review and download. Part D sponsors can use the Patient Safety reports to compare their performance to overall averages and monitor their progress in improving their measure rates. In the

April 17, 2023, HPMS memorandum titled “Information to Review Data Used for Medicare Part C and D Star Ratings and Display Measures,” CMS reminded sponsors of the various datasets and reports available for sponsors to review their underlying measure data that are the basis for the Part C and D Star Ratings and display measures, including the monthly Part D Patient Safety measure reports. We expect sponsors to review their monthly Patient Safety reports that include measure rates along with available underlying administrative data and alert CMS of potential errors or anomalies in the rate calculations per the measure specifications in advance of CMS's plan preview periods to allow sufficient time to investigate and resolve them before the release of the Star Ratings.

Reviewing administrative data for the Patient Safety measures is a time-consuming process. In addition, once CMS implements sociodemographic status (SDS) risk adjustment for the three Medication Adherence measures, as finalized in the April 2023 final rule (88 FR 22265–22270), the final measure rates, which are calculated in July after the end of the measurement period, will require increased processing time to calculate. To allow enough time for CMS to review a sponsor's administrative data and ensure the accuracy of the final calculated Patient Safety measure rates, we are proposing that sponsors' requests for CMS review of administrative data must be received no later than the annual deadline set by CMS.

Beginning with the 2025 measurement year (2027 Star Ratings), we propose at §§ 422.164(h)(3) and 423.184(h)(3) that any requests by an MA organization or Part D sponsor to review its administrative data for Patient Safety measures be made by the annual deadline set by CMS for the applicable Star Ratings year. Similar to the implementation of §§ 422.164(h)(1) and (2) and 423.184(h)(1) and (2), to provide flexibility to set the deadline contingent on the timing of the availability of data for plans to review, we intend to announce the deadline in advance either through the process described for changes in and adoption of payment and risk adjustment policies section 1853(b) of the Act (that is, the annual Advance Notice and Rate Announcement) or an HPMS memorandum.

Given the timing of the publication of the Advance Notice of Methodological Changes for Calendar Year (CY) 2025 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies and of this proposal, we intend

to announce the deadline for measurement year 2025 in the final rule, should this proposal be finalized. In subsequent years, we will announce annual deadlines in advance via annual Advance Notice and Rate Announcement, or by a HPMS memorandum. For the 2025 measurement year (2027 Star Ratings), we expect this deadline to be May 18, 2026. In establishing this deadline, we factored in data completeness along with operational deadlines to produce the final Star Ratings. These requests may be time-consuming to review, and it is beneficial to receive the requests before the final rates are calculated and before the first plan preview. Historically, we find that PDE data for performance measurement are complete by April of the following year (that is, PDE data for Year of Service (YOS) 2025 is generally complete by April of 2026) even though the PDE submission deadline is established at the end of June following the payment year.

E. Categorical Adjustment Index (§§ 422.166(f)(2) and 423.186(f)(2))

We propose to calculate the percentage LIS/DE enrollees and percentage disabled enrollees used to determine the Categorical Adjustment Index (CAI) adjustment factor in the case of contract consolidations based on the combined contract enrollment from all contracts in the consolidation beginning with the 2027 Star Ratings. The methodology for the CAI is codified at §§ 422.166(f)(2) and 423.186(f)(2). The CAI adjusts for the average within-contract disparity in performance associated with the percentages of enrollees who receive a low-income subsidy or are dual eligible (LIS/DE) or have disability status within that contract. Currently, the percentage LIS/DE enrollees and percentage disabled enrollees for the surviving contract of a consolidation that are used to determine the CAI adjustment factor are calculated using enrollment data for the month of December for the measurement period of the Star Ratings year for the surviving contract as described at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B). To more accurately reflect the membership of the surviving contract after the consolidation, we propose to determine the percentage LIS/DE enrollees and percentage disabled enrollees for the surviving contract by combining the enrollment data across all contracts in the consolidation.

We propose to modify §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) to calculate the percentage LIS/DE enrollees and the

percentage disabled enrollees for the surviving contract for the first two years following a consolidation by combining the enrollment data for the month of December for the measurement period of the Star Ratings year across all contracts in the consolidation. Once the enrollment data are combined across the contracts in the consolidation, all other steps described at §§ 422.166(f)(2)(i)(B) and 423.186(f)(2)(i)(B) for determining the percentage LIS/DE enrollees and percentage disabled enrollees would remain the same, but we are proposing to restructure that regulation text into new paragraphs (f)(2)(i)(B)(2) through (4). We are proposing this change since §§ 422.166(b)(3) and 423.186(b)(3) do not address the calculation of enrollment for the CAI in the event of a contract consolidation; rather, they focus on the calculation of measure scores in the case of consolidations.

F. Health Equity Index Reward
(§§ 422.166(f)(3) and 423.186(f)(3))

We are proposing how to calculate the health equity index (HEI) reward in the case of contract consolidations beginning with the 2027 Star Ratings. (The 2027 Star Ratings will be the first Star Ratings to include the HEI.) The methodology for the HEI reward is codified at §§ 422.166(f)(3) and 423.186(f)(3). The HEI rewards contracts for obtaining high measure-level scores for the subset of enrollees with the specified social risk factors (SRFs). The goal of the HEI reward is to improve health equity by incentivizing MA, cost, and PDP contracts to perform well among enrollees with specified SRFs. In calculating the HEI reward for the surviving contract of a consolidation, we want to avoid masking the scores of contracts with low performance among enrollees with the specified SRFs under higher performing contracts. We also want to avoid masking contracts that serve relatively few enrollees with the specified SRFs under contracts that serve relatively many more of these enrollees.

For the first year following a consolidation, we propose to add new paragraphs §§ 422.166(f)(3)(viii)(A) and 423.186(f)(3)(viii)(A) to assign the surviving contract of a consolidation the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using enrollment from July of the most recent measurement year used in calculating the HEI reward; the existing rules laid out at §§ 422.162(b)(3)(iv) and 423.182(b)(3)(iv) address how CMS will handle combining measures scores for consolidations, but do not address how CMS will handle the calculation of the

HEI when contracts consolidate since the HEI is not a measure. We propose that contracts that do not meet the minimum percentage of enrollees with the specified SRF thresholds or the minimum performance threshold described at §§ 422.166(f)(3)(vii) and 423.186(f)(3)(vii) would have a reward value of zero used in calculating the enrollment-weighted mean reward. For the second year following a consolidation, we propose at new paragraphs §§ 422.166(f)(3)(viii)(B) and 423.186(f)(3)(viii)(B) that, when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score would be combined across the contracts in the consolidation prior to calculating the HEI score. The HEI score for the surviving contract would then be used to calculate the HEI reward for the surviving contract following the methodology described in §§ 422.166(f)(3)(viii) and 423.186(f)(3)(viii).

G. Quality Bonus Payment Rules
(§ 422.260)

Sections 1853(n) and 1853(o) of the Act require CMS to make QBP to MA organizations that achieve at least 4 stars in a 5-star quality rating system. In addition, section 1854(b)(1)(C) of the Act ties the share of savings that MA organizations must provide to enrollees as the beneficiary rebate to the level of an MA organization's QBP rating. The administrative review process for an MA contract to appeal its QBP status is laid out at § 422.260(c). As described in the final rule titled "Medicare Program; Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012 and Other Changes," which was published in the **Federal Register** on April 15, 2011 (76 FR 21490–91), § 422.260(c)(1) and (2) create a two-step administrative review process that includes a request for reconsideration and a request for an informal hearing on the record, and § 422.260(c)(3) imposes limits on the scope of requests for an administrative review. We propose to revise the language at § 422.260(c)(2)(vii) to provide the CMS Administrator the opportunity to review and modify the hearing officer's decision within 10 business days of its issuance. We propose that if the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding. Under this proposal, if the Administrator does review and modify the hearing officer's decision, a new decision will be issued as directed by the Administrator. If finalized, this proposed amendment

would be implemented for all QBP appeals after the effective date of the final rule.

VIII. Improvements for Special Needs Plans

A. Verification of Eligibility for C-SNPs
(§ 422.52(f))

Section 1859(b)(6) of the Act defines specialized MA plans for special needs individuals, as well as the term "special needs individual." Section 1859(f)(1) of the Act provides that notwithstanding any other provision of Part C of the Medicare statute and in accordance with regulations of the Secretary, an MA special needs plan (SNP) may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals. The regulation governing eligibility for MA SNPs is at § 422.52. In addition to meeting the definition of a special needs individual in § 422.2 and the general eligibility requirements for MA enrollment in § 422.50, an individual must meet the eligibility requirements for the specific MA SNP in which the individual seeks to enroll. Currently, § 422.52(f) provides that each MA SNP must employ a process approved by CMS to verify the eligibility of each individual enrolling in the SNP. CMS adopted this provision in paragraph (f) in the final rule with comment period "Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions," which appeared in the **Federal Register** on January 12, 2009 (74 FR 1494). Historically, we have provided operational guidance related to eligibility criteria for enrollment in an MA SNP that exclusively enrolls individuals who meet the definition of special needs individual under § 422.2 in our sub-regulatory manuals.¹⁴⁸

We propose to revise paragraph § 422.52(f) to codify, with minor modifications and clarifications, our longstanding guidance on procedural steps MA plans must take to verify an individual's eligibility for enrollment in a chronic condition SNP (C-SNP). C-SNPs are SNPs that restrict enrollment to special needs individuals with specific severe or disabling chronic conditions, defined at § 422.2. By codifying the verification requirements, we intend to provide transparency and stability for MA organizations offering C-SNPs and other interested parties

¹⁴⁸ This guidance can be found at <https://www.cms.gov/files/document/cy2021-ma-enrollment-and-disenrollment-guidance.pdf> and <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf>.

about this aspect of the MA program. It will also clarify the SNP's roles and responsibilities and further assist MA organizations in meeting the requirements pertaining to verification of eligibility for C-SNPs.

Specifically, we propose in new § 422.52(f)(1) to codify existing guidance stating that for enrollments into a C-SNP, the MA organization must contact the individual applicant's current physician to confirm that the enrollee has the specific severe or disabling chronic condition(s). Although the current sub-regulatory guidance in chapter 16-B, section 40.2.1 of the Medicare Managed Care Manual refers only to the applicant's existing provider, we believe that a physician—either the applicant's primary care physician or a specialist treating the qualifying condition(s)—should provide the required verification of the applicant's condition to ensure the accuracy and integrity of the verification process. Therefore, we are proposing to use the term “physician” throughout proposed new § 422.52(f).

To further clarify the verification process, we also propose in new § 422.52(f)(1)(i) that the physician must be the enrollee's primary care physician or specialist treating the chronic condition, or conditions in the case of an individual seeking enrollment in a multi-condition C-SNP. The MA organization may either (1) as proposed at new § 422.52(f)(1)(i), contact the applicant's physician or physician's office and obtain verification of the condition prior to enrollment, or (2) as proposed at new § 422.52(f)(1)(ii), use a Pre-enrollment Qualification Assessment Tool (PQAT) prior to enrollment and subsequently (which can be after enrollment) obtain verification of the condition(s) from the enrollee's physician no later than the end of the individual's first month of enrollment in the C-SNP.¹⁴⁹ Both proposed options are discussed in the current guidance. We continue to believe that these procedures will allow the MA organization to efficiently serve

special needs populations while maintaining the integrity of SNP offerings under the MA program.

As part of this process, we propose at new § 422.52(f)(1)(i) that verification of the chronic condition(s) from the applicant's primary care physician or treating specialist must be in a form and manner authorized by CMS. Existing guidance states that this verification can be in the form of a note from a provider or the provider's office or documented telephone contact with the physician or physician's office confirming that the enrollee has the specific severe or disabling chronic condition. These would remain acceptable under this proposal. Performing this pre-enrollment verification with the applicant's primary care physician or specialist treating the qualifying condition will mean that the C-SNP may process the enrollment promptly.

Use of the PQAT requires both pre-enrollment and post-enrollment actions by the C-SNP to conduct an assessment and subsequently confirm the information. The PQAT, per existing guidance,¹⁵⁰ would collect information about the chronic condition(s) targeted by the C-SNP directly from the enrollee and must include a signature line for a physician to confirm the individual's eligibility for C-SNP enrollment. In order for the PQAT to be complete, a physician must be the person who goes through the PQAT with the enrollee. The physician that goes through the PQAT with the enrollee can be either the enrollee's physician or a physician employed or contracted by the plan. A physician must later review the document to confirm that the information supports a determination that the enrollee is eligible for the C-SNP, even without their presence at the time of the determination by the physician. The physician providing the review and signature must be the enrollee's physician. Ultimately, a physician's review of and signature on the completed PQAT provide verification of the applicant's special needs status with regards to the applicable chronic condition(s). Currently, C-SNPs are not required to submit the PQAT to CMS for review and approval before the PQAT is used by the C-SNP and CMS proposes to codify that policy. The PQAT must meet the standards articulated in proposed § 422.52(f)(1)(ii)(A), and therefore review and approval of plan-specific tools by CMS are not required.

- As proposed at § 422.52(f)(1)(ii)(A)(1), the PQAT must include a set of clinically appropriate questions relevant to the chronic condition(s) on which the C-SNP focuses. For example, an MA organization sponsoring a Diabetes Mellitus C-SNP would perhaps include questions related to diagnoses of diabetes, such as blood glucose level or whether the enrollee is currently taking a medication for diabetes mellitus.

- As proposed at § 422.52(f)(1)(ii)(A)(2), the PQAT must gather information on the applicant's past medical history, current signs and/or symptoms, and current medications sufficient to provide reliable evidence that the applicant has the applicable condition(s).

- As proposed at § 422.52(f)(1)(ii)(A)(3), the PQAT must include the date and time of the assessment if completed during a face-to-face interview with the applicant, or the receipt date if the C-SNP receives the completed PQAT by mail or by electronic means (if available).

- As proposed at § 422.52(f)(1)(ii)(A)(4), the PQAT must include a signature line for and be signed by a physician to confirm the individual's eligibility for C-SNP enrollment. (We are also proposing that this signature be from the applicant/enrollee's primary care physician or treating specialist.)

- As proposed at § 422.52(f)(1)(ii)(B), the C-SNP must conduct a post-enrollment confirmation of each enrollee's information and eligibility using medical information (medical history, current signs and/or symptoms, diagnostic testing, and current medications) provided by the enrollee's primary care physician or the specialist treating the enrollee's chronic condition.

- As proposed at § 422.52(f)(1)(ii)(C), the C-SNP must include the information gathered in the PQAT and used in this verification process in the records related to or about the enrollee that are subject to the confidentiality requirements in § 422.118.

- As proposed at § 422.52(f)(1)(ii)(D), the C-SNP must track the total number of enrollees and the number and percent by condition whose post-enrollment verification matches the pre-enrollment assessment and the data and supporting documentation must be made available upon request by CMS.

In addition, we propose to codify at § 422.52(f)(1)(ii)(E) our longstanding

¹⁴⁹ CMS provides an outline of the Pre-enrollment Qualification Assessment Tool in section 40.2.1 of chapter 16-B of the Medicare Managed Care Manual (MMCM). In 2017, CMS released a memo entitled, “Discontinuation of CMS Approval Process for C-SNP Pre-Enrollment Qualification Assessment Tool,” stating that we would no longer require chronic condition special needs plans (C-SNPs) to seek CMS approval prior to using a Pre-Enrollment Qualification Assessment Tool. CMS approval is granted for tools that meet the standards articulated in section 40.2.1 of the MMCM and individual review and approval of plan-specific tools is not required. Therefore, MA organizations are no longer required to submit these tools individually to CMS for approval so long as the standards outlined in the guidance are met.

¹⁵⁰ This guidance can be found in chapter 16-B, Special Needs Plans, section 40.2 of the Medicare Managed Care Manual.

guidance¹⁵¹ to MA organizations offering C-SNPs that choose to use a PQAT that the MA organization has until the end of the first month of enrollment to confirm that the individual has the qualifying condition(s) necessary for enrollment into the C-SNP. If the C-SNP cannot confirm that the enrollee has the qualifying condition(s) within that time, the C-SNP has the first seven calendar days of the following month (*i.e.*, the second month of enrollment) in which to send the enrollee notice of disenrollment for not having the qualifying condition(s). Disenrollment is effective at the end of the second month of enrollment; however, as also outlined in current guidance, the C-SNP must continue the individual's enrollment in the C-SNP if confirmation of the qualifying condition(s) is obtained at any point prior to the end of the second month of enrollment. We propose to codify at § 422.52(f)(1)(ii)(F), consistent with existing guidance, that the C-SNP must continue the enrollment of the individual in the C-SNP if the C-SNP confirms the qualifying condition(s) prior to the disenrollment effective date.

Lastly, we propose to codify at § 422.52(f)(1)(iii) that the C-SNP is required to have the individual's current physician (primary care physician or specialist treating the qualifying condition) administer the PQAT directly with the enrollee or provide confirmation (with or without the presence of the enrollee) that the information in the document supports a determination that the individual is eligible for the C-SNP. Once the physician has confirmed that the PQAT contains information that supports the applicant's chronic condition and signs it, the PQAT is complete. Without a physician's signature, the process is incomplete, and thus, the applicant must be denied enrollment if the enrollment has not yet happened or disenrolled by the end of the second month if the applicant had been enrolled. If the individual is disenrolled because the person's eligibility cannot be verified, SNPs must recoup any agent/broker compensation consistent with § 422.2274(d)(5)(ii).

These proposals represent the codification of existing guidance outlining the procedural steps MA organizations currently take to verify an individual's eligibility for enrollment in a C-SNP, with minor modifications and clarifications. Therefore, we believe that

this proposal would not result in a new or additional paperwork burden, as the policy to verify eligibility for C-SNPs has been in existence for some time. All burden impacts related to the SNP eligibility verification procedures have already been accounted for under OMB control number 0938-0753 (CMS-R-267). These requirements have been previously implemented and are currently being followed by MA organizations. Similarly, we do not believe the proposed changes would have any impact to the Medicare Trust Fund.

B. I-SNP Network Adequacy

In accordance with § 422.116, CMS conducts evaluations of the adequacy of provider networks of all MA coordinated care plans to ensure access to covered benefits for enrollees. For MA coordinated care plans, which generally base coverage or cost sharing on whether the provider that furnishes services to an MA enrollee is in-network or out-of-network, these evaluations are particularly important. All MA special needs plans (SNP) are coordinated care plans and subject to the current requirements for network adequacy. Within the MA program, SNPs are classified into three distinct types: Chronic Care special needs plan (C-SNP), Dual Eligible special needs plan (D-SNP), and Institutional special needs plan (I-SNP). An I-SNP is a SNP that restricts enrollment to MA-eligible individuals who meet the definition of institutionalized and institutionalized-equivalent. One specific subtype of I-SNP is the facility-based I-SNP. Here, we use the term ("facility-based I-SNP") to refer to an I-SNP that restricts enrollment to MA-eligible individuals who meet the definition of institutionalized; owns or contracts with at least one institution, specified in the definition of institutionalized in § 422.2, for each county within the plan's county-based service area; and owns or has a contractual arrangement with each institutional facility serving enrollees in the plan. Historically, the I-SNP industry has stated that CMS's current network adequacy criteria under § 422.116 create challenges for facility-based I-SNPs because facility-based I-SNP enrollees access services and seek care in a different way than enrollees of other plan types.

In the "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of

All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications" proposed rule, which appeared in the **Federal Register** on December 27, 2022 (87 FR 79452) ("the December 2022 proposed rule"), we explained in detail how I-SNPs restrict enrollment to MA-eligible individuals who are institutionalized or institutionalized-equivalent, as those terms are defined in § 422.2 and proposed new definitions for the different types of I-SNPs. As a result, the enrollees in I-SNPs are individuals who continuously reside in or are expected to continuously reside for 90 days or longer in one of the specified facilities listed in the definition of "institutionalized" at § 422.2 or individuals ("institutionalized-equivalent") who are living in the community but require an institutional level of care. We refer readers to the December 2022 proposed rule for a more detailed discussion of the eligibility requirements for I-SNPs. (87 FR 79566 through 79568) See also chapter 16-B, section 20.3 of the Medicare Managed Care Manual.¹⁵² Our use of the term "facility-based I-SNP" in this proposed rule aligns with the proposed definition of "Facility-based Institutional special needs plan (FI-SNP)" in the December 2022 proposed rule.

Per section 1859(f)(2) of the Act, I-SNPs restrict enrollment to MA-eligible individuals who, for 90 days or longer, have had or are expected to need the level of services provided in a long-term care (LTC) facility, which includes: a skilled nursing facility (SNF), a nursing facility (NF), an intermediate care facility for individuals with intellectual disabilities (ICF/IDD), an inpatient psychiatric hospital, a rehabilitation hospital, an LTC hospital, or a swing-bed hospital. See § 422.2 for the definition of "institutionalized" for the details of the types of facilities. Facility-based I-SNPs serve a vulnerable cohort of Medicare beneficiaries with well over 95 percent of facility-based I-SNP enrollees being eligible for both Medicare and Medicaid. Generally, facility-based I-SNP enrollees reside either temporarily or permanently in an institution, therefore, these enrollees typically receive most of their health care services through or at the facility in which they reside, most often a SNF. As a result of the way that these enrollees receive covered services, CMS's established network adequacy time and distance standards under § 422.116 may

¹⁵¹ This guidance can be found in chapter 2, section 20.10, and chapter 16-B, Special Needs Plans, section 40.2 of the Medicare Managed Care Manual.

¹⁵² <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/mc86c16b.pdf>.

not be a meaningful way to measure provider network adequacy for and ensure access to covered benefits for enrollees of this plan type. Time and distance standards are created using several factors, including pattern of care. In order to comply with the network evaluation requirements in § 422.116, a facility-based I-SNP must contract with sufficient providers of the various specialties within the time and distance requirements specified in that regulation. The I-SNP industry has indicated through public comments and in prior correspondence to CMS that many facility-based I-SNPs have difficulty contracting with providers outside their facilities, due to their model of care. This is because these providers know that enrollees of the I-SNP will not routinely seek care with these providers since they generally do not travel away from the facility for care.

The MA organizations offering and those that are interested in offering facility-based I-SNPs have raised questions about whether our network standards are appropriate considering the nature of the facility-based I-SNP coverage model. The residential nature of this model creates inherent differences in patterns of care for facility-based I-SNP enrollees as compared to the prevailing patterns of community health care delivery in other MA plan types. For example, most residents of a facility receive their care from a provider at the facility rather than traveling to a provider outside the facility whereas individuals who live at home in the community would need to travel to a provider to receive health care services.

To address these concerns, CMS is proposing to adopt a new exception for facility-based I-SNP plans from the network evaluation requirements. This provision would apply only to facility-based I-SNPs.

CMS adopted minimum access requirements for MA coordinated care plans (which include all SNPs) in § 422.112 and network evaluation criteria in § 422.116 as means to implement and ensure compliance with section 1852(d)(1)(A) of the Act, which permits MA plans to limit coverage to items and services furnished by or through a network of providers subject to specific exceptions (such as emergency medical services) and so long as the MA organization makes benefits available and accessible to their enrollees. Currently, § 422.116(f) allows an MA plan to request an exception to network adequacy criteria when both of the following occur: (1) certain

for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file (that is, a cross-sectional database that includes information on provider and facility name, address, national provider identifier, and specialty type and is posted by State and specialty type); and (2) the MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care. In evaluating exception requests, CMS considers whether: (i) the current access to providers and facilities is different from the Health Service Delivery (HSD) reference file (as defined at 42 CFR 422.116(a)(4)(i)) and Provider Supply files for the year; (ii) there are other factors present, in accordance with § 422.112(a)(10)(v), that demonstrate that network access is consistent with or better than the Traditional Medicare pattern of care; and (iii) the approval of the exception is in the best interests of beneficiaries.

CMS has provided examples of situations that meet the first requirement for an exception to be requested in sub-regulatory guidance, specifically the Medicare Advantage and section 1876 Cost Plan Network Adequacy Guidance.¹⁵³ The following examples of situations where providers or facilities are not available to contract with the MA plan do not account for the issues that are unique to facility-based I-SNPs:

- Provider is no longer practicing (for example, deceased, retired),
- Provider does not contract with any organizations or contracts exclusively with another organization,
- Provider does not provide services at the office/facility address listed in the supply file,
- Provider does not provide services in the specialty type listed in the supply file,
- Provider has opted out of Medicare, or
- Provider is sanctioned and on the List of Excluded Individuals and Entities.

In addition, the use of Traditional Medicare telehealth providers or mobile providers and the specific patterns of care in a community that would be the basis for an approval exception do not account for the provider network issues unique to facility-based I-SNPs that we propose to address in this rule. Therefore, we are proposing to amend

our network adequacy regulations at § 422.116(f) to establish an additional exception to the current CMS network adequacy requirements outlined in § 422.116 and we are proposing that this exception be specific to facility-based I-SNPs. Under this proposal, facility-based I-SNPs would not be required to meet the current two prerequisites to request an exception from the network adequacy requirements in § 422.116 but would have alternate bases on which to request an exception.

First, CMS is proposing to broaden the acceptable rationales for an exception from the requirements in § 422.116(b) through (e) for facility-based I-SNPs. We are proposing that a facility-based I-SNP may request an exception from the network adequacy requirements in § 422.116 when one of two situations occurs. To add these proposed new rationales to § 422.116(f)(1), we are reorganizing the current regulation text; the two current requirements for an exception request will be moved to new paragraphs (f)(1)(i)(A) and (B) and the proposed new rationales for an exception request will be in new paragraphs (f)(1)(ii)(A) and (B). Second, we are proposing new considerations CMS will use when determining whether to grant an exception under § 422.116(f) that are specific to the proposed new acceptable rationales for an exception request. We are proposing to add a new paragraph (f)(2)(iv) to specify the proposed new considerations that will apply to the new exceptions for facility-based I-SNPs, which will be added to the existing considerations in § 422.116(f)(2).

Our proposal includes new bases on which only facility-based I-SNPs may request an exception from the network adequacy requirements, additional considerations for CMS when deciding whether to approve an exception request from a facility-based I-SNP, and a new contract term for facility-based I-SNPs that receive the exception from the § 422.116 network adequacy evaluation. Because we evaluate network adequacy and grant an exception at the contract level, the proposed new exception is limited to contracts that include only facility-based I-SNPs.

The first proposed new basis for an exception request is that a facility-based I-SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I-SNPs receive care. For purposes of this first proposed new basis for an exception, the inability to contract means the MA organization offering the facility-based

¹⁵³ <https://www.cms.gov/files/document/medicare-advantage-and-section-1876-cost-plan-network-adequacy-guidance08302022.pdf>.

I-SNP could not successfully negotiate and establish a contract with a provider, including individual providers and facilities. This is broader than the existing condition for an exception that certain providers are unavailable for the MA plan. The non-interference provision at section 1854(a)(6) of the Act prohibits CMS from requiring any MA organization to contract with a particular hospital, physician, or other entity or individual to furnish items and services or require a particular price structure for payment under such a contract. As such, CMS cannot assume the role of arbitrating or judging the bona fides of contract negotiations between an MA organization and available providers or facilities. Currently, CMS does not regard an MA organization's inability to contract with a provider as a valid rationale for an exception from the network adequacy evaluation but interested parties have indicated through public comments and in prior correspondence to CMS that, historically, facility-based I-SNP plans have encountered significant struggles contracting with the necessary number of providers to meet CMS network adequacy standards due to their unique care model. We propose to add this new basis for an exception request to § 422.116(f)(1)(ii)(A). CMS is also proposing that its decision whether to approve an exception for a facility-based I-SNP on this specific basis (that the I-SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I-SNPs receive care) will be based on whether the facility-based I-SNP submits evidence of the inability to contract with certain specialty types required under § 422.116 due to the way enrollees in facility-based I-SNPs receive care. For example, an organization could submit letters or emails to and from the providers' offices demonstrating that the providers were declining to contract with any facility-based I-SNP. CMS proposes to add this requirement in a new paragraph (f)(2)(iv)(A). Under this proposal, CMS will also consider the existing factors in addition to the new factors proposed here that are unique to the specific new exception proposed for facility-based I-SNPs. We solicit comment on this proposed new rationale for an exception from the network adequacy requirements in § 422.116(b) through (e) and on the type of evidence we should consider in determining whether to grant an exception.

We are also proposing a second basis on which a facility-based I-SNP may

request an exception from the network adequacy requirements in § 422.116(b) through (e) if:

(1) A facility-based I-SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (in compliance with § 422.135) when using telehealth providers of the specialties listed in paragraph (d)(5) in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e).

(2) Substantial and credible evidence that sufficient and adequate access to basic benefits is provided to enrollees using additional telehealth benefits (in compliance with § 422.135) furnished by providers of the specialties listed in paragraph (d)(5) of this section and the facility-based I-SNP covers out-of-network services furnished by a provider in person when requested by the enrollee as provided in § 422.135(c)(1) and (2), with in-network cost sharing for the enrollee.

We believe it is appropriate to permit exceptions in these situations because enrollees in facility-based I-SNP plans do not generally travel to receive care, so the time and distance standards that apply to other plan types are not appropriate for I-SNP plans. As part of this proposal, we are proposing to add to the factors that CMS will consider whether to approve the exception request a new factor specifically related to this type of exception.

Finally, we are proposing regulation text to ensure that the exception for facility-based I-SNPs is used by and available only to facility-based I-SNPs. We are proposing a new paragraph (f)(3) at § 422.116 to require any MA organization that receives the exception provided for facility-based I-SNPs to agree to offer only facility-based I-SNPs on the contract that receives the exception. To support the provision outlined at § 422.116(f)(3), CMS also proposes to add, at § 422.504(a)(21), a new contract provision that MA organizations must not establish additional plans (or plan benefit packages, called PBPs) that are not facility-based I-SNPs to a contract that is within the scope of proposed § 422.116(f)(3). This will ensure MA organizations that have received the exception do not submit additional PBPs that are not facility-based I-SNPs to their facility-based I-SNP-only contracts. CMS reviews networks at the contract level which means if an MA organization were to add an MA plan (that is, a PBP) that is not a facility-based I-SNP to a contract, the exception we propose here would not be appropriate. We welcome comment on this aspect of our proposal and whether

additional guardrails are necessary to ensure that the proposed new exception from network adequacy evaluations is limited to facility-based I-SNPs consistent with our rationale for it.

Under our proposal, facility-based I-SNPs would still be required to adhere to § 422.112 regarding access to covered benefits. For example, § 422.112(a)(1)(iii) requires an MA coordinated care plan to arrange for and cover any medically necessary covered benefit outside of the plan provider network, but at in-network cost sharing, when an in-network provider or benefit is unavailable or inadequate to meet an enrollee's medical needs. Because all SNPs, including facility-based I-SNPs, are coordinated care plans, this beneficiary protection applies to them. Similarly, the timeliness of access to care requirements newly adopted at § 422.112(a)(6)(i) would apply. We believe that our proposal appropriately balances the need to ensure access to covered benefits for enrollees in facility-based I-SNPs while recognizing the unique way this type of MA plan furnishes benefits and how enrollees generally receive services at the institution where the enrollee resides. Expanding this proposed new exception from the § 422.116 network adequacy requirements to other I-SNPs that enroll special needs individuals that reside in the community or other SNPs or MA plans that are not designed to furnish services to institutionalized special needs individuals would not be appropriate or serve the best interests of the Medicare program or Medicare beneficiaries.

We request comment on this proposal.

C. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38)

Dually eligible individuals face a complex range of enrollment options based on MA plan types (that is, HMOs, PPOs, private fee-for-service plans, MA special needs plans, etc.), enrollment eligibility, and plan performance, but which do not consider the enrollee's Medicaid choice. Further, many of the coverage options available to dually eligible individuals—even including many dual eligible special needs plans (D-SNP)—do not meaningfully integrate Medicare and Medicaid, chiefly because the parent organization of the D-SNP does not also provide the enrollee's Medicaid services. The current managed care enrollment and eligibility policies have resulted in a proliferation of such D-SNPs and leave dually eligible

individuals susceptible to aggressive marketing tactics from agents and brokers throughout the year.

Over the last decade, we have taken numerous steps to improve the experiences and outcomes for dually eligible individuals through various forms of Medicare-Medicaid integrated care. Despite progress, there remain a significant number of enrollees who receive Medicare services through one managed care entity and Medicaid services through a different entity (misaligned enrollment), rather than from one organization delivering both Medicare and Medicaid services (aligned enrollment¹⁵⁴). In the final rule titled Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021 (CMS-4185-F) (hereinafter referred to as the April 2019 final rule), we expressed our belief that aligned enrollment, and especially exclusively aligned enrollment, is a critical part of improving experiences and outcomes for dually eligible individuals. Exclusively aligned enrollment (EAE) occurs when enrollment in a parent organization's D-SNP is limited to individuals who are also enrolled in that organization's Medicaid managed care organization. Congress' advisory commissions have emphasized similar themes: the Medicare Payment Advisory Commission (MedPAC) has "long believed that D-SNPs should have a high level of integration so they have the proper incentives to coordinate care across Medicare and Medicaid."¹⁵⁵ The

Medicaid and CHIP Payment and Access Commission's (MACPAC's) "long-term vision is for all dually eligible beneficiaries to be enrolled in an integrated model"¹⁵⁶ and has noted that a key feature of integrated care is "financial alignment where a single entity receives a single payment to cover all Medicare and Medicaid services."¹⁵⁷

Longer term, for dually eligible individuals who are in Medicare and Medicaid managed care, we believe that we should continue to drive toward increasing aligned enrollment until it is the normative, if not only, managed care enrollment scenario. Our proposals here represent an incremental step in that direction, balancing our long-term policy vision with our interest in limiting disruption in the short term. For dually eligible individuals that elect MA plans, we are focused on increasing enrollment in integrated D-SNPs: fully integrated dual eligible special needs plans (FIDE SNPs),¹⁵⁸ highly integrated dual eligible special needs plans (HIDE SNPs),¹⁵⁹ and applicable integrated plans (AIPs).¹⁶⁰ These D-SNP types

more meaningfully integrate Medicare and Medicaid services than coordination-only D-SNPs¹⁶¹ that are not also AIPs.

In this section we describe interconnected proposals that would (1) replace the current quarterly special enrollment period (SEP) with a one-time-per month SEP for dually eligible individuals and other LIS eligible individuals to elect a standalone PDP, (2) create a new integrated care SEP to allow dually eligible individuals to elect an integrated D-SNP on a monthly basis, (3) limit enrollment in certain D-SNPs to those individuals who are also enrolled in an affiliated Medicaid managed care organization (MCO), and (4) limit the number of D-SNPs an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, can offer in the same service area as an affiliated Medicaid MCO in order to reduce "choice overload" of D-SNP options in certain markets. Affiliated Medicaid MCOs are Medicaid MCOs offered by the MA organization, the same parent organization, or another subsidiary of the parent organization. In combination, our proposals would create more opportunities for dually eligible individuals to elect integrated D-SNPs, more opportunities to switch to Traditional Medicare, and fewer opportunities to enroll in MA-PD plans that do not integrate Medicare and Medicaid services. Table HC1 summarizes the combined effects of these proposals, then we describe each proposal in greater detail.

of the following: home health services, medical supplies, equipment and appliances (DME), or nursing facility services.

¹⁶¹ Dual eligible special needs plans (D-SNPs) are defined at § 422.2. "Coordination-only" D-SNPs are D-SNPs that neither meet the FIDE SNP nor HIDE SNP definition at § 422.2 and for which there are no Federal requirements to cover any Medicaid benefits either directly or through an affiliated Medicaid managed care plan.

¹⁵⁴ 42 CFR 422.2 (definition of "aligned enrollment").

¹⁵⁵ MedPAC response to Congressional request for information on dual-eligible beneficiaries, page 2, January 13, 2023.

¹⁵⁶ MACPAC response to proposed rule on policy and technical changes to Medicare Advantage and Medicare Part D for contract year 2024 (CMS-4201-P), page 1, February 13, 2023.

¹⁵⁷ MACPAC response to request for information on data and recommendations to improve care for dually eligible beneficiaries, page 3, January 13, 2023.

¹⁵⁸ Effective 2025, FIDE SNPs as defined in § 422.2 are required to have EAE and would therefore be AIPs by definition. To receive the FIDE designation, a D-SNP would be required to provide nearly all Medicaid services, including long-term services and supports, Medicaid behavioral health services, home health and DME.

¹⁵⁹ HIDE SNPs as defined in § 422.2 are required to cover long-term services and supports or behavioral health services but may have more Medicaid services carved out relative to plans with the FIDE designation. HIDE SNPs that also operate with EAE would meet the definition of an AIP, but there is no requirement for EAE for the HIDE designation.

¹⁶⁰ AIPs as defined in § 422.561 are D-SNPs with EAE, where the companion Medicaid MCO covers Medicaid benefits including primary care and acute care, Medicare cost-sharing, and at a minimum one

TABLE HC1: ENROLLMENT SCENARIOS UNDER CURRENT RULES AND PROPOSED AMENDMENT—INDIVIDUAL PERSPECTIVE*(NOTE: This table does not include other applicable seps)*

Scenarios for Dually Eligible Individuals	Current Rules under Quarterly Dual SEP	Proposed Monthly Dual/LIS SEP, Integrated Care SEP, and Enrollment Limitations for Non-Integrated MA-PD Plans
Elect any MA plan during initial coverage election period (ICEP) or annual election period (AEP), or switch between any plans during MA open enrollment period (MA-OEP)	Permitted	Permitted, except individuals in Medicaid MCOs would not be able to select a misaligned D-SNP where applicable ¹⁶²
Elect Medicare fee-for-service (FFS) and standalone prescription drug plan (PDP), mid-year	One change permitted per quarter (except the last quarter)	Permitted each month
Elect an integrated D-SNP (FIDE SNP, HIDE SNP, or AIP) as eligible, mid-year		Permitted each month, but must be aligned enrollment
Elect a non-integrated D-SNP or other MA plan, mid-year		Not permitted
Scenarios for LIS individuals without Medicaid	Current rules	As proposed
Elect any MA plan during ICEP or AEP, or switches between any plans during MA-OEP	Permitted	Permitted
Elect Medicare FFS and standalone PDP, mid-year	One change permitted per quarter (except the last quarter)	Permitted each month
Elect an MA plan, mid-year		Not permitted

Our proposals create a new SEP and revise the duals/LIS SEP, but otherwise do not change the remaining SEPs. To highlight the changes in our proposals without overly complicating this table, we did not reference the other SEPs.

1. Changes to the Special Enrollment Periods for Dually Eligible Individuals and Other LIS Eligible Individuals

Section 1860D–1(b)(3)(D) of the Act directs the Secretary to establish a SEP for full-benefit dually eligible individuals under Part D. The SEP, subsequently referred to as the continuous dual SEP, codified at § 423.38(c)(4), was later extended to all other subsidy-eligible beneficiaries by

regulation.¹⁶³ The continuous dual SEP allowed eligible beneficiaries to make Part D enrollment changes (that is, enroll in, disenroll from, or change Part D plans, including Medicare Advantage Prescription Drug (MA–PD) plans) throughout the year, unlike other Part D enrollees who generally may switch plans only during the AEP or via other applicable SEPs each year.

In the April 2018 final rule, we cited concerns with usage of the continuous dual SEP related to enrollees changing plans frequently, hindering care coordination efforts by D–SNPs; plans having less incentive to innovate and

invest in serving high-cost enrollees who may disenroll at any time; and agents and brokers targeting dually eligible individuals due to their ability to make enrollment elections throughout the year (83 FR 16514). We had considered limiting use of the SEP to once per calendar year, limiting use of the SEP to two or three uses per calendar year, or prohibiting use of the SEP for enrollment into non-integrated MA–PD plans, but allowing continuous use of the SEP to allow eligible beneficiaries to enroll into (a) integrated D–SNPs for dually eligible individuals or (b) standalone PDPs (83 FR 16515). We received a mix of concern and support from commenters on our proposals.

¹⁶² We propose that during AEP and other available enrollment periods, MA organizations would not be permitted to enroll dually eligible individuals into a D–SNP where such enrollment would not result in aligned enrollment with an affiliated Medicaid MCO offered in the same service area (that is, a Medicaid MCO offered by the MA organization, its parent organization, or another subsidiary of the parent organization).

¹⁶³ Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (CMS–4085–F) (75 FR 19720 (April 15, 2010)).

Ultimately, the April 2018 final rule amended the continuous dual SEP to allow usage once per calendar quarter during the first nine months of the year (that is, one election during each of the following time periods: January–March, April–June, July–September). We noted that our changes struck a balance between allowing dually eligible individuals opportunities to change plans while also maintaining stability with care coordination and case management (83 FR 16515).

The quarterly dual SEP reduced individuals moving from one Part D plan (including an MA–PD) to another Part D plan (including an MA–PD) as frequently. However, we have concerns with the quarterly dual SEP:

- **Marketing.** We finalized numerous policies to reduce aggressive marketing tactics in the April 2023 final rule,¹⁶⁴ but we remain concerned about marketing opportunities, especially when they focus on dually eligible individuals who, as a group, have lower levels of education, health literacy, and access to resources that could help overcome sub-optimal coverage decisions. Because the quarterly dual SEP still allows the vast majority of dually eligible individuals to enroll in almost any MA–PD plan, they remain a target for marketing activities from all types of plans throughout the year.

- **Ability to enroll in integrated D–SNPs.** The quarterly dual SEP does not allow dually eligible individuals to enroll in integrated D–SNPs after those individuals have exhausted the opportunities allowed by the quarterly dual SEP.

- **Complexity for States.** State Medicaid agencies have shown interest in opportunities to bring Medicare and Medicaid managed care enrollment policies into greater alignment and reduce complexity. The quarterly dual SEP has created some challenges related to aligning Medicare and Medicaid enrollment dates for dually eligible individuals seeking to enroll in integrated products. For example, California needed expenditure authority to waive § 438.56(e)(1) under a section 1115(a) demonstration to allow for a Medicaid MCO disenrollment to be delayed during the last calendar quarter to maintain exclusively aligned enrollment with a corresponding D–SNP. This expenditure authority would not have been necessary if the dual SEP was available to make elections

throughout the year. In the capitated financial alignment models of the Financial Alignment Initiative (FAI), we waived the quarterly dual SEP rules at State request to allow for monthly opportunities for individuals to enroll or disenroll. This alleviated the complexity of different Medicare and Medicaid enrollment periods and allows dually eligible individuals more opportunities to enroll in integrated products.

- **Complexity for enrollment counselors and individuals.** Enrollment counselors such as State Health Insurance Assistance Programs (SHIPs) and State ombudsman programs have also noted that the once-per-quarter rule is complicated. Without any accessible central data source on who has already used the quarterly dual SEP, it is not clear to options counselors (or sometimes to beneficiaries themselves) what enrollment options are truly available to dually eligible individuals at any given time.

To further protect Medicare beneficiaries, reduce complexity for States and enrollment counselors, and increasingly promote integrated care, we are proposing two SEP changes. Section 1860D–1(b)(3)(D) of the Act requires the Secretary to establish special enrollment periods for full-benefit dually eligible individuals, although it does not specify the frequency or mechanics of those SEPs. Further, section 1860D–1(b)(3)(C) of the Act grants the Secretary the authority to create SEPs for individuals who meet other exceptional circumstances.¹⁶⁵ Section 1859(f)(1) of the Act permits the Secretary to set forth regulations related to how MA organizations restrict the enrollment of individuals who are within one or more classes of special needs individuals. Section 1859(f)(6) establishes the authority to adopt a transition process to move dually eligible individuals out of SNPs when they are not eligible for the SNP. Section 1859(f)(8) of the Act also reflects an interest in and goal of furthering the integration of D–SNPs; the requirement for us to establish procedures for unified grievance and appeals processes and requirement, in section 1859(f)(8)(D), for a mandatory minimum level of integration illustrate how efforts to increase integration in implementing and adopting standards for the MA program further the goals of the program. Based on these authorities, we propose to amend § 423.38(c)(4)(i) to replace the quarterly dual SEP with a

simpler new dual/LIS SEP. The proposed dual/LIS SEP would allow dually eligible and other LIS-enrolled individuals to enroll once per month into any standalone prescription drug plan.

Functionally, the revised dual/LIS SEP would mean that such individuals could, in any month, switch PDPs or leave their MA–PD for Traditional Medicare plus a standalone PDP (plans that only offer prescription drug coverage). However, the dual/LIS SEP would no longer permit enrollment into MA–PD plans or changes between MA–PD plans, although such options would still be available where another election period permits.

In conjunction, based on the statutory authorities described above, we also propose to create a new integrated care SEP at § 423.38(c)(35) for dually eligible individuals. This new integrated care SEP would allow enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans.

In combination, our SEP proposals draw heavily from MedPAC's 2008 recommendation to Congress, which proposed eliminating dually eligible individuals' ability to enroll in MA–PD plans, except special needs plans with State contracts, outside of open enrollment. MedPAC also recommended dually eligible individuals be able to disenroll from an MA–PD plan and return to Traditional Medicare at any time of the year.¹⁶⁶

For dually eligible individuals, our two SEP proposals would allow a *monthly* election to:

- Leave an MA–PD plan for Traditional Medicare by enrolling in a standalone PDP,
- Switch between standalone PDPs, or
- Enroll in an integrated D–SNP such as a FIDE, HIDE, or AIP.

If an eligible individual attempts to use, or uses, both the monthly dual/LIS SEP and the integrated care SEP within the same month, the application date of whichever SEP is elected last in time is the SEP effectuated the first of the following month.

As a result of these proposals, dually eligible and other LIS-eligible individuals, like other Medicare beneficiaries, would be able to enroll into non-AIP coordination-only D–SNPs¹⁶⁷ or other MA plans only during

¹⁶⁴ Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS–4201–F) (88 FR 22122 (April 12, 2023)).

¹⁶⁵ Medicare Program; Policy and Technical Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs (CMS–4085–F) (75 FR 19720 (April 15, 2010)).

¹⁶⁶ Medicare Payment Advisory Commission, "Report to Congress: Medicare Payment Policy," March 2008.

¹⁶⁷ Dual eligible special needs plans (D–SNPs) are defined at § 422.2. "Coordination-only" D–SNPs are

the ICEP, AEP, or where another SEP permits. While the proposed changes constrain some enrollment options at certain times of the year, dually eligible individuals and other LIS-eligible individuals would never have fewer choices than people who are not dually or LIS eligible.

We believe the proposed SEP changes would:

- Create more opportunity for dually eligible or LIS individuals to leave MA–PD plans if MA is not working well for them, by providing an opportunity to enroll in a standalone PDP, which results in disenrollment from the MA–PD plan and enrollment in Traditional Medicare.¹⁶⁸

- Reduce the incentive for most plans to deploy aggressive sales tactics targeted at dually eligible or LIS-enrolled individuals outside of the AEP. Based on our review of 2023 plans, approximately 5 percent of the plans that can currently enroll dually eligible individuals using the quarterly dual SEP would be available as options for dually eligible individuals using the proposed new monthly integrated care SEP.

- Increase transparency for Medicare beneficiaries and enrollment counselors—such as SHIPs—on opportunities to change plans, by eliminating the need to determine whether the current once-per-quarter SEP opportunity had already been used.

- Create more opportunities for enrollment into integrated D–SNPs through which an individual could receive Medicare and Medicaid services and care coordination from the same organization.

- Reduce the burden on States working to align Medicaid MCO enrollment to D–SNP enrollment, particularly for States transitioning their FAI demonstrations to integrated D–SNPs (all FAI demonstration States waived the implementation of the quarterly dual SEP as it proved too operationally challenging to implement for Medicare-Medicaid Plans).

- Strengthen incentives for MA sponsors to also compete for Medicaid managed care contracts.

While there are advantages to the new proposed SEP changes, we recognize there are potential challenges:

- In States with few or no integrated D–SNPs, dually eligible individuals would not be able to change MA–PD plans outside of the AEP, MA–OEP, or

other available SEPs, limiting their ability to change plans as their needs change. Choices outside of AEP, MA–OEP, or other available SEPs would similarly be limited in States where integrated D–SNPs only serve limited geographic regions.

- MA plans may have marginally less incentive to innovate and invest in meeting the needs of high-cost dually eligible enrollees in a situation where these enrollees may disenroll at any time. This could exacerbate the phenomenon of higher-cost dually eligible individuals disenrolling from MA.¹⁶⁹ 170 171

- Some dually eligible individuals would be able to change between integrated care plans monthly, which could hinder care coordination and case management efforts by those plans.

- Finally, since LIS individuals without Medicaid are ineligible for integrated D–SNPs, our proposal would limit how the dual/LIS SEP can be used for these individuals compared to the current scope of the SEP. LIS eligible individuals without full Medicaid and partial-benefit dually eligible individuals would have the opportunity to disenroll from an MA–PD plan (to Traditional Medicare) in any month throughout the year, and could switch between standalone PDPs on a monthly basis, but—with few exceptions—could not use the new integrated care SEP to enroll in an MA–PD.¹⁷² These individuals could elect an MA–PD or non-AIP coordination-only D–SNP for which they are eligible only during the ICEP, the AEP, the MA–OEP (as applicable), or by using a different SEP. We estimate approximately one million partial-benefit dually eligible individuals and other LIS eligible individuals, or 7.5 percent of all individuals with LIS, would no longer be able to make quarterly MA–PD elections.¹⁷³ Dually eligible and other LIS-eligible individuals would also

continue to be eligible, if applicable, for other SEPs outlined in §§ 422.62(b) and 423.38(c), which include circumstances like enrolling into a 5-star plan, change in residence, or enrollment in PACE.¹⁷⁴

Section 423.40(c) currently provides that the effective date of an enrollment change in Part D during a special enrollment period specified in § 423.38(c), including the existing SEP for dually eligible and other LIS-eligible individuals, will be the first day of the calendar month following the month in which the election is made, unless otherwise noted. We are considering using flexibilities at section 1851(f)(4) of the Act (as cross-referenced at section 1860D–1(b)(1)(B)(iv) of the Act) and at § 423.40(c) to establish a Medicare enrollment effective date for the proposed integrated care SEP at § 423.38(c)(35) that differs from the effective date in the current quarterly dual/LIS SEP at § 423.38(c)(4). Establishing a different enrollment effective date could allow better alignment with Medicaid enrollment effective dates, for example, in situations where States are unable to enroll individuals on the first of the month following an enrollment request after a certain cut-off date and delay the effective date until the first of the following month. However, aligning with Medicaid enrollment effective dates may delay enrollment in integrated care plans and prevent dually eligible individuals from selecting an integrated D–SNP on a monthly basis.

We welcome comments on utilizing these flexibilities to establish a different enrollment effective date for the proposed integrated care SEP. See section VIII.E. for further discussion of alignment of enrollment effective dates and a request for comments on this topic.

We also welcome comments on the proposed changes to the dual SEP, the proposed integrated care SEP, and their combined impacts.

2. Enrollment Limitations for Non-Integrated Medicare Advantage Plans

Aligned enrollment is a key feature of the FAI, PACE, and other long-standing integrated care programs such as the Massachusetts' Senior Care Options and Minnesota's Senior Health Options that started as demonstration programs that were precursors to D–SNPs. Individual States may also use their State Medicaid agency contracts (SMAC) to limit

D–SNPs that neither meet the FIDE SNP nor HIDE SNP definition at § 422.2 and are not required to cover any Medicaid benefits.

¹⁶⁸ We note that enrollment in a standalone PDP would not result in automatic disenrollment from a Medicare MA-only Private Fee-for-Service plan unless that plan also offers Part D.

¹⁶⁹ GAO Report to Congressional Requesters, Medicare Advantage Disenrollment, pages 19–20, June 2021.

¹⁷⁰ <https://www.gao.gov/assets/gao-17-393.pdf>.

¹⁷¹ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.0272>.

¹⁷² There is no Federal prohibition on partial-benefit dually eligible individuals enrolling in HIDE SNPs. However, most States limit enrollment in HIDE SNPs to full-benefit dually eligible individuals.

¹⁷³ Section 11404 of the Inflation Reduction Act (IRA) amended section 1860D–14 of the Act to expand eligibility for the full LIS to individuals with incomes up to 150 percent of the Federal poverty level (FPL) beginning on or after January 1, 2024. See Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (CMS–4201–F) (88 FR 22123 (April 12, 2023)).

¹⁷⁴ Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS–4182–F) (83 FR 16516 (April 16, 2018)).

enrollment in a D-SNP to the enrollees in an affiliated Medicaid MCO. Further, we have adopted, as part of the definition in § 422.2, enrollment limits for FIDE SNPs that require, beginning January 1, 2025, FIDE SNPs to have exclusively aligned enrollment.

Separate from contracting with D-SNPs via SMACs, States have discretion in how they arrange their Medicaid managed care programs and may use Medicaid MCOs to cover a comprehensive scope of Medicaid benefits or use prepaid health plans to cover a smaller scope of Medicaid benefits.¹⁷⁵ Many States with Medicaid managed care programs select a limited number of Medicaid MCOs through a competitive procurement process. State approaches vary regarding eligibility for Medicaid MCOs that are part of the State's managed care program (for example, whether plans cover just dually eligible enrollees or additional Medicaid populations), service areas, and carved-in benefits for dually eligible enrollees. While there may be some overlap in plan parent organizations operating both Medicaid MCOs and D-SNPs within a State, it is not always the case.¹⁷⁶ Service areas are commonly misaligned between Medicaid MCOs and D-SNPs. States have the option to pursue EAE when it meets their own Medicaid managed care policy goals and objectives; however, placing responsibility solely on States to implement and facilitate EAE has often led to a complex market of D-SNPs, many of which only meet minimum integration requirements, as well as a complex set of Federal and State enrollment policies for States, plans, advocates, and beneficiaries to navigate.

In many service areas, dually eligible individuals face complicated enrollment policies, overwhelming marketing, and an increasingly complex array of plans purportedly designed especially for them but that do not offer meaningful Medicare and Medicaid integration due to service area and enrollment misalignment. Enrollment in D-SNPs has increased rapidly and now exceeds five million. We estimate that approximately 1.26 million were in aligned enrollment as of July 2022, and this number has also grown over time.¹⁷⁷ However, the majority of D-

SNP enrollment remains in unaligned plans where the individual is either in a non-AIP coordination-only D-SNP or in one parent organization's D-SNP and another parent organization's Medicaid MCO, and the increases in enrollment in such plans has exceeded the increases in enrollment for integrated D-SNPs.¹⁷⁸ Analysis by MedPAC in 2019 found that "14 percent of [D-SNP] enrollees qualify for full Medicaid benefits and are in D-SNPs that have a companion managed long term services and supports (MLTSS) plan run by the same parent company, but they are not enrolled in that MLTSS plan." As MedPAC noted, "some enrollees may not be required to enroll in an MLTSS plan, but for those who are, these cases of misaligned enrollment are unlikely to lead to any meaningful integration given the inherent challenges of coordinating the efforts of two separate managed care companies."¹⁷⁹

While some States have utilized SMACs and selective contracting to limit the availability of D-SNPs in the State to those MA organizations that also have contracts with the State to cover Medicaid services, other D-SNP markets have grown without any limitations on non-integrated plans. In some markets, parent organizations of MA organizations have acquired multiple D-SNPs by purchasing smaller plans and have not consolidated the various plans, resulting in one parent organization operating multiple D-SNPs within a single State, often with overlapping service areas. For States that do not require parent organizations to consolidate their plans, multiple D-SNPs of this type may continue to operate indefinitely. This creates a market with a large number D-SNP options that often do not offer significantly different benefits or

eligible individuals were enrolled in managed care arrangements where the same organization covers both Medicare and Medicaid services. CMS utilized the underlying data to estimate that of the 1.75 million, 1.26 million were enrolled in a D-SNP and affiliated Medicaid MCO offered by the same organization. The remaining half million were enrolled in Medicare-Medicaid plans, PACE, and managed fee-for-service arrangements. The FY22 Medicare-Medicaid Coordination Office Report to Congress can be accessed here: <https://www.cms.gov/files/document/mmco-report-congress.pdf>.

¹⁷⁸ Velasquez, David E., E. John Orav, and José F. Figueroa. Enrollment and characteristics of dual-eligible Medicare and Medicaid beneficiaries in integrated care programs, *Health Affairs* 42, No. 5 (2023), 685.

¹⁷⁹ MedPAC Report to Congress, Promoting integration in dual-eligible special needs plans, Chapter 12, page 422, June 2019. Retrieved from https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.

networks, which creates confusion for plan selection and could lead to individuals choosing unaligned Medicare and Medicaid plans.

One State provides a useful (but not necessarily unique) example. In this State, for 2023, there are 47 D-SNP plan benefit packages (PBPs) offered through 24 different plan contracts. A few parent organizations' D-SNPs account for a large share of the plans in this State: UnitedHealth Group operates 15 D-SNP PBPs across six different MA contracts, Humana offers eight D-SNP PBPs across two MA contracts, and Centene offers five D-SNP PBPs across three MA contracts. A search of available options in Medicare Plan Finder (MPF) for a dually eligible individual in a zip code in this State yields 69 MA-PD options, including 19 D-SNPs. Of the 19 D-SNPs, five are offered by Centene, three are offered by Elevance, three are offered by UnitedHealth Group, and two are offered by Humana. The large number of D-SNPs operated by a relatively small group of parent organizations in this State illustrates the "choice overload" faced by dually eligible individuals, their families, advocates, and enrollment counselors.

Although Medicaid managed care in this State is mandatory for dually eligible individuals, and many of the same D-SNP parent organizations operate Medicaid MCOs in the State, there is currently no EAE required. Additionally, D-SNP and Medicaid MCO service areas are misaligned throughout the State, hindering meaningful integration and robust care coordination for enrollees despite a relatively small group of parent organizations. Further, the abundance of non-AIP coordination-only D-SNP options reduces the likelihood that a dually eligible individual would select a more integrated option. Additionally, numerous plan options in one service area increases the potential for marketing issues including agents and brokers targeting dually eligible individuals to switch into another plan.

We recognize that States have policy interests and goals that shape their Medicaid managed care programs, and our intent is to help further support States interested in implementing EAE. We have historically deferred to States to use SMACs to align Medicare and Medicaid plan offerings consistent with State policy priorities. However, as the number of dually eligible individuals with misaligned enrollment and sheer number of D-SNPs have grown, we now believe that Federal rulemaking is warranted to promote greater alignment of D-SNPs and Medicaid MCOs and to begin to simplify the array of choices.

¹⁷⁵ See 42 CFR 438.2 for definitions of the terms managed care organization (MCO), prepaid ambulatory health plan, and prepaid inpatient health plan.

¹⁷⁶ MedPAC Report to Congress, Promoting integration in dual-eligible special needs, table 12-6, page 436, June 2019.

¹⁷⁷ The FY22 CMS Medicare-Medicaid Coordination Office Report to Congress indicates that as of July 2022, 1.75 million full-benefit dually

We have authority, per section 1857(e)(1) of the Act, to add MA contract terms and conditions not inconsistent with the MA statute (that is Part C of Title XVIII of the Act) as the Secretary may find necessary and appropriate. Given how section 1859(f)(8) of the Act reflects a goal of furthering the integration of D-SNPs and how our proposal is designed to reduce choice overload situations for dually eligible individuals while furthering opportunities for enrollment in integrated D-SNPs (that is, FIDE SNPs, HIDE SNPs, and AIPs), we believe that the standard in section 1857(e)(1) is met. Further, section 1854(a)(5) of the Act is clear that we are not obligated to accept any and every MA plan bid.

Based on these authorities, we are proposing new regulations (at §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii)) related to how MA organizations offer and enroll eligible individuals into D-SNPs. Proposed § 422.503(b)(8) would establish a new qualification for an MA organization (or new applicant to be an MA organization) to offer D-SNP(s) while proposed § 422.504(a)(20) would establish a new contract term for certain MA organizations; both are tied to the substantive limits we are proposing in § 422.514(h). Proposed § 422.514(h) would establish conditions for how certain MA organizations and D-SNPs may enroll dually eligible individuals and limit the number of D-SNPs that may be offered by certain MA organizations. Finally, proposed § 422.530(c)(4)(iii) would establish a new crosswalk to authorize MA organizations that are subject to these new enrollment limitations to crosswalk their enrollees to a single D-SNP to accomplish aligned enrollment.

Together, our proposals at §§ 422.503(b)(8), 422.504(a)(20), and 422.514(h)(1) and (2) would require the following:

- Beginning in plan year 2027, when an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, also contracts with a State as a Medicaid MCO that enrolls dually eligible individuals in the same service area, D-SNPs offered by the MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, must limit new enrollment to individuals enrolled in (or in the process of enrolling in) the D-SNP's affiliated Medicaid MCO. This would apply when any part of the D-SNP service area(s) overlaps with any part of the Medicaid MCO service area, even if the two service areas do not perfectly

align. Additionally, only one D-SNP may be offered by an MA organization, its parent organization, or another MA organization with the same parent organization in the same service area as the aligned Medicaid MCO. We would only enter into a contract with one D-SNP for full-benefit dually eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO (with limited exceptions as described below).

- Beginning in 2030, such D-SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO. Therefore, by 2030, integrated D-SNPs would be required to disenroll individuals who are not enrolled in both the D-SNP and Medicaid MCO offered under the same parent organization (that is, offered by the parent organization or any subsidiary), except that D-SNPs would still be able to use a period of deemed continued eligibility to retain enrollees who temporarily lost Medicaid coverage as described in § 422.52(d). This also means that where an enrollee is temporarily disenrolled from the affiliated Medicaid MCO but is expected to be re-enrolled in the affiliated Medicaid MCO within the period of deemed continued eligibility, the D-SNP would not be required to disenroll that enrollee during that period.

Consistent with how CMS believes MA organizations under the same parent organization share operational and administrative functions, we are proposing to apply the proposed regulations at the parent organization level.

We are proposing a corresponding new provision at § 422.530(c)(4)(iii) that would provide a new crosswalk exception to allow one or more MA organizations that share a parent organization and offer D-SNPs subject to these proposed new limits to crosswalk enrollees (within the same parent organization and among consistent plan types) when the MA organization chooses to non-renew or consolidate its current D-SNPs to comply with the new rules in proposed §§ 422.504(a)(20) and 422.514(h). Currently, § 422.530(a)(2) does not allow enrollee crosswalks across different contracts or plan types. The proposed new crosswalk exception would explicitly permit moving enrollments across contracts held by MA organizations with the same parent organization; because we are not including any explicit exception from the rule in § 422.530(a)(2) prohibiting crosswalks to different plan types, the receiving D-SNP must be the same plan

type as the D-SNP out of which the enrollees are crosswalked. We expect MA organizations who offer D-SNPs to leverage § 422.530(c)(4)(iii)—as well as standard MA processes to add or remove service areas—to come into compliance with § 422.514(h).

We believe that allowing this crosswalk would limit enrollee disruption if MA organizations non-renew D-SNPs to comply with our proposal. In addition, we believe this new crosswalk is consistent with preserving the evergreen nature of enrollee elections given the differences in the benefits being offered by the D-SNPs that are owned or controlled by the same parent organization are generally not meaningful beyond the scope of annual changes explained in the Annual Notice of Change. For example, in contract year 2023, there is one parent organization with three MA organizations that offer a total of 13 HMO D-SNP benefit packages in one State. Only five of those D-SNPs enroll full-benefit dually eligible individuals, and the benefits offered in each of the D-SNPs are substantively similar.

We are proposing the following exceptions to our proposals at §§ 422.504(a)(20) and 422.514(h)(1) and (2):

- In certain circumstances, State D-SNP policy may require the need for more than one D-SNP for full-benefit dually eligible individuals to operate in the same service area. Under § 422.514(h)(3)(i), we propose to permit an MA organization, its parent organization, or an entity that shares a parent organization with the MA organization, offering more than one D-SNP for full-benefit dually eligible individuals in the same service area as that MA organization's affiliated Medicaid MCO only when a SMAC requires it. For example, where a SMAC limits enrollment for certain groups into certain D-SNPs (such as by age group), the MA organization may offer additional D-SNPs for different groups of full-benefit dually eligible individuals in the same service area accordingly. This exception allows for States that currently have different integrated D-SNP programs based on age or benefit design to continue to operate these programs and allows States the flexibility to design future integrated D-SNP programs with eligibility nuances should they so choose. This proposed exception would only be available where the SMAC requires different eligibility groups for the different D-SNPs that are offered by the same MA organization, its parent organization, or another MA

organization that shares the parent organization.

- Numerous parent organizations operate both HMO and PPO D-SNPs in States where they also contract with a State as a Medicaid MCO, and the proposed regulation at §§ 422.504(a)(20) and 422.514(h)(1) and (2) would apply to both HMO and PPO D-SNPs.

However, as noted above, § 422.530(a)(2) does not allow enrollee crosswalks across different plan types, and we are not including any exception from that existing rule in the new crosswalk exception proposed at § 422.530(c)(4)(iii). To minimize enrollee disruption, our proposal would not prohibit an MA organization, its parent organization, or another MA organization that shares a parent organization with the MA organization, from continuing to operate both an HMO D-SNP and a PPO D-SNP in a State where the proposed new policy applies. However, to achieve the goals of the new regulation, including simplification of the D-SNP market and promotion of integrated care through aligned Medicare and Medicaid products, we propose at

§ 422.514(h)(3)(ii) that the MA organization, its parent organization, or another MA organization that shares a parent organization with the MA organization may offer (or continue to offer) both the HMO and PPO D-SNPs only if they no longer accept new full-benefit dually eligible enrollees in the same service area as the D-SNP affected by the new regulations at §§ 422.504(a)(20) and 422.514(h). Under this proposal, the MA organization, its parent organization, and another MA organization that shares a parent organization with the MA organization may only accept new enrollment in one D-SNP for full-benefit dually eligible individuals in the same service area as an affiliated Medicaid MCO, and such new enrollment is limited to the full-benefit dually eligible individuals who are enrolled (or are enrolling) in the affiliated Medicaid MCO.

We also propose at § 422.503(b)(8) that in service areas in which a D-SNP limits enrollment to individuals enrolled in (or in the process of enrolling in) an affiliated Medicaid MCO, the MA organization, its parent organization, or entities that share a

parent organization with the MA organization may not newly offer another D-SNP for full-benefit dually eligible individuals, if it would result in noncompliance with § 422.514(h). Additionally, we propose at § 422.504(a)(20) to establish a new contract term for MA organizations that offer D-SNPs to require compliance with the enrollment limits we are proposing to add to § 422.514(h). These proposals would apply regardless of any EAE requirements in State SMACs, unless the exception to accommodate State policy choices, described in proposed § 422.514(h)(3)(i), applies.

Table HC2 summarizes enrollment scenarios to illustrate the combined effects of our proposed SEP changes and enrollment limitations. The term “D-SNP’s parent organization” as used in the table includes the MA organization that offers the D-SNP, the MA organization’s parent organization, and any other entity (MA organization or otherwise) that shares the parent organization with the MA organization that offers the D-SNP.

TABLE HC2: 2027 SCENARIOS FOR D-SNP ENROLLMENT UNDER THE PROPOSED INTEGRATED CARE SEP AND PROPOSED ENROLLMENT LIMITATIONS—PLAN PERSPECTIVE

Scenario	Who can enroll in the D-SNP?	When can such individuals enroll in the D-SNP?
D-SNP’s parent organization <u>has</u> an affiliated Medicaid MCO that enrolls <u>full-benefit</u> dually eligible individuals in same service area	Only enrollees in the parent organization’s companion Medicaid MCO who also meet eligibility requirements based on terms of that State’s SMAC	Each month
D-SNP’s parent organization <u>does NOT have</u> an affiliated Medicaid MCO that enrolls <u>full-benefit</u> dually eligible individuals in same service area	Any individuals who meet eligibility requirements based on terms of that State’s SMAC	Only during ICEP, AEP, MA-OEP, or via an existing SEP

We look to a hypothetical example of how the proposed regulations would likely play out in the market. For this example, Parent Organization Alpha

operates three MA organizations in Montgomery County. For the sake of this example, the service areas for all D-SNPs encompass Montgomery County,

and each of the D-SNPs enrolls both full-benefit and partial-benefit dually eligible individuals of all ages.

TABLE HC3: HYPOTHETICAL EXAMPLE—D-SNP CURRENT LANDSCAPE

Parent Organization Alpha			
MA Organization Gamma	MA Organization Omega		Medicaid MCO Omega (in Montgomery County)
HIDE HMO D-SNP Gamma 001	HIDE PPO D-SNP Omega	HIDE HMO D-SNP Omega 001	

We anticipate that under proposed § 422.514(h), for periods beginning on or after January 1, 2027, Parent Organization Alpha would have to choose one of the three D-SNPs offered by its MA organization subsidiaries to align with the Plan Omega Medicaid MCO. For this example, MA Organization Omega chooses HIDE D-SNP Omega 001 to serve as the D-SNP aligned with Medicaid MCO Omega and permitted to continue under proposed

§ 422.514(h). Under the proposed crosswalk authority at § 422.530(c)(4)(iii), MA Organization Omega and MA Organization Gamma would be able to move enrollees from Gamma 001 into Omega 001 on January 1, 2027. MA Organization Gamma could then convert HIDE D-SNP Gamma 001 to coordination-only D-SNP Gamma 001 and keep that plan open for partial-benefit dually eligible individuals, or elect to non-renew Gamma 001 and

keep only Omega 001 as the plan aligned with the Omega Medicaid MCO into which full-benefit dually eligible individuals may enroll so long as they are also enrolled in the Omega Medicaid MCO. Further, under proposed § 422.514(h)(3)(ii), MA Organization Omega could retain the HIDE PPO D-SNP, but it would be closed to new enrollment for full-benefit dually eligible individuals in Montgomery County.

TABLE HC4: HYPOTHETICAL EXAMPLE – POSSIBLE D-SNP LANDSCAPE AFTER POTENTIAL ACTIONS BY PARENT ORGANIZATION*

Parent Organization Alpha-under proposed rule		
MA Organization Omega		Medicaid MCO Omega (in Montgomery County)
HIDE PPO D-SNP Omega* Now frozen to new enrollment	HIDE HMO D-SNP Omega 001* now aligned with Medicaid MCO Omega for full-benefit dually eligible individuals: • 2027: new enrollment limited to individuals enrolled in (or in the process of enrolling in) Medicaid MCO Omega • 2030: 100 percent of enrollment aligned with Medicaid MCO Omega; unaligned enrollees would be disenrolled	

*In Table HC4, MA organization has non-renewed Gamma 001.

Our proposals on enrollment limitations for non-integrated D-SNPs would apply based on an MA organization having an affiliated Medicaid MCO. However, we are considering whether our proposals should apply where an MA organization has other affiliated Medicaid managed care plan options as well, including prepaid inpatient health plans (PIHPs) and prepaid ambulatory health plans (PAHPs). PIHPs and PAHPs are limited

in what they cover and do not have comprehensive risk contracts. Some States use PIHPs or PAHPs to deliver specific categories of services, like behavioral health, or a single benefit, such as non-emergency medical transportation, using a single contractor. The revenue for a PIHP or PAHP is usually less than the revenue for an MCO. As such, to the extent our proposal incentivizes an organization to end its Medicaid managed care

contracts to avoid our new contracting limitations, that incentive would be stronger for a PIHP or PAHP than an MCO. Therefore, we are concerned that applying our proposals to PIHPs and PAHPs could create incentives that are disruptive yet do not significantly further the goals of our proposals. We welcome comments on this issue.

If we finalize our proposals, we would consider updates to the systems and supports designed to aid individuals in

making Medicare choices. This would include MPF, HPMS, and other resources that help to outline available plan choices to individuals, SHIP counselors, and others. This may be especially important where dually eligible individuals have choices that would vary based on the type of plan and time of year. We would consider the best ways to show only those plans available to individuals and highlight options that align with Medicaid enrollment. We welcome recommendations on how the choice architecture could best support the proposals or objectives described in this section.

Overall, we believe our proposals at §§ 422.503(b)(8), 422.504(a)(20), 422.514(h), and 422.530(c)(4)(iii) would:

- Increase the percentage of D-SNP enrollees who are in aligned enrollment, and—over time—exclusively aligned enrollment (EAE), which would increase access to the comprehensive coordination of care, unified appeal processes across Medicare and Medicaid, continuation of Medicare services during an appeal, and integrated materials that come with enrollment in one or more of the various types of integrated D-SNPs. The impact would be concentrated in those States that have Medicaid managed care but do not have EAE requirements already. In such States, to comply with the proposals, MA organizations that have multiple D-SNP PBPs available to full-benefit dually eligible individuals and that also offer (or have parent organizations that offer) Medicaid MCOs in the same service area would likely choose to consolidate their PBPs down to a single PBP for full-benefit dually eligible individuals that is aligned with their Medicaid MCO that fully or partially overlaps the D-SNPs service area. Such MA organizations could operate non-AIP coordination-only D-SNPs both for service areas where they do not serve beneficiaries on the Medicaid side and for partial-benefit dually eligible individuals. (We believe that consolidation is more likely due to the potential administrative burden of offering multiple D-SNPs for which enrollment is restricted.)

- Reduce the number of D-SNP options overall, and thus reduce choice overload and market complexity where parent organizations offer multiple D-SNP options in the same or overlapping service areas.

- Remove some incentives for agents and brokers to target dually eligible individuals (especially among employed or captive agents affiliated with plans that do not offer integrated D-SNPs), thus lessening the assistance needed

from advocates and SHIP counselors to correct enrollment issues.

- Simplify provider billing and lower the risk of inappropriate billing, as more enrollees would be in D-SNPs with aligned enrollment.

- Promote integrated care and create more opportunities to provide truly integrated experience for beneficiaries by requiring plans to align enrollment (for example, D-SNPs can better coordinate care across Medicare and Medicaid when plans are aligned).

- In 2030, increase the number of D-SNPs with EAE, and therefore increase the number of D-SNPs that would be AIPs that are required to use unified appeals and grievance procedures and continuation of Medicare benefits pending appeal.

- Potentially lead to more States requiring D-SNP-only contracts (see § 422.107(e)) after 2030, as aligned enrollment and service areas for D-SNPs with affiliated Medicaid MCOs would be Federally required, allowing States to receive the benefits of D-SNP-only contracts (like HPMS access for oversight and information sharing, greater transparency on Star Ratings specific to D-SNP enrollees in their State, increased transparency on health care spending, among other benefits).¹⁸⁰

While there are many benefits to our proposals, we acknowledge there are certain challenges:

- Our proposals would reduce the number of D-SNP options for Medicaid MCO enrollees in some States. In general, we share MedPAC's assessment that cases of misaligned enrollment are unlikely to lead to any meaningful integration. However, it is plausible that some dually eligible individuals could benefit from the unique combinations of provider networks and supplemental benefits that could be possible only by enrolling in misaligned Medicare and Medicaid plans.

- Making plan choices clear under our proposals to dually eligible individuals, SHIP counselors and others would require changes to MPF, HPMS, and other CMS public materials explaining Medicare coverage options. Systems changes often present unknown challenges and a learning curve for users while they become accustomed to new updates.

- It also may seem that our proposal on limiting enrollment in D-SNPs offered by MA organizations with affiliated Medicaid MCOs, in isolation, would disadvantage parent organizations that choose to offer

Medicaid MCOs as well as D-SNPs because such organizations would be limited in the number of D-SNP offerings and would be required to align their enrollment between D-SNP and MCO for full-benefit dually eligible individuals. However, our SEP proposals would have the opposite effect by permitting enrollment into integrated D-SNP options that cover both Medicare and Medicaid benefits using the new one-time-per month SEP. Therefore, we believe our proposals, in combination, would maintain a high level of competition and choice, even while imposing some new constraints.

- MA organizations that operate both D-SNPs and Medicaid MCOs might elect to participate in fewer competitive Medicaid procurements (or exit Medicaid managed care in "any willing provider" States) to be exempted from the proposed restrictions on plan enrollment and number of plan offerings. This could adversely affect competition and the minimum choice requirements in § 438.52 for Medicaid managed care programs. However, our SEP proposals would have the opposite effect, since only integrated D-SNPs could benefit from the new integrated care SEP, and overall, we believe our proposals, in combination, maintain strong incentives for organizations to compete for Medicaid managed care contracts.

- The enrollment and eligibility restrictions—without the offsetting proposed SEP changes—could incentivize sponsors to create D-SNP look-alikes or other types of MA plans to build enrollment of dually eligible individuals without being subject to the enrollment limits and integration requirements associated with D-SNPs (although we plan to mitigate this risk with proposed revisions to § 422.514(d) and (e) in section VIII.G of this proposed rule). Finally, beginning in 2030, our proposal would no longer allow some enrollees to stay in their current D-SNPs, causing some enrollee disruption where the D-SNPs were unable to completely align their D-SNP and Medicaid MCO populations.

We welcome comments on our overall policy direction, specific proposals, and analysis of their likely effects.

D. Comment Solicitation: Medicare Plan Finder and Information on Certain Integrated D-SNPs

Medicare Plan Finder (MPF) is an online searchable tool located on the Medicare.gov website that allows individuals to compare options for enrolling in MA or Part D plans. Medicare beneficiaries can also enroll in a plan using MPF. Each year, we work

¹⁸⁰ MMCO memo on 42 CFR 422.107(e) available here: <https://www.cms.gov/files/document/stateopsintegratedcareprogs.pdf>.

to improve its functionality by implementing enhancements to MPF.

MPF users can find information on D-SNPs that also provide Medicaid benefits for dually eligible individuals. However, the extent to which MPF highlights those plans is currently limited. We are soliciting comment to inform our intent to improve MPF functionality in the future to make it easier for dually eligible MPF users to assess MA plans that cover their full array of Medicare and Medicaid benefits.

One important consideration is how MPF displays benefits offered by MA and Part D plans. Currently, MPF only displays benefits that are included in the MA plan benefit package (PBP) (that is, Medicare Parts A and B benefits, Part D coverage, approved Medicare supplemental benefits, and Value Based Insurance Design (VID)/Uniform Flexibility (UF)/Supplemental Benefits for Chronically Ill (SSBCI)). For most MPF users, this represents the totality of their coverage.

However, for applicable integrated plans (AIPs), as defined at § 422.561, D-SNP enrollment is limited to those individuals who also receive Medicaid benefits through the D-SNP or affiliated Medicaid managed care organization (MCO) under the same parent organization. For these D-SNPs, the benefits listed in MPF accurately reflect those covered by Medicare but do not reflect all the benefits available to all enrollees in the D-SNP.

For example, in most States, all dually eligible individuals who qualify to enroll in an AIP would have access to Medicaid-covered non-emergency medical transportation (NEMT). However, MPF currently only displays NEMT as a covered benefit for any MA plan if it is also covered as an MA supplemental benefit. As such, all other things equal, an MA plan that offers NEMT as an MA supplemental benefit appears in MPF to have more generous coverage than an AIP that does not cover NEMT as an MA supplemental benefit but does cover it under the affiliated Medicaid MCO contract.

Information about only Medicare benefits covered by MA plans available to the individual, although accurate, may not provide as much information to dually eligible MPF users as would be beneficial, since the combination of available Medicare and Medicaid benefits available through some integrated D-SNPs may be greater than the Medicare benefits reflected in MPF. It may also create a perverse incentive for D-SNPs to offer certain types of supplemental benefits for Medicare marketing purposes even when the same

services are already available to all enrollees in the plan through Medicaid.

We believe there is an opportunity to better inform dually eligible MPF users. For AIPs, we are considering adding a limited number of specific Medicaid-covered benefits (for example, dental, NEMT, certain types of home and community-based services, or others) to MPF when those services are available to enrollees through the D-SNP or the affiliated Medicaid MCO. We would limit this functionality to AIPs, because in such plans all enrollees—by definition—receive Medicaid benefits through the AIP.

We would not include in the MPF display any Medicaid benefits that are available but only through a separate carve-out. Consider, for example, a State in which NEMT is available to dually eligible individuals but through a Statewide vendor separate from the AIP. In this instance, displaying NEMT in MPF would accurately represent that all D-SNP enrollees have coverage for NEMT in Medicaid, but it would not accurately characterize the D-SNP's role (or the role of the affiliated Medicaid MCO offered by D-SNP parent organization) in delivering the service.

We continue to consider whether to indicate which services are Medicare supplemental benefits and which are Medicaid, weighing whether the additional information would be worth the added complexity.

Displaying Medicaid benefits in MPF, even with the limitations described above, would present new operational challenges for CMS. We do not currently capture the necessary information for AIPs or other D-SNPs in a systematic manner to populate MPF with information about Medicaid benefits covered by D-SNPs. (Medicaid benefit information is included in State Medicaid agency contracts (SMACs) that D-SNPs submit annually to CMS, but the information is not standardized and can be inconsistent and difficult to retrieve. Also, the current timing of SMAC submissions by the first Monday in July may not allow CMS enough time to review the SMACs and make the Medicaid benefits information available to MPF for an early October release.) Another way to potentially capture the necessary information would be for us to provide a mechanism by which D-SNPs can report it to us annually. We solicit comment on the practicality and means for accomplishing this. Our experiences with integrated PBPs in the Medicare-Medicaid Financial Alignment Initiative would inform our implementation, but enhancements to MPF would require effort and some opportunity cost. Nonetheless, we

believe we can better inform dually eligible MPF users about the benefits to which they are entitled and, in doing so, better integrate their experience across Medicare and Medicaid. With support from the Administration for Community Living and the National Council on Aging, the My Care My Choice website is currently available to showcase integrated care plan options (and more) for three States (California, Michigan, and Ohio).¹⁸¹ We are also interested in stakeholders submitting comments about any features from the My Care My Choice website that are particularly helpful for individuals in understanding and making plan choices.

Such enhancements to MPF would not require rulemaking. We are soliciting comments on the concepts described above to inform our decision about whether and how to implement changes to MPF along these lines.

E. Comment Solicitation: State Enrollment Vendors and Enrollment in Integrated D-SNPs

We, along with our State partners, have worked to create integrated care options for dually eligible individuals. When individuals choose to enroll, we want the enrollment process to be easy to navigate. Unfortunately, there remain technical challenges that can impede the ease of enrollment in integrated D-SNPs, including misalignment of Medicare and Medicaid enrollment processes, start dates, and related operational challenges for States and plans, as well as potentially confusing non-integrated enrollee communication materials.

In the FAI, CMS delegated eligibility and enrollment functions for Medicare-Medicaid Plans (MMPs) to States by waiving regulations at 42 CFR part 422, subpart B, insofar as they were inconsistent with the passive enrollment process used for each demonstration and with limiting enrollment in MMPs to certain dually eligible individuals. Operationally, many States have leveraged their State Medicaid enrollment vendors to operationalize enrollment, eligibility, or both. Which functions FAI States have chosen to delegate to their enrollment vendors or keep in-house (for example, enrollment vendor call center, enrollment noticing, eligibility determinations and enrollment processing) vary depending on the State.

Within the context of the FAI demonstrations, the use of a State enrollment vendor serves multiple purposes:

¹⁸¹ The My Care My Choice website is available at: <https://www.mycaremychoice.org/en>.

- Effectuating Medicare and Medicaid enrollment simultaneously to avoid misalignment between enrollment start and end dates,

- Serving as an unbiased source of information about integrated managed care plans and coverage options, and

- Reducing the risk of real or perceived conflicts of interest when plans initiate enrollment directly.

Outside of the FAI, dually eligible individuals elect MA plans, including D-SNPs, by enrolling directly with the plan, or Third-Party Marketing Organizations, or via 1-800-Medicare and the Medicare Online Enrollment Center. This creates special challenges for D-SNPs that have exclusively aligned enrollment (EAE) with affiliated Medicaid MCOs because these D-SNPs then need to separately coordinate enrollment of the dually eligible individual into the D-SNP's affiliated Medicaid MCO. Some States have expressed interest in leveraging State enrollment vendors, including enrollment brokers as described in section 1903(b)(4) of the Act, to effectuate EAE for integrated D-SNPs and their affiliated Medicaid MCOs.

Based on this experience, we are assessing ways to:

- Promote enrollment in integrated D-SNPs and reduce the likelihood of misaligned Medicare and Medicaid managed care enrollment for beneficiaries,
- Work toward an integrated D-SNP enrollment process that is operationally practical for both CMS and States,
- Create alignment—to the extent feasible—between Medicare and Medicaid managed care enrollment start and end dates,
- Protect beneficiaries from abusive enrollment practices without creating barriers to enrollment into a plan of choice, and
- Streamline beneficiary messaging and communication related to enrollment.

1. Current Opportunity for Use of State Enrollment Vendors for Enrollment in Integrated D-SNPs

States can utilize Medicaid enrollment vendors for enrollment in integrated D-SNPs through requirements in the SMAC required by § 422.107. States may thus require D-SNPs to contract directly with the State's enrollment vendor to verify D-SNP eligibility and effectuate D-SNP enrollment transactions. While these contracts could govern the respective obligations of the broker and the D-SNP, they would have to be uniform for all D-SNPs in the State, and in order to avoid a violation of section 1903(b)(4) of

the Act and §§ 438.71(c)(2) and 438.810 regarding a broker having a financial interest in a provider or managed care plan in the State, the State would have to compensate its enrollment broker for performing these functions. D-SNPs would be in the position to provide the necessary information and oversight of the enrollment mechanisms and activities. D-SNPs would still be subject to existing regulations at § 422.504(i), maintaining ultimate responsibility for adhering to and complying with all terms and conditions of their contract with CMS.

States can implement, and require of D-SNPs, specific messaging directing dually eligible individuals to take enrollment actions via the State's enrollment vendor only, similar to the noticing and messaging that applies in the FAI demonstrations. States could choose which functions to direct the D-SNPs to contract with the enrollment vendor for via the SMAC. States could also choose to direct the D-SNPs via the SMAC to not elect use of the Medicare Online Enrollment Center.

States could require D-SNPs to transfer prospective enrollees to the State's enrollment vendor for eligibility confirmation, as MMPs are required to do under the FAI demonstrations (for example, via warm transfer, in which the D-SNP staff transfers the prospective enrollee to the State's enrollment vendor but passes on the relevant information about the prospective enrollee). The enrollment vendor or the D-SNP—depending upon the contractual arrangement—would then effectuate the enrollment or disenrollment for Medicare and Medicaid. States could also require plans to direct enrollees to their vendor for disenrollments. Currently, under FAI, MMPs cannot accept enrollment requests directly from an individual or process the request, but instead they must forward the request to the State or State's enrollment vendor within two business days.

Under an arrangement in which a State requires D-SNPs to contract with the State's enrollment vendor, D-SNPs would retain the responsibility to oversee any functions delegated to the State's enrollment vendor under § 422.504 provisions that require MA plans to oversee first tier, downstream, and related entities. However, as noted earlier, financial arrangements would need to be structured to avoid violating the independence and conflict of interest limitations that apply to enrollment brokers under section 1903(b)(4) of the Act and §§ 438.71(c) and 438.810.

Requiring D-SNPs to contract with a State's enrollment vendor for enrollment and eligibility functions could create a simpler, streamlined enrollment experience for dually eligible individuals and may reduce the risk of misaligned Medicare and Medicaid enrollment. As in the FAI demonstrations, the State's enrollment vendor would need to implement Medicare managed care eligibility and enrollment policies, such as Medicare special enrollment periods and Comprehensive Addition and Recovery Act provisions.

Finally, like the FAI demonstrations, States can prohibit D-SNPs, via SMACs, from using agents and brokers to perform the activities described in §§ 422.2274 and 423.2274.

2. Medicaid Managed Care Enrollment Cut-Off Dates

One challenge of applying FAI enrollment processes outside the demonstration context is alignment of Medicaid and Medicare managed care enrollment start and end dates. Sections 1851(f)(2) and 1860D-1(b)(1)(B)(iv) of the Social Security Act, and regulations codified at §§ 422.68 and 423.40(c) respectively, generally require that Medicare enrollments become effective on the first day of the first calendar month following the date on which the election or change is made, although section 1851(f)(4) of the Act and §§ 422.68(d) and 423.40(c) allow CMS flexibility to determine the effective dates for enrollments that occur in the context of special enrollment periods. Medicaid managed care regulations at § 438.54 do not specify the timelines or deadlines by which any enrollment must be effective.

Some States have cut-off dates after which enrollment in a Medicaid managed care plan is not effectuated until the first calendar day of the next month after the following month. (For example, an application received on March 28 would be effective May 1 in some States.) If a dually eligible individual is trying to enroll in an integrated D-SNP at the end of a month in a State with a Medicaid managed care enrollment cut-off date, there could be a monthlong lag between their Medicare managed care effective date and Medicaid managed care effective date. The lag in start dates between Medicare and Medicaid services for an integrated D-SNP can be confusing to enrollees, operationally challenging for integrated plans, and difficult to describe in plan materials, particularly in instances where the D-SNP and Medicaid MCO are described as a single integrated organization.

We are interested in learning more about reasons for implementing Medicaid managed care enrollment cut-off dates and the barriers, as well as potential solutions, to aligning Medicare and Medicaid managed care enrollment start and end dates. We invite comment from interested parties, including States, D-SNPs, and Medicaid managed care plans, about their specific operational challenges related to potential changes to Medicaid cut-off dates to align them with the Medicare start date.

3. Comment Solicitation

We are seeking feedback on the feasibility of the approach to enrollment outlined above (requiring integrated D-SNPs to contract with State enrollment brokers), as well as any specific concerns about States implementing it.

We are soliciting comments on, but not limited to, the following topics:

- What challenges do individuals face when trying to enroll in integrated D-SNPs?

- What are States' reasons for having a specific Medicaid managed care enrollment cut off date in place?

- What type of operational or systems barriers do States and Medicaid managed care plans face to making changes to their Medicaid enrollment cut-off date to align with the Medicare managed care enrollment start date?

- What potential concerns would stakeholders have about CMS using flexibilities at section 1860D-1(b)(1)(B)(iv) of the Act and § 423.40(c) to determine effective dates for Medicare enrollments that occur in the context of our proposed special enrollment period for integrated care? (For example, Medicare enrollment effective dates that align with Medicaid enrollment effective dates, even if they are not the first day of the first calendar month following the date on which the election or change is made.)

- Are there operational or systems barriers for States and Medicaid managed care plans to align disenrollment dates with Medicare?

- What concerns, if any, should we consider with States requiring D-SNPs to route enrollment through the State enrollment vendor via the SMAC? Are there any Federal regulations, other than or in addition to the limitations on enrollment brokers under section 1903(b)(4) and §§ 438.71(c) and 438.810, that interested parties view as an impediment to this option?

- What type of technical assistance related to effectuating MA plan and D-SNP enrollment and eligibility processes would be helpful to States?

- What concerns should we consider about potential abusive enrollment practices?

- What are States' current requirements and policies related to agents and brokers?

- Are there other aspects of the integrated enrollment and disenrollment processes in FAI that should apply to D-SNPs?

F. Clarification of Restrictions on New Enrollment Into D-SNPs via State Medicaid Agency Contracts (SMACs) (§§ 422.52 and 422.60)

To elect a specialized MA plan for special needs individuals as defined at § 422.2 (special needs plans or SNPs), an individual must meet the eligibility requirements for the specific type of SNP in which the individual wishes to enroll. At § 422.52(b), we define the eligibility requirements for individuals to enroll in a SNP. These eligibility requirements indicate that an individual must meet the regulatory definition of a special needs individual at § 422.2, meet the eligibility requirements for the specific SNP they elect to enroll in, and be eligible to elect an MA plan under § 422.50. For D-SNPs, we also require at § 422.107(c)(2) that the categories and criteria for eligibility for dually eligible individuals to enroll in the SNP be included in the SMAC between the State and the D-SNP. D-SNPs must restrict enrollment eligibility categories or criteria consistent with the SMAC.

Currently, numerous States add eligibility categories and criteria to their SMACs that restrict new D-SNP enrollment to prioritize and promote integrated care. For example, some States only allow D-SNPs to enroll full-benefit dually eligible individuals. Other States only allow D-SNPs to enroll individuals who are also in an affiliated Medicaid managed care plan, creating exclusively aligned enrollment. State restrictions serve an important purpose in maximizing the number of dually eligible individuals who receive coordinated services through the same organization for both Medicare and Medicaid; minimizing disruption for enrollees currently served by existing D-SNPs; and allowing for the creation of D-SNP benefit packages that are tailored to certain subsets of dually eligible individuals.

State limitation of D-SNP enrollment to certain populations has been a feature throughout the history of D-SNPs. Nonetheless, we believe we can further clarify our regulations.

We propose to revise § 422.52(b)(2) to be explicit that to be eligible to elect a D-SNP, an individual must also meet any additional eligibility requirements

established in the SMAC. We also propose to revise § 422.60(a)(1) and add § 422.60(a)(3) to be more explicit that MA organizations may restrict enrollment in alignment with § 422.52(b)(2). Neither proposal is intended to change our longstanding policy. We do not expect any new burden associated with these proposed changes because States are already including eligibility categories and criteria in their SMACs and we are reviewing those accordingly.

G. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes (§ 422.514)

In the final rule titled Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program which appeared in the **Federal Register** on June 2, 2020 (85 FR 33796) (hereinafter referred to as the June 2020 final rule), CMS finalized the contracting limitations for D-SNP look-alikes at § 422.514(d) and the associated authority and procedures for transitioning enrollees from a D-SNP look-alike at § 422.514(e). For plan year 2022¹⁸² and subsequent years, as provided in § 422.514(d)(1), CMS does not enter into a contract for a new non-SNP MA plan that projects, in its bid submitted under § 422.254, that 80 percent or more of the plan's total enrollment are enrollees entitled to medical assistance under a State plan under Title XIX. For plan year 2023 and subsequent years, as provided in § 422.514(d)(2), CMS will not renew a contract with a non-SNP MA plan that has actual enrollment, as determined by CMS using the January enrollment of the current year, consisting of 80 percent or more of enrollees who are entitled to medical assistance under a State plan under Title XIX, unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination.

We established these contract limitations to address the proliferation and growth of D-SNP look-alikes, which raised concerns related to effective implementation of requirements for D-SNPs established by section 1859 of the Act (including amendments made by the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110-275) and the Bipartisan Budget Act of

¹⁸² CMS amended § 422.514(d)(1) in the April 2023 final rule, so the regulation text now refers to plan year 2024 and subsequent years; however, the regulation was in effect, with the reference to 2022 and subsequent years, as described here.

2018 (Pub. L. 115–123)). We adopted the regulation to ensure full implementation of requirements for D–SNPs, such as contracts with State Medicaid agencies, a minimum integration of Medicare and Medicaid benefits, care coordination through health risk assessments (HRAs), and evidence-based models of care. In addition, we noted how limiting these D–SNP look-alikes would address beneficiary confusion stemming from potentially misleading marketing practices by brokers and agents that market D–SNP look-alikes to dually eligible individuals. For a more detailed discussion of D–SNP look-alikes and their impact on the implementation of D–SNP Medicare and Medicaid integration, we direct readers to the June 2020 final rule (85 FR 33805 through 33820) and the proposed rule titled Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly (85 FR 9018 through 9021) (also known as the February 2020 proposed rule).

In the April 2023 final rule, we finalized amendments to close unforeseen loopholes in the scope of the regulation adopted to prohibit D–SNP look-alikes. Specifically, we finalized language at § 422.514(g) to apply the prohibitions on contracting with D–SNP look-alikes to individual segments of an MA plan. We also finalized language at § 422.514(d)(1) to apply the D–SNP look-alike contracting limitation to both new and existing (that is, renewing) MA plans that are not SNPs and submit bids with projected enrollment of 80 percent or more enrollees of the plan's total enrollment that are dually eligible for Medicare and Medicaid.

1. Reducing Threshold for Contract Limitation on D–SNP Look-Alikes

Our contracting limitations at § 422.514(d) mean that we do not contract with non-SNP MA plans that have enrollment consisting of 80 percent or more of enrollees who are

entitled to Medicaid. We set the threshold at 80 percent or higher based on a 2019 MedPAC analysis that showed the proportion of dually eligible individuals in most geographic areas did not exceed the 80-percent threshold;¹⁸³ at that time, no MA plan service area had more than 50 percent dually eligible beneficiaries, and therefore dually eligible enrollment of 80 percent or greater would not be the result of any plan that had not intended to achieve high enrollment of dually eligible individuals (85 FR 33812). The 80-percent threshold also captured almost three-quarters of the non-SNP MA plans with more than 50 percent dually eligible enrollees (85 FR 33812). As described in the June 2020 final rule, we also considered two other approaches: (1) setting the threshold at the higher of 50 percent dually eligible enrollment or the proportion of dually eligible MA-eligible individuals in the plan service area plus 15 percentage points; and (2) setting a lower threshold for dually eligible enrollment at a point between 50 and 80 percent (85 FR 33807). In addition to 80 percent or higher being an indicator that the plan is designed to attract disproportionate dually eligible enrollment, we believed this threshold would be easier for MA organizations to determine prospectively and operationally easier for CMS to implement than a threshold that varied across each service area.

A number of commenters on the February 2020 proposed rule recommended that we set a threshold lower than 80 percent. These commenters expressed concern that a threshold of 80 percent could be “gamed” by MA organizations to keep enrollment of dually eligible individuals just under the ceiling. Some commenters recommended that CMS set the ceiling for dually eligible enrollment at 50 percent with a commenter citing MACPAC analysis showing faster growth in projected enrollment among

MA plans with dual eligible enrollment greater than 50 percent than among those greater than 80 percent. Another commenter recommended a threshold of 60 percent.

In the June 2020 final rule, we responded that we believed the 80-percent threshold was reasonable because, based on the 2019 MedPAC analysis on 2017 data, it far exceeded the share of dually eligible individuals in any given MA plan service area—no MA plan service area had more than 50 percent dually eligible beneficiaries—and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. We also stated that we would monitor for potential gaming after implementation of the final rule by reviewing plan enrollment data and consider future rulemaking as needed (85 FR 33812).

In response to our proposals to close unforeseen D–SNP look-alike loopholes in the April 2023 final rule, some commenters again recommended we lower the threshold to less than 80 percent (88 FR 22131). A few commenters recommended we lower the threshold below 80 percent without recommending a specific percentage, and other commenters recommended we lower the threshold to 50 percent. The commenters suggested that lowering the threshold further would promote integrated care and minimize beneficiary confusion. As one of these commenters, MACPAC noted that it “remains concerned that while CMS’s focus on plans where 80 percent or more of all enrollees are dually eligible addresses the most egregious instances, there could still be a real risk of growth in non-SNP MA plans falling below the 80-percent threshold and thus continuing to detract from Federal and State efforts to integrate care.” We analyzed the percentage of non-SNP MA plans’ dually eligible enrollment as a percentage of total enrollment from plan years 2017 through 2023. Our analysis shows that the number of non-SNP MA plans with high levels of dually eligible individuals has grown substantially.

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¹⁸³ See June 2019 MedPAC Report to Congress, Chapter 12 at http://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.

TABLE 1: TOTAL NUMBER OF NON-SNPS BY DUALY ELIGIBLE INDIVIDUALS AS PERCENT OF TOTAL ENROLLMENT AND YEAR

Year	Total Number of Non-SNP MA Plans with 50-60% Dually Eligible Individuals	Total Number of Non-SNP MA Plans with 60-70% Dually Eligible Individuals	Total Number of Non-SNP MA Plans with 70-80% Dually Eligible Individuals	Total Number of Non-SNP MA Plans with 50-80% Dually Eligible Individuals
2017	9	4	2	15
2018	13	6	5	24
2019	16	19	17	52
2020	30	18	17	65
2021	33	25	19	77
2022	58	35	26	119
2023	58	40	30	128
Percent growth from 2017 to 2023	544%	900%	1,400%	753%

Source: CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023.

TABLE 2: TOTAL ENROLLMENT IN NON-SNPS BY PERCENT OF DUALY ELIGIBLE INDIVIDUALS ENROLLED AND YEAR

Year	Total Enrollees in Non-SNP MA Plans with 50-60% Dually Eligible Individuals	Total Enrollees in Non-SNP MA Plans with 60-70% Dually Eligible Individuals	Total Enrollees in Non-SNP MA Plans with 70-80% Dually Eligible Individuals	Total Enrollees in Non-SNP MA Plans with 50-80% Dually Eligible Individuals
2017	26,231	3,091	246	29,568
2018	26,132	2,570	2,957	31,659
2019	9,204	8,171	16,459	33,834
2020	46,319	15,939	20,320	82,578
2021	54,185	29,738	23,652	107,575
2022	75,926	45,522	26,481	147,929
2023	105,534	92,100	53,334	250,968
Percent growth from 2017 to 2023	302%	2,880%	21,580%	749%

Source: CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023.

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The rate of growth from 2017 to 2023 in the number of non-SNP MA plans with 50 to 60 percent (544 percent increase), 60 to 70 percent (900 percent), and 70 to 80 percent dually eligible individuals as a percent of total

enrollment (1,400 percent)¹⁸⁴ exceeded the rate of enrollment growth for all MA-PD plans (109 percent) over the

¹⁸⁴ CMS analysis of Integrated Data Repository (IDR) data for January of each respective year. Analysis conducted in April 2023, as shown in Table 1.

same period of time.¹⁸⁵ The increased growth in non-SNP MA plans with dually eligible individuals between 50 and 80 percent of total enrollment suggests to us that MA organizations are

¹⁸⁵ CMS data from the Contract Year 2021 and 2023 Landscape Plan shows the total number of MA-PD plans in 2017 was 2,332 and the total number of MA-PD plans in 2023 is 4,875.

offering plans for dually eligible individuals but circumventing rules for D-SNPs, including requirements from the Bipartisan Budget Act of 2018, and detracting from Federal and State efforts to better integrate Medicare and Medicaid benefits. This growth in enrollment in these non-SNP plans is likely also drawing enrollment from integrated care D-SNPs and similar integrated programs. Recent analysis found that almost one-third of dually eligible individuals newly enrolled in D-SNP look-alikes were previously enrolled in fully integrated dual eligible SNPs (FIDE SNPs), other D-SNPs, PACE plans, or MMPs.¹⁸⁶

We also conducted analysis with 2023 data mimicking MedPAC's 2019 analysis showing the share of dually eligible individuals enrolled in non-SNP MA plans against the share of beneficiaries in a plan service area who are dually eligible individuals.¹⁸⁷ MedPAC's analysis showed that in most MA markets, the share of beneficiaries in a plan service area who are dually eligible was clustered in the 10 to 25 percent range and in no county exceeded 50 percent. Their analysis showed that dually eligible individuals generally represented 30 percent or less of non-SNP MA plans' total enrollment. MedPAC's analysis informed our decision to set the threshold for dually eligible enrollment at 80 percent of a non-SNP MA plan's enrollment because it far exceeded the share of dually eligible individuals in any given market (by 30 percentage points or more) at that point in time and, therefore, would not be the result for any plan that had not intended to achieve high dually eligible enrollment. Similar to the earlier MedPAC analysis, our analysis of 2023 data shows the share of beneficiaries in a plan service area who are dually eligible is clustered in the 10 to 30 percent range and does not exceed 49 percent except in one county (at 56 percent).¹⁸⁸ Also like MedPAC, we found that for most non-SNP MA plans, dually eligible individuals generally represent 30 percent or less of the plan's total enrollment. However, whereas

MedPAC found 13 non-SNP MA plans with dually eligible enrollment between 50 percent and 80 percent for 2017,¹⁸⁹ we found 128 non-SNP MA plans with enrollment in that range for 2023.¹⁹⁰

To address the substantial growth in non-SNP MA plans with disproportionately high enrollment of dually eligible individuals, we propose lowering the D-SNP look-alike threshold from 80 percent to 60 percent incrementally over a two-year period. We propose to lower the threshold for dually eligible enrollment to 60 percent of a non-SNP MA plan's enrollment because it exceeds the share of dually eligible individuals in any given MA plan service area currently and, therefore, would not be the result for any plan that simply reflected the concentration of dually eligible enrollees in its service area.

We propose a limitation on non-SNP MA plans with 70 or greater percent dually eligible individuals for contract year 2025. For contract year 2026, we propose to reduce the threshold from 70 percent to 60 percent or greater dually eligible enrollment as a share of total enrollment. This incremental approach would minimize disruptions to dually eligible individuals and allow MA organizations and CMS to operationalize these transitions over a two-year period. As discussed in more detail below, we would maintain processes to minimize disruption for the enrollees in plans affected by this proposed change.

Based on 2023 data, we expect the lower threshold would impact 30 non-SNP MA plans with dually eligible individuals representing 70 to 80 percent of total enrollment and 40 non-SNP MA plans with dually eligible individuals representing 60 to 70 percent of total enrollment. Some of the plans that could be affected by our proposal are offered in States (that is, California, Massachusetts, Minnesota) that limit contracting to integrated D-SNPs, such as FIDE SNPs and AIPs. Based on 2023 plan data, 12 non-SNP MA plans in California, Massachusetts, and Minnesota have shares of dually eligible enrollment between 60 and 80 percent. These States have chosen to limit their markets to certain D-SNPs to integrate Medicare and Medicaid for dually eligible individuals. Lowering the D-SNP look-alike contracting limitation to 60 percent will help to

simplify choices for dually eligible individuals in these States and promote Medicare and Medicaid integration objectives.

We propose revisions to the rule on dually eligible enrollment at § 422.514(d)(1) to apply the lower thresholds to new and existing non-SNP MA plan bids. Specifically, we propose amending paragraph (d)(1)(ii) such that CMS would not enter into or renew a contract for a new or existing non-SNP MA plan that projects enrollment in its bid of 80 percent or more dually eligible individuals for plan year 2024 (as is already the case under current regulations); 70 percent or more dually eligible individuals for plan year 2025; and 60 percent or more dually eligible individuals for plan year 2026 and subsequent years. Consistent with our current practice, we would apply the proposed changes at § 422.514(d)(1)(ii) to all bids for the next plan year, including any bids for non-SNP MA plans projected to exceed the threshold even if the actual enrollment for the current plan year is under the threshold at § 422.514(d)(1).

Similarly, we propose revisions to paragraph (d)(2) to apply the lower thresholds to non-SNP MA plan enrollment. Specifically, we propose to amend paragraph (d)(2)(ii) to state that we will not renew a contract with a non-SNP MA plan that has actual enrollment, using January enrollment of the current year, in which dually eligible individuals constitute 80 percent or more dually eligible individuals for plan year 2024 (as is already the case under current regulations); 70 percent or more dually eligible individuals for plan year 2025; or 60 percent or more dually eligible individuals for plan year 2026 or subsequent years. In operationalizing these proposed changes, for example, we would use January 2024 enrollment data to identify non-SNP MA plans that exceed the proposed 70-percent threshold, for purposes of determining whether to renew contracts with these plans for plan year 2025. We would use January 2025 enrollment data to identify non-SNP MA plans that exceed the proposed 60-percent threshold for purposes of determining whether to renew contracts with these plans for plan year 2026. Consistent with existing rules, we would not apply the contracting limitation in § 422.514(d)(2) to any non-SNP MA plan that has been active for less than one year and has enrollment of 200 or fewer individuals.

We considered lowering the threshold to 50 percent, given the growth in the number of non-SNP MA plans between 50 and 60 percent dually eligible

¹⁸⁶ Ma, Y., Austin F., Roberts, E., Johnston, K., Phelan, J., and Figueroa, J. "Rapid Enrollment Growth in 'Look-Alike' Dual-Eligible Special Needs Plans: A Threat To Integrated Care", *Health Affairs* (July 2023) 919–927. Retrieved from <https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2023.00103>.

¹⁸⁷ See June 2019 MedPAC Report to Congress, Chapter 12 at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.

¹⁸⁸ CMS analysis of 2023 non-SNP MA plan data in the IDR. Analysis conducted in April 2023, as shown in Table 1.

¹⁸⁹ June 2019 MedPAC Report to Congress, Chapter 12, calculated from Table 12–9 at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun19_ch12_medpac_reporttocongress_sec.pdf.

¹⁹⁰ CMS analysis of 2023 non-SNP MA plan data in the IDR. Analysis conducted in April 2023, as shown in Table 1.

individuals as a share of total enrollment. MedPAC's analysis of 2017 data and our analysis of 2023 data showed that there are some service areas where the entire Medicare population is around 50 percent dually eligible individuals and 50 percent non-dually eligible individuals. As such, lowering the threshold to 50 percent could prohibit plans that reflect the distribution of eligibility in that community. Also, it is less clear that a plan is designed to target dually eligible individuals and circumvent the statutory D-SNP requirements when a plan appeals equally to dually eligible individuals and non-dually eligible individuals. Although we propose to lower the threshold to 60 percent, we solicit comments on whether the alternative to reduce the threshold to 50 percent is more appropriate to protect against plans circumventing the requirements for D-SNPs while enrolling a disproportionate number of dually eligible individuals.

2. Amending Transition Processes and Procedures for D-SNP Look-Alikes

Section 422.514(e) establishes parameters for transitioning individuals who are enrolled in a D-SNP look-alike to another MA-PD plan (or plans) offered by the MA organization to minimize disruption as a result of the prohibition on contract renewal for existing D-SNP look-alikes. Under the existing processes and procedures, an MA organization with a non-SNP MA plan determined to meet the enrollment threshold in proposed paragraph (d)(2) could transition enrollees into another MA-PD plan (or plans) offered by the same MA organization, as long as any such MA-PD plan meets certain proposed criteria. This transition process allows MA enrollees to be transitioned at the end of the year from one MA plan offered by an MA organization to another MA-PD plan (or plans) without having to complete an election form or otherwise indicate their enrollment choice as typically required, but it also permits the enrollee to make an affirmative choice for another MA plan or standalone Part D plan of his or her choosing during the annual election period (AEP) preceding the year for which the transition is effective. Consistent with our description of the transition process in the June 2020 final rule (85 FR 33816), if a transitioned enrollee elects to enroll in a different plan during the AEP, enrollment in the plan the enrollee selected would take precedence over the plan into which the MA organization transitioned the enrollee. Transitioned enrollees would also have additional opportunities to

select another plan through the Medicare Advantage Open Enrollment Period described in § 422.62(a)(3) from January 1 through March 31. Affected individuals may also qualify for a SEP, depending on the circumstances.

Existing provisions at paragraphs (e)(1)(i) through (iv) outline specific criteria for any MA plan to receive enrollment through this transition process to ensure that enrollees receive coverage under their new MA plan that is similarly affordable as the plan that would not be permitted for the next year. At existing paragraph (e)(1)(i), we allow a non-renewing D-SNP look-alike to transition that plan's enrollment to another non-SNP plan (or plans) only if the resulting total enrollment in each of the MA plans receiving enrollment consists of less than the threshold established in paragraph (d)(2)(ii) (now, 80 percent but with the proposed amendment, this would refer to the scheduled change in the threshold). SNPs receiving transitioned enrollment are not subject to this proposed limit on dually eligible individual enrollment. Under existing paragraph (e)(1)(ii), we require that any plan receiving transitioned enrollment be an MA-PD plan as defined in § 422.2. Under existing paragraph (e)(1)(iii), any MA plan receiving transitioned enrollment from a D-SNP look-alike is required to have a combined Part C and D beneficiary premium of \$0 after application of the premium subsidy for full subsidy eligible individuals described at § 423.780(a). Finally, paragraph (e)(1)(iv) requires that the receiving plan be of the same plan type (for example, HMO or PPO) of the D-SNP look-alike out of which enrollees are transitioned.

At existing paragraph (e)(2)(ii), the current transition process requires MA organizations to describe changes to MA-PD benefits and provide information about the MA-PD plan into which the individual is enrolled in the Annual Notice of Change (ANOC) that the MA organization must send, consistent with §§ 422.111(a), (d), and (e) and 422.2267(e)(3). Consistent with § 422.111(d)(2), enrollees receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first day of the AEP.

At existing paragraph (e)(4), the regulation addresses situations where the prohibition on contracting or renewing a D-SNP look alike is applied and the D-SNP look alike is terminated. In such situations where an MA organization does not transition some or all current enrollees from a D-SNP look-alike to one or more of the MA

organization's other plans as provided in proposed paragraph (e)(1), the MA organization is required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2).

This transition process is conceptually similar to "crosswalk exception" procedures at § 422.530(c). However, in contrast to the crosswalk exceptions, our transition process at § 422.514(e) permits transition across contracts and across MA organizations under the same parent organization, as well as from non-SNP plans to SNPs.

We propose to apply the existing transition processes and procedures at § 422.514(e) to non-SNP MA plans that meet the proposed D-SNP look-alike contracting limitation of 70 percent or more dually eligible individuals effective plan year 2025 and 60 percent or more dually eligible individuals effective plan year 2026. Consistent with the initial years of implementation of the D-SNP look-alike contract limitations with the 80-percent threshold, maintaining these transition processes and procedures will help to minimize disruption as a result of the prohibition on contract renewal for existing D-SNP look-alikes. However, for plan year 2027 and subsequent years, we propose to limit the § 422.514(e) transition processes and procedures to D-SNP look-alikes transitioning dually eligible enrollees into D-SNPs. Based on our experience with D-SNP look-alike transitions effective plan year 2023, the vast majority of enrollees are transitioned to other MA-PDs under the same parent organization as the D-SNP look-alike. Based on our review of D-SNP look-alike transition plans thus far, we expect the experience for transitions effective plan year 2024 to follow a similar pattern. We propose this new limitation on the transition process at new paragraph (e)(1)(v).

MA organizations can utilize other CMS processes to transition D-SNP look-alike enrollees to non-D-SNPs. For example, an MA organization can utilize the CMS crosswalk process if it is transitioning the full D-SNP look-alike enrollment to one non-SNP plan benefit package (PBP) of the same type offered by the same MA organization under the same contract provided all requirements at § 422.530 for a crosswalk are met. An MA organization moving the entire enrollment of the D-SNP look-alike PBP to another PBP of the same type under the same contract may structure this action as a consolidation of PBPs and use the crosswalk for consolidated renewal process, under § 422.530(b)(1)(ii). An MA organization

may utilize the crosswalk exception process at § 422.530(c)(2) to request to transition the entire enrollment of the MA contract (including the D-SNP look-alike) to another MA contract offered by another MA organization with the same parent organization as part of a contract consolidation of separate MA contracts. As part of reviewing a request for a crosswalk exception under § 422.530(c)(2), CMS reviews the contract consolidation to ensure compliance with the change of ownership regulations (§§ 422.550 through 422.553).

While multiple options exist for MA organizations to transition D-SNP look-alike enrollees to other non-SNP MA plans, these pathways are not available for moving enrollees from D-SNP look-alikes to D-SNPs. We believe it is appropriate to limit the transition process in § 422.514(e) since although other options remain available to transition enrollees from the D-SNP look-alike, MA organizations do not have other options to transition D-SNP look-alike enrollees into D-SNPs, and movement into D-SNPs encourages enrollment in integrated plans. Furthermore, we are concerned that if D-SNP look-alikes continue to be allowed to transition enrollees into non-D-SNPs indefinitely, there is little incentive for MA organizations to avoid non-compliance with the D-SNP look-alike thresholds. Thus, for plan year 2027 and subsequent years, we propose to add new paragraph § 422.514(e)(1)(v) to limit the existing D-SNP look-alike transition pathway to MA organizations with D-SNP look-alikes transitioning enrollees into D-SNPs.

We are also considering an alternative to our proposal that would eliminate the 70-percent threshold applying for plan year 2025 but would involve additional conditions and changes related to the transition authority. Specifically, this alternative would:

- Apply the 60-percent threshold beginning in plan year 2026;
- Permit use of the transition authority into non-SNP MA plans (as currently permitted under § 422.514(e)) for plan year 2025; and
- Limit use of transition authority under § 422.514(e) to transition D-SNP look-alike enrollees into D-SNPs for plan year 2026 and beyond.

Relative to our proposal, this alternative would give plans with dually eligible individual enrollment between 70 and 80 percent of total enrollment (based on January 2024 enrollment data) one additional year to apply for a new D-SNP or service area expansion to an existing D-SNP, such that these plans could transition enrollees into a D-SNP

for plan year 2026. The alternative would balance the additional year using the existing 80-percent enrollment threshold to identify prohibited D-SNP look-alikes with an earlier limitation on the § 422.514(e) transition authority to enrollees transitioning into non-SNPs. We solicit comment on whether this alternative is a better balance of the goals of our policy to prohibit circumvention of the requirements for D-SNPs and to encourage and incentivize enrollment in integrated care plans. Among the factors we would consider in adopting the alternative instead of our proposal is the extent to which plans with between 70 and 80 percent dually eligible enrollment in plan year 2024 expect to be able to establish a D-SNP in the same service area as the D-SNP look-alike if given an additional year (that is, 2026) to transition enrollees. Based on 2023 plan year data, approximately two-thirds of the MA organizations with non-SNP MA plans with between 70 and 80 percent dually eligible individuals already have a D-SNP under the same MA organization with the vast majority of those D-SNPs having a service area that covers the same service area as the non-SNP MA plan. The other approximately one-third of the MA organizations with non-SNP MA plans with between 70 and 80 percent dually eligible individuals do not have a D-SNP in the same service area in plan year 2023. If given an additional year, these MA organizations would have more time in which to establish D-SNPs in the same service areas as non-SNP MA plans and transition the enrollees into a D-SNP.

We also propose a technical edit at § 422.514(e)(1)(i) to make the term “specialized MA plan for special needs individuals” lowercase, consistent with the definition of D-SNPs at § 422.2.

H. For D-SNP PPOs, Limit Out-of-Network Cost Sharing (§ 422.100)

MA organizations offer a range of health plan options including Medicare savings account (MSA) plans, private fee-for-service (PFFS) plans, preferred provider organizations (PPOs), health maintenance organizations (HMOs) and health maintenance organizations with point of services benefits (HMO/POS). (See § 422.4.) The most common health plan options are HMOs and PPOs. HMOs generally require enrollees to use network providers. PPOs have a network of providers but also pay for services delivered by providers not contracted with the MA organization as a network provider. PPOs can be attractive to Medicare beneficiaries who want a broader choice of providers than would be available through an HMO or

who have a specific preferred provider, like a psychiatrist, who is not in network. MA organizations offer PPOs that are open to all Medicare beneficiaries as well as D-SNP PPOs that enroll only individuals dually eligible for Medicare and Medicaid.¹⁹¹

Enrollment in D-SNP PPOs has increased in recent years, rising to approximately 925,000 enrollees as of May 2023, accounting for about 17 percent of total D-SNP enrollment. D-SNP PPO enrollment has increased by 38 percent from May 2022 to May 2023.¹⁹² Four national MA sponsors account for over 98 percent of D-SNP PPO enrollment.¹⁹³

Like PPOs offered primarily to Medicare beneficiaries not entitled to Medicaid benefits, D-SNP PPOs generally have higher cost sharing for out-of-network services than for the same services obtained from network providers. For non-D-SNP PPOs, the higher out-of-network cost sharing is meant to incentivize use of in-network providers. In D-SNP PPOs, however, the large majority of enrollees are protected from being billed for covered Medicare services by Medicare providers, including out-of-network providers. Instead, when these enrollees access services, either State Medicaid agencies pay the cost sharing or, if State payment of cost sharing is limited by a Medicaid rate for the service that is lower than the amount the D-SNP paid the provider, the provider must forego receipt of the cost sharing amounts.

Those cost sharing amounts for out-of-network services in D-SNP PPOs are often significantly higher than the cost sharing for the same services under original Medicare.

Our review of D-SNP PPO out-of-network cost sharing shows that for some important services, the cost sharing applicable to out-of-network services far exceeds the Medicare FFS cost sharing for these Part A and B benefits. For example, as of 2023:

- *Primary care providers*: 59 percent of D-SNP PPOs charge out-of-network coinsurance above 20 percent, with most ranging from 30 to 40 percent.
- *Part B prescription drugs*: 53 percent of D-SNP PPOs charge an out-of-network coinsurance above 20 percent, with most ranging from 30 to 40 percent.

¹⁹¹ There are currently no D-SNP PFFS plans. MSA plans are prohibited from enrolling dually eligible individuals. HMO/POS plans have 1,423,000 enrollees as of July 2023.

¹⁹² D-SNP PPO enrollment was at approximately 668,000 as of May 2023.

¹⁹³ The four sponsors are UnitedHealth Group (69 percent of national D-SNP PPO enrollment), Humana (23 percent), Centene (4 percent), and Elevance (2 percent).

- *DME*: 50 percent of D–SNP PPOs charge an out-of-network coinsurance above 20 percent, with most ranging from 30 to 50 percent.
- *Home health*: 41 percent of D–SNP PPOs charge an out-of-network coinsurance for home health services (original Medicare has no coinsurance). Out-of-network coinsurance ranged from 20 percent to 40 percent.
- *Dialysis*: Three percent of D–SNP PPOs charge an out-of-network coinsurance above 20 percent for dialysis.
- *Skilled Nursing Facility (SNF)*: 46 percent of D–SNP PPOs charge between 20 and 50 percent coinsurance for out-of-network SNF stays, considerably more than Traditional Medicare, which charges nothing for the first 20 days of a stay and a per diem charge for days 21–100.
- *Inpatient Hospital (Acute)*: 47 percent of D–SNP PPOs charged between 20 and 50 percent for an inpatient stay at an out-of-network acute care hospital, which can be substantially more than the Part A deductible in Traditional Medicare.
- *Inpatient Hospital (Psychiatric)*: 46 percent of D–SNP PPOs charge between 20 and 50 percent coinsurance for out-of-network inpatient psychiatric services, substantially greater than the inpatient deductible charged under Traditional Medicare.

By contrast, cost sharing for in-network services in these D–SNP PPOs largely tracks the cost sharing structure in Traditional Medicare. Seventy-nine percent charge a Part B deductible. Eighty-five percent charge 20 percent for professional services, like visits with primary care and specialist physicians, and 100 percent charge 20 percent coinsurance for Part B drugs and DME, consistent with Traditional Medicare. While this in-network benefit design is consistent with statutory and regulatory requirements for overall and service-specific limits under § 422.100(f)(6) (which sets specific cost sharing limits for certain in-network services tied to the maximum out-of-pocket (MOOP) limit used by the plan) and (j) (which identifies services for which in-network cost sharing must not exceed cost sharing in Traditional Medicare) for in-network benefits, it differs from non-D–SNP PPOs which generally provide greater reductions in in-network cost sharing (compared to Traditional Medicare cost sharing) as supplemental benefits.

This higher cost sharing for out-of-network services in D–SNP PPOs raises several concerns.

First, when State Medicaid agencies pay the cost sharing for out-of-network

services, these levels of cost sharing raise costs for State Medicaid programs. This is especially true for those few States that, by policy, pay the full Medicare cost sharing amounts for all Medicare services, rather than for specific services in the Medicaid benefit.

Second, certain dually eligible enrollees, specifically full-benefit dually eligible enrollees who are not Qualified Medicare Beneficiaries (QMBs), are liable for cost sharing if they go out of network to providers not enrolled in Medicaid, as services from these providers are not covered by Medicaid unless the provider is enrolled in Medicaid. (QMBs, in contrast, have applicable Medicare cost-sharing amounts covered by Medicaid based on coverage of cost-sharing for Medicare covered services.) Non-QMB full-benefit dually eligible individuals are protected from cost sharing under § 422.504(g)(1)(iii) if they use in-network providers, including providers not enrolled in Medicaid. The regulation imposes obligations on MA organizations to ensure that their contracted—that is, in-network—providers do not collect cost sharing from enrollees when the State is responsible for paying such amounts. However, this protection does not extend to out-of-network providers not enrolled in Medicaid.

Third, the higher out-of-network cost sharing disadvantages out-of-network safety net providers serving D–SNP PPO enrollees in States where limits established by Medicaid rates for the service result in no State payment of cost sharing.¹⁹⁴ In such a scenario, the provider may receive 70 or 60 percent of the Traditional Medicare rate for the services rather than the 80 percent that the provider would receive under Traditional Medicare (or as an in-network provider). We are concerned that this effective payment cut disincentivizes providers from serving dually eligible enrollees, which may compromise access to services for these enrollees. In addition, we are concerned that such disincentives undermine the promise of out-of-network access that is a key component of how D–SNP PPOs are marketed to potential enrollees.

In addition to the potential impact on States, safety net providers and dually

¹⁹⁴ For example, if the Medicare (or MA) rate for a service is \$100, of which \$20 is beneficiary coinsurance, and the Medicaid rate for the service is \$90, the State would only pay \$10. If the Medicaid rate is \$80 or lower, the State would make no payment. This is often referred to as the “lesser of” policy. Under the “lesser of” policy, a State caps its payment of Medicare cost-sharing at the Medicaid rate for a particular service.

eligible individuals of this cost sharing structure, we believe such higher cost sharing for out-of-network services may result in situations that are inconsistent with the policy goals underlying section 1852(a)(2) of the Act. Section 1852(a)(2)(A) of the Act describes how MA organizations can satisfy the requirement to cover Traditional Medicare services (that is, Part A and B benefits, with limited exceptions) under section 1852(a)(1)(A) when covered services are furnished by non-contracted (that is, out-of-network) providers. This statute provides that the MA organization has satisfied its coverage obligation for out-of-network services if the plan provides payment in an amount “so that the sum of such payment and any cost sharing provided for under the plan is equal to at least the total dollar amount for payment for such items and services as would otherwise be authorized under parts A and B (including any balance billing permitted under such parts).”

For a non-D–SNP PPO, in which the majority of plan enrollees must pay plan cost sharing, the total dollar amount for a service paid at the Medicare rate will equal the total dollar amount under parts A and B, even if the cost sharing exceeds the cost sharing under original Medicare.

For a D–SNP PPO, however, the vast majority of plan enrollees are not liable for cost sharing for out-of-network services, just as they are not liable for such cost sharing under Traditional Medicare.¹⁹⁵ Therefore, whenever State Medicaid limits on payment of Medicare cost sharing result in no payment of cost sharing or payment of only a portion of cost sharing, the total dollar amount of payment received by the out-of-network provider for these covered services is less than the provider would collect under Traditional Medicare whenever the plan out-of-network cost sharing exceeds the cost sharing for those services under Traditional Medicare.

For example, a provider in a State that capped its cost sharing payments at a Medicaid primary care rate that is 70 percent of the Medicare rate would receive just 70 percent of that Medicare rate when the provider is not in the PPO’s network and the PPO’s out-of-network cost sharing is 30 percent or higher. That provider would receive 80 percent of the Medicare rate under

¹⁹⁵ For more information on cost sharing protections applicable to dually eligible individuals, see: [https://www.cms.gov/medicare-medicare-and-medicare-coordination/medicare-and-medicare-coordination-office/qmb](https://www.cms.gov/medicare-medicare-and-medicare-coordination/medicare-and-medicare-coordination/medicare-medicare-coordination-office/qmb).

Traditional Medicare for the covered service.

This lesser net out-of-network provider payment in a D-SNP PPO undermines the balance of obligations and benefits among MA organizations and Medicare providers that the statute creates to regulate out-of-network payments and beneficiary access for the MA program. While section 1852(a)(2)(A) of the Act requires the total dollar amount to be at least as much as would be authorized under Traditional Medicare, Medicare providers are required by sections 1852(k)(1) and 1866(a)(1)(O) of the Act to accept such amounts as payment in full. When a D-SNP PPO imposes cost sharing greater than Traditional Medicare and that cost sharing is unpaid by the State and uncollectable from the beneficiary, the MA organization has, in effect, failed to fulfill the spirit of its side of this statutory scheme and the providers are in effect forced to accept less than they would receive under original Medicare if they agree to treat the D-SNP PPO enrollee.

In a D-SNP PPO, therefore, we are concerned that the combination of these issues results in a situation frustrating the underlying intent of section 1852(a)(2)(A) of the Act because, for services furnished to many (if not all) enrollees in the D-SNP PPO, the out-of-network provider potentially receives a total payment that is less than the total payment available under Traditional Medicare. To address these concerns, we are proposing new limits on out-of-network cost sharing under D-SNP PPOs. We have authority under section 1856(b)(1) of the Act to establish standards for MA organizations and MA plans to carry out the MA statute (that is, Part C of Title XVIII of the Act) in addition to authority, under section 1857(e)(1) of the Act, to adopt additional terms and conditions for MA contracts that are not inconsistent with the Part C statute and that are necessary and appropriate for the MA program. Further, CMS is not obligated to accept any and every bid from an MA organization and is authorized to negotiate MA bids under section 1854(a)(5)(C) and (a)(6)(B) of the Act. This proposal would establish minimum standards for D-SNP PPO plans that are consistent with and necessary and appropriate for the MA program to address our concerns.

We propose at § 422.100(o)(1) that an MA organization offering a local PPO plan or regional PPO plan that is a dual eligible special needs plan (that is, a D-SNP) cap out-of-network cost sharing for professional services at the cost sharing limits for such services established at § 422.100(f)(6) when such services are delivered in network starting in 2026. The term “professional services” as used here means the same thing as it does in existing § 422.100(f)(6)(iii) and includes primary care services, physician specialist services, partial hospitalization, and rehabilitation services. Under this proposal, a D-SNP PPO with a catastrophic limit set at the mandatory MOOP limit in 2026 and subsequent years must have cost sharing for a visit with an out-of-network psychiatrist or other specialist (that is, cost sharing subject to paragraph (f)(6)(iii)) that is capped at 30 percent coinsurance. If the catastrophic limit is set at the intermediate MOOP limit in 2026 and subsequent years, the coinsurance cap would be set at 40 percent. If the catastrophic limit is set at the lower MOOP limit in 2026 and subsequent years, the coinsurance cap would be 50 percent. Under our proposal, the rules in § 422.100(f)(6) and (j)(1) about how we assess that copayments that are actuarially equivalent to coinsurance would apply here as well.

We propose to apply cost sharing limits on out-of-network professional services because this category of services includes the physician and psychiatry services most utilized out-of-network in D-SNP PPOs. In addition, physician services are among the services for which Medicaid rates will most commonly either result in no payment of cost sharing due to limits on Medicaid rates or will increase State liability for cost sharing but still not result in total payment of at least 80 percent of the Medicare rate.¹⁹⁶

Our proposal at § 422.100(o)(1) also would require that cost sharing for out-of-network acute and psychiatric inpatient services be limited by the cost sharing caps under § 422.100(f)(6) that now apply only to in-network benefits.

Using the same methodology to calculate comparable FFS cost sharing in § 422.100(f)(6)(iv), the cost sharing limit for a D-SNP PPO with a catastrophic limit set at the mandatory MOOP limit could not exceed 100 percent of estimated Medicare FFS cost sharing, including the projected Part A deductible and related Part B costs, for each length-of-stay scenario in an out-of-network inpatient or psychiatric hospital. For catastrophic limits equivalent to the intermediate and lower MOOP amounts, higher cost sharing for out-of-network cost sharing for inpatient and psychiatric stays could be charged as described at § 422.100(f)(6)(iv)(D)(2) and (3), respectively.

We also propose at § 422.100(o)(2), by cross-referencing § 422.100(j)(1), that cost sharing for out-of-network services under D-SNP PPOs be limited to the existing cost sharing limits now applicable to specific in-network services for all MA plans:

- Cost sharing for chemotherapy administration services, including chemotherapy/radiation drugs and radiation therapy integral to the treatment regimen, other Part B drugs, and renal dialysis services as defined at section 1881(b)(14)(B) of the Act, would be capped at the cost sharing applicable for those service under Traditional Medicare.

- For skilled nursing care, defined as services provided during a covered stay in a skilled nursing facility (SNF) during the period for which cost sharing would apply under Traditional Medicare, cost sharing would be limited to the cost sharing amounts under Traditional Medicare when the MA plan establishes the mandatory MOOP catastrophic limit under § 422.101(d)(3). When the MA plan establishes the lower MOOP catastrophic limit, the cost sharing could not be greater than \$20 per day for the first 20 days of a SNF stay. When the MA plan establishes the intermediate MOOP catastrophic limit, the cost sharing could not be greater than \$10 per day for the first 20 days of a SNF stay.

- Regardless of the MOOP amount established by the MA plan, the per-day cost sharing for days 21 through 100 could not be greater than one eighth of the projected (or actual) Part A deductible amount.

¹⁹⁶ Only 14 States have Medicaid primary care rates that are greater than 80 percent of the Medicare rate. See: <https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D>.

- For home health services (as defined in section 1861(m) of the Act), when the MA plan establishes a mandatory or intermediate MOOP type, cost sharing could not be greater than Traditional Medicare. When the MA plan establishes the lower MOOP catastrophic limit, the cost sharing could not be greater than 20 percent coinsurance or an actuarially equivalent copayment.

- Cost sharing could not be greater than the applicable cost sharing under Traditional Medicare, when the MA plan establishes the mandatory MOOP catastrophic limit for the following specific service categories of durable medical equipment (DME): equipment, prosthetics, medical supplies, diabetes monitoring supplies, diabetic shoes or inserts.

For regional PPO D-SNPs, we propose to exclude paragraph (j)(1)(C)(2) and the last sentence of paragraph (j)(1)(E) regarding overall actuarial equivalence requirements to avoid conflict with section 1852(a)(1)(B)(ii) of the Act.

We propose applying out-of-network cost sharing limits to those services enumerated at § 422.100(f)(6) and (j)(1) because MA organizations and CMS have experience limiting cost sharing to Traditional Medicare for these categories of services when they are furnished in-network. In addition, this would establish alignment and consistency between the in-network and out-of-network cost sharing used by D-SNP PPOs for these services. We also note that section 1852(a)(1)(B)(iv) of the Act limits cost sharing for some of these services, including chemotherapy administration and dialysis, to cost sharing levels in Traditional Medicare, which CMS has implemented in § 422.100(j) to apply to in-network benefits. As noted above, these services are among those services for which D-SNP PPOs most often impose cost sharing greater than Traditional Medicare.

We are considering a requirement to limit all D-SNP PPO out-of-network cost sharing to no greater than Traditional Medicare, or using a limit specifically for physician services, including psychiatric and other mental health services, rather than using the cost sharing limits in § 422.100(f)(6). These are among the most commonly accessed services out-of-network in D-SNP PPOs, and these safety net providers are most likely to see reduced payment compared to their Traditional Medicare patients, which weighs in favor of requiring cost sharing to align with Traditional Medicare. Although we continue to consider these alternatives and request comment on them, we

decided to propose application of the cost sharing limits that are applicable for in-network coverage for specific benefit categories, some of which are capped at Traditional Medicare cost sharing and some of which are higher. We propose to take this measured approach on the one hand to impose cost sharing limits on those services where the limits would have the most impact—those services most used out-of-network in D-SNP PPOs and where the greater cost sharing has the most impact on provider payment and, for those dually eligible beneficiaries liable for cost sharing, ability to pay. We also believe this approach, at least initially, would mitigate any negative impact on MA organizations and D-SNP PPO enrollees as MA organizations redirect funds from other supplemental benefits to reduce cost sharing for these out-of-network services. However, we seek comment on whether there are additional out-of-network services for which cost sharing should be limited to the levels applicable in Traditional Medicare.

We considered proposing out-of-network cost sharing limits for D-SNP PPOs only for services for which the Medicaid payment of cost sharing did not result in a total payment that was at least equivalent to the payment under Traditional Medicare. That approach would address our concern about how high out-of-network costs sharing by D-SNP PPOs appears to circumvent the goal of section 1852(a)(2)(A) of the Act that the out-of-network providers that furnish covered services to enrollees in MA plans receive the amount that the provider would have received under Traditional Medicare. However, such an approach would create an overly complex and likely unworkable system of cost sharing limits that differed both by State (depending on whether State policy limited cost sharing for specific services), by service, and—in some cases—by individual provider. For example, a State may pay the full Medicare cost sharing for Part B drugs administered by an oncologist but set the rate for administration of those drugs at 50 percent of the Medicare rate, resulting in no payment of cost sharing. That would result in two parts of a single services—payment for chemotherapy drugs and administration of such drugs—being subject to different cost sharing limits. The services subject to cost sharing limits could also change over time as States changed the rates at which they reimbursed for such services.

We also considered proposing out-of-network cost sharing limits only for services furnished out of network to

QMBs because they are always protected from being billed cost sharing (see sections 1848(g)(3), 1866(a)(1)(A), 1902(n), and 1905(p)(3) of the Act). However, this would not allow for the MA organization to apply its benefit uniformly to all its members, as required by 42 CFR 422.100(d)(2)(i), unless the SMAC limits enrollment in the D-SNP PPO to QMBs. In addition, managing cost sharing benefits in a non-uniform way could be administratively burdensome for both MA organizations and providers or difficult to clearly and accurately explain to enrollees in the member materials.

Finally, we believe our proposed uniform application of out-of-network cost sharing limits for all PPO D-SNPs is the appropriate way to address our concerns about section 1852(a)(2)(A), the shifting of costs to States, the reduction in net payments to safety net providers, and the potential for excessive cost sharing for those dually eligible individuals, who, while low income, do not benefit from cost sharing protections out of network.

To provide the industry time to adjust to and for CMS to operationalize these new requirements, we propose to implement these new limits starting for the 2026 plan year.

Currently, D-SNP PPOs already submit out-of-network benefits for a limited review to ensure that cost sharing does not exceed 50 percent of the costs (as required by § 422.100(f)(6)(i)) and in-network benefits for a review to ensure compliance with the cost sharing limits we propose to apply to out-of-network cost sharing. Therefore, we do not believe this proposed rule creates substantial information collection requirements.

We do not expect any new burden to be associated with these proposed changes, as MA organizations are currently required to include information on MA cost sharing in their bids. Further, we do not expect any additional burden on CMS, as modifications to account for this proposed provision would be completed as part of normal business operations.

IX. Updates to Program of All-Inclusive Care for the Elderly (PACE) Policy

A. Corrective Action (§ 460.194)

Sections 1894(e)(4) and 1934(e)(4) of the Act require CMS, in cooperation with the State administering agency (SAA), to conduct comprehensive reviews of PACE organizations' compliance with all significant program requirements. Additionally, sections 18941(e)(6)(A)(i) and 1934(e)(6)(A)(i) of

the Act condition the continuation of the PACE program agreement upon timely execution of a corrective action plan if the PACE provider fails to substantially comply with the program requirements as set forth in the Act and regulation. In the 1999 PACE interim final rule, we specified at § 460.194(a) and (c) that PACE organizations must take action to correct deficiencies identified by CMS or the SAA, or PACE organizations may be subject to sanction or termination (84 FR 66296). The 2019 PACE final rule amended § 460.194(a) to expand the ways CMS or the SAA may identify deficiencies that the PACE organization must correct (84 FR 25677). These include ongoing monitoring, reviews, audits, or participant or caregiver complaints, and for any other instance in which CMS or SAA identifies programmatic deficiencies requiring correction (84 FR 25677).

The 1999 PACE interim final rule also specified at § 460.194(b) that CMS or the SAA monitors the effectiveness of PACE organizations' corrective actions. The burden on CMS and SAAs to always monitor the effectiveness of every corrective action taken by the organization after an audit is high, and the number of audits, and thus the number of instances in which monitoring is required, increases each year because the PACE program continues to rapidly grow, and CMS is required to conduct audits in each year of the three-year trial period for new PACE contracts. However, our experience overseeing this program has shown that it is not always necessary or worthwhile for CMS to monitor the effectiveness of every corrective action taken by an audited organization. For example, a PACE organization may implement a corrective action that impacts its unscheduled reassessments due to a change in participant status, but historically, these types of assessments are not conducted frequently, therefore, it may not be worthwhile for CMS or the states to spend resources monitoring the effectiveness of that correction due to limited data available for CMS or the SAA to monitor. Therefore, we propose to revise § 460.194(b) to specify that, at their discretion, CMS or the SAA may monitor the effectiveness of corrective actions. This proposal would give CMS and the SAA the flexibility to determine

how to use their oversight resources most effectively, which will be increasingly important as PACE continues to grow.

This proposal would not change our expectation that PACE organizations expeditiously and fully correct any identified deficiencies, and CMS and the SAAs would continue to engage in monitoring efforts that prioritize participant health and safety and program integrity. In addition, as a part of a PACE organization's oversight compliance program, we require at § 460.63 that PACE organizations adopt and implement effective oversight requirements, which include measures that prevent, detect and correct non-compliance with CMS's program requirements. A PACE organization's oversight compliance program must, at a minimum, include establishment and implementation of procedures and a system for promptly responding to compliance issues as they are raised. In addition, compliance oversight programs must ensure ongoing compliance with CMS requirements.

Since the effect of the proposed change would be to provide CMS and the SAA more flexibility when monitoring the effectiveness of corrective actions without placing new requirements on CMS, the SAAs, or PACE organizations, we believe this change would create no additional burden for PACE organizations. Additionally, we do not expect this change to have economic impact on the Medicare Trust Fund.

We solicit comment on this proposal.

B. Service Determination Requests Pending Initial Plan of Care (§ 460.121)

Sections 1894(b)(2)(B) and 1934(b)(2)(B) of the Act specify that PACE organizations must have in effect written safeguards of the rights of enrolled participants, including procedures for grievances and appeals. Along with the regulations at § 460.120 related to grievances, and § 460.122 related to appeals, CMS created a process for service determination requests, the first stage of an appeal, at § 460.121.

The PACE regulations define a service determination request as a request to initiate a service; modify an existing service, including to increase, reduce, eliminate, or otherwise change a service; or to continue coverage of a service that

the PACE organization is recommending be discontinued or reduced (see § 460.121(b)(1)(i) through (iii)). In the January 2021 final rule (86 FR 6024), we finalized an exception to the definition of service determination request at § 460.121(b)(2), which, as amended, provides that requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care. When we proposed this exception in the February 2020 proposed rule, we noted that the exception would apply any time before the initial plan was finalized and discussions among the interdisciplinary team (IDT) ceased (85 FR 9125). We explained that we believed this change would benefit both participants and PACE organizations because it would allow the IDT and the participant and/or caregiver "to continue to discuss the comprehensive plan of care taking into account all aspects of the participant's condition as well as the participant's wishes" (*Id.*). We also stated that "if a service was not incorporated into the plan of care in a way that satisfies the participant, the participant would always have the right to make a service determination request at that time" (85 FR 9126).

Our intention for this provision was that the IDT would discuss specific requests made by a participant and/or caregiver as part of the care planning process and determine whether these requests needed to be addressed in the plan of care. We stated in the February 2020 proposed rule that if a participant asked for a specific number of home care hours, that the request would not need to be processed as a service determination request because the IDT was actively considering how many home care hours the participant should receive as part of the development of the initial plan of care (85 FR 9125). This rationale is also consistent with our statement in the proposed rule titled "Medicare and Medicaid Programs; Programs of All-Inclusive Care for the Elderly (PACE)," which appeared in the August 16, 2016 **Federal Register**, that "CMS expects the plan of care to reflect that the participant was assessed for all services even where a determination is made that certain services were unnecessary at that time" (81 FR 54684).

However, as part of our oversight and monitoring of PACE organizations, we have found that often requests made by participants and/or caregivers prior to the finalizing of the care plan are not discussed during the care planning process and are therefore not considered by the IDT. These requests are some of the first communications from participants related to the care they will be receiving from the PACE organization and would otherwise be considered service determination requests at any other stage of their enrollment. While we continue to believe that it is not prudent for the PACE organization to process these requests as service determination requests, it is important that the IDT consider these requests and determine whether they are necessary for the participant.

Therefore, we propose to modify the regulation text at § 460.121(b)(2) to specify that service requests made prior to developing the participant's initial plan of care must either be approved and incorporated into the participant's initial plan of care, or the rationale for why it was not approved and incorporated must be documented. Specifically, we propose to add the add the following language at § 460.121(b)(2). For all requests identified in this section, the interdisciplinary team must—

- Document the request; and
- Discuss the request during the care plan meeting and either—

++ Approve the requested service and incorporate it into the participant's initial plan of care; or

++ Document their rationale for not approving the service in the initial plan of care.

We believe this change is consistent with existing plan of care requirements at § 460.104(b) and aligns with our plan of care proposals in the December 2022 proposed rule (87 FR 79452).

As the development of the plan of care is a typical responsibility for the IDT, any burden associated with this would be incurred by persons in their normal course of business. Therefore, the burden associated with documenting the determination of any assessment of a participant and/or caregiver service request during the initial care planning process is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

X. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq.*), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a “collection of information,” as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations, is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection requirement should be approved by OMB, section 3506(c)(2)(A) of the PRA

requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment (see section VII.D. of this preamble for further information) on each of these issues for the following sections of this document that contain information collection requirements. Comments, if received, will be responded to within the subsequent final rule.

A. Wage Data

1. Private Sector

To derive mean costs, we are using data from the most current U.S. Bureau of Labor Statistics' (BLS's) National Occupational Employment and Wage Estimates for all salary estimates (https://www.bls.gov/oes/2022/may/oes_nat.html), which, at the time of publication of this proposed rule, provides May 2022 wages. In this regard, Table J1 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE J1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

	Occupation Code	Mean Hourly Wage (\$/hr)	Fringe Benefits and Other Indirect Costs (\$/hr)	Adjusted Hourly Wage (\$/hr)
Business operations specialists (all others)	13-1199	39.75	39.75	79.50
Compliance officers	13-1041	37.01	37.01	74.02
Computer programmer	15-1251	49.42	49.42	98.84
Insurance Sales Agent (Agent-Broker)	41-3021	37.00	n/a	n/a
Pharmacist	29-1051	62.22	62.22	124.44
Pharmacy Technician	29-2052	19.35	19.35	38.70
Physician all others	29-1229	114.76	114.76	229.52
Software and Web Developers, Programmers, Testers	15-1250	60.07	60.07	120.14
Software Developers	15-1252	63.91	63.91	127.82
Registered Nurse	24-1141	42.8	42.8	85.6

As indicated, except for Insurance Sales Agents, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe

benefits and other indirect costs vary significantly from employer to employer and because methods of estimating these costs vary widely from study to study. In this regard, we believe that

doubling the hourly wage to estimate costs is a reasonably accurate estimation method.

However, the mean wage for Insurance Sales Agent is being applied

to Agent-Brokers who work on behalf of Medicare Advantage plans. We are not adjusting their mean hourly wage for fringe benefits and other indirect costs because this proposed rule includes a proposal which accounts for payments for certain administrative activities while explicitly precluding others. These proposed payments would have their own annual update.

2. Beneficiaries

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of \$20.71/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of \$998, divided by 40 hours to calculate an hourly pre-tax wage rate of \$24.95/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of \$20.71/hr. Unlike our private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

For valuing time spent outside of work, there is logic to this approach but also to using a fully loaded wage. In the past we have used occupational code 00–0000, the average of all occupational codes, which currently is \$29.76/hr. Thus we propose a range for enrollees of \$20.71/hr–\$29.76/hr. Nevertheless, the upper limit is based on an average over all occupations while the lower limit reflects a detailed analysis by ASPE targeted at enrollees many of whom are over 65 and unemployed; consequently, in our primary estimates we will use the lower limit as we consider it more accurate. The effect of this range will be footnoted in Table J5 and the summary table. Since the impact to beneficiaries is approximately \$54,000, increasing the wage by 50 percent would result in a roughly \$24,000 increase.

B. Proposed Information Collection Requirements (ICRs)

The following ICRs are listed in the order of appearance within the preamble of this proposed rule.

1. ICRs Regarding Network Adequacy in Behavioral Health (§ 422.116(b)(2) and (d)(2) and (5))

The following proposed changes will be submitted to OMB for review under control number 0938–1346 (CMS–10636).

To ensure that MA enrollees have access to provider networks sufficient to provide covered services, including behavioral health service providers, we are proposing to add one new facility-specialty type that will be subject to network adequacy evaluation under § 422.116. As discussed in the “Expanding Network Adequacy Requirements for Behavioral Health” section of the preamble, we are proposing to amend the network adequacy requirements to add one combined facility-specialty category called “Outpatient Behavioral Health” under § 422.116(b)(2) and to add “Outpatient Behavioral Health” to the time and distance requirements in § 422.116(d)(2). This new category can include, for network adequacy evaluation purposes, provider types including Marriage and Family Therapists (MFTs), Mental Health Counselors (MHCs), Opioid Treatment Program (OTP) providers Community Mental Health Centers or other behavioral health and addiction medicine specialists and facilities. Based on the current regulation at § 422.116(e)(2) for all facility-specialty types other than acute inpatient hospitals, the minimum provider number requirement for this proposed new provider type is one. Finally, we also propose to add the new “Outpatient Behavioral Health” facility-specialty type to the list at § 422.116(d)(5) of the specialty types that will receive a 10-percentage point credit towards the percentage of beneficiaries that reside within published time and distance standards for certain providers when the plan includes one or more telehealth providers of that specialty type that provide additional telehealth benefits, as defined in § 422.135, in its contracted network. To determine the potential burden regarding this proposal, we considered cost estimates for MA organizations to update policies and procedures. However, the burden for updating the HPMS system is a burden to CMS and its contractors and hence not subject to COI review.

Although there is a no cost for MA organizations to report new specialty types to CMS for their network adequacy reviews as this proposal requires, we have determined that there is a minimal one-time cost for MA organizations to update their policies

and procedures associated with this proposal.

First, regarding reporting the proposed new specialty types to CMS, MA organizations are already conducting ongoing work related to network adequacy reviews that happen during the initial or service area application, or every 3 years for the triennial review. This proposal would only require that the proposed specialty type be added to the Health Services Delivery (HSD) tables during any network adequacy evaluation requested by CMS. The time to conduct tasks related to adding additional specialty types on the HSD tables is negligible.

We understand that MA organizations will need to update their policies and procedures related to submission of HSD tables to ensure that the new required behavioral health specialty type is included. We estimate that it would take 5 minutes (0.0833 hr) at \$79.50/hr for a business operations specialist to update of policies and procedures related to this task. In aggregate we estimate a one-time burden of 62 hours (742 MA contracts * 0.0833 hr) at a cost \$4,929 (62 hr * \$79.50/hr).

2. ICRs Regarding Standards for Electronic Prescribing (§ 423.160 and 45 CFR 170.205 and 170.299)

In section III.B. of this proposed rule, we propose updates to the standards to be used for electronic transmission of prescriptions and prescription-related information for Part D covered drugs for Part D eligible individuals. This includes: (1) after a transition period, requiring the National Council for Prescription Drug Plans (NCPDP) SCRIPT standard version 202301, proposed for adoption at 45 CFR 170.205(b)(2), and retiring use of NCPDP SCRIPT standard version 2017071 for communication of a prescription or prescription-related information supported by Part D sponsors; (2) requiring use of NCPDP RTPB standard version 13 for prescriber RTBTs implemented by Part D sponsors beginning January 1, 2027; and (3) requiring use of NCPDP Formulary and Benefit (F&B) standard version 60, proposed for adoption at 45 CFR 170.205(u), and retiring use of NCPDP F&B version 3.0 for transmitting formulary and benefit information between prescribers and Part D sponsors. These proposals update existing standards that have historically been exempt from the PRA, as explained in this section.

The initial electronic prescribing standards for the Medicare Part D program were adopted in the final rule “Medicare Program; Standards for E-

Prescribing Under Medicare Part D and Identification of Backward Compatible Version of Adopted Standard for E-Prescribing and the Medicare Prescription Drug Program (Version 8.1)” (Initial Standards final rule), which appeared in the April 4, 2008, **Federal Register** (73 FR 18917). The Initial Standards final rule implemented the first update to the electronic prescribing foundation standards in the Part D program that had been adopted in the final rule “Medicare Program; E-Prescribing and the Prescription Drug Program” (Foundation Standards final rule), which appeared in the November 7, 2005, **Federal Register** (70 FR 67567). The Initial Standards final rule adopted the updated the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 8.1 and retired the previous NCPDP SCRIPT standard version 5.0. With respect to ICRs in the Initial Standards final rule, CMS stated that as a third-party disclosure requirement subject to the PRA, Medicare Part D sponsors must support and comply with the adopted e-prescribing standards relating to covered Medicare Part D drugs, prescribed for Medicare Part D eligible individuals. However, the requirement that Medicare Part D sponsors support electronic prescription drug programs in accordance with standards set forth in this section, as established by the Secretary, does not require that prescriptions be written or transmitted electronically by prescribers or dispensers. These entities are required to comply with the adopted standards when they electronically transmit prescription or prescription-related information for covered transactions. Testimony presented to the [National Committee on Vital and Health Statistics] indicates that most health plans/[pharmacy benefit managers] currently have [electronic] prescribing capability either directly or through contract with another entity. Therefore, we do not believe that utilizing the adopted standards will impose an additional burden on Medicare Part D sponsors. Since the standards that have been adopted are already familiar to industry, we believe the requirement to utilize them in covered [electronic] prescribing transactions constitutes a usual and customary business practice. As such, the burden associated with the requirements is exempt from the PRA as stipulated under 5 CFR 1320.3(b)(2).

Subsequent rules which have updated electronic prescribing standards in the Medicare Part D program have not included any burden estimates. Specifically—

- The “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, DME Face-to-Face Encounters, Elimination of the Requirement for Termination of Non-Random Prepayment Complex Medical Review and Other Revisions to Part B for CY 2013” final rule, which appeared in the November 16, 2012, **Federal Register** (77 FR 68891). This final rule updated the electronic prescribing standards in Medicare Part D from NCPDP SCRIPT standard version 8.1 to version 10.6;

- The “Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014” final rule, which appeared in the **Federal Register** December 10, 2013 (78 FR 74229). This final rule updated the electronic prescribing standards in Medicare Part D from NCPDP Formulary and Benefit (F&B) standard version 1.0 to 3.0; and

- The “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” final rule, which appeared in the **Federal Register** April 16, 2018 (83 FR 16640). This final rule updated the electronic prescribing standards in Medicare Part D from NCPDP SCRIPT standard version 10.6 to 2017071.

Rationale that further supports CMS’s longstanding approach to not estimate burden associated with updating electronic prescribing standards is described in the proposed rule “Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program” (November 2017 proposed rule), which appeared in the November 28, 2017, **Federal Register** (82 FR 56336). When describing the proposed update of the NCPDP SCRIPT standard from version 10.6 to 2017071 in the November 2017 proposed rule, CMS stated that we believe that transitioning to the new 2017071 versions of the transactions already covered by the current Part D [electronic] prescribing standard (version 10.6 of the NCPDP SCRIPT) will impose de minimis cost on the industry as the burden in using the updated standards is anticipated to be the same as using the old standards for the transactions currently covered by the program. We believe that prescribers and dispensers that are now prescribing [electronically] largely invested in the

hardware, software, and connectivity necessary to prescribe [electronically]. We do not anticipate that the retirement of NCPDP SCRIPT 10.6 in favor of NCPDP SCRIPT 2017071 will result in significant costs.

Similarly, Part D sponsors have been required support real-time benefit tools (RTBTs) since January 1, 2021, as finalized in the “Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses” final rule, which appeared in the **Federal Register** May 23, 2019 (84 FR 23832). Because Part D sponsors have invested in the hardware, software, and connectivity necessary to utilize RTBTs, we believe that adopting the NCPDP Real-Time Prescription Benefit (RTPB) standard version 13 will impose de minimis cost on the industry and that costs will be largely offset by the advantages and efficiencies associated with interoperability that a standard brings.

The operations associated with updates to standards that we propose in this proposed rule are analogous to the operations associated with updates to standards in the prior rules described. Therefore, the proposals in section III.B. of this proposed rule are exempt from the PRA.

3. ICRs Regarding to Improvements to Drug Management Programs (§§ 423.100 and 423.153)

The following proposed changes will be submitted to OMB for review under control number 0938–TBD (CMS–10874). At this time, the OMB control number has not been determined, but it will be assigned by OMB upon their clearance of our proposed collection of information request. We intend to identify the new control number in the subsequent final rule. The control number’s expiration date will be issued by OMB upon their approval of our final rule’s collection of information request. When ready, the expiration date can be found on [reginfo.gov](https://www.reginfo.gov).

Ordinarily, the proposed changes would be submitted to OMB for review under control number 0938–0964 (CMS–10141), where the current OMB-approved Part D drug management program (DMP) information collection and burden is located. However, based on internal review, we are removing the DMP information collection and related burden from CMS–10141 and submitting it under a new collection of information request (OMB 0938–TBD, CMS–10874). This change will streamline clearance processes and minimize duplicative administrative burden for CMS and other stakeholders. Although we are proposing to remove

DMP burden from CMS–10141, that collection will continue to include burden associated with many other aspects of the Part D program.

As described in section III.E. of this proposed rule, we propose to amend regulations regarding Part D DMPs for beneficiaries at risk of abuse or misuse of frequently abused drugs (FADs). Specifically, we propose to amend the definition of “exempted beneficiary” at § 423.100 by replacing the reference to “active cancer-related pain” with “cancer-related pain.” This proposed change would reduce the overall burden associated with sponsors providing DMP case management and notices to potentially at-risk beneficiaries (PARBs) and at-risk beneficiaries (ARBs) because some beneficiaries identified as PARBs under the current definition would be excluded under the amended definition.

Under § 423.153(a), all Part D plan sponsors must have a DMP to address overutilization of FADs for enrollees in their prescription drug benefit plans. Based on 2023 data, there are 319 Part D parent organizations. The provisions codified at § 423.153(f)(2) require that Part D sponsors conduct case management of beneficiaries identified by the minimum overutilization monitoring system (OMS) criteria through contact with their prescribers to determine if a beneficiary is at-risk for abuse or misuse of opioids and/or benzodiazepines. Case management must include informing the beneficiary’s prescriber(s) of the beneficiary’s potential risk for misuse or abuse of FADs and requesting information from the prescribers relevant to evaluating the beneficiary’s risk, including whether they meet the regulatory definition of exempted beneficiary. Under current CMS regulations at § 423.100, if a beneficiary meets the definition of an exempted beneficiary, the beneficiary does not meet the definition of a PARB. For this reason, exempted beneficiaries cannot be placed in a Part D sponsor’s DMP.

In 2022, the OMS identified 43,915 PARBs meeting the minimum criteria prior to applying exclusions and 30,411 after excluding exempted beneficiaries. Thus, 13,504 beneficiaries (43,915 – 30,411) met the definition of exempted beneficiary. Amending the definition of “exempted beneficiary” at § 423.100 by replacing the reference to “active cancer-related pain” with “cancer-related pain” would result in 46

additional enrollees meeting the definition of exempted beneficiary, or 13,550 exempted beneficiaries total (13,504 + 46). This yields 30,365 (43,915 – 13,550) instead of 30,411 beneficiaries requiring case management under the amended definition.

We estimate it takes an average of 5 hours for a sponsor to conduct case management for a PARB. We assume certain components of case management can be completed by staff of differing specialization and credentialing. Of the 5 hours, we assume that 2 hours at \$124.44/hr would be conducted by a pharmacist (such as initial review of medication profiles, utilization, etc.), 2 hours at \$38.70/hr would be conducted by a pharmacy technician, and 1 hour at \$229.52/hr would be conducted by a physician to work directly with prescribers on discussing available options and determining the best course of action. The case management team would require 5 hours at a cost of \$555.80 per PARB case managed ($[2 \text{ hr} \times \$124.44/\text{hr}] + [2 \text{ hr} \times \$38.70/\text{hr}] + [1 \text{ hr} \times \$229.52/\text{hr}]$). Therefore, the case management team’s average hourly wage is \$111.16/hr ($\$555.80/5 \text{ hr}$). In aggregate, we estimate annual burden with the proposed changes for case management is 151,825 hours (30,365 enrollees subject to case management * 5 hr/response) at a cost of \$16,876,867 (30,365 enrollees * (5 hr * \$111.16/hr); see case management row in Table J3. CMS 10141 included an estimate for the current case management burden of 178,855 hours and, with the hourly wage updated, a cost of \$19,881,522; see case management row in Table J2. Thus, we calculate a savings of 27,033 hours (178,855 – 151,825) and \$3,004,655 ($\$19,955,671 - \$16,876,867$) with this current proposed burden; see case management row in Table J4 and note that in Table J4 we list savings as a negative number.

As a result of case management, a portion of PARBs may receive notice from a plan sponsor, informing the beneficiary of the sponsor’s intention to limit their access to coverage of opioids and/or benzodiazepines. Approximately 5 percent of PARBs identified by OMS criteria receive an initial and either a second notice or an alternate second notice. Amending the definition of “exempted beneficiary” would reduce the number of notices sent. Therefore, it follows that 2 fewer PARBs would receive notices (46 additional

individuals * 0.05) and there would be 4 fewer notices total (2 enrollees * 2 notices/enrollee). Approximately 1,518 (30,365 * 0.05) PARBs overall would receive an initial and second notice (or alternate second notice) annually. We estimate it takes a pharmacy technician at \$38.70/hr approximately 5 minutes (0.0833 hr) to send each notice and a total of 10 minutes (0.1667 hr) per enrollee to send both notices. In aggregate, we estimate an annual burden with the proposed changes for sending notices of 253 hours (1,518 enrollees * 0.1667 hr) at a cost of \$9,791 (253 hr * \$38.70/hr) to send both notices; see the row for notification for enrollees in Table J3. CMS 10141, presenting the current burden, includes an estimated notice burden of 1,319 hours and, with the hourly wage updated, a cost of \$51,045; see the row for notification for enrollees in Table J2. Thus, we calculate a savings of 1,066 hours (1,319 – 253) and \$41,254 ($\$51,045 - \$9,791$) with this current proposed burden; see the row for notification for enrollees in Table J4 and note that in Table J4 we list savings as a negative number.

Amending the definition of “exempted beneficiary” would also reduce the burden of disclosure of DMP data to CMS based on the outcome of case management of PARBs. Using 30,365 beneficiaries requiring DMP data disclosure, we estimate that it would take (on average) 1 minute (0.0167 hr) at \$38.70/hr for a sponsor’s pharmacy technician to document the outcome of case management and any applicable coverage limitations in OMS and/or MARx. In aggregate, we estimate an annual burden with the proposed changes for notification to CMS of 507 hours (30,365 PARBs * 0.0167 hr) at a cost of \$19,621 (507 hr * \$38.70/hr); see the row for notification to CMS in Table J3. CMS–10141, presenting the current burden, includes an estimated data disclosure burden of 597 hours and, with updated hourly wages, a cost of \$23,104; see the row for notification to CMS of Table J2. Thus, we calculate a savings of 90 hours (597 – 507) and \$3,483 ($\$23,104 - \$19,621$) with this current proposed burden; see the row for notification to CMS in Table J4 and note that in Table J4 we list savings as a negative number.

Table J2, presents information from the current package, CMS–10141, with wages adjusted to 2022 wages.

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TABLE J2: CURRENTLY APPROVED BURDEN ESTIMATES WITH UPDATED WAGES

Regulatory Citation	Subject	Number of Respondents	Number of Responses	Time per Response (hr)	Total Time	Labor Cost (hr)	Total Cost
423.153(f)(2)	Conduct Case Management (Annualized)	306	35,771	5	178,855	111.16	19,881,522
423.153(f)(5-8)	Send Notices (Annualized)	306	7,911	0.1667	1,319	38.70	51,045
423.153(f)(15)	Report to CMS (Annualized)	306	35,771	0.0167	597	38.70	23,104
Total		306	79,453	Varies	180,771	Varies	19,955,671

Table J3 presents the estimated burden proposed in this rule which will be submitted with the new package, CMS–10874, which uses the currently approved burden from CMS–10141 as a baseline.

TABLE J3: ESTIMATED BURDEN FROM THIS PROPOSED RULE

Regulatory Citation	Subject	Number of Respondents	Number of Responses (PARBs after exclusions)	Time per Response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Proposed Burden
423.153(f)(2)	Conduct Case Management (Annualized)	319	30,365	5	151825	111.16	\$16,876,867
423.153(f)(5-8)	Send Notices (Annualized)	319	1,518	0.1667	253	38.70	\$9,791
423.153(f)(15)	Report to CMS (Annualized)	319	30,365	0.0167	507	38.70	\$19,621
Total		319	62,248	Varies	152,585	Varies	\$16,906,279

In aggregate, these proposed changes will result in an annual reduction of cost of \$3,049,392 and reduction of 28,186 hours. The aggregate burden change (reduction) is presented in table J4, and will be submitted with the new package, CMS–10874.

TABLE J4: BURDEN CHANGES *

Regulatory Citation	Subject	Number of responses (PARBs after exclusion)	Time per response (hr)	Total Time (hr)	Labor Cost (\$/hr)	Total Proposed Burden
423.153(f)(2)	Conduct Case Management (Annualized)	(5,406)	5	(27,030)	111.16	(3,004,655)
423.153(f)(5-8)	Send Notices (annualized)	(6,393)	0.1667	(1,066)	38.70	(41,254)
423.153(f)(15)	Report to CMS (annualized)	(5,406)	0.0167	(90)	38.70	(3,483.00)
Total				(28,186)	Varies	(3,049,392)

* Table J4 is obtained by subtracting from Table J3 (burden of proposed regulation), Table J2 (current burden). For example, for Case Management, -27,030=151,825 – 171,855.

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4. ICRs Regarding Additional Changes to an Approved Formulary—Biosimilar Biological Product Maintenance Changes and Timing of Substitutions (§§ 423.4, 423.100, and 423.120(e)(2))

In section III.F. of this proposal, we are proposing a limited number of changes to update regulatory text we originally proposed in section III.Q. Changes to an Approved Formulary of the December 2022 proposed rule. In the December 2022 proposed rule, we proposed to reorganize current regulatory text to incorporate and as necessary conform with longstanding sub-regulatory guidance and operations with respect to changes to an approved formulary and associated notice provisions. We also proposed to permit the immediate substitution of interchangeable biological products. The proposals discussed in section III.Q. of the December 2022 proposed rule have not been finalized and remain under consideration.

Specifically, in section III.F. of this proposed rule, we are now proposing to update the regulatory text proposed in December 2022 to the extent necessary to permit Part D sponsors to treat substitutions of biosimilar biological products other than interchangeable biological products as “maintenance changes” under § 423.100 as proposed in the December 2022 rule. We also are proposing to revise paragraphs (1) and (2) of the § 423.100 definition of “maintenance changes” to clarify that certain substitutions need not take place “at the same time” but that Part D sponsors can remove or make negative changes to a brand name drug or

reference product within a certain time period after adding a corresponding drug or a biosimilar biological product other than an interchangeable biological product to the formulary. Lastly, we are proposing a few technical changes, including in support of the above specified proposals.

In section VII.B.10. of the December 2022 proposed rule (87 FR 79680), we outlined ICRs regarding the proposed provision “Changes to an Approved Formulary.” We described the methodology used to quantify burden, labor, and non-labor costs incurred by Part D plan sponsors related to making changes to their approved Part D formularies. The information collection responses included: (1) submitting a negative change request to CMS; (2) updating the formulary in CMS’s Health Plan Management System (HPMS); (3) updating the formulary and providing online notice of changes on the plan website; and (4) providing direct written notice to affected enrollees. The burden estimates in the December 2022 proposed rule were based on actual formulary changes submitted to CMS since the “Changes to an Approved Formulary” proposals set out to codify existing guidance that Part D sponsors had already been following.

We are not revising the December 2022 proposed rule’s burden estimates for the purposes of this CMS-4205-P proposal which permits formulary substitutions of a biosimilar biological product other than an interchangeable biological product for the reference product as a maintenance change. New drugs and biological products are approved or licensed by the FDA and become available on the market at

irregular intervals. Therefore, with respect to this provision, we cannot predict when new biosimilar biological products will enter the market or to what extent Part D sponsors will make formulary substitutions as a result. Several biosimilar biological products entered the market in 2023,¹⁹⁷ but CMS has not seen a corresponding influx of non-maintenance negative change requests from Part D sponsors. It is unclear whether Part D sponsors are not requesting midyear formulary changes due to concerns about patient and provider hesitancy towards biosimilar biological products, or if the current policy that treats such formulary changes as non-maintenance changes disincentivizes Part D sponsors from making midyear formulary changes that will not apply to all enrollees currently taking the reference product.

We will continue to base our burden estimates on CMS’s internal data on formulary changes from a recent contract year, as described in section VII.B.10. of the December 2022 proposed rule and will consider comments received. We will revise our estimates, as appropriate, based on current data when finalizing the proposals from the December 2022 proposed rule. The changes will also be posted for public review under control number 0938–0964 (CMS–10141) using the standard non-rule PRA process which includes the publication of 60- and 30-day **Federal Register** notices. The 60-day notice will publish soon

¹⁹⁷ Billingsly A. Is There a Biosimilar for Humira? Yes, Here Are 9 Humira Biosimilars Launching in 2023. GoodRxHealth. July 12, 2023. Available from: <https://www.goodrx.com/humira/biosimilars>.

after the publication of the CMS–4205–F final rule.

5. ICRs Regarding Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

In section III.H. of this proposed rule, we discuss two proposals to improve access to MA encounter data for certain purposes. We noted that our current regulatory language limits CMS's ability to use and disclose MA encounter data to States for activities in support of administration or evaluation of the Medicaid program, including care coordination. Further, the regulation delays when CMS may share MA encounter data to State Medicaid agencies for care coordination and quality review and improvement activities for the Medicaid program, particularly with regard to dually eligible individuals. Our proposals to improve access to MA encounter data include all the following:

- Adding “and Medicaid programs” to the current MA risk adjustment data use purposes codified at § 422.310(f)(1)(vi) and (vii).
- Adding § 422.310(f)(3)(v) to allow for risk adjustment data to be released prior to reconciliation if the data will be released to States for the purpose of coordinating care for dually eligible individuals.

Together, these proposals aim to clarify and broaden the allowable data uses for CMS and external entities (for data disclosed in accordance with § 422.310(f)(2) and (3)). We discuss the regulatory impact on CMS review and fulfillment of new MA encounter data requests in section XI., explaining that we do not anticipate any significant impact to CMS.

As discussed in sections III.H. and XI., these proposed provisions would allow States to voluntarily request MA encounter data from CMS for certain allowable purposes to support the Medicaid program. Currently, States can request MA encounter data to support the administration of the Medicare program or Medicare-Medicaid demonstrations, and to conduct evaluations and other analysis to support the Medicare program (including demonstrations). In addition, we interpret the regulation as permitting use and disclosure of the MA encounter data for quality review and improvement activities for Medicaid as well as Medicare.

When determining the potential burden of these proposals on States, we considered our existing data sharing program for States to request Medicare data for initiatives related to their dually

eligible population. We expect the process to request MA encounter data would be similar to the process that States currently undertake to request new Medicare FFS claims and events data files or to update allowable data uses. All States, including the District of Columbia, maintain agreements with CMS that cover operational data exchanges related to the Medicare and Medicaid program administration as well as optional data requests for Medicare claims and events data. Therefore, States interested in requesting MA encounter data would not need to complete and submit a new data agreement for MA encounter data; instead, they would submit a use justification for the new data request and update their existing data agreement form. We note that requesting Medicare data is voluntary and that not all States currently request Medicare FFS claims or prescription drug events data for coordinating care of dually eligible beneficiaries, and of those States that request Medicare data, not all States request the same Medicare data files. As with Medicare FFS claims and events data, States would maintain the ability to choose if and when they want to request MA encounter data for existing or newly expanded uses. We further note that the process for States to submit a request for data and for CMS to review these requests are part of standard operations for CMS and many States. Additionally, we have technical assistance support to help States navigate the data request process and help States maintain their data agreements.

In the August 2014 final rule, when we established several of the current provisions around CMS disclosure of MA encounter data, we explained that we had determined that “the proposed regulatory amendments would not impose a burden on the entity requesting data files.” (79 FR 50445). Similarly, for the proposed refinements to the approved data uses and the data disclosure in this proposed rule, we do not anticipate a significant change in burden for States as a result of these proposals, which clarify and expand MA encounter data uses and timing of data release. We solicit comment on our analysis.

6. ICRs Regarding Standards for Determining Whether a Special Supplemental Benefit for the Chronically Ill Has a Reasonable Expectation of Improving the Health or Overall Function of an Enrollee (§ 422.102(f)(3)(iii) and (iv) and (f)(4))

The following proposed changes will be submitted to OMB for review under

control number 0938–0753 (CMS–R–267).

As explained in section IV.B. of this rule, due to increased offering of SSBCI, we are proposing to: (1) require the MA organization to establish, by the date on which it submits its bid, a bibliography of “relevant acceptable evidence” related to the item or service the MA organization would offer as an SSBCI during the applicable coverage year; (2) require that an MA plan follow its written policies (that must be based on objective criteria) for determining eligibility for an SSBCI when making such determinations; (3) require the MA plan to document denials of SSBCI eligibility rather than approvals; and (4) codify CMS's authority to decline to accept a bid due to the SSBCI the MA organization includes in its bid and to review SSBCI offerings annually for compliance, taking into account the evidence available at the time. We now estimate burden.

Item (4) is a burden specific to CMS and is therefore not subject to collection of information requirements. We choose to combine the burdens of: (1) and (2) as the evidence gathered under (1) will likely directly inform the criteria established under (2).

In estimating the impact, we note the following: (i) Not all contracts offer SSBCI (only about 40 percent); (ii) not all plan benefit packages (PBP) offer them (only about 20 percent); (iii) the distribution of the number of SSBCI per PBP is highly skewed (for example, for 2023 the average is about 8 while the median is 2); and (iv) both the median and 3rd quartile of the number of SSBCI per PBP reflect only a handful of SSBCI offered.

Based on internal CMS data we are using 10,000 SSBCI per year for the three-year estimates required by the Collection of Information requirements. To comply with the requirements of the provision that would require bibliography, a staff member knowledgeable in health should be deployed. We are using a registered nurse. Establishing a bibliography requires research, including reading papers and assessing their quality. Because the bibliography would contain only citations and copies of the necessary information, and not any narrative, we assume these activities would take a day of work (8 hours), which can refer to the aggregate activity of 1 nurse working 8 hours or 2 nurses working 4 hours each. A plan would need to review and update its bibliography annually. We assume that updating an existing bibliography would take less time than establishing an initial bibliography. We estimate that

it would take 8 hours each year to update existing bibliographies.

To create a single line-item, we estimate that it would take 8 hours at \$85.60/hr for a registered nurse to create the bibliography for one plan. Thus, the median burden per plan is 16 hours (8/hr per SSBCI * a median of 2 SSBCI) at a cost of \$1,397 (\$85.60/hr * 16 hr). The aggregate cost across all plans would be 80,000 hours (8 hours per SSBCI * 10,000 aggregate SSBCI) at a cost of \$6,848,000 (80,000 * \$85.60/hr).

Regarding the requirement for plans to document denials of SSBCI, it is reasonable that plans already have this information stored in their systems. Thus, we assume that plans will need to compile data already collected into a report or other transmittable format. We estimate that it would take 2 hours at \$98.84/hr for a programmer to complete the initial software update. In aggregate, we estimate a one-time burden of 1,548 hours (774 plans * 2 hr) at a cost of \$153,004 (1,548 hr * \$98.84/hr).

7. ICRs Regarding Mid-Year Notice of Unused Supplemental Benefits (§§ 422.111 and 422.2267)

The following proposed changes will be submitted to OMB for review under control number 0938-0753 (CMS-R-267).

As explained in section IV.C of this proposed rule, per CMS regulations at § 422.101, MA organizations are permitted to offer mandatory supplemental benefits, optional supplemental benefits, and special supplemental benefits for the chronically ill (SSBCI). The number of supplemental benefit offerings has risen significantly in recent years, as observed through trends identified in CMS's annual PBP reviews. At the same time, CMS has received reports that MA organizations have observed low utilization for many of these benefits by their enrollees and it is unclear whether plans are actively encouraging utilization of these benefits by their enrollees. Currently, there is no requirement for MA organizations to conduct outreach to enrollees to encourage utilization of supplemental benefits.

We have several concerns about this low utilization of some supplemental benefits. First, we are concerned that beneficiaries may be making enrollment decisions based on the allure of supplemental benefits that are extensively marketed by a given MA plan during the annual election period (AEP), but once enrolled in the plan the beneficiaries do not fully utilize, or utilize at all, those supplemental benefits during the plan year. Such

under-utilization of supplemental benefits may hinder or nullify any potential health benefit value offered by these extra benefits. Additionally, section 1854(b)(1)(C) of the Act requires MA plans to provide the value of the MA rebates to enrollees; per CMS regulations at § 422.266, MA rebates must be provided to enrollees in the form of payment for supplemental benefits (including reductions in cost sharing for Part A and B benefits compared to Original Medicare), or payment of Part B or D premiums. Therefore, CMS has an interest in ensuring that the MA rebate is provided to enrollees in a way that they can benefit from the value of these rebate dollars.

Hence, we are proposing to require plans engage in targeted outreach to inform enrollees of their unused supplemental benefits they have not yet accessed. This targeted outreach aims to increase utilization of these benefits, as it would increase enrollees' awareness of the supplemental benefits available to them.

This proposed requirement would still ensure that a minimum outreach effort is conducted by MA organizations to inform enrollees of supplemental benefits available under their plans they have not yet accessed. We propose that, beginning January 1, 2026, MA organizations must mail a mid-year notice annually, but not sooner than June 30 and not later than July 31 of the plan year, to each enrollee with information pertaining to each supplemental benefit available through the plan year that the enrollee has not accessed, by June 30 of the plan year. For each covered mandatory supplemental benefit and optional supplemental benefit (if elected) the enrollee is eligible for but has not accessed, the MA organization must list in the notice the information about each such benefit that appears in the Evidence of Coverage (EOC). For SSBCI, the notice must also include the proposed new SSBCI disclaimer. Finally, we are proposing that all notices must include the scope of the supplemental benefit(s), applicable cost-sharing, instructions on how to access the benefit(s), applicable information on use of any network providers application information for each available benefit consistent with the format of the EOC, and a toll free customer service number and, as required, corresponding TTY number to call if additional help is needed.

In estimating the burden of this provision, we first note that plans already keep track of utilization patterns of benefits by enrollees. The primary

burden is therefore dissemination of notices. In this regard there are three burdens: (1) a one-time update to software systems to produce reports; (2) a one-time update of policies and procedures; and (3) the printing and sending of notices to beneficiaries.

- We estimate that a software developer working at \$127.82/hr would take about 4 hours to update systems. In aggregate we estimate a one-time burden of 3,096 hours (774 prepaid contracts * 4 hr/contract) at a cost of \$395,731 (3,096 hr * \$127.82/hr).

- We estimate that a business operations specialist working at \$79.50/hr would take 1 hour to update of policies and procedures. In aggregate we estimate a one-time burden of 774 hours (774 prepaid contracts * 1 hour/contract) at a cost of \$61,533 (774 hr * \$79.50/hr).

- The major cost would be printing and dissemination. There have been several recent CMS rules in which such printing and dissemination has been estimated.

A recent estimate was presented in proposed rule, "Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications," CMS-4201-P, (87 FR 79452) published on December 27, 2022. We have checked the prices listed there for paper and toner and found them consistent with current pricing.

- *Cost of paper:* We assume \$3.50 for a ream of 500 sheets. The cost for one page is \$0.007 (\$3.50/500 sheets).

- *Cost of toner:* We assume a cost of \$70 for 10,000 pages. The toner cost per page is \$0.007 (\$70/10,000 pages).

- *Cost of postage:* We estimate a bulk rate mailing of \$0.12 for 1,000 notices, or \$0.00012. We particularly solicit stakeholder feedback on their experience in bulk rates. We note that the particular provision for which this estimate was provided in CMS-4201, DMP, had HIPPA requirements necessitating first class postage. However, notifications about the lack of use of supplemental benefits would be similar to EOBs which need not be sent by first class postage.

We believe it reasonable that every MA enrollee has at least one supplemental benefit that they have not used. Since PDPs do not provide supplemental benefits, we would

require 32 million mailings for the 32 million enrollees in prepaid contracts. Thus, the expected price per page of mailing is \$0.01412 (\$0.007 for paper plus \$0.007 for toner plus 0.00012 for postage). The aggregate non-labor cost for 32 million mailings of one page would be \$451,840 ($32,000,000 * \$0.01412$). We do not have a definite basis for estimating the average number of pages needed per enrollee. Some enrollees may only require 1 page listing 1 to 3 benefits with all information required by CMS. Some enrollees may require more. We are estimating 3 pages on average per enrollee but solicit stakeholder feedback. Thus, the total non-labor cost would be \$1,355,520 (3 pages * \$451,840/page).

8. ICRs Regarding New Requirements for the Utilization Management Committee (§ 422.137)

As discussed in section IV.D. of this proposed rule, we are adding new requirements related to the Utilization Management (UM) Committee established at § 422.137.

The following proposed changes will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

We are proposing at § 422.137(c)(5) to require a member of the UM committee have expertise in health equity. Reviewing UM policies and procedures is an important beneficiary protection, and adding a committee member with expertise in health equity will ensure that policies and procedures are reviewed from a health equity perspective. We estimate that a compliance officer working at \$74.02/hr would take 30 minutes for a one-time update of the policies and procedures. In aggregate, we estimate a one-time burden of 483 hours (966 plans * 0.5 hr) at a cost of \$35,752 (483 hr * \$74.02/hr).

The following proposed changes will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

We are proposing at § 422.137(d)(6) to require the UM committee to conduct an annual health equity analysis of the use of prior authorization and publicly post the results of the analysis to the plan's website. The analysis would examine the impact of prior authorization, at the plan level, on enrollees with one or more of the following social risk factors: (i) receipt of the low-income subsidy for Medicare Part D, or being dually eligible for Medicare and Medicaid, or (ii) having a disability, as reflected in CMS's records regarding the basis for Medicare Part A entitlement. To gain a deeper understanding of the impact of

prior authorization practices on enrollees with the specified SRFs, the proposed analysis must compare metrics related to the use of prior authorization for enrollees with the specified SRFs to enrollees without the specified SRFs. The metrics that must be stratified and aggregated for all items and services for this analysis are as follows:

- The percentage of standard prior authorization requests that were approved.
- The percentage of standard prior authorization requests that were denied.
- The percentage of standard prior authorization requests that were approved after appeal.
- The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved.
- The percentage of expedited prior authorization requests that were approved.
- The percentage of expedited prior authorization requests that were denied.
- The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations.
- The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations.

We estimate that a software and web developer working at an hourly wage of \$120.14/hr would take 8 hours at a cost of \$961 (8 hr * \$120.14/hr) for developing the software necessary to collect and aggregate the data required to produce the report. In aggregate, we estimate a one-time burden of 7,728 hr (966 plans * 8 hr/plan) at a cost of \$928,442 (7,728 hr * \$120.14/hr).

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

Annually, the report must be produced and posted to the plan's website. The health equity analysis and public reporting must be easily accessible, without barriers, including but not limited to ensuring the information is available: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); to automated searches and direct file downloads through a link posted in the footer on the plan's publicly available website, and includes a txt file in the root directory that includes a direct link to the machine-readable file of public reporting and health equity analysis to establish and maintain

automated access. We believe that making this information more easily accessible to automated searches and data pulls and capturing this information in a meaningful way across MA organizations will help third parties develop tools and researchers conduct studies that further aid the public in understanding the information. We assume the plans' programmers will make this an automated process accessing data already in the plans' systems; hence, we estimate minimal time to produce and inspect the report prior to posting. We estimate a Business Operations Specialist working at \$79.50/hr would take 0.1667 hr (10 minutes) to produce, inspect, and post the report at a cost of \$13 (\$79.50/hr * 0.1667 hr). In the aggregate, we estimate an annual burden of 161 hours (966 plans * 0.1667 hr/plan) at a cost of \$12,800 (161 hr * \$79.50/hr).

9. ICRs Regarding Agent Broker Compensation (§ 422.2274)

The following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–273).

Currently, agents and brokers are compensated by MA plans at a base rate with a maximum of \$601 per enrollee, plus administrative payments. In section VI.B. of this proposed rule, we are proposing to raise the maximum compensation rate to a fixed amount that covers two basic activities that agents and brokers perform: (1) training and testing; and (2) other necessary administrative activities such as recording and transcription. The training and testing focus on the information that agents and brokers may or may not disclose about the Medicare program and the plans they represent. The training and testing involve the transmission of information to agents and brokers about Medicare rules.

Prior to stating our estimates, we emphasize that there are numerous data challenges in formulating an exact amount of compensation. Therefore, we especially invite stakeholder comments on all our assumptions and conclusions. More specifically, the estimates that follow address three areas where we have uncertainty: (1) the number of agent and brokers actively working in selling Medicare products; (2) the number of new enrollees in non-employer MA plans and PDPs; and (3) the percent of new enrollments effected by agent and brokers. Our assumptions and supportive data are presented in Table J5.

TABLE J5: THREE ESTIMATES USED IN THE ANALYSIS

Item	Estimate	Partially Supportive Data
Number of agent brokers selling Medicare	100,000	The Bureau of Labor Statistics occupational handbook lists about 340,000 insurance agents (including life insurance agents, auto insurance agents etc.). We assume one third are involved with health plans (https://www.bls.gov/oes/2022/may/oes413021.htm).
Number of new enrollees per year for non-employer MA plans and stand-alone prescription drug plans	2 million	Published CMS data (https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/mcradvpartdenrolldata) shows MA non employer enrollment increasing steadily by 2 million a year since 2020. It shows PDP enrollment decreasing steadily by ½ million a year. This number is an overestimate since it includes deaths, ignores migrations from MA to FFS, ignores the downward trend in PDPs, and ignores migrations between plans.
Per cent of new enrollments effected by agent brokers	50%	We do not have any data on this. Furthermore, many agents work for themselves and do not have to report to CMS about the number of new enrollments they effect. Traditionally we have used 50% when we do not have data. Additionally, we are soliciting stakeholder comment in this area.

We now present estimates for the two activities listed previously: (1) training and testing per enrollee, and (2) other necessary administrative activities such as recording and transcription.

a. Cost of Training

CMS requires that agents be certified, as evidenced by attending training and passing certain tests, in order to sell Medicare products. Many agents and brokers and many plans prefer the use of a recognized certification organization such as AHIP (<https://www.ritterim.com/blog/what-is-ahip-certification-and-how-do-i-get-it/#pdp-ebook>) for training and testing. The AHIP training and certification costs \$175. However, some plans provide a discount of \$50; and some plans will pay for the training. The training allows three attempts at passing. If the agent or broker fails three times, some plans will not recognize their certification even if they eventually pass. For those plans that do recognize continued attempts, the agent must pay an additional \$175. Therefore, we believe it reasonable to set the average cost of training at \$125 and assume that most agents and brokers pass within their first three attempts (we lack data on this and invite stakeholder comment). We are treating the \$125 as a non-labor business expense (and invite comments on this assumption). Finally, we note that this \$125 fee, corresponds to \$12.50 per enrollee, since we estimate there are 2

million new enrollees, half of which (1 million enrollees) are affected by the 100,000 agent and brokers, implying that on average each agent and broker recruits 10 enrollees. Therefore, the \$125 cost when divided by the number of enrollees gives a \$12.50/enrollee cost (\$125/10).

b. Burden Associated With Transcription and Recording

We are estimating 30 minutes (0.5 hr) to account for the time and expense of recording and storing calls (and solicit stakeholder comment on this assumption). As already noted, based on the occupational title “Insurance Sales agents” we assume a mean hourly wage of \$37.00/hr. Thus, the fair market value (FMV) per enrollee for transcription and recording would be \$18.50 (\$37.00/hr * 0.5 hr).

c. Total Cost

Thus, the aggregate cost per enrollee is \$31 (\$18.50 for transcription and recording + \$12.50 for training and testing). The aggregate cost over all new enrollees would be \$31 million (\$31/enrollee * 1,000,000 new enrollees affected annually).

We have focused on new enrollments, since the cost of the administrative activities discussed is predominantly overhead not closely connected with actual enrollments, and we are more accurately able to track new enrollments, so they serve as a better basis for attaching these payments.

10. ICRs Regarding Adding Proposed New Rationale for an Exception From the Network Adequacy Requirements in § 422.116(b) Through (e)

The following proposed changes will be submitted to OMB for review under control number 0938–1346 (CMS–10636).

Historically, the industry has stated that CMS’s current network adequacy criteria under § 422.116 create challenges for facility-based Institutional Special Needs Plans (I–SNP) because facility-based I–SNP enrollees access services and seek care in a different way than enrollees of other plan types. Thus, we are proposing to broaden our acceptable rationales for facility-based I–SNPs when submitting a network exception under § 422.116(f). The first proposed new basis for an exception request is that a facility-based I–SNP is unable to contract with certain specialty types required under § 422.116(b) because of the way enrollees in facility-based I–SNPs receive care. Facility-based I–SNP may also request an exception from the network adequacy requirements in § 422.116(b) through (e) if: The I–SNP covers Additional Telehealth Benefits (ATBs) consistent with § 422.135 and uses ATB telehealth providers of the specialties listed in paragraph (d)(5) to furnish services to enrollees; When substituting ATB telehealth providers of the specialties listed in paragraph (d)(5) for in-person providers, the facility-

based I-SNP would fulfill the network adequacy requirements in § 422.116(b) through (e); The I-SNP complies with § 422.135(c)(1) and (2) by covering in-person services from an out-of-network provider at in-network cost sharing for the enrollee who requests in-person services instead of ATBs; and the I-SNP provides substantial and credible evidence that the enrollees of the facility-based I-SNP receive sufficient and adequate access to all covered benefits.

To determine the potential burden regarding this proposal, we considered the one-time burden for MA organizations to update policies. The other burdens associated with this provision involve updates to the HPMS system, which is done by CMS and its contractors and not subject to COI review.

MA organizations that offer Facility-based I-SNPs are already required to conduct work related to network adequacy reviews that happen during the initial or service area expansion application process, or every 3 years for the triennial review. Further, MA organizations that offer facility-based I-SNPs should already have measures in place to submit data to meet CMS network adequacy review requirements to CMS, so there is no additional burden.

We understand that MA organizations will need to update their policies and procedures related to broadening our acceptable rationales for facility-based I-SNPs when submitting a network exception. We estimate that a business operations specialist working at \$79.50/hr would take 5 minutes (0.0833 hr) to update policies and procedures related to this task. In aggregate, we estimate a one-time burden of 0.8 hour (10 facility-based I-SNP contracts * 0.0833 hr) at a cost \$64 (0.8 hr * \$79.50/hr).

11. ICRs Regarding Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38)

At § 423.38(c)(4) we are proposing to replace the current quarterly special enrollment period (SEP) with a one-time-per month SEP for dually eligible individuals and others enrolled in the Part D low-income subsidy program to elect a standalone PDP. At § 423.38(c)(35), we propose a new integrated care SEP to allow dually eligible individuals to elect an integrated D-SNP on a monthly basis. The burden associated with the current quarterly dual/LIS SEP at § 423.38(c)(4) is currently approved by OMB under

control number 0938–0964 (CMS–10141).

The proposed changes related to a new integrated care SEP at § 423.38(c)(35) will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

In section VIII.C. of this proposed rule, we propose amending §§ 422.514(h), 422.503(b), 422.504(a), and 422.530(c). Proposed § 422.514(h) would require an MA organization's parent organization, where that MA organization offers a D-SNP (and that parent organization also contracts with the State as a Medicaid managed care organization (MCO) in the same service area), to only offer one D-SNP for full-benefit dually eligible individuals. The proposed regulation at § 422.514(h) would also require the affected D-SNP to limit new enrollment to individuals enrolling in, or in the process of enrolling in, the affiliated Medicaid MCO effective 2027, and further require the D-SNP to limit all enrollment to individuals enrolled in, or in the process of enrolling in the affiliated MCO effective 2030. A new contract provision at § 422.503(b)(8) would prohibit parent organizations from offering a new D-SNP when that D-SNP would result in noncompliance with the proposed regulation at § 422.514(h). Additionally, the proposed regulation at § 422.504(a)(20) would require compliance with § 422.514(h). To support parent organizations seeking to consolidate D-SNPs, we also propose § 422.530(c)(4)(iii) that would provide a new crosswalk exception to allow D-SNP parent organizations to crosswalk enrollees (within the same parent organization and among consistent plan types) where they are impacted by the requirements at § 422.514(h). The proposed changes related to MA organizations that offer multiple D-SNPs in a service area (§§ 422.514(h), 422.503(b), 422.504(a), and 422.530(c)) with a Medicaid MCO will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

a. MA Plan Requirements and Burden

We are proposing to redesignate § 423.38(c)(35) as § 423.38(c)(36) and proposing a new integrated care special enrollment period (SEP) at § 423.38(c)(35) that would allow enrollment in any month into FIDE SNPs, HIDE SNPs, and AIPs for those dually eligible individuals who meet the qualifications for such plans. The proposed integrated care SEP at § 423.38(c)(35) would require plans to update guidance and train staff. That new burden would be limited to FIDE SNPs, HIDE SNPs, and AIPs. We expect

that plans would need one software engineer working 4 hours to update software and one business operations specialist working 4 hours to update plan policies and procedures and train staff in the first year with no additional burden in future years. In aggregate, we estimate a one-time burden (for plan year 2025) of 904 hours (113 plans * 8 hr/plan) at a cost of \$93,709 (113 plans * [(4 hr * \$127.82/hr) + (4 hr * \$79.50/hr)]). We do not anticipate any new burden to plans after the initial year. This will be submitted to OMB for review under control number 0938–0964 (CMS–10141).

The proposed provisions at §§ 422.514(h) and 422.530(c)(4)(iii) would create burden for MA organizations where they offer multiple D-SNPs in a service area with a Medicaid MCO. Impacted MA organizations would need to non-renew or (more likely) combine plans and update systems as well as notify enrollees of plan changes. We expect that MA organizations would need two software engineers working 4 hours to update software in the first year with no additional burden in future years and one business operations specialist working 4 hours to update plan policies and procedures in the first year with no additional burden in future years. In aggregate, we estimate a one-time burden (for plan year 2027) of 600 hours (50 plans * 12 hr/plan) at a cost of \$67,028 (50 plans * [(8 hr * \$127.82/hr) + (4 hr * \$79.50/hr)]). This will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

b. Medicare Enrollee Requirements and Burden

Proposed amendments to § 423.38(c)(4) and (35) would affect the circumstances in which individuals can change plans. Individuals can complete an enrollment form to effectuate such changes, and we have previously estimated that the forms take 0.3333 hours (20 min) to complete as cited under OMB control number 0938–0964 (CMS–10141). However, Medicare beneficiaries make enrollment choices currently, and we do not expect the overall volume of enrollment selections to materially change if our proposals are finalized. Therefore, we do not believe the proposals at § 423.38(c)(4) and (35) would impact the burden estimates that are currently approved under 0938–0964 (CMS–10141). Similarly, we are not proposing any changes to that collection's currently approved forms.

In the section XI. of this proposed rule, we describe the impacts related to the expected enrollment shift from non-

integrated MA-PDs into FIDE SNPs, HIDE SNPs, and AIPs over time as more D-SNPs align with Medicaid MCOs.

12. ICRs Regarding Contracting Standards for Dual Eligible Special Needs Plan (D-SNP) Look-Alikes (§ 422.514)

The following proposed changes will be submitted to OMB for review under control number 0938-0753 (CMS-R-267) consistent with burden on MA plans identified as D-SNP look-alikes under § 422.514(d) through (e) (see section VIII.G. of this proposed rule).

As described in section VIII.G. of this proposed rule, we propose lowering the D-SNP look-alike threshold from 80 percent to 60 percent over a two-year period. We propose a limitation on non-SNP MA plans with 70 or greater percent dually eligible individuals for CY 2025. For CY 2026, we are proposing to reduce the threshold from 70 percent to 60 percent or greater dually eligible enrollment as a share of total enrollment. This incremental approach would minimize disruptions to dually eligible individuals and allow plans and CMS to operationalize these transitions over a two-year period.

We would maintain processes to minimize disruption for the enrollees in plans affected by this proposed change. We propose to apply the existing transition processes and procedures at § 422.514(e) to non-SNP MA plans that meet the proposed D-SNP look-alike contracting limitation of 70 percent or greater dually eligible individuals effective plan year 2025 and 60 percent or greater dually eligible individuals effective plan year 2026. Consistent with the initial years of implementation of the D-SNP look-alike contract limitations with the 80-percent threshold, maintaining these transition processes and procedures would help to minimize disruption for current enrollees as a result of the prohibition on contract renewal for existing D-SNP look-alikes. For plan year 2027 and subsequent years, we propose to limit the § 422.514(e) transition processes and procedures to D-SNP look-alikes transitioning dually eligible enrollees into D-SNPs. Based on our experience with D-SNP look-alike transitions through plan year 2023, the vast majority of enrollees transitioned to other MA-PDs under the same parent organization as the D-SNP look-alike. Based on our review of D-SNP look-alike transition plans thus far, we expect the experience for transitions effective plan year 2024 to follow a similar pattern.

MA organizations can utilize other CMS processes to transition D-SNP

look-alike enrollees to other MA plans. For example, an MA organization can utilize the CMS crosswalk process if it is transitioning the full D-SNP look-alike enrollment to one non-SNP plan benefit package (PBP) of the same type offered by the same MA organization under the same contract and the requirements at § 422.530 for a crosswalk are met. An MA organization moving the entire enrollment of the D-SNP look-alike PBP to another PBP of the same type under the same contract may structure this action as a consolidation of PBPs and use the crosswalk for consolidated renewal process, under § 422.530(b)(1)(ii). An MA organization may utilize the crosswalk exception process, subject to CMS approval, at § 422.530(c)(2) to transition the entire enrollment of the MA contract (including the D-SNP look-alike) to another MA contract (of the same type) offered by another MA organization with the same parent organization as part of a contract consolidation of separate MA contracts. While multiple options exist for MA organizations to transition D-SNP look-alike enrollees to other non-SNP MA plans, these pathways are not available for moving enrollees to D-SNPs.

Using data from the 2023 contract year, we estimate that there are 30 non-SNP MA plans¹⁹⁸ that have enrollment of dually eligible individuals of 70 percent through 79.9 percent of total enrollment and 40 non-SNP MA plans¹⁹⁹ that have enrollment of dually eligible individuals of 60 percent through 69.9 percent of total enrollment. As of January 2023, the 30 non-SNP MA plans have total enrollment of 53,334 enrollees and the 40 non-SNP MA plans have 92,100 enrollees collectively. Of the 30 non-SNP MA plans with 70–79.9 percent dually eligible enrollment, 28 are in States where for contract year 2023 there are D-SNPs or comparable managed care plans and would be subject to § 422.514(d).²⁰⁰ Of the 40 non-SNP MA plans with 60–69.9 percent dually eligible enrollment, all are in States where for contract year 2023 there are D-SNPs or comparable

managed care plans and would be subject to § 422.514(d). As of January 2023, these 68 plans have total enrollment of 145,434 for contract year 2023. If these plans all have the same enrollment pattern in 2024, MA organizations would need to non-renew for plan year 2025 those 28 plans that exceed our proposed criteria to lower the threshold to 70 percent for plan year 2025.²⁰¹ Similarly, MA organizations with plans that exceed our proposed criteria to lower the threshold to 60 percent for plan year 2026 would need to non-renew 40 plans for plan year 2026.²⁰² Each MA organization would have the opportunity to make an informed decision to transition enrollees into another MA-PD plan (offered by it or by its parent organization) by: (1) identifying, or applying, or contracting for, a qualified MA-PD plan, including a D-SNP, in the same service area; or (2) creating a new D-SNP through the annual bid submission process. Consistent with our experience with D-SNP look-alikes non-renewing for plan years 2021 through 2023, we expect the vast majority of D-SNP look-alike enrollees to be transitioned into a plan offered by the same parent organization as the D-SNP look-alike, and we expect in rare instances that the non-renewing plan may choose to not transition enrollees. Plan year 2023 was the only plan year when D-SNP look-alikes transitioned enrollees to Traditional Medicare rather than an MA plan under the same parent organization. In plan year 2023, 9 of the 47 D-SNP look-alikes transitioned approximately 3,300 enrollees to Traditional Medicare, which accounted for less than 2 percent of total enrollees transitioned from D-SNP look-alikes. The changes required of MA organizations based on this proposed rule would impact D-SNP look-alikes and their enrollees (see section VIII.G. of this proposed rule). While we cannot predict the actions of each affected MA organization with 100 percent certainty, we base our burden estimates on the current landscape of D-SNP look-alikes and our experience with transitions of D-SNP look-alikes through plan year 2023.

a. MA Plan Requirements and Burden

As indicated, the following proposed changes will be submitted to OMB for review under control number 0938-0753 (CMS-R-267).

²⁰¹ These 28 plans have total enrollment of 53,334 individuals as of January 2023.

²⁰² These 40 plans have total enrollment of 92,100 individuals as of January 2023.

¹⁹⁸ These 30 non-SNP MA plans are located in Arizona, California, Connecticut, Idaho, Illinois, Louisiana, Nevada, New Hampshire, New Mexico, Oklahoma, Oregon, Pennsylvania, Tennessee, Vermont, and Virginia.

¹⁹⁹ These 40 non-SNP MA plans are located in Arkansas, California, Connecticut, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Mexico, New York, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, and Tennessee.

²⁰⁰ The 2 non-SNP MA plans are located in New Hampshire and Vermont, neither of which have a D-SNP as of contract year 2023.

At § 422.514(e), we established a process for an MA organization with a D–SNP look-alike to transition individuals who are enrolled in its D–SNP look-alike to another MA–PD plan offered by the MA organization, or by the same parent organization as the MA organization, to minimize disruption as a result of the prohibition on contract renewal for existing D–SNP look-alikes. This process allows, but does not require, the MA organization to transition dually eligible enrollees from D–SNP look-alikes into D–SNPs and other qualifying MA–PD plans for which the enrollees are eligible without the transitioned enrollees having to complete an election form. This transition process is conceptually similar to the proposed “crosswalk exception” procedures at § 422.530(a) and (b); however, § 422.514(e) allows the transition process to apply across contracts or legal entities and from non-SNP to SNPs provided that the receiving plan is otherwise of the same plan type

(for example, HMO or PPO) as the D–SNP look-alike. Based on the experience of D–SNP look-alike transitions through plan year 2023, we believe 95 percent of D–SNP look-alikes for plan years 2025 and 2026 would be able to move enrollees into another MA–PD plan using the transition process established at § 422.514(e) or existing crosswalk functionality at § 422.530 and would choose to transition enrollment for plan years 2025 and 2026. All are in States where for contract year 2023 there are D–SNPs or comparable managed care plans that would be subject to § 422.514(d). Therefore, we are assuming the burden of 27 of the 28 non-SNP MA plans with 70–79.9 percent dually eligible enrollment and offered in a State with a D–SNP would transition enrollees for plan year 2025 (for a January 2025 effective date) and 38 of the 40 non-SNP MA plans with 60–69.9 percent dually eligible enrollment would transition enrollees

for plan year 2026 (for a January 2026 effective date). Consistent with our estimates from the June 2020 final rule, we estimate each plan will take a one-time amount of 2 hours at \$79.50/hr for a business operations specialist to submit all enrollment changes to CMS necessary to complete the transition process. D–SNP look-alikes that transition enrollees into another non-SNP plan will take less time than D–SNP look-alikes that transition eligible beneficiaries into a D–SNP because they would not need to verify enrollees’ Medicaid eligibility. The 2-hour time estimate would account for any additional work to confirm enrollees’ Medicaid eligibility for D–SNP look-alikes transitioning eligible enrollees to a D–SNP. Based on the previous discussion, the estimates for the burden for MA organizations to transition enrollees to other MA–PD plans during the 2025 to 2027 plan years is summarized in Table J6.

TABLE J6: BURDEN FOR TRANSITIONING D-SNP LOOK-ALIKE ENROLLEES INTO ANOTHER MA-PD

Year	Number of Plans	Time per Response (hr)	Total Time (hr)	Total Cost (using \$79.50/hr for a business operations specialist) (\$)
2025	27	2	54	4,293
2026	38	2	76	6,042
2027	12	2	24	1,908
Total	77	6	154	12,243
Average	25.667 (77/3)	2 (6/3)	51.334 (154/3)	4,081 (12,243/3)

Based on our experience through plan year 2023, we expect the vast majority of MA organizations with non-SNP MA plans with dually eligible enrollment between 60 and 80 percent of total enrollment also have an MA–PD plan with a premium of \$0 or a D–SNP in the same service area as the D–SNP look-alike. Based on 2023 plan year data, of the 30 non-SNP MA plans with 70 to 79.9 percent dually eligible enrollment, 19 of these plans (63 percent) have a D–SNP within the same service area or nearly the same service area. Also based on 2023 plan year data, of the 40 non-SNP MA plans with 60 to 69.9 percent dually eligible enrollment, 24 of these plans (60 percent) have a D–SNP within the same service area or nearly the same service area. An MA organization with one of these non-SNP MA plans could expand its service area for an existing

MA–PD plan or D–SNP. The MA organizations with the non-SNP MA plans between 60 and 79.9 percent dually eligible enrollment already have the opportunity to establish a D–SNP and expand their service areas. Any burden associated with these MA organizations establishing new D–SNPs and/or expanding their service areas would already be captured under currently approved burden under control number 0938–0935 (CMS–10237) for creating a new MA–PD plan to receive non-SNP MA plan enrollees. Per § 422.514(e)(2)(ii), in the Annual Notice of Change (ANOC) that the MA organization must send consistent with § 422.111(a), (d), and (e), the MA organization would be required to describe changes to the MA–PD plan benefits and provide information about

the MA–PD plan into which the individual is enrolled. Consistent with § 422.111(d)(2), enrollees will receive this ANOC describing the change in plan enrollment and any differences in plan enrollment at least 15 days prior to the first date of the annual election period (AEP). As each MA plan must send out the ANOC to all enrollees annually, we do not estimate that MA organizations will incur additional burden for transitioned enrollees. The current burden for the ANOC is approved by OMB under control number 0938–1051 (CMS–10260). We expect 1 plan for plan year 2025 and 2 plans for plan year 2026 would be required to send affected enrollees a written notice consistent with the non-renewal notice requirements at § 422.506(a)(2) and described at

§ 422.514(e)(4), as we anticipate—based on our experience with transitions through plan year 2023—not all D–SNP look-alikes would be able to transition their enrollees into another MA–PD plan (or plans).

b. Enrollee Requirements and Burden

In 2027 and subsequent years, we estimate that 12 plans per year would be identified as D–SNP look-alikes under § 422.514(d). We base our estimate on the fact that there are 12 D–SNP look-alikes for plan year 2024, which is the first year following the phase in of the 80-percent threshold. We expect our proposal to lower the threshold for identifying D–SNP look-alikes from 80 percent to 60 percent would increase the number of plans identified as D–SNP look-alikes. However, we expect this increase to be offset by a reduction in D–SNP look-alikes due to our proposed changes to the § 422.514(e) transition process, which would limit use of the § 422.514(e) transition process to D–SNP look-alikes transitioning dually eligible enrollees into D–SNPs. Under our proposal, D–SNP look-alikes transitioning effective for plan year 2025 and plan year 2026—including the newly identified D–SNP look-alikes based on the proposed threshold lowered to 70 percent and then 60 percent—could continue to use the existing transition process under § 422.514(e). Once the newly identified D–SNP look-alikes at the lower thresholds complete their transitions for plan year 2025 and plan year 2026, the § 422.514(e) transition process could only be used for D–SNP look-alike transitioning enrollees into D–SNPs. We believe this proposed limit would give MA organizations a stronger incentive to

avoid creating D–SNP look-alikes, due to the more limited opportunity for these plans to transition enrollees to non-D–SNPs. The proposed limit on the § 422.514(e) transitions would be effective for plan year 2027 and subsequent years. We believe that these 12 D–SNP look-alikes would non-renew and transition their enrollment into a D–SNP or other MA–PD plan. The annual burden is summarized in Table J6. We welcome comment on these assumptions.

As indicated, the following proposed changes will be submitted to OMB for review under control number 0938–0753 (CMS–R–267).

An individual transitioned from a D–SNP look-alike to another MA–PD plan may stay in the MA–PD plan receiving the enrollment or, using the AEP or another enrollment period (such as the MA OEP), make a different election. The enrollees may choose new forms of coverage for the following plan year, including a new MA–PD plan or receiving services through Traditional Medicare and enrollment in a stand-alone PDP. Because the enrollment transition process is effective on January 1 and notices would be provided during the AEP, affected individuals have opportunities to make different plan selections through the AEP (prior to January 1) or the MA open enrollment period (OEP) (after January 1). Affected individuals may also qualify for a special enrollment period (SEP), such as the SEP for plan non-renewals at § 422.62(b)(1) or the SEP for dually eligible/LIS beneficiaries at § 423.38(c)(4), which this rule proposes to revise as discussed in section VIII.C. of this proposed rule. Based on our experience with D–SNP look-alike

transitions through plan year 2023, we estimate that 99 percent of the 53,334 D–SNP look-alike enrollees (52,801 enrollees = 53,334 enrollees × 0.99) in the 30 non-SNP MA plans with dually eligible enrollment of 70 to 79.9 percent and 99 percent of the 92,100 D–SNP look-alike enrollees (91,179 enrollees = 92,100 enrollees × 0.99) in the 40 non-SNP MA plans with dually eligible enrollment of 60 to 69.9 percent would transition into another plan under the same parent organization as the D–SNP look-alike. Of these 143,980 transitioning enrollees (52,801 enrollees + 91,179 enrollees), our experience with D–SNP look-alike transitions through plan year 2023 suggests that 14 percent would select a new plan or the Traditional Medicare and PDP option rather than accepting the transition into a different MA–PD plan or D–SNP under the same MA organization as the D–SNP in which they are currently enrolled. For plan year 2025, we estimate that 7,392 enrollees (52,801 transitioning D–SNP look-alike enrollees × 0.14), would opt out of the new plan into which the D–SNP look-alike transitioned them. For plan year 2026, we estimate that 12,765 enrollees (91,179 transitioning D–SNP look-alike enrollees × 0.14), would opt out of the new plan into which the D–SNP look-alike transitioned them. Consistent with the per response time estimate that is currently approved by OMB under control number 0938–0753 (CMS–R–267), we continue to estimate that the enrollment process requires 20 minutes (0.3333 hr).

Based on the aforementioned discussion, Table J7, summarizes the hour and dollar burden for added enrollments for years 2025 to 2027.

TABLE J7: BURDEN ON ENROLLEES FOR YEARS 2025-2027

Year	Number of Affected Enrollees	Time /Enrollee (hr)	Total Time (hr)	Total Cost (@ \$20.71/hr) (\$)*
2025	7,392	0.3333	2,464	51,029
2026	12,765	0.3333	4,255	88,121
2027	3,490	0.3333	1,163	24,085
Total	23,647	0.9999	7,882	163,235
Average	7,882 (23,647/3)	0.3333 (0.9999/3)	2,627 (7,882/3)	54,412 (163,235/3)

*Had we used \$29.76/hour the mean wage for occupational code 00-0000 representing all occupations, the burden would change from \$54,412 to \$78,189 an increase of \$23,777

As stated previously, we believe that in 2027 and subsequent years, 12 plans would be identified as D–SNP look-

alikes and therefore this proposed rule would have a much smaller impact on MA enrollees after the initial period of

implementation. Since the current 70 non-SNP MA plans with dually eligible enrollment of 60.0 to 79.9 percent have

145,434 enrollees in 70 plans, we estimate 24,932 enrollees (145,434 enrollees * 12/70 plans) in 12 plans. The burden is summarized in Table J6. The average annual enrollee burden over 3 years is also presented in Table J6.

13. ICRs Regarding Update to the Multi-Language Insert Regulation (§§ 422.2267 and 423.2267)

The following proposed changes will be submitted to OMB for review under control number 0938–1421 (CMS–10802).

The multi-language insert (MLI) required at §§ 422.2267(e)(31) and 423.2267(e)(33) is a standardized communications material that informs enrollees and prospective enrollees that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese. These are the 15 most common non-English languages in the United States. Additionally, §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i) require plans to provide the MLI in any non-English language that is the primary language of at least 5 percent of the individuals in a PBP service area but is not already included on the MLI. These regulations also provide that a plan may opt to include the MLI in any additional languages that do not meet the 5 percent threshold, where it determines that including the language would be appropriate.

As discussed in section III.G. of this proposed rule, we are proposing to update §§ 422.2267(e)(31) and 423.2267(e)(33) to require that notice of availability of language assistance services and auxiliary aids and services be provided in English and the 15 languages most commonly spoken by individuals with limited English proficiency in a State and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication. Thus, under our proposal, MA organizations and Part D sponsors would send the Notice of Availability in English and the 15 most common non-English languages in a State instead of the current MLI in the 15 most common non-English languages nationally. This proposed policy is consistent with a proposed rule that OCR published in August 2022 (87 FR 47824). We also expect that this proposed policy would better align with the Medicaid translation requirements

at § 438.10(d)(2).²⁰³ We propose to modify the language to note that this is a model communication material rather than a standardized communication material because we are no longer specifying the exact text that must be used. Even though the MA organizations and Part D sponsors could change the Notice of Availability, we are not accounting for such changes because we do not expect any MA organizations or Part D sponsors to make such changes.

We do not expect this proposed policy to create any new collection of information burden for MA organizations or Part D sponsors since the August 2022 proposed rule indicates that OCR would provide the translated language for the Notice of Availability in the 15 most common non-English languages in a State or States. Also, the MA organizations and Part D sponsors are already distributing the MLI and, under this proposal, would instead distribute the Notice of Availability, so we do not anticipate any new burden associated with printing or mailing. In addition, the Notice of Availability would be a one-page document that would never be sent alone and therefore does not create additional postage costs.

We expect some new burden for MA organizations and Part D sponsors operating plans across multiple States. Rather than sending the same MLI with the same 15 non-English language translations to plans in any State, under the proposed rule the plans under these MA organizations or Part D sponsors would need to send the Notice of Availability with translations in the 15 most common non-English languages in each State in which the plan operates. Based on plan year 2023 data, we estimate there are approximately 20 MA parent organizations offering MA plans in multiple States with approximately 3,900 PBPs and approximately 20 Part D sponsors offering Part D plans in multiple States with approximately 1,400 Part D plans. Since many of these parent organizations have MA organizations at the State level, we estimate that these 20 parent organizations have approximately 220 MA organizations covering PBPs by State. Similarly, we estimate that the 20 Part D sponsors have approximately 50 parent organizations covering PBPs by State. We believe the parent

²⁰³ We expect the 15 most common languages for a given State to include any language required by the Medicaid program at § 438.10(d)(2). Therefore, our proposed rule would not impose additional burden on fully integrated dual eligible special needs plans and highly integrated dual eligible special needs plans, as defined at § 422.2, and applicable integrated plans, as defined at § 422.561, to comply with regulations at §§ 422.2267(a)(4) and 423.2267(a)(4).

organizations would update systems software and plan policies and procedures as well as train staff at the MA organization and Part D sponsor level to cover all PBPs and Part D plans, respectively, offered in a State. We expect that MA organizations and Part D sponsors would need one software engineer working one hour to update systems software in the first year with no additional burden in future years and one business operations specialist working one hour to update plan policies and procedures and train staff in the first year with no additional burden in future years. For MA organizations, we estimate the burden for plan year 2025 at 440 hours (220 MA organizations * 2 hr/plan) at a cost of \$56,241 (440 hr * \$127.82/hr) for a software engineer to update systems to ensure the Notice of Availability with the correct State-specific languages is distributed with other communications and marketing materials. We estimate the burden for MA organizations for plan year 2025 to be 440 hours (220 MA organizations * 2 hr/plan) at a cost of \$34,980 (440 hr * \$79.50/hr) for a business operations specialist to update plan policies and procedures and train staff. For Part D sponsors, we estimate the burden for plan year 2025 at 100 hours (50 Part D sponsors * 2 hr/plan) at a cost of \$12,782 (100 hr * \$127.82/hr) for a software engineer to update systems to ensure the Notice of Availability with the correct State-specific languages is distributed with other communications and marketing materials. We estimate the burden for Part D sponsors for plan year 2025 to be 100 hours (50 Part D sponsors * 2 hr/plan) at a cost of \$7,950 (100 hr * \$79.50/hr) for a business operations specialist to update plan policies and procedures and train staff. We do not anticipate any new burden to plans after the initial year. We will submit this burden to OMB for review under control number 0938–1421 (CMS–10802).

We also note that, as part of the current MLI required at §§ 422.2267(e)(31) and 423.2267(e)(33), MA organizations and Part D sponsors must already include additional languages that meet the 5 percent service area threshold as required under §§ 422.2267(a)(2) and 423.2267(a)(3). Thus, MA organizations and Part D sponsors must currently review the most frequently used languages in a service area beyond the top 15 national languages. As a result, we do not believe the burden will be greater than our estimate note previously. We welcome comment on our assumptions.

*C. Summary of Proposed Information
Collection Requirements and Associated
Burden*

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TABLE J8: SUMMARY OF ANNUAL INFORMATION COLLECTION REQUIREMENTS AND BURDEN*

Section(s) under Title 42 of the CFR	Item	OMB Control No. (CMS ID No.)	Respondents	Number of Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost of Reporting (\$/hr)	Total Cost First Year (\$)	Total Cost Subsequent Years (\$)
422.116(b)(2) and (d)(2) and (5)	Network Adequacy in Behavioral Health	0938-1346 (CMS-10636)	742	742	0.0833	62	79.50	4,929	0
423.153(f)(2)	DMP: Case Management	0938-TBD (CMS-10874)	319	(5,406)	5	(27,030)	111.16	(3,004,655)	(3,004,655)
423.153(f)(5-8)	DMP: Enrollee notification	0938-TBD (CMS-10874)	319	(6,393)	0.1667	(1,066)	38.70	(41,254)	(41,254)
423.153(f)(15)	DMP: CMS Notification	0938-TBD (CMS-10874)	319	(5,406)	0.0167	(90)	38.70	(3,483)	(3,483)
422.102(f)(3)(iii) and (iv) and (f)(4)	SSBCI, expectation of health improvement	0938-0753 (CMS-R-267)	10,000	10,000	8	80,000	85.60	6,848,000	6,848,000
422.102(f)(3)(iii) and (iv) and (f)(4)	SSBCI, Documentation	0938-0753 (CMS-R-267)	774	774	2	1,548	98.84	153,004	0
422.111 and 422.2267	Increased Utilization of Supplemental Benefits, Software Updates	0938-0753 (CMS-R-267)	774	774	4	3,096	127.82	395,731	0
422.111 and 422.2267	Increased Utilization of Supplemental Benefits, Policy Updates	0938-0753 (CMS-R-267)	774	774	1	774	79.50	61,533	0
422.111 and 422.2267	Increased Utilization of Supplemental Benefits, Mailings	0938-0753 (CMS-R-267)	774	32,000,000	Non Labor	Non Labor	Non Labor	1,355,520 (Non Labor)	1,355,520 (Non Labor)
422.137	UM Committee, update policies	0938-0964 (CMS-10141)	966	966	0.5	483	74.02	35,752	0
422.137	UM Committee, Annual Health Equity Analysis	0938-0964 (CMS-10141)	966	966	8	7,728	120.14	928,442	0
422.137	UM Committee, Website Posting	0938-0753 (CMS R 267)	966	966	0.1667	161	79.50	12,800	12,800
422.2274	Agent Broker C	0938-0753 (CMS R 267)	966	100,000	NA	NA	31	31,000,000	31,000,000

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422.116	I-SNPs	0938-1346 (CMS-10636)	10	10	0.0833	1	79.50	64	0
423.38(c)(35)	D-SNP; SEP Programmers	0938-0964 (CMS-10141)	113	113	8	904	Varies	93,709	0
422.514(h) and 422.530(c)(4)(iii)	D-SNP Combining Plans, Programmer	0938-0753 (CMS-R-267).	50	50	12	600	Varies	67,208	0
422.514(d) and (e)	D-SNP Look-Alikes, Transitioning to other MA PD, Plan Burden	0938-0753 (CMS-R-267).	25.667***	27	2	51.334	79.50	4,081	4,081
422.514(d) and (e)	D-SNP Look-Alikes, Transitioning to other MA-PD, Enrollee Burden**	0938-0753 (CMS-R-267).	7882	7,882	0.3333	2,627	20.71	54,412	54,412
422.2267 and 423.2267	Notice of Availability; Part C Update of Systems	0938-1421 (CMS-10802)	220	220	2	440	127.82	56,241	0
422.2267 and 423.2267	Notice of Availability; Part C Update of Policies	0938-1421 (CMS-10802)	220	220	2	440	79.50	34,980	0
422.2267 and 423.2267	Notice of Availability; Part D Update of Systems	0938-1421 (CMS-10802)	50	50	2	100	127.82	12,782	0
422.2267 and 423.2267	Notice of Availability; Part D Update of Policies	0938-1421 (CMS-10802)	50	50	2	100	79.50	7,950	0
Totals			32,136,318	INSERT	Varies	70,928	Varies	38,077,501	36,225,414

*Agent broker dollar burden includes both labor and non-labor components as explained in the narrative

** Had we used \$29.76/hour the mean wage for occupational code 00-0000 representing all occupations, the burden would change from \$54,412 to \$78,189 an increase of \$23,777

*** The three-place accuracy is necessary to synchronize Table J6 with Table J8. Had we rounded the annual costs would not sync.

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at <https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pralisting>, or call the Reports Clearance Office at 410-786-1326.

We invite public comments on these potential information collection requirements. If you wish to comment, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS-4205-P), the ICR's CFR citation, and the OMB control number.

XI. Regulatory Impact Analysis

A. Statement of Need

The primary purpose of this proposed rule is to amend the regulations for the Medicare Advantage (Part C) program, Medicare Prescription Drug Benefit (Part D) program, Medicare cost plan program, and Programs of All-Inclusive Care for the Elderly (PACE). This proposed rule includes several new policies that would improve these programs beginning with contract year 2025 as well as codify existing Part C and Part D sub-regulatory guidance. This proposed rule also includes revisions to existing regulations in the Risk Adjustment Data Validation (RADV) audit appeals process and the appeal process for quality bonus payment determination that would take effect 60 days after publication of a final rule. Revisions to existing regulations for the use and release of risk adjustment data would also take effect 60 days after publication of a final rule. Additionally, this proposed rule would implement certain sections of the following Federal laws related to the Parts C and D programs:

- The Bipartisan Budget Act (BBA) of 2018.
- Consolidated Appropriations Act (CAA) of 2023.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review

(January 18, 2011), Executive Order 14094 entitled "Modernizing Regulatory Review" (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), 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). The Executive Order 14094, entitled "Modernizing Regulatory Review" (hereinafter, the Modernizing E.O.), amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of \$200 million or more in any 1 year, or adversely affecting in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). The total economic impact for this proposed rule exceeds \$200 million in several years. Therefore, based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the \$200 million or more in any one year and also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also known as the Congressional Review Act). Accordingly, we have prepared a Regulatory Impact Analysis that to the

best of our ability presents the costs and benefits of the rulemaking.

Cost of reviewing the rule. Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that:

- The hourly cost per reviewer for reviewing this proposed rule is \$123.06 per hour, including overhead and fringe benefits https://www.bls.gov/oes/current/oes_nat.htm. Had a general business operations specialist been used (say for an entity without medical and health service managers) the cost per hour would be less than that for a medical and health services manager. Therefore, we are at most overestimating the cost per hour and will use \$123.06/hr.

- We estimate that there will be less than 2,000 reviewers of this proposed rule: There are currently less than 1,000 contracts (which includes MA, MA-PD, and PDP contracts), 55 State Medicaid agencies, and 300 Medicaid MCOs. We also expect a variety of other organizations to review (for example, consumer advocacy groups, PBMs). We expect that each organization will designate one person to review the rule. Therefore, a reasonable maximal number is 2,000 total reviewers. We note that other assumptions are possible.

- The rule is about 150,000 words. Average reading speeds vary from 180 to 240 words per minute. Since the rule is technical and presumably notes are being taken, we use the lower estimate. Furthermore, since in addition to notetaking, summaries would be submitted to leadership we are lowering the 180 words/minutes to 150. Accordingly, we assume it would take staff 17 hours to review this proposed rule (150,000 words/150 words per minute/60 minutes hour). This may be an overestimate since each entity will likely only read the provisions affecting them and not the entire rule.

- Therefore, the estimated cost per reviewing entity for reading this entire rule is \$2,100 (17 hr × \$123.06/hr), and the total cost over all entities for reviewing this entire proposed rule is \$4.2 million (\$2,100 × 2,000 reviewers). However, we expect that many reviewers, for example pharmaceutical companies and PBMs, will not review the entire rule but just the sections that are relevant to them. Thus, it is very likely that on average only half or a quarter of the rule will be read resulting in a range of \$2 million to \$5 million.

Note that this analysis assumes one reader per contract. Some alternatives include assuming one reader per parent organization. Using parent organizations instead of contracts will reduce the

number of reviewers. However, we believe it is likely that review will be performed by contract. The argument for this is that a parent organization might have local reviewers assessing potential region-specific effects from this proposed rule.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by OMB.

C. Impact on Small Businesses—Regulatory Flexibility Analysis (RFA)

The RFA, as amended, requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions.

A wide range of policies are being proposed in this rule. These policies

codify, modify, and update current guidance governing MA organization bid requirements.

This rule has several affected stakeholders. They include: (1) MA organizations such as HMOs, local and regional PPOs, MSAs, PFFS and Part D sponsors; (2) providers, including institutional providers, outpatient providers, clinical laboratories, and pharmacies; and (3) enrollees. Some descriptive data on these stakeholders are provided in Table K–1.

TABLE K-1: STAKEHOLDERS AFFECTED BY THIS RULE, THEIR NAICS CODE, AND THRESHOLD FOR SMALL BUSINESS STATUS

Stakeholder	NAICS Code*	Threshold for Small Business (in millions of dollars)**
Pharmacy and Drug stores	456110	37.5
Direct Health and Medical Insurance Carriers	524114	47
Ambulatory Health Services	621	
Dialysis Centers	621492	47
Physician offices	621111	16
Hospitals	622	47
Skilled Nursing Facilities	623110	34

We are certifying that this proposed rule does not have a significant economic impact on a substantial number of small entities. To explain our position, we explain certain operational aspects of the Medicare program.

Each year, MA plans submit a bid for furnishing Part A and B benefits and the entire bid amount is paid by the government to the plan if the plan’s bid is below an administratively set benchmark. If the plan’s bid exceeds that benchmark, the beneficiary pays the difference in the form of a basic premium (note that a small percentage of plans bid above the benchmark, whereby enrollees pay basic premium, thus this percentage of plans is not “significant” as defined by the RFA and as justified in this section of this proposed rule).

MA plans can also offer extra benefits, that is, benefits not covered under Traditional Medicare Parts A and B, called supplemental benefits. These benefits are paid for through enrollee premiums, rebate dollars or a combination. Under the statutory payment formula, if the bid submitted by a Medicare Advantage plan for furnishing Parts A and B benefits is lower than the administratively set benchmark, the government pays a portion of the difference to the plan in

the form of a rebate. The rebate must be used to provide supplemental benefits (that is benefits not covered under Traditional Medicare, including lower cost sharing) and or/lower beneficiary Part B or Part D premiums. Some examples of these supplemental benefits include vision, dental, and hearing, fitness and worldwide coverage of emergency and urgently needed services.

To the extent that the government’s payments to plans for the bid plus the rebate exceeds costs in Traditional Medicare, those additional payments put upward pressure on the Part B premium, which is paid by all Medicare beneficiaries, including those in Traditional Medicare who do not have the additional health services available in many MA plans.

Part D plans, including MA–PD plans, submit bids and those amounts are paid to plans through a combination Medicare funds and beneficiary premiums. In addition, for enrolled low-income beneficiaries, Part D plans receive special government payments to cover most of the premium and cost sharing amounts those beneficiaries would otherwise pay.

Thus, the cost of providing services by MA and Part D plans is funded by a variety of government funding sources

and in some cases by enrollee premiums. As a result, MA and Part D plans are not expected to incur burden or losses since the private companies’ costs are being supported by the government and enrolled beneficiaries. This lack of expected burden applies to both large and small health plans.

Small entities that must comply with MA and Part D regulations, such as those in this proposed rule, are expected to include the costs of compliance in their bids, thus avoiding additional burden, since the cost of complying with any final rule is funded by payments from the government and, if applicable, enrollee premiums.

For Direct Health and Medical Insurance Carriers, NAICS 524114, plans estimate their costs for the upcoming year and submit bids and proposed plan benefit packages. Upon approval, the plan commits to providing the proposed benefits, and CMS commits to paying the plan either (1) the full amount of the bid, if the bid is below the benchmark, which is a ceiling on bid payments annually calculated from Traditional Medicare data; or (2) the benchmark, if the bid amount is greater than the benchmark.

If an MA plan bids above the benchmark, section 1854 of the Act requires the MA plan to charge enrollees

a premium for that amount. Historically, at most 2 percent of plans bid above the benchmark, and they contain roughly 1 percent of all plan enrollees. The CMS threshold for what constitutes a substantial number of small entities for purposes of the RFA is 3 to 5 percent. Since the number of plans bidding above the benchmark is 2 percent, this is not considered substantial for purposes of the RFA.

The preceding analysis only shows that MA plans, whether small or large, are not affected by this proposed rule since a significant number of them (all but at most 2 percent) will have their costs subsidized by the Government.

Therefore, we next examine in detail each of the other stakeholders and explain how they can bear cost. Each of the following are providers (inpatient, outpatient, or pharmacy) that furnish plan-covered services to plan enrollees for:

- Pharmacies and Drug Stores, NAICS 446110;
- Ambulatory Health Care Services, NAICS 621, including about two dozen sub-specialties, including Physician Offices, Dentists, Optometrists, Dialysis Centers, Medical Laboratories, Diagnostic Imaging Centers, and Dialysis Centers, NAICD 621492;
- Hospitals, NAICS 622, including General Medical and Surgical Hospitals, Psychiatric and Substance Abuse Hospitals, and Specialty Hospitals; and
- SNFs, NAICS 623110.

Whether these providers are contracted or, in the case of PPOs and PFFS MA plans, not contracted with the MA plan, their aggregate payment for services is the sum of the enrollee cost sharing and plan payments.

- For non-contracted providers, § 422.214 and sections 1852(k)(1) and 1866(a)(1)(O) of the Act require that a non-contracted provider that furnishes covered services to an MA enrollee accept payment that is at least what the provider would have been paid had the services been furnished to a Medicare FFS beneficiary.
- For contracted providers, § 422.520 requires that the payment is governed by a mutually agreed upon contract between the provider and the plan. CMS is prohibited from requiring MA plans to contract with a particular health care provider or to use a particular price structure for payment by section 1854(a)(6)(B)(iii) of the Act.

Consequently, for providers, there is no additional cost burden above the already existing burden in Traditional Medicare. In other words, the provisions of this proposed rule do not create a significant burden for providers.

Based on the previous discussion, the Secretary certifies that this proposed rule will not have a significant impact on a substantial number of small entities.

There are certain indirect consequences of these provisions which also create impact. We have already explained that at least 98 percent of the plans bid below the benchmark. Thus, their estimated costs for the coming year are fully paid by the Federal Government. However, the government additionally pays the plan an MA “beneficiary rebate” amount that is an amount equal to a percentage (between 50 and 70 percent depending on a plan’s quality rating) multiplied by the amount by which the benchmark exceeds the bid. The rebate is used to provide additional benefits to enrollees in the form of reduced cost-sharing or other supplemental benefits, or to lower the Part B or Part D premiums for enrollees. (Supplemental benefits may also be paid by enrollee premiums to the extent that the MA rebate is not sufficient to cover those costs.) However, as noted previously, the number of MA plans bidding above the benchmark to whom this burden applies does not meet the RFA criteria of a significant number of plans.

It is possible that if the provisions of this proposed rule would otherwise cause MA plan bids to increase, plans will reduce their profit margins, rather than substantially change their benefit package. This may be in part due to market forces; a plan lowering supplemental benefits may lose its enrollees to competing plans that offer these supplemental benefits. Thus, it may, in certain cases, be advantageous for a plan to reduce profit margins, rather than reduce supplemental benefits. Most likely an increase in bids would result in a combination of reduction in supplemental benefits and reduction in profit margins (not 100 percent one or the other). Part of the challenge in pinpointing the effects of an increase in bids is that there are many other factors combining with the effects of proposed and final rules, making it effectively impossible to determine whether a particular policy had a long-term effect on supplemental benefits.

We also note that we do not have definitive data on this. Plans do not report to CMS the strategies behind their bids. More specifically, when plans do reduce supplemental benefits, we have no way of knowing the cause for this reduction, whether it be new provisions, market forces, or other causes.

D. Anticipated Effects

Many provisions of this proposed rule have negligible impact either because they are technical provisions, clarifications, or are provisions that codify existing guidance. Other provisions have an impact that cannot be quantified. Throughout the preamble, we have noted when we estimated that provisions have no impact either because they are codifying already existing practices, or, for example, because contractors for CMS have asserted that changes work within their current contract without the need for additional compensation. Additionally, this Regulatory Impact Statement discusses several provisions with either zero impact or impact that cannot be quantified. The remaining provisions’ effects are estimated in section XXX of this proposed rule and in this RIA. Where appropriate, when a group of provisions have both paperwork and non-paperwork impact, this Regulatory Impact Statement cross-references impacts from section XXX of this proposed rule in order to arrive at total impact.

1. Effects of Expanding Permissible Data Use and Data Disclosure for MA Encounter Data (§ 422.310)

In section III.H. of this proposed rule, we discussed two proposals to improve access to MA encounter data for certain purposes. We noted that our current regulatory language limits CMS’s ability to use and disclose MA encounter data for activities in support of administration or evaluation of the Medicaid program, including care coordination. Further, the regulation delays when CMS may share MA encounter data to State Medicaid agencies for care coordination and quality review and improvement activities for the Medicaid program, particularly with regard to dually eligible individuals. Our proposals to improve access to MA data include the following:

- Adding “and Medicaid programs” to the current MA risk adjustment data use purposes codified at § 422.310(f)(1)(vi) and (vii).
- Adding a new § 422.310(f)(3)(v) to allow for risk adjustment data to be released prior to reconciliation if the data will be released to State Medicaid agencies for the purpose of coordinating care for dually eligible individuals.

Together, these proposals aim to clarify and broaden the allowable data uses for CMS and external entities (for data disclosed in accordance with § 422.310(f)(2) and (3)). These proposals do not change the external entities

allowed to request MA encounter data from CMS.

As discussed in sections X and III.H., these proposed provisions would allow external entities to voluntarily request MA encounter data for allowable data uses to support the Medicare program, Medicaid program, and Medicare and Medicaid combined purposes. There is one area where this provision could impact the burden to CMS: CMS reviewing and fulfilling new MA encounter data requests. However, in the FY 2015 Hospital Inpatient Prospective Payment System (IPPS)/Long-term Care Hospital Prospective Payment System (LTCH PPS) final rule, when we initially established CMS disclosure of MA encounter data, we explained that we had determined that “there are not any economically significant effects of the proposed provisions” (79 FR 50445). The same applies for the proposed refinements to the approved data uses and the data disclosure in this proposed rule.

2. Increasing the Percentage of Dually Eligible Managed Care Enrollees Who Receive Medicare and Medicaid Services From the Same Organization (§§ 422.503, 422.504, 422.514, 422.530, and 423.38)

We discussed collection of information burden associated with this provision in section X.B.11 of this proposed rule. In this section, we describe the impacts of our proposed change to the dual/LIS SEP, new integrated care SEP, and contract limitations for non-integrated MA–PD plans.

These proposals would impact dually eligible and other LIS eligible individuals that currently use the quarterly dual/LIS SEP to change their enrollment in MA–PD plans. We are proposing to change the quarterly dual/LIS SEP to a one-time-per month SEP for dually eligible individuals and other LIS eligible individuals to elect a standalone PDP. The proposal would allow individuals to switch PDPs or leave their MA–PD plans for Traditional Medicare (with a standalone PDP) in any month. The proposed dual/LIS SEP would no longer permit enrollment into MA–PD plans or changes between MA–PD plans (although such options would remain available through other enrollment periods and SEPs). In addition, we propose a new integrated care SEP that would allow enrollment in any month into a FIDE SNP, HIDE SNP, or AIP for dually eligible individuals who meet the qualifications of such plans.

Proposed §§ 422.504(a)(20) and 422.514(h) would establish a new

requirement for an MA organization, that, beginning in plan year 2027, when an MA organization, its parent organization, or an entity that shares a corporate parent organization with the MA organization, also contracts with a State as a Medicaid MCO that enrolls dually eligible individuals in the same service area, that the MA organization’s D–SNPs must limit new enrollment to individuals enrolled in (or in the process of enrolling in) the D–SNP’s aligned Medicaid MCO. Additionally, an MA organization (or its parent organization or another MA organization with the same parent organization) in this situation would only be able to offer one D–SNP for full-benefit dually eligible individuals in the same service area as that MA organization’s affiliated Medicaid MCO (with limited exceptions as described in section VIII.C. of this proposed rule). Further, beginning in plan year 2030, such D–SNPs must only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the affiliated Medicaid MCO.

Full-benefit dually eligible individuals enrolled in a D–SNP that consolidate due to our proposals at §§ 422.504(a)(20) and 422.514(h) would be moved into a new plan. The impacted enrollees would receive materials about the plan consolidation and materials associated with the new plan. We believe the plan benefit packages of the plans required to consolidate to be similar if not the same and do not expect impact to enrollees.

We expect there to be an enrollment shift from MA–PDs into FIDE SNPs, HIDE SNPs, or AIPs over time as more D–SNPs align with Medicaid MCOs. Starting in plan year 2027, we expect new D–SNP enrollment to be limited and then we expect integrated D–SNP enrollment to accelerate in 2030 when D–SNPs under a parent organization with an affiliated Medicaid MCO would need to disenroll individuals who are not enrolled in both the D–SNP and affiliated MCO.

We examined contract year 2023 bid data for D–SNPs that enroll beneficiaries in States that also use Medicaid managed care to cover some or all benefits for dually eligible individuals. In general, the data shows that the more integrated D–SNPs have higher per capita MA rebates than those in less integrated plans. MA rebates are used to reduce beneficiary cost sharing, lower beneficiary premiums, and provide additional supplemental benefits. MA rebates are calculated by multiplying the difference in the risk-adjusted benchmarks and the risk-adjusted bids by a percentage called the rebate

percentage. The Federal Government retains the complement of the rebate percentage (or $1 - \text{rebate percentage}$) multiplied by the difference in the risk-adjusted benchmarks and bids. The (risk-adjusted) bid-to-benchmark ratios, in general, are smaller for the more integrated plans versus the less integrated plans. This suggests that the more integrated D–SNPs can provide Traditional Medicare benefits (represented by the risk adjusted bid) at a lower or more efficient level than the less integrated D–SNPs. We have assumed that this provision’s requirement for greater alignment between the D–SNP and the affiliated Medicaid MCO will lead to greater health benefit efficiencies and incur Federal Government savings since the Federal Government retains the complement of the difference between the submitted risk adjusted bids and benchmarks.

In calculating our estimates, we assumed savings would begin in 2027 when new D–SNPs enrollment would be limited. We expect integrated D–SNP enrollment and related savings to accelerate in 2030 when D–SNPs under a parent organization participating in Medicaid managed care would need to disenroll individuals who are not enrolled in both the D–SNP and affiliated Medicaid MCO under the same parent organization. We estimated that the other elements of this proposal (including the proposed changes to the SEP) would have a negligible impact.

To develop the savings projections, we calculated the bid-to-benchmark ratios for the integrated D–SNPs based on the calendar year 2023 plan data and applied them to the coordination-only D–SNPs that we assume would convert to aligned D–SNPs by 2030. We assumed that a large percentage of the coordination-only D–SNP enrollment would convert to integrated D–SNPs by 2030. For trending purposes, we used 2023 bid data and 2023 enrollment data as the starting point and trended those data points by values found in the 2023 Medicare Trustees Report. We calculated gross costs (savings are represented by negative dollar amounts) by multiplying the per member per month expenditure differences by the enrollment that is projected to switch to aligned plans. Then, we calculated the net cost by multiplying the gross costs by the net of Part B premium amount which averages between 85.1 percent and 84.6 percent from 2025–2034. This yields an overall annual estimate of net Part C costs ranging from –\$6 million in contract year 2027 to –\$207 million in contract year 2034.

TABLE K-2: ESTIMATED PART C COSTS (SAVINGS) PER YEAR (\$ MILLIONS) TO THE MEDICARE TRUST FUND FOR PROPOSALS TO INCREASE THE PERCENTAGE OF DUALY ELIGIBLE MANAGED CARE ENROLLEES WHO RECEIVE MEDICARE AND MEDICAID SERVICES FROM THE SAME ORGANIZATION

Contract Year	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
BID + REBATE PMPM Difference	-	-	(13.10)	(13.16)	(13.02)	(12.89)	(12.93)	(13.04)	(13.92)	(14.51)	
PROJECTED CO D-SNP Enrollment Switchers to Aligned Medicare and Medicaid MCOs	-	-	41,578	81,567	119,630	1,303,863	1,334,476	1,361,197	1,385,109	1,405,696	
Gross Cost (\$ millions):	-	-	(7)	(13)	(19)	(202)	(207)	(213)	(231)	(245)	(1,136)
Net of Part B Premium:	85.1%	85.0%	84.9%	84.8%	84.8%	84.7%	84.7%	84.6%	84.6%	84.6%	
Net Cost (\$ millions):	-	-	(6)	(11)	(16)	(171)	(175)	(180)	(196)	(207)	(961)

We performed a similar comparison of contract year 2023 bids for Part D on the same MA plans and their associated population. The data also suggests that the more integrated D-SNPs had lower combined bid and reinsurance amounts for contract year 2023. As a result, we also projected that there would be efficiencies when D-SNPs aligned more with the Medicaid MCOs. The observed 2023 difference (efficiency) in the combined bid and reinsurance amounts is projected with the corresponding D-SNP trend assumed in the 2023 Medicare Trustees' Report (not shown

in that report). The Part D gross savings are the product of the efficiency and the associated switchers from Table K-3. Since the premiums for the Medicaid beneficiaries are subsidized, there would be no premium offset. As a result, the net savings would be the same as the gross savings. We estimated the net costs would range from –\$7 million in contract year 2027 to –\$286 million in contract year 2034.

We also have reviewed the impact to the Medicaid program and have concluded that the Medicaid impacts would be negligible. The majority of States have a “lesser-of” policy, under

which the State caps its payment of Medicare cost sharing so that the sum of Medicare payment and cost-sharing does not exceed the Medicaid rate for a particular service. Under this proposed policy, the Medicare payment and the cost sharing are not expected to increase resulting in non-significant impacts to Medicaid payments. For Part D, given that the Medicaid liability is limited to the beneficiary cost sharing and that the vast majority of dually eligible individuals qualify for low-income cost sharing, we anticipate no significant impacts to Medicaid costs.

TABLE K-3: ESTIMATED PART D COSTS (SAVINGS) PER YEAR (\$ MILLIONS) TO THE MEDICARE TRUST FUND FOR PROPOSALS TO INCREASE THE PERCENTAGE OF DUALY ELIGIBLE MANAGED CARE ENROLLEES WHO RECEIVE MEDICARE AND MEDICAID SERVICES FROM THE SAME ORGANIZATION

Contract Year	2025	2026	2027	2028	2029	2030	2031	2032	2033	2034	Total
BID + REINSURANCE PMPM Difference	-	-	(14.09)	(14.25)	(14.67)	(15.00)	(15.30)	(15.87)	(16.47)	(16.97)	
Gross Cost (\$ millions):	-	-	(7)	(14)	(21)	(235)	(245)	(259)	(274)	(286)	(1,341)
Net Part D Premium:	0	0	0	0	0	0	0	0	0	0	0
Net Cost (\$ millions):	-	-	(7)	(14)	(21)	(235)	(245)	(259)	(274)	(286)	(1,341)

In addition to the estimated savings from limiting enrollment into certain D-SNPs starting in plan year 2027, these provisions require updates to a variety of CMS manual systems.

The proposed change to § 423.38(c)(4) and the proposed provision at § 423.38(c)(35) would create burden for CMS to update MA-PD plan manual chapters, the plan communication user guide (PCUG), and model enrollment notices. Additionally, the MARx system would require coding changes for the proposed amended dual/LIS SEP at § 423.38(c)(4) and proposed integrated care SEP at § 423.38(c)(35). The CMS call center 1-800-MEDICARE would need training on the proposed SEPs to be able to identify beneficiaries eligible

for the SEPs. The updates and changes would require two GS-13 staff 20 hours to complete the necessary updates. We estimate the burden for plan year 2025, would be at 40 hours (2 GS-13 * 20 hrs) at a cost of \$2,433 (40 hrs * \$60.83) for two GS-13 staff to update manual chapters, the PCUG, enrollment notices, and complete coding for MARx. This is a one-time cost that would not create new burden in subsequent years.

The new provision at § 422.514(h)(3)(ii) would allow plans to continue operating a PPO and HMO in the same service area but not allow new enrollments of full-benefit dually eligible individuals into the plan (or plans) that are not aligned with the affiliated MCO as described

§ 422.514(h)(1). This provision would not create new burden for CMS since CMS would use its existing process to suppress these plans from Medicare Plan Finder.

The new provision at § 422.530(c)(4)(iii) allowing a crosswalk exception for plans consolidating their D-SNPs would create burden for CMS. The coding to create the crosswalk exception would require one GS-13 10 hours to complete the necessary updates. The burden for plan year 2025, is estimated at 10 hours (1 GS-13 * 10 hrs) at a cost of \$608.30 (10 hrs * \$60.83) for a GS-13 to complete coding for crosswalk exceptions. This is a one-time cost that would not create new burden in subsequent years. The burden

associated with crosswalks and plan consolidation could create additional burden such as breaking plans into different PBPs or having fewer PBPs to manage in the future. We cannot estimate these actions and associated burden but generally believe they would cancel each other out.

3. Effects of Additional Changes to an Approved Formulary—Biosimilar Biological Product Maintenance Changes and Timing of Substitutions (§§ 423.4, 423.100, and 423.120(e)(2))

We do not estimate any impact on the Medicare Trust Fund as a result of the proposal to treat substitutions of biosimilar biological products other than interchangeable biological products as a maintenance change. New biosimilar biological products are approved or licensed by the FDA and become available on the market at irregular intervals. Therefore, with respect to this provision, we cannot predict when new biosimilar biological products will enter the market or to what extent Part D sponsors will make formulary substitutions as a result. Several biosimilar biological products entered the market in 2023,²⁰⁴ but CMS has not seen a corresponding influx of non-maintenance negative change requests from Part D sponsors. It is unclear whether Part D sponsors are not requesting midyear formulary changes due to concerns about patient and provider hesitancy towards biosimilar biological products, or if the current policy that treats such formulary changes as non-maintenance changes disincentivizes Part D sponsors from making midyear formulary changes that will not apply to all enrollees currently taking the reference product. The introduction of biosimilar biological products to the market is relatively recent compared to generic small molecule drugs. We believe there is a potential for savings to the Medicare Trust Fund in the long term as acceptance of biosimilar biological products grows and increased competition drives down costs; however, a number cannot be estimated right now.

4. Mid-Year Notice of Unused Supplemental Benefits

This proposal would require plans to notify enrollees about any supplemental benefit they have not used during the first half-year of the contract year. We lack data to quantify the effects of this

provision. Therefore, we present a qualitative analysis below. The provision has 3 impacts on plans and the MA program.

One impact is the burden to plans to notify enrollees. This burden has been quantified in the Collection of Information in section X. of this proposed rule. The burden consists of: (1) a system update to identify supplemental benefits not utilized by enrollees; and (2) the burden to notify enrollees.

The second impact relates to the intent of the provision, which is to increase utilization of benefits when appropriate. This would initially involve a cost to both enrollees for their share of cost sharing, and to the plans for providing the benefit. In assessing the impact, there are several dimensions of impact for which we lack data: (1) how many plans offer these supplemental benefits; (2) which supplemental benefits are not being utilized at all by some enrollees; (3) for each plan offering supplemental benefits, how many enrollees do and do not utilize these benefits; (4) how many more enrollees would utilize these benefits as a result of the notification; and (5) what is the range and distribution of the cost to provide these supplemental benefits.

The third impact relates to savings expected from increased utilization. Normally, such savings are considered consequences of a provision and not typically analyzed in an RIA. We use dental and gym benefits to show several complications and possibilities in this analysis.

Enrollees who use their preventive supplemental dental benefits may uncover problems early, thus preventing unnecessary complications. For example, the filling of cavities may prevent a costlier root canal later. Also note that the filling may happen in one plan while the costlier root canal that was prevented refers to a possible event several years later possibly in another plan (or out of pocket for the enrollee).

An interesting subtlety of this example is that enrollees who have preventive dental checkups may do so annually or semi-annually. The effect of the notification might be to increase annual checkups to semi-annual checkups. It is harder to quantify the savings from such a change in frequency.

From discussions with plans, we know that enrollees may incur the cost of a gym membership benefit without utilizing it. The intent of the provision would be to increase gym utilization. In the case of gym benefits the savings from increased prevention is

challenging to analyze since different frequencies of gym attendance have different effects on health. An enrollee, for example, who decides to visit the gym only once because of the notification might not have any significant health benefits generating savings; even enrollees who switch to monthly visits may not experience savings. The savings on enrollees who decide to continue gym visit on a regular basis might arise from varied consequences since increased exercise has the potential to “reduce risk of chronic conditions like obesity, type 2 diabetes, heart disease, many types of cancer, depression and anxiety, and dementia.”²⁰⁵

In summary, this is the type of provision that has a savings impact that can be analyzed only after several years of experience with the provision.

We solicit public comment on the economic cost and benefits of this proposal.

5. Agent Broker Compensation (§ 422.2274)

In this rule we are proposing to: (1) generally prohibit contract terms between MA organizations and agents, brokers, or other TMPOs that may interfere with the agent's or broker's ability to objectively assess and recommend the plan which best fits a beneficiary's health care needs; (2) set a single agent and broker compensation rate for all plans, while revising the scope of what is considered “compensation;” and (3) eliminate the regulatory framework which currently allows for separate payment to agents and brokers for administrative services. We are also proposing to make conforming edits to the agent broker compensation rules at § 423.2274.

The proposed changes to the MA and Part D agent broker compensation regulations at 42 CFR 422.2274 and 423.2274 have potential economic effects on agents/brokers, plans, and Medicare beneficiaries. Since we lack the data to quantify these effects, we discuss them qualitatively. Agents and brokers may lose certain excess payments that would be prohibited under the proposed regulation; on the other hand, they would receive an increased FMV calculation for compensation per enrollment. A typical agent or broker might work on behalf of many insurance companies and their associated plans, including commercial, Medicare, Medicaid, Medigap etc. A reduction in net payment for Medicare Advantage enrollments may cause

²⁰⁴ Billingsly A. Is There a Biosimilar for Humira? Yes, Here Are 9 Humira Biosimilars Launching in 2023. GoodRxHealth. July 12, 2023. Available from: <https://www.goodrx.com/humira/biosimilars>.

²⁰⁵ <https://www.cdc.gov/chronicdisease/resources/infographic/physical-activity.htm#>.

agents or brokers to reapportion their time and focus instead on other areas of the industry, resulting in decreased MA plan enrollment; however, we believe this impact would swiftly be offset by increased marketing and other adjustments made by the MA plans, as discussed below.

Another effect on agents and brokers from this provision is the requirement of uniform payment to agents and brokers and the resulting increased transparency. More specifically, agents and brokers who might have been receiving excess payments for targeting certain plans will no longer be financially incentivized to target these plans resulting in a more equitable distribution of efforts.

Plans are already spending a standard amount of \$601 per new enrollee on agents and brokers. We do not believe the increased compensations of \$31 extra (about a 5 percent increase) per agent per enrollee would have any significant financial impact on plans given the proposal to prohibit excess payments in the form of administrative payments.

On the other hand, if some agents and brokers withdraw or lower efforts for Medicare Advantage and Part D plans, resulting in possibly lower enrollment, plans may increase money allocated to outreach and advertising. Overall, we do not expect a decrease in enrollment because of the agent and broker compensation provisions since plans meticulously monitor enrollment trends and possess a variety of vehicles to counteract any significant changes. Indeed, in assessing the impact of the agent broker compensation provision it is important to emphasize that people join plans because of outreach from a wide variety of sources and therefore no single source is critical.

We solicit public comment on the economic cost and benefits of this proposal.

6. Enhancing Enrollees' Right To Appeal an MA Plan's Decision To Terminate Coverage for Non-Hospital Provider Services (§ 422.626)

In § 422.626, we are proposing to (1) require the QIO instead of the MA plan, to review untimely fast-track appeals of an MA plan's decision to terminate services in an HHA, CORF, or SNF; and (2) fully eliminate the provision requiring the forfeiture of an enrollee's right to appeal a termination of services decision when they leave the facility or end home health, CORF, or home-based hospice services before the proposed terminate date.

Currently, there is no data collected on the volume of fast-track appeals

conducted by MA plans for untimely requests. The QIO conducts appeals for FFS fast-track appeals for untimely requests but does not formally collect data on appeals based on untimely requests from MA enrollees. Thus, the following estimates are speculative given the lack of precise data on the number of the fast-track appeals for untimely FFS requests.

Anecdotal data from the QIOs conducting these fast-track appeals indicates that approximately 2.5 percent of all fee-for-service (FFS) fast-track appeal requests are untimely. In CY 2021 (most recent year available), there were 190,031 MA fast-track appeals to the QIO. Thus, we estimate that approximately 4,751 fast track appeals will be shifted from MA plans to the QIO ($0.025 \times 190,031$).

The shift of these untimely appeals from the QIOs to the MA plans will result in an increased burden. There is an estimated per case cost for QIOs to conduct these appeals (per the Financial Information and Vouchering System (FIVS) from 5/1/2019–7/31/2023), while MA plans are not specifically reimbursed for this activity. The average QIO appeal of this type takes 1.69 hours at \$85.18/hr.

In aggregate we estimate an annual burden of 8,029 hours (4,751 responses * 1.69 hr/response) at a cost of \$683,910 (8,029 hr * \$85.18/hr).

We are unable to estimate how many new QIO reviews will be conducted under the proposed provision at § 422.626(a)(3) to eliminate the provision requiring the forfeiture of an enrollee's right to appeal a termination of services decision when they leave the skilled nursing facility or end home health, CORF, or home-based hospice services before the proposed termination date. No entity tracks how many appeals are not conducted because the enrollee stopped the services at issue before the last day of coverage. Further, because this provision has never existed for FFS, we have no basis from which to derive an estimate.

E. Alternatives Considered

In this section, CMS includes discussions of alternatives considered. Several provisions of this proposed rule reflect a codification of existing policy where we have evidence, as discussed in the appropriate preamble sections, that the codification of this existing policy would not affect compliance. In such cases, the preamble typically discusses the effectiveness metrics of these provisions for public health. Also, in these cases, traditional categories of alternative analysis such as different

compliance dates, different enforcement methods, different levels of stringency, as outlined in section C of OMB's Circular A–4, are not fully relevant since the provision is already being complied with adequately. Consequently, alternative analysis is not provided for these provisions.

1. Contracting Standards for Dual Eligible Special Needs Plan Look-Alikes (§ 422.514)

We are proposing to lower the threshold for D–SNP look-alikes from 80 percent to 60 percent over a 2-year period. We considered an alternative proposal to lower the D–SNP look-alike threshold to 60 percent in 1 year, allowing an earlier phase-out of these non-SNP MA plans. But we are proposing the more incremental approach to minimize disruptions to dually eligible individuals and allow plans and CMS more time to operationalize these transitions.

We are considering and soliciting comment on an alternative to our proposal that would eliminate the proposed 70 percent threshold for plan year 2025 but would involve additional conditions and changes related to the transition authority. Specifically, this alternative would—

- Apply the 60 percent threshold beginning in plan year 2026;
- Permit use of the transition authority into non-SNP MA plans (as currently permitted under § 422.514(e)) for plan year 2025; and
- Limit use of transition authority under § 422.514(e) to transition D–SNP look-alike enrollees into D–SNPs for plan year 2026 and subsequent plan years.

Relative to our proposal, this alternative would give plans with dually eligible individual enrollment between 70 and 80 percent of total enrollment based on January 2024 enrollment data one additional year to apply for a new D–SNP or service area expansion to an existing D–SNP, such that these plans could transition enrollees into a D–SNP for plan year 2026. The alternative would balance the additional year using the existing 80 percent enrollment threshold to identify prohibited D–SNP look-alikes with an earlier limitation on the § 422.514(e) transition authority to enrollees transitioning into non-SNPs. We solicit comment on whether this alternative is a better balance of the goals of our policy to prohibit circumvention of the requirements for D–SNPs and to encourage and incentivize enrollment in integrated care plans.

Among the factors we would consider in adopting the alternative instead of

our proposal is the extent to which plans with 70 percent or more dually eligible enrollment in plan year 2024 expect to be able to establish a D–SNP in the same service area as the D–SNP look-alike if given an additional year (that is, 2026) to transition enrollees. Based on 2023 plan year data, approximately two-thirds of the MA organizations with non-SNP MA plans with between 70 and 80 percent dually eligible individuals already have a D–SNP under the same MA organization with the vast majority of those D–SNPs having a service area that covers the service area as the non-SNP MA plan. The other approximately one-third of the MA organizations with non-SNP MA

plans with between 70 and 80 percent dually eligible individuals do not have a D–SNP in the same service area in plan year 2023. If given an additional year, these MA organizations would have more time in which to establish D–SNPs in the same service areas as non-SNP MA plans and transition the enrollees into a D–SNP.

F. Accounting Statement and Table

As required by OMB Circular A–4 (available at https://obamawhitehouse.archives.gov/omb/circulars_a004_a-4/) in Table K–4, we have prepared an accounting statement showing the costs and transfers associated with the provisions of this

proposed rule for calendar years 2025 through 2034. Table K4 is based on Tables K–5a and Table K5-b which list savings and costs by provision and year. Tables K4, K5a and K5b with costs listed as positive numbers and savings listed as positive numbers. As can be seen, the net annualized savings of this proposed rule is between \$150 and \$200 million per year. The net savings reflect a mixture of several provisions that save and cost. Minor seeming discrepancies in totals in Tables K4, K5a, and K5b reflect use of underlying spreadsheets, rather than intermediate rounded amounts. A breakdown of these costs of this proposed rule by provision may be found in Tables K5a and K5b.

TABLE K4: ACCOUNTING TABLE (\$ MILLIONS)*

Item	Annualized at 3%	Annualized at 7%	Period	Who is affected
Net Annualized Monetized Savings	176.3	155.0	CYs 2025-2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Annualized Monetized Savings	216.5	195.2	CYs 2025-2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,
Annualized Monetized Cost	40.2	40.2	CYs 2025-2034	MA Organizations, Part D Sponsors, Contractors for the Federal Government, MA Enrollees, Agents and Brokers,

* The savings and cost are expressed with positive numbers. For example, at 3%, this proposed rule annually saves \$216.5 million but costs \$40.2 million resulting in a net savings of \$176.3 million.

The following Tables K5a and K5b summarize costs, and savings by provision and year, and forms a basis for the accounting Table K4. In Tables K5a and K5b, costs and savings are expressed as positive numbers (except in the row with header “Aggregate savings” where positive numbers reflect

savings and negative numbers reflect cost). The provisions increasing enrollment for D–SNPs Part C and Part D—effect the Medicare Trust Fund. In these rows, positive numbers reflect reduced dollar spending to the Trust Fund, that is savings. The savings (and costs) in these tables are true costs and

savings reflecting increases or decreases in consumption of services and goods. Tables K5a and K5b combine related provisions. For example, all provisions related to the utilization management committee in the COI summary table are combined into one-line item in the RIA.

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TABLE K5a: SAVINGS AND COSTS (millions \$) BY PROVISION AND YEAR (YEARS 2025 – 2029) *

	2025 Savings	2025 Costs	2025 Transfers	2026 Savings	2026 Costs	2026 Transfers	2027 Savings	2027 Costs	2028 Savings	2028 Costs	2029 Savings	2029 Costs
Total Savings	3.0			3.0			15.6		27.9		40.0	
Total Costs		41.8			39.9			39.9		39.9		39.9
Aggregate Total	(38.7)			(36.9)			(24.3)		(12.0)		0.0	
Savings of the Medicare Trust Fund												
Increased enrollment in D-SNPs, Part C							5.5		10.9		15.9	
Increased enrollment in D-SNPs, Part D							7.0		13.9		21.1	
Increased enrollment in D-SNPs, Paperwork		0.2			-			-		-		-
DMP	3.0			3.0			3.0		3.0		3.0	
SSBCI		7.0			6.8			6.8		6.8		6.8
Increased Utilization of Supplementary Benefits		1.8			1.4			1.4		1.4		1.4
UM Committee		0.9										
Enhanced Appeal Rights		0.7			0.7			0.7		0.7		0.7
Agent Broker		31.0			31.0			31.0		31.0		31.0
D-SNP Look-Alikes		0.1			0.1			0.1		0.1		0.1
Notice of Availability		0.1										

*Table K5a is continued in Table K5b.

TABLE K5b: SAVINGS AND COSTS (millions \$) BY PROVISION AND YEAR (YEARS 2030 – 2034)*

	2030 Savings	2030 Costs	2031 Savings	2031 Costs	2032 Savings	2032 Costs	2033 Savings	2033 Costs	2034 Savings	2034 Costs	Raw 10-Year Totals
Total Savings	408.7		423.4		442.5		472.4		496.3		2,329.80
Total Costs		39.9		39.9		39.9		39.9		39.9	401.3
Aggregate Total	368.7		383.5		402.5		432.5		456.3		1,931.6
Savings of the Medicare Trust Fund											-
Increased Enrollment in D-SNPs, Part C	170.8		175.3		180.3		195.7		206.9		961.4
Increased Enrollment in D-SNPs, Part D	234.8		245.0		259.2		273.7		286.3		1,340.9
Increased Enrollment in D-SNPs, Paperwork		-		-		-		-		-	0.2
DMP	3.0		3.0		3.0		3.0		3.0		30.5
SSBCI		6.8		6.8		6.8		6.8		6.8	68.6
Increased Utilization of Supplementary Benefits		1.4		1.4		1.4		1.4		1.4	14.0
UM Committee											0.9
Enhanced Appeal Rights		0.7		0.7		0.7		0.7		0.7	6.8
Agent Broker		31.0		31.0		31.0		31.0		31.0	310.0
D-SNP Look-Alikes		0.1		0.1		0.1		0.1		0.1	0.6
Notice of Availability											0.1

*Continued from Table K5a.

NOTES:

1. Except for the row with "aggregate total", positive numbers in the cost columns reflect costs while positive numbers in the savings column reflect savings. The aggregate column subtracts the costs from the savings and therefore lists the difference as a negative number when the aggregate effect is a cost and as a positive when it is a savings.
2. Two of the line items effect the Trust Fund "Increased Enrollment in D-SNPs, Part C", and "Increased Enrollment in D-SNPs, Part D". Over 10 years they save, \$961, and \$1,341 million respectively.
3. When the aggregate of line items for a provision is below \$50,000, for example the paperwork burden of \$4,929 associated with the provision for network adequacy of behavioral health, or the cost to CMS staff to perform certain tasks listed in this section, they were not included in the table (since they do not have an effect on numbers). However, when the aggregate of several provisions rounded to at least \$0.1 million it was included.

G. Conclusion

In aggregate this proposed rule saves significantly. Two provisions reduce spending by the Medicare Trust Fund: (1) the effect on Part C plans from the provisions designed to increase enrollment D-SNPs; and (2) the effect on Part D plans from these D-SNP provisions. Over a 10-year period they reduce spending of the Medicare Trust Fund of \$28, \$961, and \$1,341 million respectively. The provisions for the Drug Management Program should reduce paperwork burden by \$3 million annually saving \$30 million over 10 years. The agent broker provision is expected to cost \$31 million and \$310 million over 10 years.

XII. Response to Comments

Because of the large number of public comments that we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document. In accordance with requirements this major rule has been reviewed by OMB.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on October 24, 2023.

List of Subjects

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health Insurance, Health maintenance organizations (HMO), Loan programs-health Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Incorporation by reference, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Citizenship and naturalization, Civil rights, Health, Health care, Health records, Individuals with disabilities, Medicaid, Medicare, Religious

discrimination, Reporting and recordkeeping requirements, Sex discrimination.

45 CFR Part 170

Computer technology, Health, Health care, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Public health, Reporting and recordkeeping requirements, Security measures.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV and the Department of Health and Human Services proposes to amend 45 CFR part 170 as set forth below:

Title 42

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 1. The authority citation for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

Subpart L—Medicare Contract Requirements

■ 2. Section 417.472 is amended by adding paragraph (l) to read as follows:

§ 417.472 Basic contract requirements.

(l) *Resolution of complaints in the complaints tracking module.* The HMO or CMP must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter to, through the CMS complaints tracking module as defined in § 422.125(a), address and resolve complaints received by CMS against the HMO or CMP within the required timeframes. References to the MA organization or MA plan in those regulations shall be read as references to the HMO or CMP.

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 3. The authority citation for part 422 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 4. Section 422.2 is amended by revising the definition of “Basic benefits” to read as follows:

§ 422.2 Definitions.

* * * * *

Basic benefits means Part A and Part B benefits except—

(1) Hospice services; and
(2) Beginning in 2021, organ acquisitions for kidney transplants, including costs covered under section 1881(d) of the Act.

* * * * *

■ 5. Section 422.52 is amended by:

■ a. Revising paragraph (b)(2);

■ b. Redesignating paragraph (f) as paragraph (f) introductory text; and

■ c. Adding paragraph (f)(1) and reserved paragraph (f)(2).

The revision and additions read as follows:

§ 422.52 Eligibility to elect an MA plan for special needs individuals.

* * * * *

(b) * * *

(2) Meet the eligibility requirements for that specific SNP, including any additional eligibility requirements established in the State Medicaid agency contract (as described at § 422.107(a)) for dual eligible special needs plans; and

* * * * *

(f) * * *

(1) For enrollments into a SNP that exclusively enrolls individuals that have severe or disabling chronic conditions (C-SNP), the organization must contact the applicant's current physician to confirm that the applicant has the qualifying condition(s). The organization must obtain this information in one of the following two ways described in paragraph (f)(1)(i) or (ii) of this section:

(i) Contact the physician or physician's office and obtain verification of the condition(s) prior to enrollment in a form and manner authorized by CMS from the applicant's primary care provider or specialist treating the qualifying condition(s).

(ii) Through an assessment with the enrollee using a pre-enrollment qualification assessment tool (PQAT) where the assessment and the information gathered are verified (as described in paragraph (f)(1)(iii) of this section) before the end of the first month of enrollment in the C-SNP. Use of a PQAT requires the following:

(A) The PQAT must do all of the following in paragraphs (f)(1)(i)(A)(1) through (4) of this section:

(1) Include clinically appropriate questions relevant to the chronic condition(s) on which the C-SNP focuses.

(2) Gather sufficient reliable evidence of having the applicable condition using the applicant's past medical history, current signs or symptoms, and current medications.

(3) Include the date and time of the assessment completion if done face-to-

face with the applicant, or the receipt date if the C-SNP receives the completed PQAT by mail or by electronic means (if available).

(4) Include a signature line for and be signed by a physician to confirm the individual's eligibility for C-SNP enrollment.

(B) The C-SNP conducts a post-enrollment confirmation of each enrollee's information and eligibility using medical information (medical history, current signs or symptoms, diagnostic testing, and current medications) provided by the enrollee's primary care physician or the specialist treating the chronic condition.

(C) The C-SNP must include the information gathered in the PQAT and used in this verification process in its records related to or about the enrollee that are subject to the confidentiality requirements in § 422.118.

(D)(1) The C-SNP tracks the total number of enrollees and the number and percent by condition whose post-enrollment verification matches the pre-enrollment assessment.

(2) Data and supporting documentation are made available upon request by CMS.

(E) If the organization does not obtain verification of the enrollees' required chronic condition(s) by the end of the first month of enrollment in the C-SNP, the organization must—

(1) Disenroll the enrollee as of the end of the second month of enrollment; and

(2) Send the enrollee notice of the disenrollment within the first 7 calendar days of the second month of enrollment.

(F) The organization must maintain the enrollment of the individual if verification of the required condition(s) is obtained at any point before the end of the second month of enrollment.

(iii) To complete the PQAT, the C-SNP is required to have the individual's current physician (primary care physician or specialist treating the qualifying condition) or a physician employed or contracted by the plan administer the PQAT directly with the enrollee or provide confirmation (with or without the presence of the enrollee) that the information in the document supports a determination that the individual is eligible for the C-SNP. The enrollee's physician must sign the completed PQAT.

(2) [Reserved]

■ 6. Section 422.60 is amended by revising paragraph (a)(1) and adding paragraphs (a)(3) and (h) to read as follows:

§ 422.60 Election process.

(a) * * *

(1) Except for the limitations on enrollment in an MA MSA plan

provided by § 422.62(d)(1) and except as specified in paragraphs (a)(2) and (3) of this section, each MA organization must accept without restriction (except for an MA RFB plan as provided by § 422.57) individuals who are eligible to elect an MA plan that the MA organization offers and who elect an MA plan during initial coverage election periods under § 422.62(a)(1), annual election periods under § 422.62(a)(2), and under the circumstances described in § 422.62(b)(1) through (4).

* * * * *

(3) Dual eligible special needs plans must limit enrollments to those individuals who meet the eligibility requirements established in the State Medicaid agency contract, as specified at § 422.52(b)(2).

* * * * *

(h) *Authorized representatives.* As used in this subpart, an authorized representative is an individual who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the beneficiary resides may allow, in order to execute an enrollment or disenrollment request.

(1) The authorized representative would constitute the "beneficiary" or the "enrollee" for the purpose of making an election.

(2) Authorized representatives may include court-appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under State surrogate consent laws, provided they have the authority to act for the beneficiary in this capacity.

■ 7. Section 422.62 is amended by revising paragraphs (a)(1)(i) and (a)(4) to read as follows:

§ 422.62 Election of coverage under an MA plan.

(a) * * *

(1) * * *

(i) The last day of the second month after the month in which they are first entitled to Part A and enrolled in Part B; or

* * * * *

(4) *Open enrollment period for institutionalized individuals.* After 2005, an individual who is eligible to elect an MA plan and who is institutionalized, as defined in § 422.2, is not limited (except as provided for in paragraph (d) of this section for MA MSA plans) in the number of elections or changes he or she may make.

(i) Subject to the MA plan being open to enrollees as provided under § 422.60(a)(2), an MA eligible

institutionalized individual may at any time elect an MA plan or change his or her election from an MA plan to Original Medicare, to a different MA plan, or from Original Medicare to an MA plan.

(ii) The open enrollment period for institutionalized individuals ends on the last day of the second month after the month the individual ceases to reside in one of the long-term care facility settings described in the definition of "institutionalized" in § 422.2.

* * * * *

■ 8. Section 422.68 is amended by adding paragraph (g) to read as follows:

§ 422.68 Effective dates of coverage and change of coverage.

* * * * *

(g) *Beneficiary choice of effective date.* If a beneficiary is eligible for more than one election period, resulting in more than one possible effective date, the MA organization must allow the beneficiary to choose the election period that results in the individual's desired effective date.

(1) To determine the beneficiary's choice of election period and effective date, the MA organization must attempt to contact the beneficiary and must document its attempts.

(2) If the MA organization is unable to obtain the beneficiary's desired enrollment effective date, the MA organization must assign an election period using the following ranking of election periods:

(i) ICEP/Part D IEP

(ii) MA-OEP

(iii) SEP

(iv) AEP

(v) OEPI

(3) If the MA organization is unable to obtain the beneficiary's desired disenrollment effective date, the MA organization must assign an election period that results in the earliest disenrollment.

■ 9. Section 422.100 is amended by adding paragraph (o) to read as follows:

§ 422.100 General requirements.

* * * * *

(o) *Cost sharing standards for D-SNP PPOs.* Beginning on or after January 1, 2026, a MA organization offering a local PPO plan or regional PPO plan that is a dual eligible special needs plan must establish cost sharing for out-of-network services that—

(1) Complies with the limits described in paragraph (f)(6) of this section with the exception that references to the MOOP amounts refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans; and

(2) Complies with the limits described in paragraph (j)(1) of this section with the exception that references to the MOOP amounts that refer to the total catastrophic limits under § 422.101(d)(3) for local PPOs and MA regional plans and, for regional PPO dual eligible special needs plans, excluding paragraph (j)(1)(i)(C)(2) and the last sentence of paragraph (j)(1)(i)(E) of this section.

- 10. Section 422.102 is amended by:
- a. Revising paragraph (f)(1)(i)(A)(2);
- b. Redesignating paragraph (f)(3) as paragraph (f)(4);
- c. Adding a new paragraph (f)(3);
- d. Revising newly redesignated paragraph (f)(4) introductory text and (f)(4)(iii) and (iv); and
- e. Adding paragraph (f)(5).

The additions and revision read as follows:

§ 422.102 Supplemental benefits.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(A) * * *

(2) Has a high risk of hospitalization or other adverse health outcomes; and

* * * * *

(3) *MA organization responsibilities.* An MA organization that includes an item or service as SSBCI in its bid must be able to demonstrate through relevant acceptable evidence that the item or service has a reasonable expectation of improving or maintaining the health or overall function of a chronically ill enrollee. By the date on which an MA organization submits its bid, the MA organization must establish a written bibliography of relevant acceptable evidence concerning the impact that the item or service has on the health or overall function of its recipient. For each citation in the written bibliography, the MA organization must include a working hyperlink to or a document containing the entire source cited.

(i) Relevant acceptable evidence includes large, randomized controlled trials or prospective cohort studies with clear results, published in a peer-reviewed journal, and specifically designed to investigate whether the item or service impacts the health or overall function of a population, or large systematic reviews or meta-analyses summarizing the literature of the same.

(ii) An MA organization must include in its bibliography all relevant acceptable evidence published within the 10 years prior to the June immediately preceding the coverage year during which the SSBCI will be offered.

(iii) If no evidence of the type described in paragraphs (f)(3)(i) and (ii) of this section exists for a given item or service, then MA organization may cite case studies, Federal policies or reports, internal analyses, or any other investigation of the impact that the item or service has on the health or overall function of its recipient as relevant acceptable evidence in the MA organization's bibliography.

(iv) The MA organization must make its bibliography of relevant acceptable evidence available to CMS upon request.

(4) *Plan responsibilities.* An MA plan offering SSBCI must do all of the following:

* * * * *

(iii)(A) Have and apply written policies based on objective criteria for determining a chronically ill enrollee's eligibility to receive a particular SSBCI; and

(B) Document the written policies specified in paragraph (f)(4)(iii)(A) of this section and the objective criteria on which the written policies are based.

(iv) Document each determination that an enrollee is not eligible to receive an SSBCI and make this information available to CMS upon request.

(5) *CMS review of SSBCI offerings in bids.* (i) CMS may decline to approve an MA organization's bid if CMS determines that the MA organization has not demonstrated, through relevant acceptable evidence, that an SSBCI has a reasonable expectation of improving or maintaining the health or overall function of the chronically ill enrollees that the MA organization is targeting.

(ii) CMS may annually review the items or services that an MA organization includes as SSBCI in its bid for compliance with all applicable requirements, taking into account updates to the relevant acceptable evidence applicable to each item or service.

(iii) This provision does not limit CMS's authority to review and negotiate bids or to reject bids under section 1854(a) of the Act and subpart F of this

part nor does it limit CMS's authority to review plan benefits and bids for compliance with all applicable requirements.

■ 11. Section 422.111 is amended by adding paragraph (l) to read as follows:

§ 422.111 Disclosure requirements.

* * * * *

(l) *Mid-year notice of unused supplemental benefits.* Beginning January 1, 2026, MA organizations must send notification annually, no sooner than June 30 and no later than July 31, to each enrollee with unused supplemental benefits consistent with the requirements of § 422.2267(e)(42).

■ 12. Section 422.116 is amended by:

■ a. Adding paragraph (b)(2)(xiv);

■ b. In table 1 to paragraph (d)(2), adding an entry for "Outpatient Behavioral Health" following the entry for "Orthopedic Surgery";

■ c. Adding paragraph (d)(5)(xv);

■ d. Revising paragraph (f)(1) introductory text; and

■ e. Adding paragraphs (f)(2)(iv) and (f)(3).

The additions and revisions read as follows:

§ 422.116 Network adequacy.

* * * * *

(b) * * *

(2) * * *

(xiv) Outpatient Behavioral Health, which can include Marriage and Family Therapists (as defined in section 1861(III) of the Act), Mental Health Counselors (as defined in section 1861(III) of the Act), Opioid Treatment Programs (as defined in section 1861(jjj) of the Act), Community Mental Health Centers (as defined in section 1861(ff)(3)(B) of the Act), or those of the following who regularly furnish or will regularly furnish behavioral health counseling or therapy services including, but not limited to, psychotherapy or prescription of medication for substance use disorders: physician assistants, nurse practitioners and clinical nurse specialists (as defined in section 1861(aa)(5) of the Act); addiction medicine physicians; or outpatient mental health and substance use treatment facilities.

* * * * *

(d) * * *

(2) * * *

TABLE 1 TO PARAGRAPH (d)(2)

Provider/Facility type	Large metro		Metro		Micro		Rural		CEAC	
	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance	Max time	Max distance
Outpatient Behavioral Health	20	10	40	25	55	40	60	50	110	100

* * * * *

(d) * * *

(5) * * *

(xv) Outpatient Behavioral Health, described in paragraph (b)(2)(xiv) of this section.

* * * * *

(f) * * *

(1) An MA plan may request an exception to network adequacy criteria in paragraphs (b) through (e) of this section when either paragraph (f)(1)(i) or (ii) of this section is met:

(i)(A) Certain providers or facilities are not available for the MA plan to meet the network adequacy criteria as shown in the Provider Supply file for the year for a given county and specialty type; and

(B) The MA plan has contracted with other providers and facilities that may be located beyond the limits in the time and distance criteria, but are currently available and accessible to most enrollees, consistent with the local pattern of care; or

(ii)(A) A facility-based Institutional-Special Needs Plan (I-SNP) is unable to contract with certain specialty types required under paragraph (b) of this section because of the way enrollees in facility-based I-SNPs receive care; or

(B) A facility-based I-SNP provides sufficient and adequate access to basic benefits through additional telehealth benefits (in compliance with § 422.135) when using telehealth providers of the specialties listed in paragraph (d)(5) of this section in place of in-person providers to fulfill network adequacy standards in paragraphs (b) through (e) of this section.

(2) * * *

(iv) As applicable, the facility-based I-SNP submits:

(A) Evidence of the inability to contract with certain specialty types required under this section due to the way enrollees in facility-based I-SNPs receive care; or

(B) Substantial and credible evidence that sufficient and adequate access to basic benefits is provided to enrollees using additional telehealth benefits (in compliance with § 422.135) furnished by providers of the specialties listed in paragraph (d)(5) of this section and the

facility-based I-SNP covers out-of-network services furnished by a provider in person when requested by the enrollee as provided in § 422.135(c)(1) and (2), with in-network cost sharing for the enrollee.

(3) Any MA organization that receives the exception provided for facility-based I-SNPs must agree to offer only facility-based I-SNPs under the MA contract that receives the exception.

■ 13. Section 422.125 is added to read as follows:

§ 422.125 Resolution of complaints in Complaints Tracking Module.

(a) *Definitions.* For the purposes of this section, the terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular MA organization in the Complaints Tracking Module.

Complaints Tracking Module means an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint means a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution—(1) Immediate need complaints.* The MA organization must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The MA organization must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The MA organization must resolve all other complaints within 30 calendar days of the assignment date.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the MA organization must contact the individual who filed a complaint within 3 calendar days of the assignment date.

■ 14. Section 422.137 is amended by adding paragraphs (c)(5) and (d)(6) and (7) to read as follows:

§ 422.137 Medicare Advantage Utilization Management Committee.

* * * * *

(c) * * *

(5) Beginning January 1, 2025, include at least one member with expertise in health equity. Expertise in health equity includes, but is not limited to, educational degrees or credentials with an emphasis on health equity; experience conducting studies identifying disparities amongst different population groups; experience leading organization-wide policies, programs, or services to achieve health equity; or experience leading advocacy efforts to achieve health equity.

(d) * * *

(6) Beginning in 2025, annually conduct a health equity analysis of the use of prior authorization.

(i) The final report of the analysis must be approved by the member of the committee with expertise in health equity before it is publicly posted.

(ii) The analysis must examine the impact of prior authorization on enrollees with one or more of the following social risk factors:

(A) Receipt of the low-income subsidy or being dually eligible for Medicare and Medicaid.

(B) Having a disability. Disability status is determined using the variable original reason for entitlement code (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

(iii) The analysis must use the following metrics, calculated for enrollees with the specified social risk factors and enrollees without the

specified social risk factors, to conduct the analysis at the plan level using data from the prior contract year:

(A) The percentage of standard prior authorization requests that were approved, aggregated for all items and services.

(B) The percentage of standard prior authorization requests that were denied, aggregated for all items and services.

(C) The percentage of standard prior authorization requests that were approved after appeal, aggregated for all items and services.

(D) The percentage of prior authorization requests for which the timeframe for review was extended, and the request was approved, aggregated for all items and services.

(E) The percentage of expedited prior authorization requests that were approved, aggregated for all items and services.

(F) The percentage of expedited prior authorization requests that were denied, aggregated for all items and services.

(G) The average and median time that elapsed between the submission of a request and a determination by the MA plan, for standard prior authorizations, aggregated for all items and services.

(H) The average and median time that elapsed between the submission of a request and a decision by the MA plan for expedited prior authorizations, aggregated for all items and services.

(7) By July 1, 2025, and annually thereafter, publicly post the results of the health equity analysis of the utilization management policies and procedures on the plan's website meeting the following requirements:

(i) In a prominent manner and clearly identified in the footer of the website.

(ii) Easily accessible to the general public, without barriers, including but not limited to ensuring the information is accessible:

(A) Free of charge.

(B) Without having to establish a user account or password.

(C) Without having to submit personal identifying information.

(iii) In a machine-readable format with the data contained within that file being digitally searchable and downloadable.

(iv) Include a .txt file in the root directory of the website domain that includes a direct link to the machine-readable file to establish and maintain automated access.

■ 15. Section 422.164 is amended by:

■ a. Revising paragraphs (g)(1)(iii) introductory text and (g)(1)(iii)(A);

■ b. Removing and reserving paragraphs (g)(1)(iii)(B) and (F);

■ c. Revising paragraph (g)(1)(iii)(H);

■ d. Removing and reserving paragraphs (g)(1)(iii)(I) and (J);

■ e. Revising paragraphs (g)(1)(iii)(K)(2) and (g)(1)(iii)(O); and

■ f. Adding paragraph (h)(3).

The revisions and addition read as follows:

§ 422.164 Adding, updating, and removing measures.

* * * * *

(g) * * *

(1) * * *

(iii) For the appeals measures, CMS uses statistical criteria to estimate the percentage of missing data for each contract using data from MA organizations, the independent review entity (IRE), or CMS administrative sources to determine whether the data at the IRE are complete. CMS uses scaled reductions for the Star Ratings for the applicable appeals measures to account for the degree to which the IRE data are missing.

(A)(1) The data reported by the MA organization on appeals, including the number of reconsiderations requested, denied, upheld, dismissed, or otherwise disposed of by the MA organization, and data from the IRE or CMS administrative sources, that align with the Star Ratings year measurement period are used to determine the scaled reduction.

(2) If there is a contract consolidation as described at § 422.162(b)(3), the data described in paragraph (g)(1)(iii)(A)(1) of this section are combined for the consumed and surviving contracts before the methodology provided in paragraphs (g)(1)(iii)(B) through (H) and (K) through (O) of this section is applied.

* * * * *

(H) The Part C calculated error is determined using 1 minus the quotient of the total number of cases received by the IRE and the total number of cases that should have been forwarded to the IRE. The total number of cases that should have been forwarded to the IRE is determined by the sum of the partially favorable (adverse) reconsiderations and unfavorable (adverse) reconsiderations for the applicable measurement year.

* * * * *

(K) * * *

(2) The number of cases not forwarded to the IRE is at least 10 for the measurement year.

* * * * *

(O) CMS reduces the measure rating to 1 star for the applicable appeals measure(s) if CMS does not have accurate, complete, and unbiased data to validate the completeness of the Part C appeals measures.

* * * * *

(h) * * *

(3) Beginning with the 2025 measurement year (2027 Star Ratings), an MA organization may request that CMS review its contract's administrative data for Patient Safety measures provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

* * * * *

■ 16. Section 422.166 is amended by revising paragraph (f)(2)(i)(B) and adding paragraphs (f)(3)(viii)(A) and (B) to read as follows:

§ 422.166 Calculation of Star Ratings.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year.

(1) For the first 2 years following a consolidation, for the surviving contract of a contract consolidation involving two or more contracts for health or drug services of the same plan type under the same parent organization, the enrollment data for the month of December for the measurement period of the Star Ratings year are combined across the surviving and consumed contracts in the consolidation.

(2) The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year.

(3) A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period.

(4) Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

* * * * *

(3) * * *

(viii) * * *

(A) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS calculates the HEI reward for the surviving contract accounting for both the surviving and consumed contract(s). For the first year following a consolidation, the HEI reward for the surviving contract is calculated as the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using

enrollment from July of the most recent measurement year used in calculating the HEI reward. A reward value of zero is used in calculating the enrollment-weighted mean for contracts that do not meet the minimum percentage of enrollees with the SRF thresholds or the minimum performance threshold specified at paragraph (f)(3)(vii) of this section.

(B) For the second year following a consolidation when calculating the HEI score for the surviving contract, the patient-level data used in calculating the HEI score will be combined from the consumed and surviving contracts and used in calculating the HEI score.

* * * * *

■ 17. Section 422.260 is amended by revising paragraph (c)(2)(vii) to read as follows:

§ 422.260 Appeals of quality bonus payment determinations.

* * * * *

(c) * * *
(2) * * *

(vii) After the hearing officer's decision is issued to the MA organization and the CMS Administrator, the hearing officer's decision is subject to review and modification by the CMS Administrator within 10 business days of issuance. If the Administrator does not review and issue a decision within 10 business days, the hearing officer's decision is final and binding.

* * * * *

■ 18. Section 422.310 is amended by:
■ a. Revising paragraphs (f)(1)(vi) and (vii);
■ b. Adding reserved paragraph (f)(3)(iv); and
■ c. Adding paragraph (f)(3)(v).

The revisions and addition read as follows:

§ 422.310 Risk adjustment data.

* * * * *

(f) * * *
(1) * * *

(vi) To conduct evaluations and other analysis to support the Medicare and Medicaid programs (including demonstrations) and to support public health initiatives and other health care-related research;

(vii) For activities to support the administration of the Medicare and Medicaid programs;

* * * * *

(3) * * *

(iv) [Reserved]

(v) CMS determines that releasing data to State Medicaid agencies before reconciliation for the purpose of coordinating care for dually eligible individuals is necessary and appropriate

to support activities or authorized uses under paragraph (f)(1)(vii) of this section.

* * * * *

■ 19. Section 422.311 is amended by:

- a. Revising paragraphs (a) and (c)(5)(ii)(B);
- b. Removing paragraph (c)(5)(ii)(C);
- c. Revising paragraph (c)(5)(iii);
- d. Adding paragraph (c)(5)(iv);
- e. Revising paragraphs (c)(6)(i)(A) and (c)(6)(iv)(B);
- f. Adding paragraph (c)(6)(v);
- g. Revising paragraph (c)(7)(ix);
- h. Revising paragraphs (c)(8)(iii), (c)(8)(iv) introductory text, (c)(8)(iv)(A), and (c)(8)(vi); and
- i. Adding paragraphs (c)(8)(vii) and (c)(9).

The revisions and additions read as follows:

§ 422.311 RADV audit dispute and appeal processes.

(a) *Risk adjustment data validation (RADV) audits.* In accordance with §§ 422.2 and 422.310(e), the Secretary conducts RADV audits to ensure risk-adjusted payment integrity and accuracy.

(1) Recovery of improper payments from MA organizations is conducted in accordance with the Secretary's payment error extrapolation and recovery methodologies.

(2) CMS may apply extrapolation to audits for payment year 2018 and subsequent payment years.

* * * * *

(c) * * *
(5) * * *
(ii) * * *

(B) Whether the MA organization requests a payment error calculation appeal, the issues with which the MA organization disagrees, and the reasons for the disagreements. MA organizations will forgo their medical record review determination appeal if they choose to file only a payment error calculation appeal because medical record review determinations need to be final prior to adjudicating a payment error calculation appeal.

(iii) For MA organizations that intend to appeal both the medical record review determination and the RADV payment error calculation, an MA organization's request for appeal of its RADV payment error calculation may not be filed and will not be adjudicated until:

(A) The administrative appeal process for the RADV medical record review determinations filed by the MA organization has been exhausted; or

(B) The MA organization does not timely request a RADV medical record review determination appeal at the

hearing stage and/or the CMS Administrator review stage, as applicable.

(iv) An MA organization whose medical record review determination appeal has been completed as described in paragraph (c)(5)(iii) of this section has 60 days from the date of issuance of a revised RADV audit report, based on the final medical record review determination, to file a written request with CMS for a RADV payment error calculation appeal. This request for RADV payment error calculation appeal must clearly specify where the Secretary's RADV payment error calculation was erroneous, what the MA organization disagrees with, and the reasons for the disagreements.

(6) * * *

(i) * * *

(A) Any and all HCC(s) that the Secretary identified as being in error that the MA organization wishes to appeal.

* * * * *

(iv) * * *

(B) The reconsideration official's decision is final unless it is reversed or modified by a final decision of the hearing officer as defined at paragraph (c)(7)(x) of this section.

* * * * *

(v) *Computations based on reconsideration official's decision.* (A) Once the reconsideration official's medical record review determination decision is considered final in accordance with paragraph (c)(6)(iv)(B) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the reconsideration official's payment error calculation decision is considered final in accordance with paragraph (c)(6)(iv)(B) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

* * * * *

(7) * * *

(ix) *Computations based on Hearing Officer's decision.* (A) Once the hearing officer's medical record review determination decision is considered final in accordance with paragraph (c)(7)(x) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding

all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the hearing officer's payment error calculation decision is considered final in accordance with paragraph (c)(7)(x) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

* * * * *

(8) * * *

(iii) After reviewing a request for review, the CMS Administrator has the discretion to elect to review the hearing officer's decision or to decline to review the hearing officer's decision. If the CMS Administrator does not decline to review or does not elect to review within 90 days of receipt of either the MA organization or CMS's timely request for review (whichever is later), the hearing officer's decision becomes final.

(iv) If the CMS Administrator elects to review the hearing decision—

(A) The CMS Administrator acknowledges the decision to review the hearing decision in writing and notifies CMS and the MA organization of their right to submit comments within 15 days of the date of the issuance of the notification that the Administrator has elected to review the hearing decision; and

* * * * *

(v) The CMS Administrator renders his or her final decision in writing within 60 days of the date of the issuance of the notice acknowledging his or her decision to elect to review the hearing officer's decision.

(vi) The decision of the hearing officer is final if the CMS Administrator—

(A) Declines to review the hearing officer's decision; or

(B) Does not decline to review or elect to review within 90 days of the date of the receipt of either the MA organization or CMS's request for review (whichever is later); or

(C) Does not make a decision within 60 days of the date of the issuance of the notice acknowledging his or her decision to elect to review the hearing officer's decision.

* * * * *

(vii) *Computations based on CMS Administrator decision.* (A) Once the CMS Administrator's medical record review determination decision is considered final in accordance with paragraph (c)(8)(vi) of this section, the Secretary recalculates the MA organization's RADV payment error and

issues a revised RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(B) For MA organizations appealing the RADV payment error calculation only, once the CMS Administrator's payment error calculation decision is considered final in accordance with paragraph (c)(8)(vi) of this section, the Secretary recalculates the MA organization's RADV payment error and issues a revised and final RADV audit report superseding all prior RADV audit reports to the appellant MA organization.

(9) *Final agency action.* In cases when an MA organization files a payment error calculation appeal subsequent to a medical record review determination appeal that has completed the administrative appeals process, the medical record review determination appeal final decision and the payment error calculation appeal final decision will not be considered a final agency action until the payment error calculation appeal has completed the administrative appeals process and a final revised audit report superseding all prior RADV audit reports has been issued to the appellant MA organization.

■ 20. Section 422.502 is amended by:

■ a. Revising paragraphs (b)(1)(i)(A) through (C); and

■ b. Removing paragraphs (b)(1)(i)(E)(2)(A) and (B).

The revisions read as follows.

§ 422.502 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(A) Was under intermediate sanction under subpart O of this part or a determination by CMS to prohibit the enrollment of new enrollees in accordance with § 422.2410(c), with the exception of a sanction imposed under § 422.752(d).

(B) Failed to maintain a fiscally sound operation consistent with the requirements of § 422.504(a)(14).

(C) Filed for or is currently in Federal or State bankruptcy proceedings.

* * * * *

■ 21. Section 422.503 is amended by adding paragraph (b)(8) to read as follows:

§ 422.503 General provisions.

* * * * *

(b) * * *

(8) Not newly offer a dual eligible special needs plan that would result in noncompliance with § 422.514(h).

* * * * *

■ 22. Section 422.504 is amended by revising paragraph (a)(15) and adding paragraphs (a)(20) and (21) to read as follows.

§ 422.504 Contract provisions.

* * * * *

(a) * * *

(15) As described in § 422.125, address and resolve complaints received by CMS against the MA organization in the Complaints Tracking Module.

* * * * *

(20) To comply with the requirements established in § 422.514(h).

(21) Not to establish additional MA plans that are not facility-based ISNPs to contracts described in § 422.116(f)(3).

* * * * *

■ 23. Section 422.510 is amended by adding paragraph (e) to read as follows:

§ 422.510 Termination of contract by CMS.

* * * * *

(e) *Intermediate sanctions imposed with CMS termination.* If CMS makes a determination to terminate a MA organization's contract under paragraph (a) of this section, CMS also imposes the intermediate sanctions at § 422.750(a)(1) and (3) in accordance with the following procedures:

(1) The sanction goes into effect 15 days after the termination notice is sent.

(2) The MA organization has a right to appeal the intermediate sanction in the same proceeding as the termination appeal specified in paragraph (d) of this section.

(3) A request for a hearing does not delay the date specified by CMS when the sanction becomes effective.

(4) The sanction remains in effect—

(i) Until the effective date of the termination; or

(ii) If the termination decision is overturned on appeal, when a final decision is made by the hearing officer or Administrator.

■ 24. Section 422.514 is amended by:

■ a. Revising paragraphs (d)(1) introductory text, (d)(1)(ii), (d)(2) introductory text, and (d)(2)(ii);

■ b. In paragraph (e)(1)(i), removing the phrase “Specialized MA Plan for Special Needs Individuals” and adding in its place the phrase “specialized MA plan for special needs individuals”;

■ c. In paragraph (e)(1)(iii), removing the phrase “chapter; and” and adding in its place “chapter;”;

■ d. In paragraph (e)(1)(iv), removing the phrase “of this section.” and adding in its place “of this section; and”; and

■ e. Adding paragraphs (e)(1)(v) and (h).

The revisions and additions read as follows:

§ 422.514 Enrollment requirements.

* * * * *

(d) * * *

(1) Enter into or renew a contract under this subpart for a MA plan that—
* * * *

(ii) Projects enrollment in its bid submitted under § 422.254 in which enrollees entitled to medical assistance under a State plan under title XIX constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:

(A) For plan year 2024, 80 percent.

(B) For plan year 2025, 70 percent.

(C) For plan year 2026 and subsequent years, 60 percent.

(2) Renew a contract under this subpart for an MA plan that—
* * * *

(ii) Unless the MA plan has been active for less than 1 year and has enrollment of 200 or fewer individuals at the time of such determination, has actual enrollment, as determined by CMS using the January enrollment of the current year in which enrollees who are entitled to medical assistance under a State plan under title XIX, constitute a percentage of the plan's total enrollment that meets or exceeds one of the following:

(A) For renewals for plan year 2024, 80 percent.

(B) For renewals for plan year 2025, 70 percent.

(C) For renewals for plan year 2026 and subsequent years, 60 percent.

(e) * * *

(1) * * *

(v) For transitions for plan year 2027 and subsequent years, is a dual eligible special needs plan as defined in § 422.2.
* * * *

(h) *Rule on dual eligible special needs plans in relation to Medicaid managed care.* (1) Beginning in 2027, where an MA organization offers a dual eligible special needs plan and the MA organization, its parent organization, or any entity that shares a parent organization with the MA organization also contracts with a State as a Medicaid managed care organization (MCO) (as defined in § 438.2 of this chapter) that enrolls dually eligible individuals as defined in § 423.772 of this chapter, during the effective dates and in the same service area (even if there is only partial overlap of the service areas) of that Medicaid MCO contract, the MA organization—

(i) May only offer, or have a parent organization or share a parent organization with another MA organization that offers, one D-SNP for full-benefit dually eligible individuals, except as permitted in paragraph (h)(3) of this section; and

(ii) Must limit new enrollment in the D-SNP to individuals enrolled in, or in

the process of enrolling in, the Medicaid MCO.

(2) Beginning in 2030, such D-SNPs may only enroll (or continue to enroll) individuals enrolled in (or in the process of enrolling in) the Medicaid MCO, except that such D-SNPs may continue to implement deemed continued eligibility requirements as described in § 422.52(d).

(3)(i) If a State Medicaid agency's contract with the MA organization limits enrollment for certain groups into D-SNPs (such as by age group or other criteria), the MA organization, its parent organization or an entity that shares a parent organization with the MA organization may offer one or more additional D-SNPs for full-benefit dually eligible individuals in the same service area in accordance with the group (or groups) eligible for D-SNPs based on provisions of the contract with the State Medicaid agency under § 422.107 of this chapter.

(ii) If the MA organization, its parent organization or an entity that shares a parent organization with the MA organization offers more than one D-SNP of any type (HMOs and/or PPOs), and one or more of the plans is subject to paragraph (h)(1) of this section, the plan (or plans) not subject to paragraph (h)(1) of this section may continue if they no longer accept new enrollment of full-benefit dually eligible individuals in the same service area as the plan (or plans) subject to paragraph (h)(1) of this section.

■ 25. Section 422.516 is amended by revising paragraphs (a) introductory text and (a)(2) to read as follows:

§ 422.516 Validation of Part C reporting requirements.

(a) *Required information.* Each MA organization must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, and while safeguarding the confidentiality of the doctor-patient relationship, information with respect to the following:

* * * *

(2) The procedures related to and utilization of its services and items.
* * * *

■ 26. Section 422.530 is amended by adding paragraph (c)(4)(iii) to read as follows:

§ 422.530 Plan crosswalks.

* * * *

(c) * * *

(4) * * *

(iii) For contract year 2027 and subsequent years, where one or more

MA organizations that share a parent organization seek to consolidate D-SNPs in the same service area down to a single D-SNP under one MA-PD contract to comply with requirements at §§ 422.514(h) and 422.504(a)(20), CMS permits enrollees to be moved between different contracts.

* * * *

■ 27. Section 422.582 is amended by revising paragraph (b) to read as follows:

§ 422.582 Request for a standard reconsideration.

* * * *

(b) *Timeframe for filing a request.*

Except as provided in paragraph (c) of this section, a request for reconsideration must be filed within 60 calendar days after receipt of the written organization determination notice.

(1) The date of receipt of the organization determination is presumed to be 5 calendar days after the date of the written organization determination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the plan or delegated entity specified in the MA organization's written organization determination.

* * * *

■ 27. Section 422.584 is amended by revising the paragraph (b) heading and adding paragraphs (b) introductory text and (b)(3) and (4) to read as follows:

§ 422.584 Expediting certain reconsiderations.

* * * *

(b) *Procedure and timeframe for filing a request.* A request for reconsideration must be filed within 60 calendar days after receipt of the written organization determination notice.

* * * *

(3) The date of receipt of the organization determination is presumed to be 5 calendar days after the date of the written organization determination, unless there is evidence to the contrary.

(4) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the plan or delegated entity specified in the MA organization's written organization determination.

* * * *

■ 28. Section 422.626 is amended by:

■ a. Revising paragraph (a)(2); and

■ b. Removing paragraph (a)(3).

The revision reads as follows:

§ 422.626 Fast-track appeals of service terminations to independent review entities (IREs).

(a) * * *

(2) If an enrollee makes an untimely request to an IRE, the IRE accepts the

request and makes a determination as soon as possible, but the timeframe under paragraph (d)(5) of this section and the financial liability protection under paragraph (b) of this section do not apply.

* * * * *

■ 29. Section 422.633 is amended by revising paragraph (d)(1) to read as follows:

§ 422.633 Integrated reconsiderations.

* * * * *

(d) * * *

(1) *Timeframe for filing.* An enrollee has 60 calendar days after receipt of the adverse organization determination notice to file a request for an integrated reconsideration with the applicable integrated plan.

(i) The date of receipt of the adverse organization determination is presumed to be 5 calendar days after the date of the integrated organization determination notice, unless there is evidence to the contrary.

(ii) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the applicable integrated plan.

* * * * *

■ 30. Section 422.2267 is amended by:

- a. Revising paragraph (e)(31) and paragraph (e)(34) introductory text;
- b. Redesignating paragraph (e)(34)(iii) as paragraph (e)(34)(v);
- c. Redesignating paragraph (e)(34)(ii) as paragraph (e)(34)(iii);
- d. Adding a new paragraph (e)(34)(ii);
- e. Revising newly redesignated paragraph (e)(34)(iii);
- f. Adding paragraph (e)(34)(iv);
- g. Revising newly redesignated paragraph (e)(34)(v); and
- h. Adding paragraph (e)(42).

The revisions and additions read as follows:

§ 422.2267 Required materials and content.

* * * * *

(e) * * *

(31) *Notice of availability of language assistance services and auxiliary aids and services (notice of availability).* This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.

(i) This notice of availability of language assistance services and auxiliary aids and services must be

provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(ii) If there are additional languages in a particular service area that meet the 5-percent service area threshold, described in paragraph (a)(2) of this section, beyond the languages described in paragraph (e)(31)(i) of this section, the notice of availability of language assistance services and auxiliary aids and services must also be translated into those languages. MA organizations may also opt to translate the notice in any additional languages that do not meet the 5-percent service area threshold, where the MA organization determines that this inclusion would be appropriate.

(iii) The notice must be provided with all required materials under this paragraph (e).

(iv) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(v) When used as a standalone material, the notice may include organization name and logo.

(vi) When mailing multiple required materials together, only one notice is required.

(vii) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

(34) *SSBCI disclaimer.* This is model content and must be used by MA organizations that offer CMS-approved SSBCI as specified in § 422.102(f). In the SSBCI disclaimer, MA organizations must include the information required in paragraphs (e)(34)(i) through (iii) of this section. MA organizations must—

* * * * *

(ii) List the chronic condition(s) the enrollee must have to be eligible for the SSBCI offered by the MA organization.

(A) If the number of condition(s) is five or fewer, then list all condition(s).

(B) If the number of conditions is more than five, then list the top five conditions, as determined by the MA organization.

(iii) Convey that even if the enrollee has a listed chronic condition, the enrollee will not necessarily receive the benefit because coverage of the item or service depends on the enrollee being a “chronically ill enrollee” as defined in § 422.102(f)(1)(i)(A) and on the MA organization’s coverage criteria for a

specific SSBCI item or service required by § 422.102(f)(4).

(iv) Meet the following requirements for the SSBCI disclaimer in ads:

(A) For television, online, social media, radio, or other voice-based ads, either read the disclaimer at the same pace as or display the disclaimer in the same font size as the advertised phone number or other contact information.

(B) For outdoor advertising (as defined in § 422.2260), display the disclaimer in the same font size as the advertised phone number or other contact information.

(v) Include the SSBCI disclaimer in all marketing and communications materials that mention SSBCI.

* * * * *

(42) *Mid-year supplemental benefits notice.* This is a model communications material through which plans must inform each enrollee of the availability of any supplemental benefit the enrollee has not begun to use by June 30 of the plan year.

(i) The notice must be sent on an annual basis, no earlier than June 30 of the plan year, and no later than July 31 of the plan year.

(ii) The notice must include the following content:

(A) *Mandatory supplemental benefits.* For each mandatory supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

(B) *Optional supplemental benefits.* For each optional supplemental benefit an enrollee has not used, the MA organization must include the same information about the benefit that is provided in the Evidence of Coverage.

(C) *SSBCI.* For plans that include SSBCI—

(1) The MA organization must include an explanation of SSBCI available under the plan (including eligibility criteria and limitations and scope of the covered items and services) and must include point-of-contact information for eligibility assessments, including providing point-of-contact information (which can be the customer service line or a separate dedicated line), with trained staff that enrollees can contact to inquire about or begin the SSBCI eligibility determination process and to address any other questions the enrollee may have about the availability of SSBCI under their plan;

(2) When an enrollee has been determined eligible for SSBCI but has not used SSBCI, the MA organization must include a description of the unused SSBCI for which the enrollee is eligible, and must include a description of any limitations on the benefit; and

(3) The disclaimer specified at paragraph (e)(34) of this section.

(D) *Additional notice information.* The information about all supplemental benefits listed in the notice must include all of the following:

- (1) Scope of benefit.
- (2) Applicable cost-sharing.
- (3) Instructions on how to access the benefit.
- (4) Any applicable network information.

(5) Supplemental benefits listed consistent with the format of the EOC.

(6) A customer service number, and required TTY number, to call for additional help.

■ 31. Section 422.2274 is amended by:

■ a. In paragraph (a)—

■ i. Revising paragraph (i) of the definition of “Compensation”; and

■ ii. Revising the definition of “Fair market value (FMV)”; and

■ b. Revising paragraphs (c)(5), (d)(1)(ii), (d)(2) introductory text, (d)(3) introductory text, and (e)(1) and (2).

The revisions read as follows:

§ 422.2274 Agent, broker, and other third-party requirements.

* * * * *

(a) * * *

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale, renewal, or services related to a plan or product offered by an MA organization including, but not limited to the following:

- (A) Commissions.
- (B) Bonuses.
- (C) Gifts.
- (D) Prizes or Awards.
- (E) Payment of fees to comply with State appointment laws, training, certification, and testing costs.
- (F) Reimbursement for mileage to, and from, appointments with beneficiaries.
- (G) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.
- (H) Any other payments made to an agent or broker that are tied to enrollment, related to an enrollment in an MA plan or product, or for services conducted as a part of the relationship associated with the enrollment into an MA plan or product.

* * * * *

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into an MA plan.

(i) Beginning January 1, 2021, the national FMV is \$539, the FMV for

Connecticut, Pennsylvania, and the District of Columbia is \$607, the FMV for California and New Jersey is \$672, and the FMV for Puerto Rico and the U.S. Virgin Islands is \$370.

(ii) Beginning in 2025, the FMV will be increased to account for administrative payments included under the compensation rate, beginning at \$31 and updated annually in compliance with this section.

(iii) For subsequent years, FMV is calculated by adding the current year FMV and the produce of the current year FMV and MA growth percentage for aged and disabled beneficiaries, which is published for each year in the rate announcement issued in accordance with § 422.312.

* * * * *

(c) * * *

(5) Ensure that no provision of a contract with an agent, broker, or other TPMO has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

* * * * *

(d) * * *

(1) * * *

(ii) MA organizations are limited to the compensation amounts outlined in this section.

(2) *Initial enrollment year compensation.* For each enrollment in an initial enrollment year, MA organizations may pay compensation at FMV.

* * * * *

(3) *Renewal compensation.* For each enrollment in a renewal year, MA plans may pay compensation at a rate of 50 percent of FMV.

* * * * *

(e) * * *

(1) For plan years through 2024, Payments for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Beginning in 2025, administrative payments are included in the calculation of enrollment-based compensation.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 32. The authority citation for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 33. Section 423.4 is amended by adding definitions for “Biosimilar biological product” and “Interchangeable biological product” in alphabetical order to read as follows:

§ 423.4 Definitions.

* * * * *

Biosimilar biological product means a biological product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that, in accordance with section 351(i)(2) of the Public Health Service Act (42 U.S.C. 262(i)(2)), is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and has no clinically meaningful differences between the biological product and the reference product, in terms of the safety, purity, and potency of the product.

* * * * *

Interchangeable biological product means a product licensed under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) that FDA has determined meets the standards described in section 351(k)(4) of the Public Health Service Act (42 U.S.C. 262(k)(4)).

* * * * *

■ 34. Section 423.32 is amended by adding paragraph (h) to read as follows:

§ 423.32 Enrollment process.

* * * * *

(h) *Authorized representatives.* As used in this subpart, an authorized representative is an individual who is the legal representative or otherwise legally able to act on behalf of an enrollee, as the law of the State in which the beneficiary resides may allow, in order to execute an enrollment or disenrollment request.

(1) The authorized representative would constitute the “beneficiary” or the “enrollee” for the purpose of making an election.

(2) Authorized representatives may include court-appointed legal guardians, persons having durable power of attorney for health care decisions, or individuals authorized to make health care decisions under State surrogate consent laws, provided they have the authority to act for the beneficiary in this capacity.

■ 34. Section 423.38 is amended by:

■ a. Revising paragraph (c)(4)(i);

■ b. Redesignating paragraph (c)(35) as paragraph (c)(36); and

■ c. Adding new paragraph (c)(35).

The revision and addition read as follows:

§ 423.38 Enrollment periods.

* * * *

- (c) * * *
- (4) * * *

(i) Except as provided in paragraph (c)(4)(ii) of this section, the individual is a full-subsidy eligible individual or other subsidy-eligible individual as defined in § 423.772, who is making a one-time-per month election into a PDP.

* * * *

(35) The individual is making a one-time-per month election into a fully integrated dual eligible special needs plan as defined in § 422.2 of this chapter, a highly integrated dual eligible special needs plan as defined in § 422.2, or an applicable integrated plan as defined in § 422.561 of this chapter.

* * * *

■ 35. Section 423.40 is amended by adding paragraph (f) to read as follows:

§ 423.40 Effective dates.

* * * *

(f) *Beneficiary choice of effective date.* If a beneficiary is eligible for more than one election period, resulting in more than one possible effective date, the Part D plan sponsor must allow the beneficiary to choose the election period that results in the individual's desired effective date.

(1) To determine the beneficiary's choice of election period and effective date, the Part D plan sponsor must attempt to contact the beneficiary and must document its attempts.

(2) If the Part D plan sponsor is unable to obtain the beneficiary's desired enrollment effective date, the Part D plan sponsor must assign an election period using the following ranking of election periods:

- (i) ICEP/Part D IEP.
- (ii) MA-OEP.
- (iii) SEP.
- (iv) AEP.
- (v) OEPI.

(3) If the Part D plan sponsor is unable to obtain the beneficiary's desired disenrollment effective date, the Part D plan sponsor must assign an election period that results in the earliest disenrollment.

■ 36. Section 423.100 is amended by:

■ a. Adding in alphabetical order a definition for "Corresponding drug";

■ b. Revising paragraph (3) of the definition of "Exempted beneficiary"; and

■ c. Adding in alphabetical order a definition for "Maintenance change".

The additions and revision read as follows:

§ 423.100 Definitions.

* * * *

Corresponding drug means, respectively, a generic or authorized

generic of a brand name drug, an interchangeable biological product of a reference product, or an unbranded biological product marketed under the same biologics license application (BLA) as a brand name biological product.

Exempted beneficiary * * *

(3) Is being treated for cancer-related pain; or

* * * *

Maintenance change means one of the following negative formulary changes with respect to a covered Part D drug:

(1) Making any negative formulary changes to a drug within 90 days of adding a corresponding drug to the same or a lower cost-sharing tier and with the same or less restrictive prior authorization (PA), step therapy (ST), or quantity limit (QL) requirements (other than immediate substitutions that meet the requirements of § 423.120(e)(2)(i)).

(2) Making any negative formulary changes to a reference product within 90 days of adding a biosimilar biological product other than an interchangeable biological product of that reference product to the same or a lower cost-sharing tier and with the same or less restrictive PA, ST, or QL requirements.

(3) Removing a non-Part D drug.

(4) Adding or making more restrictive PA, ST, or QL requirements based upon a new FDA-mandated boxed warning.

(5) Removing a drug deemed unsafe by FDA or withdrawn from sale by the manufacturer if the Part D sponsor chooses not to treat it as an immediate negative formulary change.

(6) Removing a drug based on long term shortage and market availability.

(7) Making negative formulary changes based upon new clinical guidelines or information or to promote safe utilization.

(8) Adding PA to help determine Part B versus Part D coverage.

* * * *

■ 37. Section 423.120 (as proposed to be amended at 87 FR 79727, December 27, 2022) is amended by revising paragraph (e)(2)(i) to read as follows:

§ 423.120 Access to covered Part D drugs.

* * * *

- (e) * * *
- (2) * * *

(i) *Immediate substitutions.* A Part D sponsor may make negative formulary changes to a brand name drug, a reference product, or a brand name biological product within 30 days of adding a corresponding drug to its formulary on the same or lower cost sharing tier and with the same or less restrictive formulary prior authorization (PA), step therapy (ST), or quantity limit

(QL) requirements, so long as the Part D sponsor previously could not have included such corresponding drug on its formulary when it submitted its initial formulary for CMS approval consistent with paragraph (b)(2) of this section because such drug was not yet available on the market, and the Part D sponsor has provided advance general notice as specified in paragraph (f)(2) of this section.

* * * *

■ 38. Section 423.129 is added to read as follows:

§ 423.129 Resolution of complaints in complaints tracking module.

(a) *Definitions.* For the purposes of this section, the following terms have the following meanings:

Assignment date is the date CMS assigns a complaint to a particular Part D sponsor in the Complaints Tracking Module.

Complaints Tracking Module is an electronic system maintained by CMS to record and track complaints submitted to CMS about Medicare health and drug plans from beneficiaries and others.

Immediate need complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 2 or fewer days.

Urgent complaint is a complaint involving a situation that prevents a beneficiary from accessing care or a service for which they do not have an immediate need. This includes when the beneficiary currently has enough of the drug or supply to which they are seeking access to last for 3 to 14 days.

(b) *Timelines for complaint resolution*—(1) *Immediate need complaints.* The Part D sponsor must resolve immediate need complaints within 2 calendar days of the assignment date.

(2) *Urgent complaints.* The Part D sponsor must resolve urgent complaints within 7 calendar days of the assignment date.

(3) *All other complaints.* The Part D sponsor must resolve all other complaints within 30 calendar days of the assignment date.

(c) *Timeline for contacting individual filing a complaint.* Regardless of the type of complaint received, the Part D sponsor must contact the individual who filed a complaint within 3 calendar days of the assignment date.

■ 39. Section 423.153 is amended by: ■ a. Removing the phrase "paragraph (f)(8)(ii)" and adding in its place

- “paragraphs (f)(8)(ii) and (iii)” in paragraph (f)(8)(i) introductory text;
- b. Revising paragraph (f)(8)(i)(A);
- c. Redesignating paragraph (f)(8)(ii) as paragraph (f)(8)(iii); and
- d. Adding a new paragraph (f)(8)(ii).

The revision and addition read as follows:

§ 423.153 Drug utilization management, quality assurance, medication therapy management programs (MTMPs), drug management programs, and access to Medicare Parts A and B claims data extracts.

* * * * *

(f) * * *

(8) * * *

(i) * * *

(A) Within 3 days of the date the sponsor makes the relevant determination.

* * * * *

(ii) In the case of a beneficiary who is determined by a Part D sponsor to be exempt, the sponsor must provide the alternate second notice within 3 days of the date the sponsor makes the relevant determination, even if such determination is made less than 30 days from the date of the initial notice described in paragraph (f)(5) of this section.

* * * * *

■ 40. Section 423.160 is amended by:

■ a. Revising paragraphs (a)(2) and (3), (b), and (c); and

■ b. Removing the section-level authority citation.

The revisions read as follows:

§ 423.160 Standards for electronic prescribing.

(a) * * *

(2) Except as provided in paragraph (a)(3) of this section, prescribers and dispensers that transmit, directly or through an intermediary, prescriptions and prescription-related information using electronic media (including entities transmitting prescriptions or prescription-related information where the prescriber is required by law to issue a prescription for a patient to a non-prescribing provider, such as a nursing facility, that in turn forwards the prescription to a dispenser), must comply with the applicable standards in paragraph (b) of this section when e-prescribing for covered Part D drugs for Part D eligible individuals.

(3)(i) Entities transmitting prescriptions or prescription-related information must utilize the NCPDP SCRIPT standard, consistent with paragraph (b)(1) of this section, in all instances other than temporary/transient network transmission failures.

(ii) Electronic transmission of prescriptions or prescription-related

information by means of computer-generated facsimile is only permitted in instances of temporary/transient transmission failure and communication problems that would preclude the use of the NCPDP SCRIPT Standard adopted by this section.

(iii) Entities may use either HL7 messages or the NCPDP SCRIPT Standard to transmit prescriptions or prescription-related information internally when the sender and the recipient are part of the same legal entity. If an entity sends prescriptions outside the entity (for example, from an HMO to a non-HMO pharmacy), it must use the adopted NCPDP SCRIPT Standard or other applicable adopted standards. Any pharmacy within an entity must be able to receive electronic prescription transmittals for Medicare beneficiaries from outside the entity using the adopted NCPDP SCRIPT Standard. This exemption does not supersede any HIPAA requirement that may require the use of a HIPAA transaction standard within an organization.

* * * * *

(b) *Standards*—(1) *Prescriptions, electronic prior authorization, and medication history.* The communication of a prescription or prescription-related information must comply with a standard in 45 CFR 170.205(b) (incorporated by reference, *see* paragraph (c) of this section) for the following transactions, as applicable to the version of the standard in use:

- (i)(A) GetMessage.
- (B) Status.
- (C) Error.
- (D) RxChangeRequest and RxChangeResponse.
- (E) RxRenewalRequest and RxRenewalResponse.
- (F) Resupply.
- (G) Verify.
- (H) CancelRx and CancelRxResponse.
- (I) RxFill.
- (J) DrugAdministration.
- (K) NewRxRequest.
- (L) NewRx.
- (M) NewRxResponseDenied.
- (N) RxTransferInitiationRequest.
- (O) RxTransfer.
- (P) RxTransferConfirm.
- (Q) RxFillIndicatorChange.
- (R) Recertification.
- (S) REMSInitiationRequest and REMSInitiationResponse.
- (T) REMSRequest and REMSResponse.
- (U) RxHistoryRequest and RxHistoryResponse.
- (V) PAInitiationRequest and PAInitiationResponse.
- (W) PAResponseRequest and PAResponseResponse.

(X) PAAppealRequest and PAAppealResponse.

(Y) PACancelRequest and PACancelResponse.

(Z) PANotification.

(ii) [Reserved]

(2) *Eligibility.* Eligibility inquiries and responses between the Part D sponsor and prescribers and between the Part D sponsor and dispensers must comply with 45 CFR 162.1202.

(3) *Formulary and benefits.* The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), April 2012 (incorporated by reference, *see* paragraph (c) of this section) or comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section) for transmitting formulary and benefits information between prescribers and Medicare Part D sponsors. Beginning January 1, 2027, transmission of formulary and benefit information between prescribers and Medicare Part D sponsors must comply with a standard in 45 CFR 170.205(u) (incorporated by reference, *see* paragraph (c) of this section).

(4) *Provider identifier.* The National Provider Identifier (NPI), as defined at 45 CFR 162.406, to identify an individual health care provider to Medicare Part D sponsors, prescribers and dispensers, in electronically transmitted prescriptions or prescription-related materials for Medicare Part D covered drugs for Medicare Part D eligible individuals.

(5) *Real-time benefit tools.* Part D sponsors must implement one or more electronic real-time benefit tools (RTBT) that are capable of integrating with at least one prescriber's e-Prescribing (eRx) system or electronic health record (EHR) to provide complete, accurate, timely, clinically appropriate, patient-specific formulary and benefit information to the prescriber in real time for assessing coverage under the Part D plan. Such information must include enrollee cost-sharing information, clinically appropriate formulary alternatives, when available, and the formulary status of each drug presented including any utilization management requirements applicable to each alternative drug. Beginning January 1, 2027, Part D sponsors' RTBT must comply with a standard in 45 CFR 170.205(c) (incorporated by reference, *see* paragraph (c) of this section).

(c) *Incorporation by reference.* The material listed in this paragraph (c) is incorporated by reference into this section with the approval of the Director of the Federal Register under 5 U.S.C.

552(a) and 1 CFR part 51. All approved incorporation by reference (IBR) material is available for inspection at the Centers for Medicare & Medicaid Services (CMS) and at the National Archives and Records Administration (NARA). Contact CMS at: CMS 7500 Security Boulevard, Baltimore, Maryland 21244; phone: (410) 786-4132 or (877) 267-2323; email: PartDPolicy@cms.hhs.gov. 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 National Council for Prescription Drug Programs, Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260-7518; phone: (480) 477-1000; email: info@ncpdp.org; website: www.ncpdp.org.

(1) The National Council for Prescription Drug Programs Formulary and Benefits Standard, Implementation Guide, Version 3, Release 0 (Version 3.0), published April 2012.

(2) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2017071, approved July 28, 2017.

(3) National Council for Prescription Drug Programs SCRIPT Standard, Implementation Guide Version 2023011, published April 2023, (Approval Date for American National Standards Institute [ANSI]: January 17, 2023).

(4) National Council for Prescription Drug Programs Real-Time Prescription Benefit Standard, Implementation Guide Version 13, published July 2023 (Approval Date for ANSI: May 19, 2022).

(5) National Council for Prescription Drug Programs Formulary and Benefit Standard, Implementation Guide Version 60, published April 2023 (Approval Date for ANSI: April 12, 2023).

■ 40. Section 423.184 is amended by:
■ a. Removing and reserving paragraph (g)(1)(ii); and

■ b. Adding paragraph (h)(3).

The addition reads as follows:

§ 423.184 Adding, updating, and removing measures.

* * * * *

(h) * * *

(3) Beginning with the 2025 measurement year (2027 Star Ratings), Part D sponsor may request that CMS review its contract's administrative data for Patient Safety measures provided that the request is received by the annual deadline set by CMS for the applicable Star Ratings year.

* * * * *

■ 41. Section 423.186 is amended by revising paragraph (f)(2)(i)(B) and

adding paragraphs (f)(3)(viii)(A) and (B) to read as follows:

§ 423.186 Calculation of Star Ratings.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(B) To determine a contract's final adjustment category, contract enrollment is determined using enrollment data for the month of December for the measurement period of the Star Ratings year.

(1) For the first 2 years following a consolidation, for the surviving contract of a contract consolidation involving two or more contracts for health or drug services of the same plan type under the same parent organization, the enrollment data for the month of December for the measurement period of the Star Ratings year are combined across the surviving and consumed contracts in the consolidation.

(2) The count of beneficiaries for a contract is restricted to beneficiaries that are alive for part or all of the month of December of the applicable measurement year.

(3) A beneficiary is categorized as LIS/DE if the beneficiary was designated as full or partially dually eligible or receiving a LIS at any time during the applicable measurement period.

(4) Disability status is determined using the variable original reason for entitlement (OREC) for Medicare using the information from the Social Security Administration and Railroad Retirement Board record systems.

* * * * *

(3) * * *

(viii) * * *

(A) In the case of contract consolidations involving two or more contracts for health or drug services of the same plan type under the same parent organization, CMS calculates the HEI reward for the surviving contract accounting for both the surviving and consumed contract(s). For the first year following a consolidation, the HEI reward for the surviving contract is calculated as the enrollment-weighted mean of the HEI reward of the consumed and surviving contracts using enrollment from July of the most recent measurement year used in calculating the HEI reward. A reward value of zero is used in calculating the enrollment-weighted mean for contracts that do not meet the minimum percentage of enrollees with the SRF thresholds or the minimum performance threshold specified at paragraph (f)(3)(vii) of this section.

(B) For the second year following a consolidation when calculating the HEI

score for the surviving contract, the patient-level data used in calculating the HEI score will be combined from the consumed and surviving contracts and used in calculating the HEI score.

* * * * *

■ 42. Section 423.503 is amended by revising paragraph (b)(1)(i)(A) and (C) to read as follows:

§ 423.503 Evaluation and determination procedures.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(A) Was under an intermediate sanction under subpart O of this part, or a determination by CMS to prohibit the enrollment of new enrollees under § 423.2410(c).

* * * * *

(C) Filed for or is currently in Federal or State bankruptcy proceedings.

* * * * *

■ 43. Section 423.505 is amended by revising paragraph (b)(22) to read as follows:

§ 423.505 Contract provisions.

* * * * *

(b) * * *

(22) As described in § 423.129, address and resolve complaints received by CMS against the Part D sponsor in the Complaints Tracking Module.

* * * * *

■ 44. Section 423.509 is amended by adding paragraph (f) to read as follows:

§ 423.509 Termination of contract by CMS.

* * * * *

(f) *Intermediate sanctions imposed with CMS termination.* If CMS makes a determination to terminate a Part D sponsor's contract under paragraph (a) of this section, CMS also imposes the intermediate sanctions at § 423.750(a)(1) and (3) in accordance with the following procedures:

(1) The sanction will go into effect 15 days after the termination notice is sent.

(2) The Part D sponsor will have a right to appeal the intermediate sanction in the same proceeding as the termination appeal specified in paragraph (d) of this section.

(3) A request for a hearing does not delay the date specified by CMS when the sanction becomes effective.

(4) The sanction will remain in effect—

(i) Until the effective date of the termination; or

(ii) If the termination decision is overturned on appeal, when a final decision is made by the hearing officer or Administrator.

■ 45. Section 423.514 is amended by revising paragraph (a) introductory text and paragraph (a)(2) to read as follows:

§ 423.514 Validation of Part D reporting requirements.

(a) *Required information.* Each Part D plan sponsor must have an effective procedure to develop, compile, evaluate, and report to CMS, to its enrollees, and to the general public, at the times and in the manner that CMS requires, information indicating the following—

* * * * *

(2) The procedures related to and utilization of its services and items.

* * * * *

46. Section 423.582 is amended by revising paragraph (b) to read as follows:

§ 423.582 Request for a standard redetermination.

* * * * *

(b) *Timeframe for filing a request.* Except as provided in paragraph (c) of this section, a request for a redetermination must be filed within 60 calendar days after receipt of the written coverage determination notice or the at-risk determination program in accordance with § 423.153(f).

(1) The date of receipt of the coverage determination or at-risk determination is presumed to be 5 calendar days after the date of the written coverage determination or at-risk determination unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the Part D plan sponsor or delegated entity specified in the Part D plan sponsor's written coverage determination or at-risk determination.

* * * * *

47. Section 423.584 is amended by revising the paragraph (b) heading and adding paragraphs (b) introductory text and (b)(3) and (4) to read as follows:

§ 423.584 Expediting certain redeterminations.

* * * * *

(b) *Procedure and timeframe for filing a request.* A request for redetermination must be filed within 60 calendar days after receipt of the written coverage determination notice or at-risk determination notice.

* * * * *

(3) The date of receipt of the coverage determination or at-risk determination is presumed to be 5 calendar days after the date of the written coverage determination or at-risk determination unless there is evidence to the contrary.

(4) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the Part D plan sponsor or delegated entity specified the Part D plan sponsor's written coverage determination or at-risk determination.

* * * * *

■ 48. Section 423.600 is amended by revising paragraph (a) to read as follows:

§ 423.600 Reconsideration by an independent review entity (IRE).

(a) An enrollee who is dissatisfied with the redetermination of a Part D plan sponsor has a right to a reconsideration by an independent review entity that contracts with CMS. The prescribing physician or other prescriber (acting on behalf of an enrollee), upon providing notice to the enrollee, may request an IRE reconsideration. The enrollee, or the enrollee's prescribing physician or other prescriber (acting on behalf of the enrollee) must file a written request for reconsideration with the IRE within 60 calendar days after receipt of the written redetermination by the Part D plan sponsor.

(1) The date of receipt of the redetermination is presumed to be 5 calendar days after the date of the Part D plan sponsor's written redetermination, unless there is evidence to the contrary.

(2) For purposes of meeting the 60-calendar day filing deadline, the request is considered as filed on the date it is received by the IRE specified in the Part D plan sponsor's written redetermination.

* * * * *

■ 49. Section 423.2267 is amended by revising paragraph (e)(33) to read as follows:

§ 423.2267 Required materials and content.

* * * * *

(e) * * *

(33) *Notice of availability of language assistance services and auxiliary aids and services (notice of availability).* This is a model communications material through which Part D sponsors must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the Part D sponsor provides language assistance services and appropriate auxiliary aids and services free of charge.

(i) This notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English

proficiency of the relevant state and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(ii) If there are additional languages in a particular service area that meet the 5-percent service area threshold, described in paragraph (a)(2) of this section, beyond the languages described in paragraph (e)(33)(i) of this section, the notice of availability of language assistance services and auxiliary aids and services must also be translated into those languages. Part D sponsors may also opt to translate the notice in any additional languages that do not meet the 5-percent service area threshold, where the Part D sponsor determines that this inclusion would be appropriate.

(iii) The notice must be provided with all required materials under this paragraph (e).

(iv) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(v) When used as a standalone material, the notice may include organization name and logo.

(vi) When mailing multiple required materials together, only one notice is required.

(vii) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

* * * * *

■ 50. Section 423.2274 is amended by:

■ a. In paragraph (a):

■ i. Revising paragraph (i) of the definition of "Compensation"; and

■ ii. Revising the definition of "Fair market value (FMV)"; and

■ b. Revising paragraphs (c)(5), (d)(1)(ii), (d)(2) introductory text, (d)(3) introductory text, and (e)(1) and (2).

The revisions read as follows:

§ 423.2274 Agent, broker, and other third-party requirements.

* * * * *

(a) * * *

Compensation. (i) Includes monetary or non-monetary remuneration of any kind relating to the sale, renewal, or services related to a plan or product offered by a Part D sponsor including, but not limited to the following:

(A) Commissions.

(B) Bonuses.

(C) Gifts.

(D) Prizes or Awards.

(E) Payment of fees to comply with State appointment laws, training, certification, and testing costs.

(F) Reimbursement for mileage to, and from, appointments with beneficiaries.

(G) Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

(H) Any other payments made to an agent or broker that are tied to enrollment, related to an enrollment in a Part D plan or product, or for services conducted as a part of the relationship associated with the enrollment into a Part D plan or product.

* * * * *

Fair market value (FMV) means, for purposes of evaluating agent or broker compensation under the requirements of this section only, the amount that CMS determines could reasonably be expected to be paid for an enrollment or continued enrollment into a Part D plan.

(i) Beginning January 1, 2021, the national FMV is 81.

(ii) Beginning in 2025, the FMV will be increased to account for administrative payments included under the compensation rate, beginning at \$31 and updated annually in compliance with this section.

(iii) For subsequent years, FMV is calculated by adding the current year FMV and the produce of the current year FMV and Annual Percentage Increase for Part D, which is published for each year in the rate announcement issued under § 422.312 of this chapter.

* * * * *

(c) * * *

(5) Ensure that no provision of a contract with an agent, broker, or other TPMP has a direct or indirect effect of creating an incentive that would reasonably be expected to inhibit an agent or broker's ability to objectively assess and recommend which plan best fits the health care needs of a beneficiary.

* * * * *

(d) * * *

(1) * * *

(ii) Part D sponsors are limited to the compensation amounts outlined in this section.

(2) Initial enrollment year compensation. For each enrollment in an initial enrollment year, Part D sponsors may pay compensation at FMV.

* * * * *

(3) *Renewal compensation.* For each enrollment in a renewal year, Part D sponsors may pay compensation at a rate of 50 percent of FMV.

* * * * *

(e) * * *

(1) For plan years through 2024, Payments for services other than enrollment of beneficiaries (for example, training, customer service, agent recruitment, operational overhead, or

assistance with completion of health risk assessments) must not exceed the value of those services in the marketplace.

(2) Beginning in 2025, administrative payments are included in the calculation of enrollment-based compensation.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 51. The authority citation for part 460 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395, 1395eee(f), and 1396u–4(f).

■ 52. Section 460.119 is added to read as follows:

§ 460.119 Resolution of complaints in the complaints tracking module.

The PACE organization must comply with requirements of §§ 422.125 and 422.504(a)(15) of this chapter to, through the CMS complaints tracking module as defined in § 422.125(a) of this chapter, address and resolve complaints received by CMS against the PACE organization within the required timeframes. References to the MA organization or MA plan in those regulations must be read as references to the PACE organization. Nothing in this section should be construed to affect the PACE organization's obligation to resolve grievances as described in § 460.120.

■ 53. Section 460.121 is amended by revising paragraph (b)(2) to read as follows:

§ 460.121 Service determination process.

* * * * *

(b) * * *

(2) *Requests that do not constitute a service determination request.* Requests to initiate, modify, or continue a service do not constitute a service determination request if the request is made prior to completing the development of the initial plan of care. For all requests identified in this section, the interdisciplinary team must—

(i) Document the request; and

(ii) Discuss the request during the care planning meeting, and either:

(A) Approve the requested service and incorporate it into the participant's initial plan of care; or

(B) Document their rationale for not approving the service in the initial plan of care.

* * * * *

■ 54. Section 460.194 is amended by revising paragraph (b) to read as follows:

§ 460.194 Corrective action.

* * * * *

(b) At their discretion, CMS or the State administering agency may monitor the effectiveness of corrective actions.

* * * * *

Title 45

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 55. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C. 300jj–14; 5 U.S.C. 552.

■ 56. Section 170.205 is amended by:

■ a. Revising paragraph (b);

■ b. Adding paragraph (c);

■ c. Adding a reserved paragraph (t); and

■ d. Adding paragraph (u).

The revision and additions read as follows:

§ 170.205 Content exchange standards and implementation specifications for exchanging electronic health information.

* * * * *

(b) *Electronic prescribing*—(1) *Standard.* National Council for Prescription Drug Programs (NCPDP): SCRIPT Standard Implementation Guide; Version 2017071 (incorporated by reference in § 170.299). The Secretary's adoption of this standard expires on January 1, 2027.

(2) *Standard.* NCPDP SCRIPT Standard, Implementation Guide, Version 2023011 (incorporated by reference in § 170.299).

(c) *Real-time prescription benefit*—(1) *Standard.* NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13 (incorporated by reference in § 170.299).

(2) [Reserved]

* * * * *

(t) [Reserved]

(u) *Formulary and benefit*—(1) *Standard.* NCPDP Formulary and Benefit Standard, Implementation Guide, Version 60 (incorporated by reference in § 170.299).

(2) [Reserved]

■ 57. Section 170.299 is amended by revising paragraph (k) to read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(k) National Council for Prescription Drug Programs (NCPDP), Incorporated, 9240 E. Raintree Drive, Scottsdale, AZ 85260–7518; phone (480) 477–1000;

email: *info@ncdpd.org*; website:
www.ncdpd.org.

(1) NCPDP SCRIPT Standard, Implementation Guide, Version 2017071 (Approval Date for ANSI: July 28, 2017); IBR approved for § 170.205(b).

(2) NCPDP SCRIPT Standard, Implementation Guide, Version 2023011, April 2023, (Approval Date for

ANSI: January 17, 2023); IBR approved for § 170.205(b).

(3) NCPDP Real-Time Prescription Benefit Standard, Implementation Guide, Version 13, July 2023 (Approval Date for ANSI: May 19, 2022); IBR approved for § 170.205(c).

(4) NCPDP Formulary and Benefit Standard, Implementation Guide, Version 60, April 2023 (Approval Date

for ANSI: April 12, 2023); IBR approved for § 170.205(u).

* * * * *

Xavier Becerra
Secretary, Department of Health and Human Services.

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